

# Evaluation of the Rapid Alert System for Food and Feed and of crisis management procedures

Annexes to the report



**food chain evaluation consortium**Civic Consulting - Agra CEAS Consulting - Arcadia
International - Van Dijk Management Consultants









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By Food Chain Evaluation Consortium (Civic Consulting - Agra

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### Annex 1: Evaluation questions (EQs) by issue and area

Evaluation issue/heading	EQs evaluation area 1: Rapid Alert System for Food and Feed	EQs evaluation area 2: Crisis and potential crisis management
Cross-cutting (relevant for both	evaluation areas)	
Effectiveness	To what extent has the RASFF achieved its objectives?  To what extent has the RASFF adapted to the changes in the regulatory framework, emerging risk, changes in market and consumer behaviour etc.?  Identify tangible and measurable criteria to evaluate effectiveness.	To what extent has the crisis management achieved [its] objectives in previous potential crisis? Where expectations have not been met, what were the factors that hindered their achievement?  Identify tangible and measurable criteria to evaluate effectiveness of existing crisis management arrangements in the EU.
Relevance	To what extent have the initial objectives remained valid?	To what extent do the provisions of Regulation (EC) No 178/2002 (Articles 55 to 57) and of relevant secondary legislation (e.g. Commission Decision 2004/478/EC) correspond to the current needs for food/feed crisis coordination?
(Legal basis and) role of the European Commission	To what extent is the EC fulfilling its obligations deriving from the Regulation?  To what extent has the EC played the role of manager and, at the same time, participant of the network?  To what extent has the adoption of the Regulation improved the functioning and monitoring of the RASFF?  To what extent has the EC contributed to the coordination of the members of the RASFF and to	To what extent have the emergency procedures been instrumental for the management of emergencies? To what extent have the mechanisms provided by Articles 53 and 54 contributed to avoid disparities and ensure a comprehensive and consistent approach to the treatment of a serious risk in relation to food or feed? To what extent the legal instrument used for the emergency measures (Decision/Regulation) have impacted on the efficiency of the measures?  To what extent is the EC fulfilling its obligations deriving from the Regulation (in particular as far as the "general plan" is concerned)?  To what extent has the EC played the role of coordinator in a potential crisis?

	the development of good and common notification practices?  To what extent have the regular Working Groups organised by the EC contributed to the better functioning of the RASFF?  To what extent are the guidelines issued by the EC on the functioning of the network clear and helpful?	To what extent has the experience gained from previous potential crisis such as the E. coli outbreak in 2011 and crisis exercises improved the crisis preparedness and the current crisis management arrangements?  To what extent has the EC contributed to the coordination of the national efforts e.g. in outbreak investigations and to the development of best practices e.g. for the design of contingency plans?
Involvement of EU Member States	To what extent have the MS adapted to meet the requirements of the Regulation? To what extent do the MS fulfil their obligations under the RASFF?  To what extent are the MS actively participating in the RASFF?  To what extent have the MS developed their legislation to meet the requirements of the Regulation?	To what extent have the MS adapted to meet the requirements of the Regulation? To what extent have the MS developed their legislation/plans/guides/infrastructure to meet the requirements of the Regulation? To what extent do the MS fulfil their obligations?  To what extent are the MS actively managing crisis or dealing with incidents such as foodborne outbreaks?
Participation of Third Countries/ International Organisations	To what extent is the RASFF open to third countries' and international organisations' participation?  How can the system be more widely used between the international communities of countries?  To what extent is the reciprocity of information flow between RASFF and the International Organisations (WHO, FAO, INFOSAN, UNIDO) appropriate?  How well does the RASFF work together with other systems (at Member State, EU and international levels)?  What are the geographic weak points in the food safety map, due to lack of food alert systems or their	To what extent are the European crisis management mechanisms open to third countries' and international organisations' participation?  How well is the information flow between to other relevant partners, competent authorities and International Organisations (WHO, FAO, INFOSAN, UNIDO)?

	weak functioning? What could be the role of RASFF there?	
Efficiency	To what extent is the RASFF efficient?  To what extent can the objectives be achieved at a lower cost with a better management of the available resources?  To what extent certain tasks – notably those which are not related to the dissemination of risk related information for the purposes of risk containment – which are currently handled by the RASFF should be better handled through other existing mechanism (computerised or not)?  Identify tangible and measurable criteria to evaluate efficiency notably in relation to its core task.	To what extent can the objectives of crisis management be achieved at a lower cost (particularly in relation to SMEs) with synergies of the available resources?  To what extent certain tasks of crisis management e.g. the dissemination of risk related information or communication issues, should be handled through alternative existing mechanism (RASFF or other systems, audio-conferences, etc.)?
Added value	What is the additional value resulting from the EU Rapid Alert System for Food and Feed compared to what could be achieved by Member States at national and/or regional levels if there would not be a RASFF?	At which point is there an additional value resulting from the EU coordinating crisis management done by different competent authorities or establishing a crisis management as foreseen in the general plan itself rather than national actions?
Specific (relevant for the RASFF of	only)	
Coherence and scope	How well does the RASFF work together with other systems (at Member State, EU and international levels)?  To what extent is the scope of the RASFF appropriate? Is the scope of the RASFF sufficiently defined?	n.a.
Risk-based operations of the RASFF	To what extent are the operations of the RASFF	n.a.

and the role of EFSA	really risk based? To what extent is risk accurately evaluated in the RASFF?  What is the role of EFSA within the RASFF? Is EFSA fulfilling its role in RASFF as laid down in the Regulation?	
Stakeholder information, transparency, and confidentiality	To what extent does the RASFF inform involved professional operators?  To what extent can stakeholders consult the information managed by the RASFF?  To what extent is the RASFF transparent and accessible to the general public?  To what extent is the classification used pertinent and clear?  To what extent is the RASFF respecting the confidentiality requirements as set in the Regulation?	n.a.

Source: Civic Consulting, on basis of TOR

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## **Annex 3: Survey questionnaires**



### EVALUATION OF THE RAPID ALERT SYSTEM FOR FOOD AND FEED AND OF CRISIS MANAGEMENT PROCEDURES

\*

# SURVEY OF RASFF NATIONAL CONTACT POINTS AND STAKEHOLDERS

The Directorate General for Health and Consumers (DG SANCO) of the European Commission has commissioned the Food Chain Evaluation Consortium (FCEC) to undertake an Evaluation of the Rapid Alert System for Food and Feed (RASFF) and of crisis management procedures.

The purpose of the evaluation is to assess whether the regulatory framework established by Articles 50 to 57 of Regulation 178/2002 is effective and efficiently working and providing added value to its stakeholders.

The information and assessments provided in your responses to this questionnaire will be crucial in assessing the effectiveness, efficiency and added value of this regulatory framework and in informing the EU policy process. For this reason we highly appreciate your taking the time to respond to this survey.

This questionnaire is targeted at key stakeholders involved in the RASFF, including members of the RASFF (i.e. RASFF National Contact Points - NCPs) and other stakeholders contributing to/using the RASFF (i.e. international organisations, relevant government bodies in third countries, organisations of food/feed business operators and consumer organisations in the EU).

Please note that this survey focuses on RASFF only. A complementary survey is being conducted on crisis management procedures (available here [LINK TO CM SURVEY]).

When completing this questionnaire, please consider the following clarifications:

- The relevant legal basis for RASFF is:
  - Regulation (EC) No 178/2002 lays down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Articles 50 to 52 of this Regulation describe the rapid alert system (Article 50), implementing measures (Article 51) and confidentiality rules for the rapid alert system (Article 52). Regulation (EC) No 178/2002 is available here [LINK TO <a href="http://eurlex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002R0178">http://eurlex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002R0178</a>].
  - Commission Regulation (EU) No 16/2011 lays down implementing measures for the Rapid alert system for food and feed. This Regulation is available here [LINK TO <a href="http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:L:2011:006:TOC">http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=OJ:L:2011:006:TOC</a>].
- Other notification systems referred to in the questionnaire include:

- o <u>Early Warning and Response System (EWRS)</u>: EWRS is a confidential computer system allowing Member States to send alerts about events with a potential impact on the EU, share information, and coordinate their response.
- TRAde Control and Expert System (TRACES): TRACES is a trans-European network for veterinary health which notifies, certifies and monitors imports, exports and trade in animals and animal products.
- o Rapid Alert system for non-food dangerous products (RAPEX) is an EU rapid alert system that facilitates the rapid exchange of information between Member States and the Commission on measures taken to prevent or restrict the marketing or use of products posing a serious risk to the health and safety of consumers with the exception of food, pharmaceutical and medical devices.
- European Community Urgent Radiological Information Exchange (ECURIE):
   ECURIE is the European early notification system in the event of a radiological or nuclear emergency.
- Epidemic Intelligence Information System (EPIS): EPIS of the ECDC is a web based communication platform for informal and technical communication between national public health experts.
- o <u>ARGUS</u> is a general European rapid alert system that has been set up with the aim to assure a coordinated and effective management of major multi-sectoral crisis that require a reaction at the European Community level. It is an internal network of the Commission.
- O International Food Safety Authorities Network (INFOSAN): INFOSAN is a global network of national food safety authorities, managed jointly by FAO and WHO with the secretariat in WHO. INFOSAN aims to promote the rapid exchange of information during food safety related events, share information on important food safety related issues of global interest; promote partnerships and collaboration between countries, and between networks; and help countries strengthen their capacity to manage food safety emergencies.

In your answer, please <u>express your expert opinion</u> based on your experiences with RASFF <u>in your country</u>. EU-level stakeholders should refer to the situation across the EU, and note any limitations in geographic coverage in the final comment field, if needed.

The names of all contributing organisations to the survey will be listed in the final report. All survey respondents will receive an electronic version of the report after publication.

Please also note that we have provided to you in our invitation to the survey a pdf document with the questionnaire to give you an overview of all questions before answering them online. Question numbering may show gaps, as only those questions are displayed that are relevant for your stakeholder group. Please submit the completed questionnaire no later than January 31<sup>st</sup>, 2015.

If you have any further questions, do not hesitate to contact:

Agathe Osinski, evaluation@civic-consulting.de

Phone: +49 30 2196 2287

## THIS QUESTIONNAIRE WILL BE IMPLEMENTED ON AN ONLINE PLATFORM. THE TYPES OF QUESTIONS ARE INDICATED AS FOLLOWS:

TF=Text field DD=Dropdown menu CB=Check box

*The following display logics apply for the questionnaire:* 

[ALL]: The question is displayed to all stakeholders

[NCP]: The question is displayed to NCPs only

[CA]: The question is displayed to other national authorities/agencies

[FBO]: The question is displayed to EU or national organisation of food/feed business operators

[CO]: The question is displayed to EU or national consumer organisations

[IS]: The question is displayed to international organisations and third country contact points

[TC]: The question is displayed to third country contact points only

[Other]: The question is displayed to other stakeholders.

#### I. IDENTIFICATION DATA

**1.** Please identify yourself: [ALL]

- a) Name of organisation (obligatory) [TF]
- b) Type of organisation (obligatory) [CB: RASFF National Contact point (NCPs); Other national authority/agency; EU or national organisation of food/feed business operators; EU or national consumer organisation; International organisation; third country contact point; Other] If other, please specify (TF)
- c) Country in which organisation is located [DD: List of 28 EU Member States, Iceland, Norway, Liechtenstein, Switzerland; Other country] If other country, please specify (TF)
- d) Contact person (name, position) [TF]
- e) Email address (obligatory) [TF]
- f) Phone number [TF]
- g) [For NCPs:]

Data on your organisation:

Please indicate the number of full-time equivalent (FTE) staff members who carry out the tasks of the <u>RASFF National Contact Point (NCP)</u> within your organisation at national level:

	FTE	Comment
Professional staff (i.e staff members with expert knowledge on food and feed safety):	[DD: 0; 0.5; 9; 9.5; 10]	[TF]
Administrative/support staff (i.e. staff members supporting professional staff members with administrative tasks):	[DD: 0; 0.5; 9; 9.5; 10]	[TF]

Note: A full-time equivalent (FTE) staff member is defined as full-time staff member working 40 hours per week. Part-time staff members/staff members working only partly on tasks relevant for the RASFF National Contact Point (NCP) are calculated by dividing the total number of hours worked per week by 40 (e.g. a staff member working 20 hours per week has a FTE count of 0.5). In case that several national level organisations share the NCP function and you are providing a consolidated answer, please present the total number of full-time

- equivalent staff members for the NCP function at national level across all organisations involved.
- h) [For NCPs:]
  In 2013, has your organisation incurred costs for training of employees of your organisation or of other relevant authorities/agencies in your country on the RASFF:
  [DD: Yes, No, Don't know]. If Yes, please specify total costs and number of persons trained [TF]

NOTE: Access to all personal data and information collected in the context of this evaluation is only granted to a defined population of users, without prejudice to a possible transmission to the bodies in charge of a monitoring or inspection task in accordance with Community legislation. These users are typically members of the Unit organising the evaluation inside the DG and its subcontractor, FCEC, acting as processor. No personal data is transmitted to parties which are outside the recipients and the legal framework mentioned.

#### II. EFFECTIVENESS OF THE RASFF

2. To what extent is the RASFF achieving the following objectives: [ALL]

a) Provide a tool for information exchange between members of the network on direct or indirect risks in relation to food or feed	[Scale 0-5: Not at all well – Very well, Don't know]	If it is not achieving objectives well, please explain [TF]	Does this objective remain valid? [Yes, No, Don't Know]	If No, please explain: [TF]
b) Inform members of the network on the <u>follow-up to notified direct or</u> <u>indirect risks</u>	As above	As above	As above	As above
c) Exchange of information between members of the network on measures to contain risk				
d) Information of third countries on risks detected to human health deriving from food and feed				
e) Information of <u>consumers on risks</u> <u>detected</u> to human health deriving from food and feed				

- **3.** Considering the objectives in question 2: do you see the need for the RASFF to address any additional objective? [DD: Yes, No, Don't know] If yes, please specify [TF] [ALL except IS]
- **4.** Have there been changes to the following areas to which the RASFF has not adapted? [ALL]

a) Changes in the regulatory framework (e.g. Regulation	[DD: Yes,	If No, please
16/2011 on implementing measures for the RASFF,	RASFF has	explain the

major legislation such as the Hygiene Package)?	adapted to changes, No, RASFF has not adapted to changes, Don't know]	changes to which the RASFF has not adapted [TF]
b) Changes in emerging risks (e.g. related to more globalised food chains)?	As above	As above
c) Changes in markets/marketing channels (e.g. e-commerce in food)?		
d) Changes in consumer behaviour (e.g. increased consumption of processed food)?		
e) Other changes. Please specify: [TF]		

- **5.** Would you have suggestions how the <u>effective</u> functioning of the RASFF could be improved (i.e. between the Commission, the Member States, EFSA, international organisations, third countries)? [DD: Yes, No, Don't know] If Yes, please specify [TF] [ALL]
- **6.** In your view, to what extent are the following <u>criteria relevant to evaluate</u> the <u>effectiveness</u> of the RASFF? [ALL]

a) Number of original notifications sent through RASFF	[Scale 0-5: Not at all relevant—Very relevant, Don't know]	Comments [TF]
b) Number of follow-up notifications sent through RASFF	As above	As above
c) Number of notifications sent to third countries		
d) Please suggest other indicators: [TF]		

#### III. SCOPE OF THE RASFF

**7.** Is the scope of the RASFF (i.e. areas covered and the type of information provided) sufficiently defined in Article 50 of Regulation 178/2002? [DD: Yes, No, Don't know] If No, please explain why: [TF] [ALL]

[Link to Regulation 178/2002]

**8.** To what extent is the scope of the RASFF <u>appropriate</u> to address the following needs? *[NCP]* 

a) A rapid and coordinated response in cases of risks	[Scale 0-5: Not	Comments
to human health deriving from food and feed	at all	[TF]
	appropriate –	
	Very	
	appropriate,	

	Don't know]	
b) The containment of food/feed safety incidents and prevention of crisis	As above	As above
c) Effective national control including border control to ensure compliance with EU rules of products placed on the EU market		
d) Prevention of disruptions of the internal market due to food/feed safety incidents		
e) Consumer confidence in safe food/feed on the EU market		
f) Protection of consumer health		
g) Other need: please specify [TF]		

**9.** Do you have suggestions how the <u>definition of the scope</u> (as defined in Article 50 of Regulation 178/2002) of the RASFF could be improved? [DD: Yes, No, Don't know] If Yes, please specify [TF] [ALL]

[Link to Regulation 178/2002]

#### IV. EVALUATION OF RISK IN THE RASFF

- **10.** Are the notifications exchanged through the RASFF <u>sufficiently risk based</u>? [DD: Yes, No, Don't know] If No, please explain why: [TF] [ALL]
- **11.** To what extent is <u>risk accurately evaluated</u> in the RASFF? [Scale 0-5: Not at all accurately Very accurately , Don't know] Please explain: [TF] [ALL]

NOTE: Point of reference is Regulation 16/2011 in which the term risk is understood as: "(...) a direct or indirect risk to human health in connection with food, food contact material or feed in accordance with Regulation (EC) No 178/2002 or as a serious risk to human health, animal health or the environment in connection with feed in accordance with Regulation (EC) No 183/2005."

**12.** Do you have suggestions how the <u>risk-based approach</u> of the RASFF could be improved? [DD: Yes, No, Don't know] If Yes, please specify [TF] [ALL]

#### V. INVOLVEMENT OF THE MEMBER STATES

- **13.** Has your country adopted <u>national legislation</u> to implement the RASFF? [DD: Yes, No, Under development, Don't know] If Yes, please specify: [TF] [NCP]
- **14.** To what extent does your country <u>fulfil the following duties</u> of Article 50 of Regulation 178/2002, as specified in detail in Articles 2 to 7 of Regulation 16/2011 laying down implementing measures for the RASFF? *[NCP]*

a) My country has <u>sent alert notifications</u> to the Commission contact point <u>within 48 hours</u> from the moment the risk was reported to the NCP	[DD: Always, Most of the time, Sometimes, Rarely, Never, Don't know]	If "Rarely" or "Never", please explain why: [TF]
b) My country has sent <u>information notifications</u> to the Commission contact point <u>without undue delay</u>	As above	As above
c) My country has sent <u>border rejection notifications</u> to the Commission contact point <u>without undue delay</u>	As above	As above
d) Whenever my country has had any additional information relating to the risk or product referred to in an original notification, it has <u>immediately transmitted a follow-up notification</u> to the Commission contact point	As above	As above
e) My country has ensured the <u>efficient functioning of the RASFF within its jurisdiction</u>	[Scale 0-5: Not at all – Very much, Don't know]	If not, please explain why [TF]
f) My country has <u>designated one contact point</u> for the RASFF	[DD: Yes, No, Don't know]	If No, please explain why: [TF]
g) My country has <u>immediately informed</u> the Commission contact point <u>of any changes in the RASFF contact</u> <u>point</u> for my country and of relevant contact details	[DD: Always, Most of the time, Sometimes, Rarely, Never, Don't know]	If "Rarely" or "Never", please explain why: [TF]
h) My country has ensured an effective communication between the RASFF NCP and the Commission contact point	[DD: Yes, No, Don't know]	If No, please explain why: [TF]
i) My country has <u>set up an effective communication</u> <u>network between the RASFF NCP and all relevant</u> <u>competent authorities</u> in my country	As above	As above
j) My country has <u>defined the roles and responsibilities of</u> <u>the RASFF NCP</u> and those of the relevant competent authorities in my country	As above	As above
k) My country has ensured the availability of an on-duty officer reachable on a 24-hour/7-day-a-week basis	As above	As above
1) Notifications have been submitted by my country using the templates provided by the Commission contact point	[DD: In all cases, In most cases, In some cases, Never, Don't know]	If "In some cases" or "Never", please explain why: [TF]

- **15.** In your view, do other MS fulfil their duties under the RASFF? [DD: Yes, all MS fulfil their duties; Yes, Most MS fulfil their duties; Yes, but only some MS fulfil their duties; No, None of the MS fulfil their duties; Don't know] Please explain: [TF] [NCP]
- **16.** To what extent are you <u>satisfied with ....? [NCP]</u>

a) How actively other MS <u>submit original notifications</u> to the RASFF	[Scale 0-5: Not at all satisfied— Very satisfied, Don't know]	If you are not satisfied, please explain: [TF]
b) The rapidity of <u>follow-up</u> notifications provided by other MS	As above	As above
c) The quality of <u>follow-up</u> notifications provided by other MS		

**17.** Do you consider that the involvement of Member States into the RASFF should be improved? [DD: Yes, No, Don't Know] If Yes, do you have suggestions on how the involvement of Member States into the RASFF could be improved? [Yes, No] If Yes, please specify. [TF] [NCP]

#### VI. ROLE OF THE EUROPEAN COMMISSION

**18.** To what extent does the EC fulfil the following duties of Article 50 of Regulation 178/2002, as specified in detail in Articles 2 to 7 of Regulation 16/2011 laying down implementing measures for the RASFF? [NCP]

a) The EC has transmitted alert notifications to all members of the network within 24 hours after reception, upon verification	[DD: Always within 24 hours, mostly within 24 hours, Sometimes, Never, Don't know]	Please explain: [TF]
b) The EC has transmitted follow-up notifications to alerts to all members of the network within 24 hours	As above	As above
c) The EC has transmitted information notifications to all members of the network without undue delay	[DD: Always, Often, Sometimes, Never, Don't know]	Please explain: [TF]
d) The EC has transmitted border rejection notifications to NCPs/border posts	As above	As above
e) The validation of notifications by the EC before transmitting them to all members of the network has been rapid	As above	As above
f) The validation of notifications by the EC before transmitting them to all members of the network has	As above	As above

been of good quality	

- g) The EC has informed our country's contact point without undue delay when notified products originated from or were distributed to our country [DD: Always, mostly, Sometimes, Never, Don't know] Please explain: [TF] [TC]
- **19.** To what extent has the EC contributed to ... [NCP]

a) The coordination of the members of the RASFF	[Scale 0-5, Not at all - Very much, Don't know]	[If not, please explain] [TF]
b) The development of good and common notification practices?	Same as above	Same as above

- **20.** To what extent have the <u>regular RASFF contact point Working Groups</u> organised by the EC contributed to the better functioning of the RASFF? [Scale 0-5: Not at all Very much, Don't know] If the Working Groups have contributed to a better functioning, please explain which outcomes you consider most relevant [TF] [NCP]
- **21.** To what extent are the <u>SOPs issued by the EC</u> on the functioning of the network...? [NCP]

a) <u>Clear</u>	[Scale 0-5, Not at all - Very much, Don't know]	[If not, please explain] [TF]
b) <u>Helpful</u>	Same as above	Same as above
c) Consistent with your needs and expectations	Same as above	Same as above

**22.** To what extent is <u>Regulation 16/2011</u> laying down implementing measures for the RASFF... ? [NCP]

c) <u>Clear</u>	[Scale 0-5, Not at all - Very much, Don't know]	[If not, please explain] [TF]
d) <u>Helpful</u>	Same as above	Same as above

**23.** Have there been cases where the <u>double role of the Commission as manager and participant</u> of the RASFF led to problems? [DD: Yes, No, Don't know] If Yes, please specify [TF] [ALL except IS]

**24.** Do you have suggestions how the <u>role of the EC in the RASFF</u> could be improved? [DD: Yes, No, Don't know] If Yes, please specify [TF] [ALL except IS]

#### VII. ROLE OF EFSA

- 25. deleted (moved to case study)
- **26.** deleted (moved to case study)

## VIII. INFORMATION FLOW TO STAKEHOLDERS AND PROFESSIONAL OPERATORS

- **27.** To what extent does the RASFF Portal <u>sufficiently</u> inform <u>professional operators</u>? [Scale 0-5 Not at all sufficient Very sufficient, Don't know] If No, please explain: [TF] [ALL]?
- **28.** Can stakeholders <u>sufficiently consult</u> the information in the RASFF Portal? [DD: Yes, No, Don't know] If No, please explain: [TF] [ALL]
- **29.** Do you consider there is a need to improve the <u>information flow to stakeholders and professional operators</u> from the RASFF? [DD: Yes, No, Don't know] If Yes, please specify [TF] [ALL]

## IX. PARTICIPATION OF THIRD COUNTRIES/INTERNATIONAL ORGANISATIONS

30.

a) For which purposes do you use notifications received through the RASFF?

i. Preventing affected consignments from	[DD: Yes, No, Don't know]
being exported to the EU	
ii. Preventing affected consignments from	As above
being imported to my country	
iii. To remove any affected consignments	
from the market in my country	
iv. To improve compliance with EU rules of	
products to be exported,	
v. To provide information to stakeholders and	
consumers	
vi. Other (please specify): [TF]	

b) To what extent is the RASFF <u>open</u> to your participation as a <u>third</u> <u>country/international organisation</u>? [Scale 0-5: Not at all – Very much, Don't know] If not, please explain [TF] *[IS]* 

- **31.** Are there any <u>obstacles</u> for your organisation preventing you <u>to provide more information</u> <u>to the RASFF</u> (such as language requirements, level of detail requested, confidentiality provisions, legal basis etc)? [DD: Yes, No, Don't know] If Yes, please specify obstacles [TF] *[IS]*
- **32.** As a third country, is the information you receive from the RASFF sufficient? [DD: Yes, No, Don't know] If No, please explain what additional information you would require [TF] [TC]
- **33.** Do you use the information in the RASFF for your official <u>controls of compliance with EU rules for products</u> exported <u>from your country to the EU?</u> [DD: Yes, No, Don't know] If Yes, please explain [TF] [TC]
- **34.** Would you need to receive more information from third countries through the RASFF? [DD: Yes, No, Don't know] If Yes, from which regions of the World as a priority? [TB: Western Balkans, North Africa, Sub-saharan Africa, Middle East and Arabian Peninsula, Asia, Oceania, Latin America and the Carribean, North America, Other] If Other, please specify [TF] [NCP]
- **35.** Do you have suggestions how the <u>participation of Third Countries/International</u> Organisations in the RASFF could be improved? [DD: Yes, No, Don't know] If Yes, please specify [TF] [ALL]
- **36.** To which extent is the RASFF complementary to the following information systems or duplicates them? (Please assess both aspects for each listed system.)

a) International level: INFOSAN [ALL]	Complementary to RASFF [Not at all – Very much, Don't know]	Duplication with RASFF [Not at all – Very much, Don't know]	Please explain [TF]
i. EWRS (Early Warning Response System) ii. TRACES (TRAde Control and Expert System) iii. RAPEX (Rapid Exchange of Information System) iv. ECURIE (European Community Urgent Radiological Information Exchange) v. EPIS (Epidemic Intelligence Information System) vi. ARGUS (General European rapid alert system) vii. Adminstrative Assistance and Cooperation	As above	As above	As above

viii. Other. Please specify [TF]	
c) National level: The alert system in your	
<u>country.</u> Please specify name of system:	
[TF] [ALL except IS]	

## X. TRANSPARENCY AND CONFIDENTIALITY

**37.** To what extent the RASFF Portal... [ALL]

a) is <u>transparent</u> to the general public?	[Scale 0-5: Not at all – Very much, Don't know]	
b) is <u>accessible</u> to the general public?	As above	As above
c) <u>addresses the needs</u> of the general public for information on unsafe food?		

**38.** To what extent is the <u>classification of notifications</u> used (alert notification, information notification, border rejection notification, follow-up notification) <u>clear?</u> [ALL]

a) For competent authorities	[Scale 0-5: Not at all clear – Very clear, Don't know]	If not, please explain: [TF]
b) For the general public	As above	As above
c) For food/feed business operators		

## **39.**

- **a)** Are the members of the RASFF <u>sufficiently respecting the confidentiality requirements</u> as set in the Regulation 178/2002 (Article 52)? [DD: Yes, No, Don't know] If No, please explain why: [TF] [ALL]
- **b)** Does the RASFF achieve an adequate balance between confidentiality and information to consumers and stakeholders? [DD: Yes, No, Don't know] If No, please explain why: [TF] [ALL]
- **40**. Do you have suggestions how the ... [ALL]

a) <u>Transparency</u> of the RASFF could be improved?	[DD: Yes, No,	If Yes, please
	Don't know]	specify [TF]
b) <u>Confidentiality</u> of the RASFF could be improved?	[DD: Yes, No, Don't know]	If Yes, please specify [TF]

# XI. EFFICIENCY

- **41.** Have the costs incurred by your country for the RASFF been appropriate when compared with the benefits of the RASFF for you? [Scale 0-5: Not at all appropriate Very appropriate, Don't know] Please explain the key benefits for your country: [TF] [NCP and TCs]
- **42.** Should the following types of notifications / messages in the future be handled through RASFF or through another information system (or mechanism)? [NCP]

a)	RASFF alert notifications	[DD: Should be handled through RASFF, Should be handled	If it should be handled through another system,
		through other system/mechanism, Don't know]	please specify [TF]
b)	RASFF information notifications	As above	As above
c)	RASFF border rejection notifications		
d)	RASFF follow-up notifications		
e)	RASFF news notifications		
f)	Status updates on crisis management measures taken in your country during a serious food/feed safety		
g)	incident (Draft) press releases in the context of crisis management measures taken in your country for information of the EC/other countries		
h)	Notifications of food fraud		
i)	Notifications of non- compliant consignments that are not related to risk containment (e.g. if MRL for a pesticide is exceeded slightly in a consignment)		
j)	Other		

- **43.** Could the <u>balance of cost and benefits</u> of the RASFF for your country be improved? [DD: Yes, No, Don't know] If Yes, please specify how: [TF] [NCPs and TCs]
- **44**. In your view, to what extent are the following <u>criteria relevant to evaluate</u> the <u>efficiency</u> of the RASFF? [ALL]

a) Costs of the RASFF for the Commission (including staff costs, training costs, costs of setting up and maintaining IT platforms including iRASFF and RASFF Window)	[Scale 0-5: Not at all relevant—Very relevant, Don't know]	Comments [TF]
b) Costs for NCPs (staff costs and costs for training of employees of relevant authorities/agencies in MS on the RASFF)	As above	As above
c) Validation time at the European Commission Contact Point - ECCP (period of time between the reception of the notification and its transmission to the members of the network)		
d) Please suggest other indicators: [TF]		

# XII. CLOSING

- **45.** Overall, to what extent are you <u>satisfied with the functioning of the RASFF</u>? [Scale 0-5: Not at all Very much, Don't know] If not, please explain [TF] [ALL]
- **46.** Do you consider that the RASFF has an <u>added value</u> compared to what could be achieved without it? [DD: Yes, No, Don't know] Please specify: [TF] [ALL]
- **47.** Any other comment? [TF] [ALL]



# EVALUATION OF THE RAPID ALERT SYSTEM FOR FOOD AND FEED AND OF CRISIS MANAGEMENT PROCEDURES

\*

# SURVEY OF COMPETENT AUTHORITIES IN THE FIELD OF FOOD/FEED CRISIS MANAGEMENT AND STAKEHOLDERS

The Directorate General for Health and Consumers (DG SANCO) of the European Commission has commissioned the Food Chain Evaluation Consortium (FCEC) to undertake an Evaluation of the Rapid Alert System for Food and Feed (RASFF) and of crisis management procedures.

The purpose of the evaluation is to assess whether the regulatory framework established by Articles 50 to 57 of Regulation 178/2002 is effective and efficiently working and providing added value to its stakeholders.

The information and assessments provided in your responses to this questionnaire will be crucial in assessing the effectiveness, efficiency and added value of this regulatory framework and in informing the EU policy process. For this reason we highly appreciate your taking the time to respond to this survey.

This questionnaire is targeted at key stakeholders involved in food/feed crisis management, including competent authorities involved in the management of food/feed incidents, emergencies and crises in Member States, international organisations, relevant government bodies in third countries, organisations of food/feed business operators and consumer organisations in the EU.

Please note that this survey focuses on crisis management procedures only. A complementary survey is being conducted on RASFF (please contact us in case you would like to respond to this survey as well).

When completing this questionnaire, please consider the following clarifications:

- The relevant <u>legal basis</u> for food/feed crisis management is:
  - o Regulation (EC) No 178/2002 lays down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. Articles 53 to 57 of this Regulation refer to emergency measures (Articles 53 and 54) and to crisis management (Articles 55 to 57). Regulation (EC) No 178/2002 is available here [LINK TO: <a href="http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002R0178">http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32002R0178</a>].
  - Commission Decision 2004/478/EC concerning the adoption of a general plan for food/feed crisis management. Available here [LINK TO: <a href="http://eur-lex.europa.eu/search.html?type=expert&qid=1412687490178">http://eur-lex.europa.eu/search.html?type=expert&qid=1412687490178</a>].
- A serious food/feed safety incident is defined in this questionnaire as a food/feed safety incident constituting a <u>serious risk</u> to human health, animal health or the environment, and with a <u>cross-border dimension</u> e.g. outbreak of Shiga toxin-

producing Escherichia coli (STEC), serotype O104:H4 in 2011 (RASFF reference 2011.0842, hereafter referred to as "*E.coli* outbreak, 2011"), presence of glass fragments in instant coffee in 2010 (RASFF 2010.0626, "Glass fragments in instant coffee, 2010"), and the melamine crisis in 2008 (i.e. melamine in food products containing milk or milk products originating in or consigned from China; RASFF News 08-459 and others; "Melamine crisis, 2008").

- <u>Crisis management</u> is defined in the context of the questionnaire as including both preparedness for and management of serious food/feed safety incidents.
- Contingency plan is defined as an operational plan setting out measures to be implemented without delay when feed or food is found to pose a serious risk to humans or animals either directly or through the environment (as defined in Article 13 of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules).
- The <u>period covered</u> by the evaluation is 2002-2013, so you may refer to serious food/feed safety incidents and your experience with crisis management during this period. In case a question refers to 'current' or 'existing' arrangements, only the status quo in terms of institutional arrangements and legal basis is relevant.

In your answer, please <u>express your expert opinion</u> based on your experiences with crisis management <u>in your country</u>. EU-level stakeholders should refer to the situation across the EU, and note any limitations in geographic coverage in the final comment field, if needed.

The names of all contributing organisations to the survey will be listed in the final report. All survey respondents will receive an electronic version of the report after publication.

Please also note that we have provided to you in our invitation to the survey a pdf document with the questionnaire to give you an overview of all questions before answering them online. Question numbering may show gaps, as only those questions are displayed that are relevant for your stakeholder group. Please submit the completed questionnaire no later than January 31<sup>st</sup> 2015.

If you have any further questions, do not hesitate to contact: Agathe Osinski evaluation@civic-consulting.de

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# THIS QUESTIONNAIRE WILL BE IMPLEMENTED ON AN ONLINE PLATFORM. THE TYPES OF QUESTIONS ARE INDICATED AS FOLLOWS:

TF=Text field

DD=Dropdown menu

CB=Check box

*The following display logics apply for the questionnaire:* 

[ALL]: The question is displayed to all stakeholders

[CA]: The question is displayed to MS national authority/agency involved in the management of food/feed incidents, emergencies and crises

[OCA]: The question is displayed to other national authorities/agencies

[FBO]: The question is displayed to EU or national organisation of food/feed business operators

[CO]: The question is displayed to EU or national consumer organisations

[IS]: The question is displayed to international organisations/third countries

[Other]: The question is displayed to other stakeholders.

## I. IDENTIFICATION DATA

- **1.** Please identify yourself: [ALL]
  - a) Name of organisation (obligatory) [TF]
  - b) Type of organisation (obligatory) [CB: MS national authority/agency involved in the management of food/feed incidents, emergencies and crises; Other national authority/agency; EU or national organisation of food/feed business operators; EU or national consumer organisation; International organisation/third country; Other] If other, please specify [TF]
  - c) Country in which organisation is located (obligatory) [DD: List of 28 EU Member States, Iceland, Norway, Liechtenstein, Switzerland; Other country] If other country, please specify (TF)
  - d) Contact person (name, position) [TF]
  - e) Email address (obligatory) [TF]
  - f) Phone number [TF]

**NOTE:** Access to all personal data and information collected in the context of this evaluation is only granted to a defined population of users, without prejudice to a possible transmission to the bodies in charge of a monitoring or inspection task in accordance with Community legislation. These users are typically members of the Unit organising the evaluation inside the DG and its subcontractor, FCEC, acting as processor. No personal data is transmitted to parties which are outside the recipients and the legal framework mentioned.

## II. EXISTING CRISIS MANAGEMENT ARRANGEMENTS IN YOUR COUNTRY

**2.** Please indicate the <u>type of contingency plan</u> (as defined in Article 13 of Regulation (EC) No 882/2004) available in the field of food/feed in your country, if any: *[CA]* 

a) A specific national contingency plan	[DD: Yes,	If Yes, please	Comments
for food/feed	available; Not	provide name of	[TF]
	yet available but	plan, year of	

	in development; No, neither available nor in development, Don't know]	adoption, and link to online version, if available [TF]	
b) A general national contingency plan which also covers food/feed incidents	As above	As above	As above
c) No national contingency plan, but a set of procedures to be used in case of emergencies in the field of food/feed			

**3.** If in your country one of the above listed types of <u>contingency plan/procedures is available</u>, please indicate whether the following items are specified for serious food/feed safety incidents: [CA]

a)	Administrative authorities to be engaged	[DD: Yes, No, Don't know]	Comments [TF]
b)	Their powers and responsibilities	As above	As above
c)	Formal coordination mechanisms between authorities at national, regional, and local levels		
d)	Channels and procedures for sharing information between relevant parties		
e)	Linkages to public health contingency planning		

**4.** Besides the elements listed in question 3, please indicate which of the following <u>other elements of crisis management</u> are available in your country: *[CA]* 

a)	Regular meetings of competent authorities in the fields of food/feed safety and public health to exchange information on relevant incidents/risks	[DD: Yes, available; Not yet available but planned; No, neither available nor planned; Don't know]	If Yes, please specify [TF]
b)	Systematic exchange of information with food/feed business operators	As above	As above
c)	A communication strategy for serious food/feed safety incidents		
d)	Designated crisis coordinator and alternate		
e)	National crisis management committee or unit		
f)	Infrastructure for the management of serious food/feed safety incidents (e.g. audio conference tools, IT tools, call centre etc).  Other. Please specify: [TF]		
g)	Other. Flease specify. [1F]		

**5.** Have you carried out <u>systematic review(s)</u> of your <u>crisis preparedness/management</u> arrangements in the field of food/feed on the basis of ...[CA]

a)	Lessons learned from past serious food/feed safety incidents	[DD: Yes, regularly; Yes, sometimes; Yes, once; No, never; Don't know]	If Yes, please specify whether the review led to improvements [Yes, No, Don't Know]	If improvements were made, please specify which [TF]
b)	Crisis simulation exercises	As above	As above	As above
	Review of organisation of the competent authority/ies Other. Please specify: [TF]			
u)	Office. Flease specify. [1F]			

**6.** Has your country established <u>criteria to define a food/feed crisis situation</u>? [DD: Yes, No, Don't know] If Yes, please specify criteria in use and link to relevant document: [TF] [ALL]

## III. EFFECTIVENESS OF EXISTING CRISIS MANAGEMENT ARRANGEMENTS

**7.** To what extent have the <u>existing crisis management arrangements</u> achieved the following in <u>past</u> serious food/feed safety incidents? [ALL except IS]

	In my country	At EU level	
a) Coordinated implementation of most effective measures to contain the risk	[Scale 0-5: Achieved not at all well - Achieved very well, Don't know]	[Scale 0-5: Achieved not at all well - Achieved very well, Don't know]	If not, please explain [TF]
b) Efficient management of serious food/feed incidents	As above	As above	As above
c) Consumers trust in food/feed safety			
d) Consumer health protection			
e) <u>Limited disruption of internal market and trade</u>			

**8.** Please assess the effectiveness of crisis management arrangements during the following <u>examples of serious food/feed safety incidents</u> that affected your country (you can add additional examples yourself, if you consider them relevant): *[ALL except IS]* 

Serious food/feed	Effectiveness of crisis management		Effectiveness of crisis management		If they were not
safety incidents	arrangements		effective, please		
	in my country at EU level		explain		

E.coli outbreak, 2011	[Scale 0-5: Not at all	[Scale 0-5: Not at all	[TF]
(RASFF 2011.0842)	effective – Very	effective – Very	
	effective, Don't	effective, Don't	
	know, My country	know]	
	was not affected]		
Glass fragments in			
instant coffee, 2010	As above	As above	As above
(RASFF 2010.0626)			
Melamine crisis,			
2008 (RASFF News			
08-459 and others)			
Additional example 1			
[TF]			
Additional example 2			
[TF]			

- **9.** Do you use <u>criteria to evaluate the effectiveness</u> of existing crisis management arrangements in your country (e.g. the duration between outbreak detection and containment)? [DD: Yes; No; Don't know] If Yes, please specify criteria in use and link to relevant document, if possible: [TF] *[CA]*
- **10.** In your view, would the <u>definition of EU harmonised criteria to evaluate the effectiveness</u> of existing crisis management arrangements be useful? [DD: Yes; No; Don't know] If Yes, please specify: [TF] [ALL except IS]
- **11.** Would you have <u>suggestions how the effective functioning</u> of existing crisis management arrangements <u>could be improved</u>? [DD: Yes, No, Don't know] If Yes, please specify [TF] [ALL]

# IV. ROLE OF THE EUROPEAN COMMISSION

**12.** Overall, to what extent has the EC played the role of coordinator in past serious food/feed safety incidents that affected your country? [ALL except IS]

a) General coordination of national efforts	[Scale 0-5: Not at all – Very much, Don't know]	If not, please explain [TF]
b) Coordination with EFSA	As above	As above
c) Coordination of communication of serious food/feed safety incidents to the public/relevant competent authorities		
d) Coordination with international organisations		
e) Coordination with third countries		

**13.** More specifically, to what extent has the EC played the role of coordinator during the following <u>examples of serious food/feed safety incidents</u> that affected your country (you can add additional examples yourself, if you consider them relevant)? [ALL except IS]

a) E.coli outbreak, 2011 (RASFF 2011.0842)	[Scale 0-5: Not	If not, please
	at all – Very	explain [TF]
	much, Don't	
	know]	
b) Glass fragments in instant coffee, 2010 (RASFF 2010.0626)	As above	As above
c) Melamine crisis, 2008 (RASFF News 08-459 and		
others)		
d) Additional example 1 [TF]		
e) Additional example 2 [TF]		

# **14.** To what extent have the following experiences <u>improved current crisis management arrangements</u>? *[CA]*

	In your	At EU level	
	country		
a) Experience gained from past serious	[Scale 0-5:	[Scale 0-5:	If not, please
food/feed safety incidents (e.g. E.coli	Not at all –	Not at all –	explain [TF]
outbreak )	Very much,	Very much,	
	Don't know]	Don't know]	
b) Experience gained from the EU-level	As above	As above	As above
Aristaeus exercise (May 2013)	As above	As above	As above
c) Experience gained from other crisis			
simulation exercises in which your country			
participated. Please specify exercise: [TF]			
d) Other type of experience. Please specify:			
[TF]			

# **15.** To what extent has the EC contributed to the <u>coordination of national efforts</u> (e.g. in outbreak investigations)? *[CA]*

a) Providing infrastructure for coordination (e.g.	[Scale 0-5: Contributed not at all–
audioconferences, meeting facilities)	Contributed very much, Don't know]
b) Providing training	As above
c) Sharing technical information	
d) Providing guidance documents/SOPs	
e) Other, please specify [TF]	

**16.** To what extent has the EC contributed to the <u>development of best practices</u> for the management of serious food/feed safety incidents (e.g. for the design of contingency plans)?

Please consider the following activities related to the management of food/feed crises: [CA]

a) Training activities organised by the EC	Participated	If Yes,	Please
	in this	please assess	explain [TF]
	activity	contribution	
	[Yes, No,	to the	
	Don't	development	
	Know]	of best	
		practices	
		[Scale 0-5:	
		Not at all –	
		Very much,	
		Don't know]	
b) Working groups organised by the EC	As above	As above	As above
c) FVO missions / reports			
d) Other. Please specify: TF			

**17.** Do you have suggestions how the <u>role of the EC as coordinator in serious food/feed safety incidents</u> could be <u>improved in the future</u>? [DD: Yes, No, Don't know] If Yes, please specify [TF] [ALL except IS]

#### V. INVOLVEMENT OF OTHER MEMBER STATES

- **18.** To what extent are you <u>satisfied with how actively other MS have managed serious food/feed safety incidents</u> that have affected your country? [Scale 0-5: Not at all satisfied Very much satisfied, Don't know] If not satisfied, please provide examples: [TF] [ALL except IS]
- **19.** Do you have suggestions how Member States could improve their crisis management? [DD: Yes, No, Don't know] If Yes, please specify [TF] [ALL except IS]

# VI. PARTICIPATION OF THIRD COUNTRIES/INTERNATIONAL ORGANISATIONS

- **20.** To what extent are the European crisis management mechanisms open to your participation as a <u>third country/international organisation</u>? [Scale 0-5: Not at all Very much, Don't know] If not, please explain [TF] [IS]
- **21.** Have there been any <u>obstacles</u> for your organisation preventing you <u>to provide more information</u> to the EC during past serious food/feed safety incidents (such as language requirements, level of detail requested, confidentiality provisions, legal basis etc)? [DD: Yes, No, Don't know] If Yes, please specify obstacles [TF] [IS]
- **22.** To what extent are you satisfied with the <u>information flow</u> between the EU and third countries/international organisations in past serious food/feed safety incidents that affected your country? [ALL]

a) Information flow between the EU and third countries	[Scale 0-5: Not	If not, please
	at all satisfied-	explain [TF]
	Very much	
	satisfied,	
	Don't know]	
b) Information flow between the EU and international organisations	As above	As above

**23.** Do you have suggestions how the information flow between the EU and third countries/international organisations could be improved for the management of serious food/feed safety incidents? [DD: Yes, No, Don't know] If Yes, please specify [TF] [ALL]

#### VII. EFFICIENCY OF EXISTING EU CRISIS MANAGEMENT ARRANGEMENTS

- **24.** In your view, has the <u>balance of costs and benefits</u> of crisis management at EU level been <u>appropriate</u>? [Scale 0-5: Not at all appropriate Very much appropriate, Don't know] If No, please specify: [TF] [CA]
- **25.** Do you have suggestions how the <u>balance of cost and benefits</u> of crisis management at EU level could be <u>improved</u>? [DD: Yes, No, Don't know] If Yes, please specify how: [TF] [CA]

#### **26.** Deleted

**27.** In your view, to what extent are the following <u>criteria/indicators relevant to evaluate</u> the efficiency of crisis management? [ALL]

a) Total costs of a serious food/feed safety incident (cost of managing food/feed safety incident and resulting economic losses)	[Scale 0-5: Not at all relevant— Very much relevant, Don't know]	Comments [TF]
b) Period of time for setting up mechanisms to ensure effective management of a serious food/feed safety incident, since the risk has been identified	As above	As above
c) Period of time until the risk has been brought under control, since it has been identified d) Please suggest other indicators: [TF]		

#### VIII. LEGAL BASIS

- **28.** To what extent have <u>emergency measures</u> ('safeguard measures'; as defined in Articles 53 and 54 of Regulation 178/2002) been effective for the management of past serious food/feed safety incidents? [Scale 0-5: Not at all Very much, Don't know] If not, please explain: [TF] [ALL except IS]
- **29.** To what extent has the <u>mechanism of emergency measures provided by Articles 53 and 54</u> of Regulation 178/2002 contributed to avoiding disparities between measures taken by different Member States and to ensuring a consistent approach during past serious food/feed safety incidents? [Scale 0-5: Contributed not at all Contributed very much, Don't know] If not, please explain: [TF] [ALL except IS]
- **30.** The general plan for food/feed crisis management provides for two layers of actions: (1) one layer of action related to potential serious risk (see Sections 2.2 and 6 of Commission Decision 2004/478/EC), where a crisis unit is not set up but adequate provisions are made to ensure effective management (2) another layer of action implying the setting up of a crisis unit
  - a) In your view, are these two layers of action <u>relevant</u>? [Scale 0-5: Not at all Very much, Don't know] If not, please explain: [TF] [ALL except IS]

- b) Are these two layers still appropriate for food/feed crisis management [Scale 0-5: Not at all Very much; Don't know] If not, please explain: [TF] [ALL except IS]
- **31.** In your view, have the <u>mechanisms foreseen in Sections 2.2 and 6 of Commission</u> <u>Decision 2004/478/EC</u> (where a crisis unit is not set up but adequate provisions are made to ensure effective management) <u>been sufficient</u> for the management of past serious food/feed safety incidents? [DD: Yes; No; Don't know] If No, please specify: [TF] [ALL except IS]
- **32.** Please assess whether or not there is a need for the following <u>measures related to crisis</u> <u>management</u> at EU level: [ALL except IS]

a) A step-wise approach for escalating measures of crisis management and for related criteria for escalation	[Scale 0-5: Not at all needed – Very much needed, Don't know]	Please explain [TF]
b) A <u>mechanism</u> that would be <u>activated at an earlier</u> stage than the general plan (as detailed in Decision 2004/478)	As above	As above
c) A greater role of the EC in the coordination of Member States' efforts		
d) Regular <u>crisis simulation exercises</u> at EU level		
e) A greater role of EFSA in the assessment of the risk		
f) A greater role of the EC in the coordination of the communication of serious food/feed safety incidents to the public/relevant competent authorities		
g) An IT tool at EU level for communication between  Member States/EC (such as an Intranet-based system for sharing relevant documents and coordinate common strategies and messages to the public)		
h) More coordination with international organisations in the event of serious food/feed safety incidents affecting the EU and other regions of the world		
i) A greater role of the EC in the coordination with third countries		
j) More EC support to Member States to manage serious food/feed safety incidents		
k) Other needs. Please specify [TF]		

## IX. CLOSING

- **33.** Do you consider that there is an <u>added value</u> resulting from the EC coordinating crisis management of the Member States concerning a serious food/feed safety incident compared to what could be achieved if there was no coordination at EU level? [Yes; No; Don't know] Please specify: [TF] [ALL]
- **34.** Are you aware of any data sources and relevant analyses concerning the <u>costs</u> and <u>economic impact of past serious food/feed safety incidents</u> that have affected your country?

[DD: Yes, No, Don't know] If Yes, do you agree to be contacted to provide us with more information on the data sources and analyses? [TB: Yes, No] [TF] [ALL]

**35.** Any other comment? [TF] [ALL]

#### Annex 4: Survey respondents' organisations

# 4.1 RASFF - Contributing organisations to the survey of RASFF National Contact Points and stakeholders as reported by respondents are:

- 1. ACCOE
- 2. Administration for food safety, veterinary sector and plant protection (Slovenia)
- 3. AGES (Austria)
- 4. Amt für Lebensmittelkontrolle und Veterinärwesen, FL-9494 Schaan (Liechtenstein)
- 5. APC EUROPE S. A.
- 6. BEMEFA vzw www.bemefa.be
- 7. Bundesamt für Verbraucherschutz Federal Office of Consumer Protection and Food Safety (BVL) (Germany)
- 8. CENTRAL CONTROLLING AND TESTING INSTITUTE IN AGRICULTURE (CCTIA)
- 9. Central institute for supervising and testing in agriculture (Slovakia)
- 10. Central Institute for Supervising and Testing in Agriculture (Slovakia)
- 11. COCERAL
- 12. Coop de France Nutrition Animal
- 13. Czech Agriculture and Food Inspection Authority (CAFIA)
- 14. Czech Agriculture and Food Inspection Authority (CAFIA)
- 15. DGAV-DSECI-DIM (Portugal)
- 16. ECDC
- 17. Estonian Veterinary and Food Board
- 18. EuroCommerce
- 19. European Association of Chemical Distributors (Fecc)
- 20. European Crop Protection Association
- 21. European Spice Association
- 22. Federal Agency for the Safety of the Food Chain (Belgium)
- 23. Federal Office for Food Safety and Veterinary Affairs (Switzerland)
- 24. FEDERATION OF HELLENIC FOOD INDUSTRIES
- 25. FEDIAF
- 26. FEDIOL

- 27. FEFAC
- 28. FEFANA Asbl
- 29. Finnish Food Safety Authority Evira
- 30. FNICGV
- 31. FNLI (Federation of the Dutch Food and Grocery Industry)
- 32. Food and Drink Federation
- 33. Food and Veterinary Service (Latvia)
- 34. Food Safety Authority of Ireland
- 35. Food Safety Commission MALTA
- 36. Food Standards Agency, United Kingdom
- 37. FOOD SUPPLEMENTS EUROPE
- 38. FoodDrinkEurope
- 39. FoodServiceEurope
- 40. FRENCH MINISTRY IN CHARGE OF AGRICULTURE AND FOOD
- 41. Główny Inspektorat Sanitarny (Chief Sanitary Inspectorate) (Poland)
- 42. Hellenic Food Authority (EFET)
- 43. Huevos Guillen S.L.
- 44. IACA
- 45. International Meat Trade Association
- 46. Irish Shellfish Association
- 47. MIAVIT NUTRICION ANIMAL S.L
- 48. MINISTERO DELLA SALUTE (Italy)
- 49. Ministry of Agriculture (Croatia)
- 50. Ministry of Agriculture and Food (Bulgaria)
- 51. Ministry of Agriculture and Rural Development of the Slovak Republic
- 52. Ministry of Agriculture of the Czech Republic
- 53. Ministry of Agriculture, Food and Environment (Spanish Feed Contact Point for RASFF)
- 54. Ministry of Agriculture, Livestock and Food Supply (Brazil)
- 55. Ministry of Food, Agriculture and Fisheries. Danish Veterinary and Food Administration

- 56. National Food Agency (Sweden)
- 57. National Food Chain Safety Office (Hungary)
- 58. National Food Chain Safety Office Food and Feed Safety Directorate (Hungary)
- 59. National Sanitary Veterinary and Food Safety Authority (Romania)
- 60. Nestlé S.A.
- 61. Norwegian Food Safety Authority
- 62. Public Health Services, Medical and Public Health Services, Ministry of Health (Cyprus)
- 63. PURATOS NV
- 64. Servicio Nacional de Sanidad y Calidad Agroalimentaria (SENASA) (SENASA: National Service of Agrifood Health and Quality Ministry of Agriculture, Livestock and Fisheries of Argentina)
- 65. Spanish Agency for Consumer Affairs, Food Safety and Nutrition
- 66. State Food and Veterinary Service of the Republic of Lithuania
- 67. State Food and Veterinary Service of the Republic of Lithuania
- 68. Swedish Board of Agriculture
- 69. The Netherlands Food and Consumer Product Safety Authority (NVWA)
- 70. The State Veterinary and Food Administration of the Slovak Republic
- 71. U.S. Food and Drug Administration
- 72. UECBV
- 73. VBT
- 74. Verband der Fleischwirtschaft e. V. (VDF)
- 75. Veterinary and Food Board (Estonia)

# 4.2 Crisis management - Contributing organisations to the survey of competent authorities in the field of food/feed crisis management and stakeholders are:

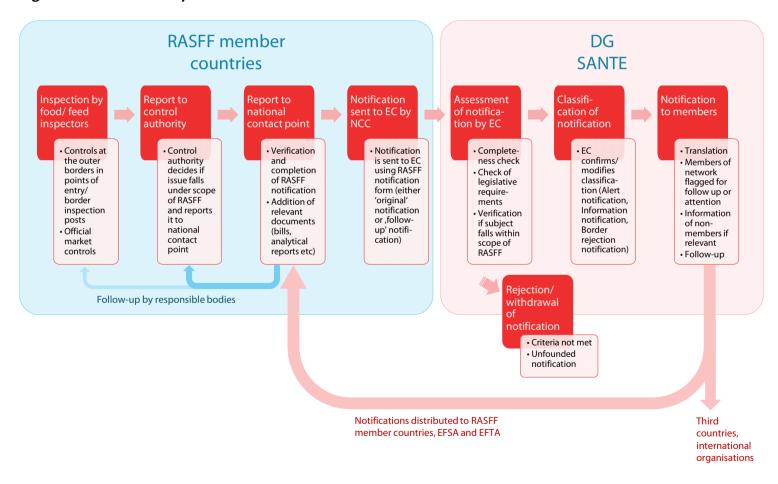
- 1. Administration for Food Safety, Veterinary Sector and Plant protection (Slovenia)
- 2. Bemefa
- 3. BFMA
- 4. Brazilian Ministry of Agriculture, Livestock and Food Supply
- 5. Chief Sanitary Inspectorate (Poland)
- 6. Danish Veterinary and Food Administration
- 7. Direction Générale de la Concurrence, de la Consommation et de la Répression des fraudes (DGCCRF) General Directorate in charge of competition, consumption and frauds (France)
- 8. ELC Federation of European Specialty Food Ingredients Industries
- 9. Estonian Veterinary and Food Board
- 10. EuroCommerce
- 11. European Centre for Disease Prevention and Control
- 12. Federal Agency for the Safety of the Food Chain (aka FASFC or Belgian Food agency)
- 13. Federal Ministry of Food and Agriculture (Germany)
- 14. Federal Office of Consumer Protection and Food Safety (Germany)
- 15. FEDERATION OF HELLENIC FOOD INDUSTRY
- 16. FEDIOL
- 17. FEFAC
- 18. FEFAC
- 19. Finnish Food Safety Authority Evira
- 20. FNICGV
- 21. FNLI (Federation of the Dutch Food and Grocery Industry)
- 22. Food and Veterinary Service (Latvia)
- 23. Food Safety Authority of Ireland
- 24. Food Standards Agency (U.K.)
- 25. FOOD SUPPLEMENTS EUROPE
- 26. FoodDrinkEurope

- 27. General Directorate for Food and Veterinary Affairs (Portugal)
- 28. HELLENIC FOOD AUTHORITY (EFET)
- 29. IACA
- 30. Ministry in charge of agriculture and food (France)
- 31. Ministry of Agriculture (Czech Repulic)
- 32. Ministry of Agriculture and Food (Bulgaria)
- 33. Ministry of Economic Affairs (EZ) and the Ministry of Health, Welfare and Sport (VWS) / Netherlands Food and Consumer Product Safety Authority (NVWA)
- 34. Ministry of Health (Austria)
- 35. National Food Chain Safety Office (Hungary)
- 36. National Sanitary Veterinary and Food Safety Authority Romania
- 37. Nestlé S.A.
- 38. Nordic Sugar
- 39. OCU organización de Consumidores y usuarios (Spain)
- 40. Public Health Services, Medical and Public Health Services, Ministry of Health (Cyprus)
- 41. PURATOS NV
- 42. SPANISH AGENCY FOR CONSUMER AFFAIRS, FOOD SAFETY AND NUTRITION (AECOSAN)
- 43. STATE GENERAL LABORATORY (Cyprus)
- 44. Swedish Board of agriculture
- 45. The Norwegian Food Safety Authority
- 46. U.S. Food and Drug Administration
- 47. UECBV

# Annex 5: Figures and tables relating to the Rapid Alert System for Food and Feed

## 5.1 Figures and tables

Figure 1: Notification process within the RASFF network and role of DG SANTE



Source: Civic Consulting

Table 1: Potential complementarities and duplications between the RASFF and other EU and international notification systems

Acronym	System	Туре	Description	Potential complementarity to RASFF	Potential duplication with RASFF
EWRS	Early Warning and Response System	EU system	The main objective of the network is to establish permanent communication between European Union Member States' public health authorities, which are responsible for determining the measures required to control communicable disease-related events. <sup>a</sup>	Exchange of information regarding the public health effects of a suspected foodborne outbreak.	No potential duplications between the RASFF and EWRS expected.
TRACES	TRAde Control and Expert System	EU system	The trade control and expert system (TRAde Control and Expert System – TRACES) created a single central database for monitoring the movements of animals and products of animal origin both within the European Union and those coming from outside of the EU. <sup>b</sup>	Provision of complementary information related to movements of animals and products of animal origin.	Border rejection notifications submitted through TRACES are synchronised with RASFF Window after verification.
RAPEX	Rapid Alert system for non-food dangerous products	EU system	The Rapid Alert System for dangerous non-food products (RAPEX) allows the 31 participating countries (EU countries, Norway, Iceland and Liechtenstein) and the EC to exchange information on products posing a risk to health and safety of consumers and on the measures taken by these countries to do away with that risk. The system also covers products posing risk to health and safety of professional users and to other public interests protected by relevant EU legislation (e.g. environment and security). <sup>c</sup>	Provision of complementary information on dangerous non-food products.	Duplication could occur between the RASFF and RAPEX in case products containing both a food and a non-food component are notified.
ECURIE	European Community Urgent	EU system	ECURIE is a system for the early notification and exchange of information in the event of a radiological or nuclear	Provision of complementary information in case a radiological or nuclear accident	In case of a radiological or nuclear accident that affects food/ feed safety, both systems may be used

	Radiological Information Exchange		emergency. It requires ECURIE Member States (EU-28 and Switzerland) that they promptly notify the EC and all the MS potentially affected when they intend to take counter-measures in order to protect their population against the effects of a radiological or nuclear accident. All MS are required to inform the EC at appropriate intervals about the measures they take and the radioactivity levels they have measured. <sup>d</sup>	leads to a contamination of the food/feed chain.	to report on measures taken and radioactivity levels measured.
EPIS	Epidemic Intelligence Information System	EU system	EPIS has been developed by the ECDC as a communication platform tool to allow risk assessment bodies to exchange non-structured and semi-structured information regarding current or emerging public health threats with a potential impact in the EU. It aims to ensure coordination and work sharing among the various national public health institutes regarding surveillance and control activities. e	EPIS can provide complementary information regarding public health effects of suspected foodborne outbreaks.	No potential duplications between the RASFF and EPIS expected.
ARGUS	The General European rapid alert system	EU system	ARGUS is a general European rapid alert system, which allows each Directorate General in the Commission to inform other DGs and services of a beginning or risk of multi-sectoral crisis via an alert exchange, provides a coordination process that can be activated in case of crisis (the crisis coordination committee), and provides a common source of information that will be used by the Commission to communicate in an effective and coherent way with citizens. <sup>f</sup>	Complementary information exchange regarding a (potential) multi-sectoral crisis.	No potential duplications between the RASFF and ARGUS expected.
AAC	Administrative Assistance and Cooperation	EU system	The AAC system is intended to provide Member States with a tool for exchanging information that is necessary to enable the	Where a non-compliance does not involve a risk which requires a notification to be transmitted	The AAC and RASFF may be used simultaneously in cases where a non-compliance also poses a risk,

	System		verification of compliance with food and feed law with their counterparts. <sup>g</sup> Administrative assistance and cooperation exchanges may take place in cases where fraudulent practices are identified along the food chain. Such exchanges would take place via the Food Fraud Network (FFN), established by the EC in 2013. While the AAC system is not currently operational, it will undergo a pilot phase in the area of food fraud before being made available for all exchanges related to administrative assistance and cooperation.	to the RASFF, the systems are used separately and are considered to be complementary in scope.	e.g. if food fraud involves a risk to human health, it may have to be notified both through the RASFF and the AAC system.
IMSOC <sup>j</sup>	Information Management System for Official Control	EU system	The (planned) IMSOC system is intended as an information management system for the integration of mechanisms and tools through which data, information and documents concerning official controls are managed and handled; i.e. to integrate the mechanisms and tools provided for in agrifood legislation for the exchange of information and data concerning official controls.	The main objective of IMSOC is to integrate the various systems used for official controls, including the RASFF. The complementarity between relevant systems would be strengthened, if the transfer of information between them is facilitated in the integration process.	Given that IMSOC aims to integrate the relevant systems, no duplications between the RASFF and IMSOC are expected.
INFOSAN	International Network of Food Safety Authorities	Inter- national system	INFOSAN is a global network of national food safety authorities, managed jointly by FAO and WHO. It aims to promote the rapid exchange of information during food safety related events, share information on important food safety related issues of global interest, promote partnerships and collaboration between countries, and between networks and help countries strengthen their capacity to manage food safety emergencies. <sup>k</sup>	Complementary information exchange regarding food safety risks that involve third countries. If the RASFF requires information from a Third Country with which it does not have direct or frequent contact, INFOSAN may serve as an intermediary between the EU and the relevant Third Country.	Duplication may occur between the RASFF and INFOSAN in specific cases: for instance, if a contaminated product originating from a Third Country is distributed to the EU and non-EU countries, both the RASFF and INFOSAN may contact the Third Country to obtain more information.

Notes: a) http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=666

b) http://europa.eu/legislation\_summaries/food\_safety/veterinary\_checks\_and\_food\_hygiene/f84009\_en.htm

c) http://ec.europa.eu/consumers/consumers\_safety/safety\_products/rapex/index\_en.htm d) http://rem.jrc.ec.europa.eu/RemWeb/activities/Ecurie.aspx

- e) http://ecdc.europa.eu/en/activities/epidemicintelligence/pages/epidemicintelligence tools.aspx
- f) http://ec.europa.eu/health/preparedness response/generic preparedness/planning/argus en.htm
- g) http://ec.europa.eu/food/safety/official\_controls/legislation/aac/index\_en.htm, Commission Implementing Decision of XXX establishing the Administrative Assistance and Cooperation system ('AAC System') pursuant to Regulation (EC) No 882/2004 of official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules. h) It is envisaged that a link between the RASFF and AAC IT tool be developed in order to enable information uploaded to one system to be made available in the other. i) European Commission, Standard Operating Procedures of the Rapid Alert System for Food and Feed, n.d. p. 21.
- j) As this system is not currently in place, it was not provided as an item for assessment by survey respondents. However, since it has been mentioned in comments respondents, it is included in this table to provide an explanation and analysis of the planned system.
- k) http://www.who.int/foodsafety/fs\_management/infosan\_brochure\_en.pdf?ua=1.

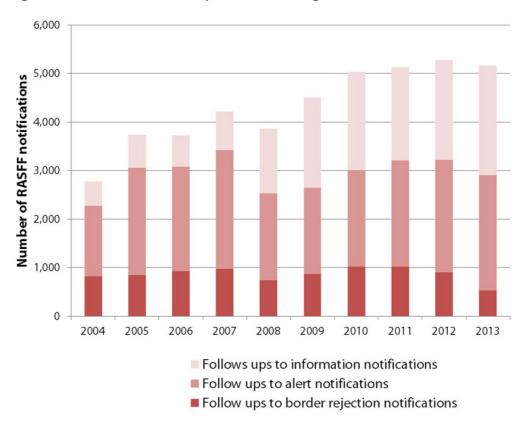


Figure 2: Trend in follow up to RASFF original notifications

Source: Civic Consulting, from data provided in RASFF Annual Report 2008, RASFF Annual Report 2009, RASFF Annual Report 2010, RASFF Annual Report 2011, RASFF Annual Report 2012, and RASFF Annual Report 2013. The distinction between "follow up to information for attention" and "follow up to information for follow-up" was introduced in 2011 and is combined in this graph. Prior to this date, data is available for the general category "follow up to information notifications".

Figure 3: Number of RASFF original notifications submitted by members of the network according to population size (2013)

Source: Civic Consulting based on population data from Eurostat (2013) and 2013 RASFF Annual Report.

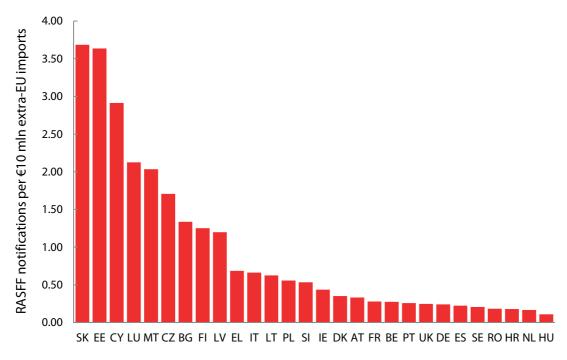


Figure 4: Number of RASFF original notifications submitted by members of the network according to value of extra-EU imports to the country (2013)

Source: Civic Consulting based on data from Eurostat (2013) on extra-EU trade in food, drink, and tobacco (Eurostat code: ext\_lt\_intratrd). Note: no data was available for EFTA countries; Croatia became a member country in the course of 2013.

Number of original notificationstransmitted  $R^2 = 0.6002$ Number of Full Time Equivalent (FTE) posts

Figure 5: Scatterplot of NCP staff posts and original notifications submitted

Source: Civic Consulting, using data provided by National Contact Points and the RASFF 2013 Annual Report.

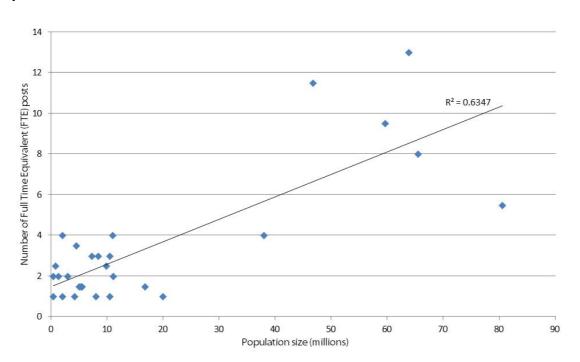
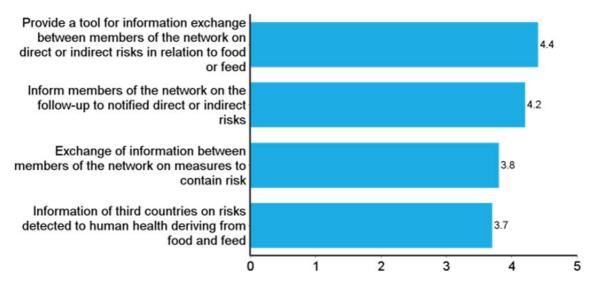


Figure 6: Scatterplot of member countries population size and NCP staff posts

Source: Civic Consulting, using data provided by National Contact Points and Eurostat population data.

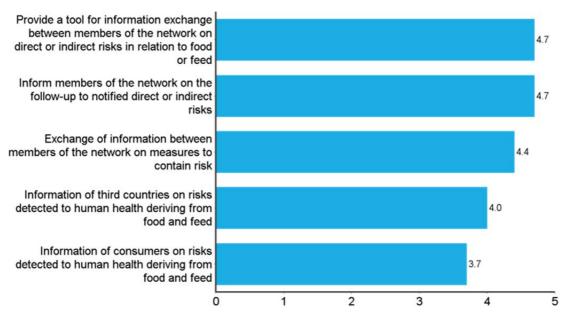
#### 5.2 Survey results

Figure 7: "To what extent is the RASFF achieving the following objectives?" (All respondents)



Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N= 54 to 65 (depending on item). Note: Based on respondents that provided an assessment.

Figure 8: "To what extent is the RASFF achieving the following objectives?" (Only National Contact Points)



Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=26-31 depending on item. Note: Based on respondents that provided an assessment.

Provide a tool for information exchange between members of the network on 4.2 direct or indirect risks in relation to food or feed Inform members of the network on the 3.8 follow-up to notified direct or indirect risks Information of third countries on risks detected to human health deriving from food and feed Exchange of information between 32 members of the network on measures to contain risk Information of consumers on risks detected to human health deriving from 3.0 food and feed

Figure 9: "To what extent is the RASFF achieving the following objectives?" (Only other stakeholders)

Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=28-35 depending on item. Note: Based on respondents that provided an assessment.

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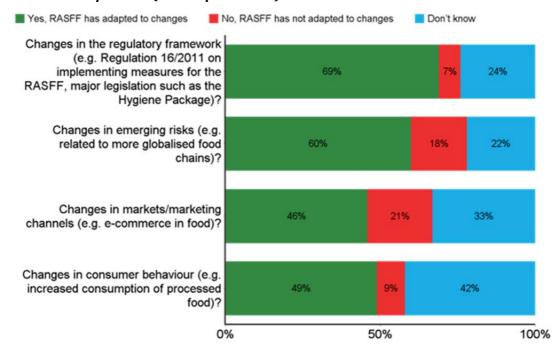


Figure 10: "Have there been changes to the following areas to which the RASFF has not adapted?" (All respondents)

Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N= 67. Note: Based on respondents that provided an assessment.

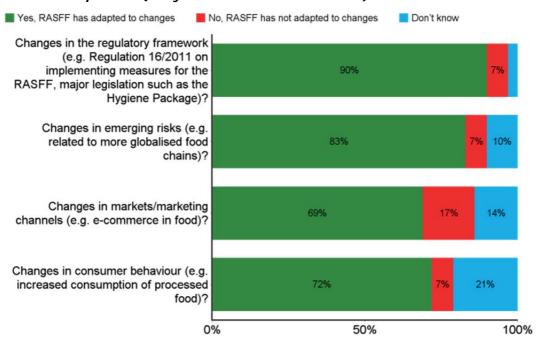


Figure 11: "Have there been changes to the following areas to which the RASFF has not adapted?" (Only National Contact Points)

Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=29-30 depending on item. Note: Based on respondents that provided an assessment.

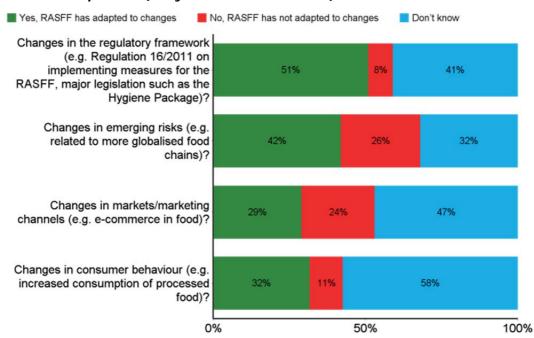


Figure 12: "Have there been changes to the following areas to which the RASFF has not adapted?" (Only other stakeholders)

Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=37-38 depending on item. Note: Based on respondents that provided an assessment.

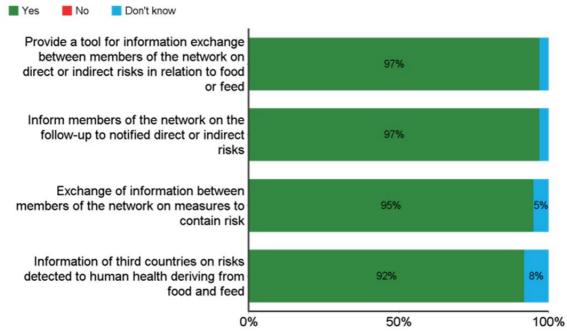


Figure 13: "Does this objective remain valid?" (All respondents)

Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N= 36 to 39 (depending on item). Note: Based on respondents that provided an assessment.

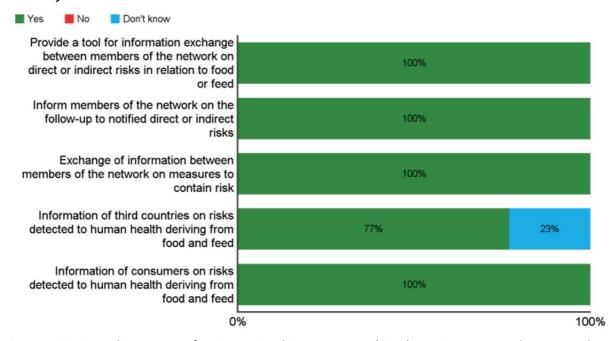


Figure 14: "Does this objective remain valid?" (Only National Contact Points)

Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=13. Note: Based on respondents that provided an assessment.

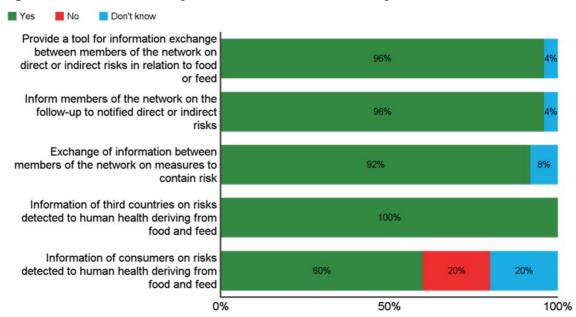


Figure 15: "Does this objective remain valid?" (Only other stakeholders)

Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=23-26 depending on item. Note: Based on respondents that provided an assessment.

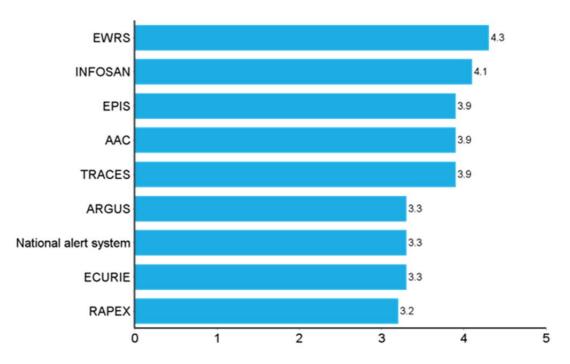


Figure 16: "To which extent is the RASFF complementary to the following information systems?" (All respondents)

Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N=11 to 45 (depending on item). Note: Based on respondents that provided an assessment.

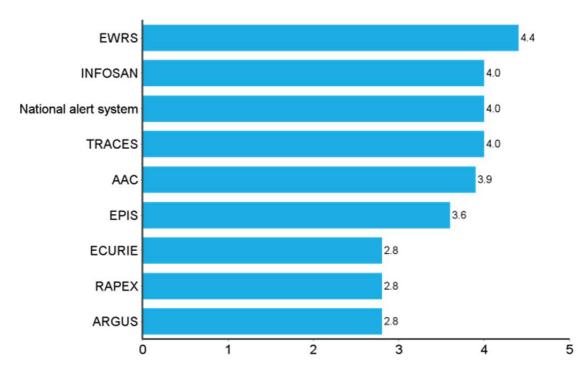


Figure 17: "To which extent is the RASFF complementary to the following information systems?" (Only National Contact Points)

Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=8-31 depending on item. Note: Based on respondents that provided an assessment.

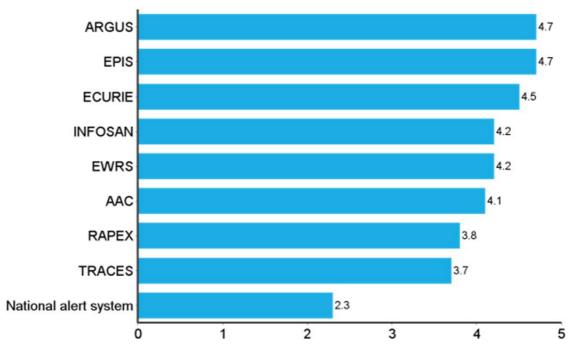


Figure 18: "To which extent is the RASFF complementary to the following information systems?" (Only other stakeholders)

Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=9-13. Note: Based on respondents that provided an assessment.

A rapid and coordinated response in cases of risks to human health deriving from food and feed

Protection of consumer health

The containment of food/feed safety incidents and prevention of crisis

Effective national control including border control to ensure compliance with EU rules of products placed on the EU market

Consumer confidence in safe food/feed on the EU market

Prevention of disruptions of the internal market due to food/feed safety incidents

3.7

Figure 19: "To what extent is the scope of the RASFF appropriate to address the following needs?" (Only National Contact Points)

Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=30-32 (depending on the item). Note: Based on respondents that provided an assessment.

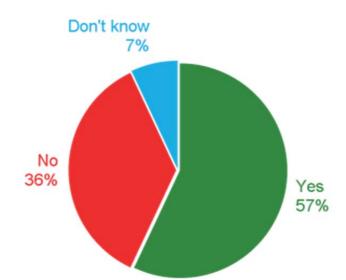
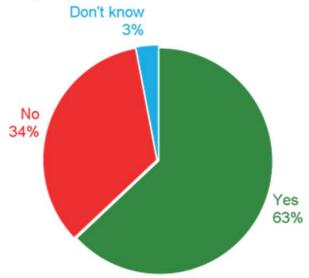


Figure 20: "Is the scope of the RASFF (i.e. areas covered and the type of information provided) sufficiently defined in Article 50 of Regulation (EC) No 178/2002?" (All respondents)

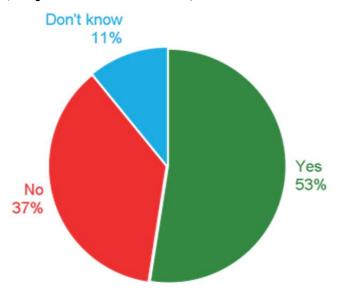
Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N=70 Note: Based on respondents that provided an assessment.

Figure 21: "Is the scope of the RASFF (i.e. areas covered and the type of information provided) sufficiently defined in Article 50 of Regulation (EC) No 178/2002?" (Only National Contact Points)



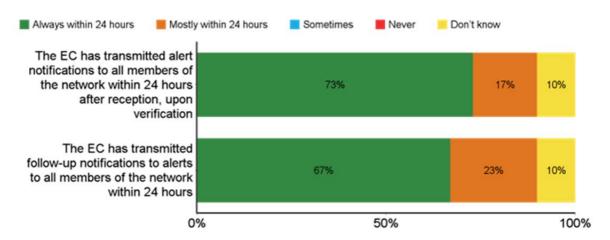
Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=32. Note: Based on respondents that provided an assessment.

Figure 22: "Is the scope of the RASFF (i.e. areas covered and the type of information provided) sufficiently defined in Article 50 of Regulation (EC) No 178/2002?" (Only other stakeholders)



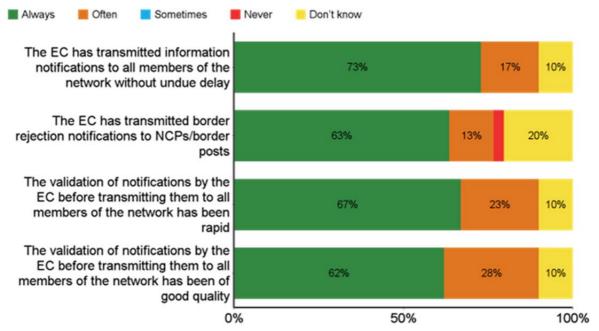
Source: Civic Consulting survey of other stakeholders involved in the RASFF, N= 38. Note: Based on respondents that provided an assessment.

Figure 23: "To what extent does the EC fulfil the following duties of Article 50 of Regulation (EC) 178/2002, as specified in detail in Articles 2 to 7 of Commission Regulation (EU) 16/2011 laying down implementing measures for the RASFF? (Only National Contact Points)



Source: Civic Consulting survey of RASFF National Contact Points, N= 30. Note: Based on respondents that provided an assessment.

Figure 24: "To what extent does the EC fulfil the following duties of Article 50 of Regulation 178/2002, as specified in detail in Articles 2 to 7 of Regulation 16/2011 laying down implementing measures for the RASFF? (Only National Contact Points)



Source: Civic Consulting survey of RASFF National Contact Points, N= 29 to 30 (depending on item). Note: Based on respondents that provided an assessment.

Pes 2%

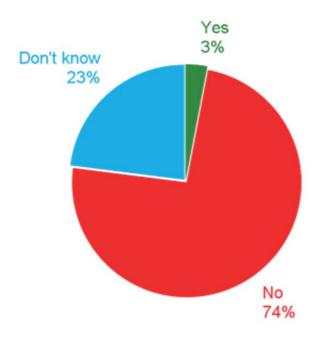
Don't know 45%

No 53%

Figure 25: "Have there been cases where the double role of the Commission as manager and participant of the RASFF led to problems?" (All respondents)

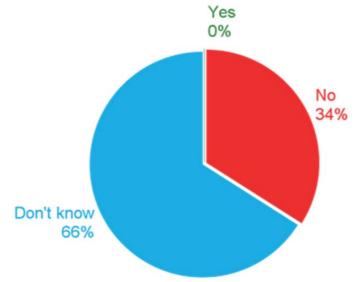
Source: Civic Consulting survey of RASFF National Contact Points and other stakeholders involved in the RASFF, N= 66. Note: Based on respondents that provided an assessment.

Figure 26: "Have there been cases where the double role of the Commission as manager and participant of the RASFF led to problems?" (Only National Contact Points)



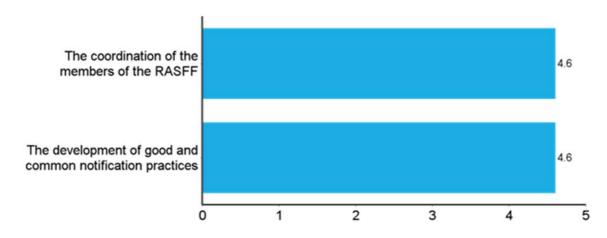
Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N= 31. Note: Based on respondents that provided an assessment.

Figure 27: "Have there been cases where the double role of the Commission as manager and participant of the RASFF led to problems?" (Only other stakeholders)



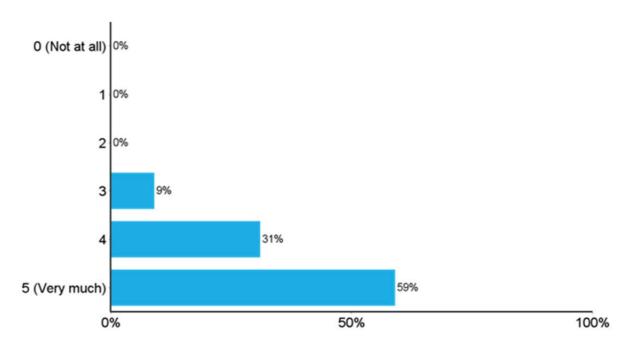
Source: Civic Consulting survey of other stakeholders involved in the RASFF, N= 35. Note: Based on respondents that provided an assessment.

Figure 28: "To what extent has the EC contributed to ...?" (Only National Contact Points)



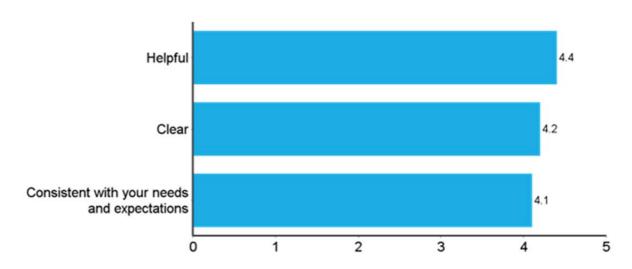
Source: Civic Consulting survey of RASFF National Contact Points, N= 32. Note: Based on respondents that provided an assessment.

Figure 29: "To what extent have the regular RASFF contact point Working Groups organised by the EC contributed to the better functioning of the RASFF?" (Only National Contact Points)



Source: Civic Consulting survey of RASFF National Contact Points, N= 32. Note: Based on respondents that provided an assessment.

Figure 30: "To what extent are the SOPs issued by the EC on the functioning of the network...?" (Only National Contact Points)



Source: Civic Consulting survey of RASFF National Contact Points, N= 31 to 32 (depending on item). Note: Based on respondents that provided an assessment.

Don't know 10% Yes 46% No 44%

Figure 31: "Are the notifications exchanged through the RASFF sufficiently risk based?" (All respondents)

Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N= 70. Note: Based on respondents that provided an assessment.



Figure 32: "Are the notifications exchanged through the RASFF sufficiently risk

Yes 66%

Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=32. Note: Based on respondents that provided an assessment.

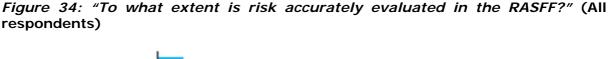
No 25%

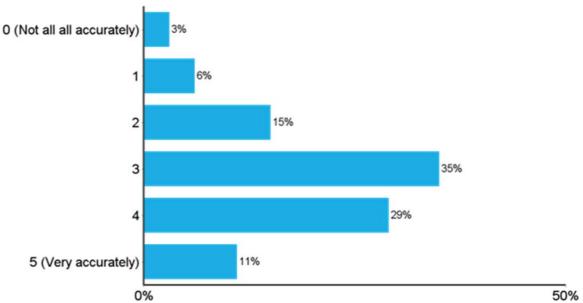
Don't know
11%
Yes
29%

Figure 33: "Are the notifications exchanged through the RASFF sufficiently risk based?" (Only other stakeholders)

Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=38. Note: Based on respondents that provided an assessment.

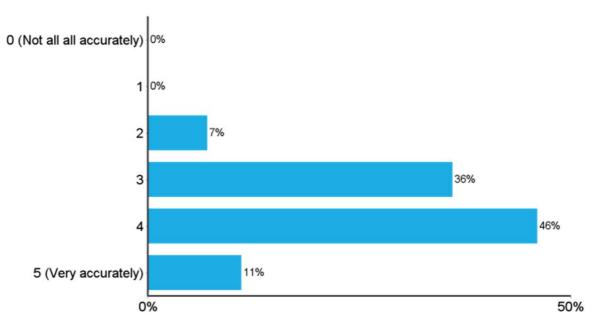
No 61%





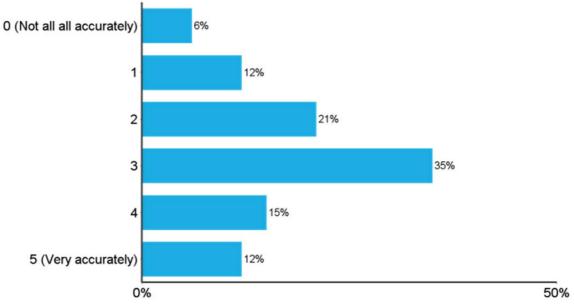
Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N= 62. Note: Based on respondents that provided an assessment.

Figure 35: "To what extent is risk accurately evaluated in the RASFF?" (Only National Contact Points)



Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=28. Note: Based on respondents that provided an assessment.

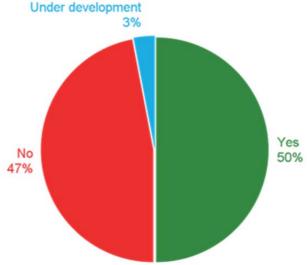
Figure 36: "To what extent is risk accurately evaluated in the RASFF?" (Only other stakeholders)



Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=34. Note: Based on respondents that provided an assessment.

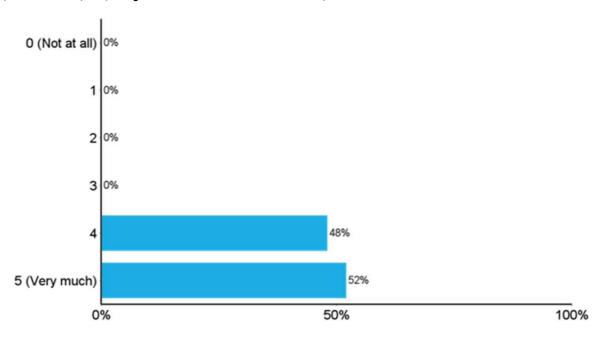
Figure 37: "Has your country adopted national legislation to implement the RASFF?" (Only National Contact Points)

Under development 3%



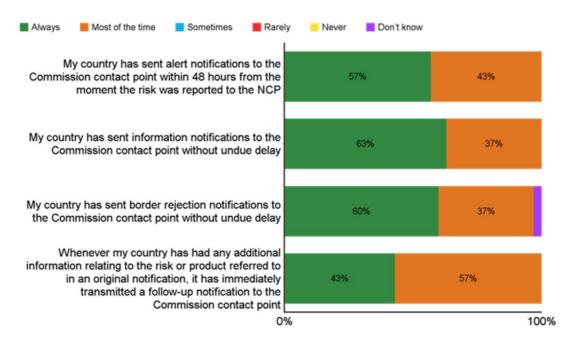
Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=32. Note: Based on respondents that provided an assessment.

Figure 38: "To what extent does your country fulfil the following duties of Article 50 of Regulation 178/2002, as specified in detail in Articles 2 to 7 of Regulation 16/2011 laying down implementing measures for the RASFF? My country has ensured the efficient functioning of the RASFF within its jurisdiction (Scale 0 -5)" (Only National Contact Points)



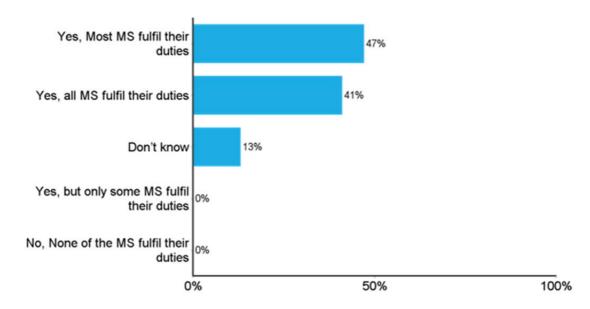
Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=31. Note: Based on respondents that provided an assessment.

Figure 39: "To what extent does your country fulfil the following duties of Article 50 of Regulation 178/2002, as specified in detail in Articles 2 to 7 of Regulation 16/2011 laying down implementing measures for the RASFF?" (Only National Contact Points)



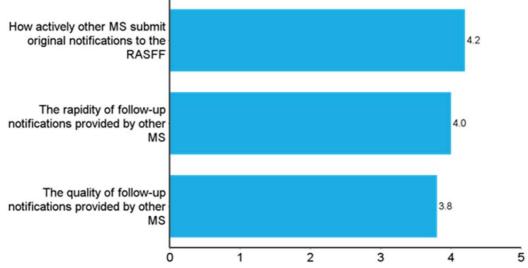
Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=30. Note: Based on respondents that provided an assessment.

Figure 40: "In your view, do other MS fulfil their duties under the RASFF?" (Only National Contact Points)



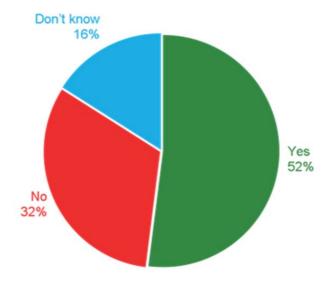
Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=32. Note: Based on respondents that provided an assessment.

Figure 41: "To what extent are you satisfied with ....?" (Only National Contact Points)



Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=26 to 29 (depending on item). Note: Based on respondents that provided an assessment.

Figure 42: "Would you need to receive more information from third countries through the RASFF?" (Only National Contact Points)



Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=31. Note: Based on respondents that provided an assessment.

Asia
Western Balkans
North America
Sold Sub-saharan Africa
Oceania

Western Balkans

8

8

Asia

Asia

Balkans

Balkans

Asia

Balkans

Ba

Figure 43: "If Yes, from which regions of the World as a priority?" (Only National Contact Points)

Source: Civic Consulting survey of RASFF National Contact Points, N=13. Note: Based on respondents that provided an assessment.

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15

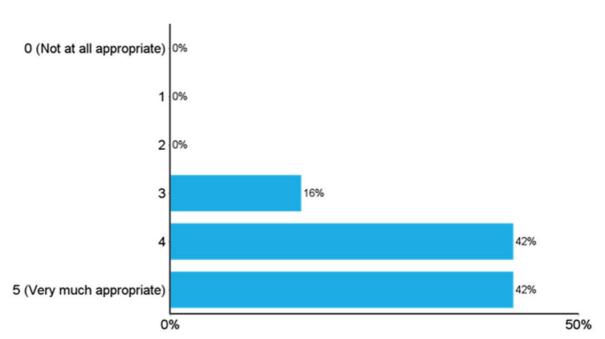


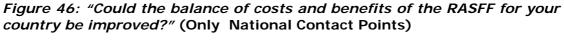
Figure 44: "Have the costs incurred by your country for the RASFF been appropriate when compared with the benefits of the RASFF for you?" (Only National Contact Points)

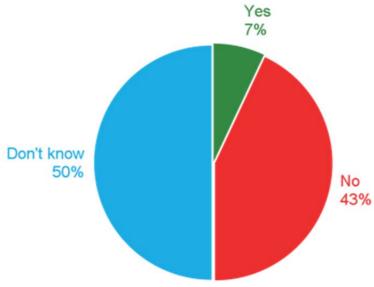
Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=31. Note: Based on respondents that provided an assessment.

Pon't know 50% No 41%

Figure 45: "Could the balance of costs and benefits of the RASFF for your country be improved?" (All respondents)

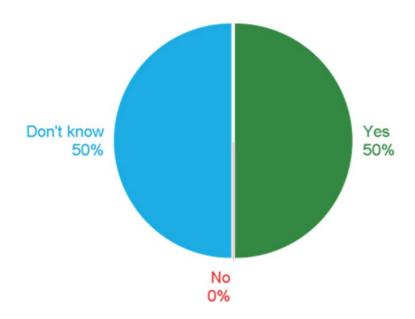
Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders (third countries) involved in the RASFF, N=32. Note: Based on respondents that provided an assessment.





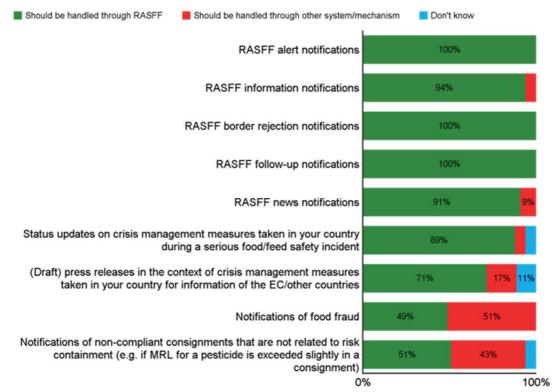
Source: Civic Consulting survey of RASFF National Contact Points, N=30. Note: Based on respondents that provided an assessment.

Figure 47: "Could the balance of costs and benefits of the RASFF for your country be improved?" (Only Third Countries)



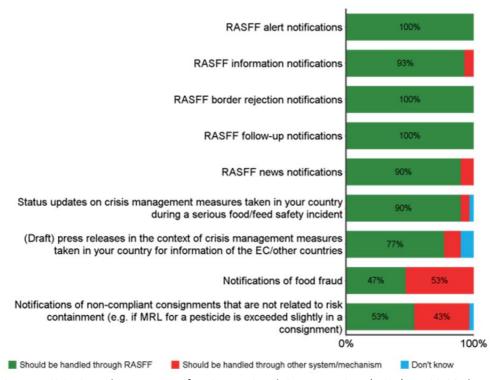
Source: Civic Consulting survey of other stakeholders involved in the RASFF (Third Countries), N=2. Note: Based on respondents that provided an assessment.

Figure 48: "Should the following types of notifications/ messages in the future be handled through RASFF or through another information system (or mechanism)?" (All respondents)



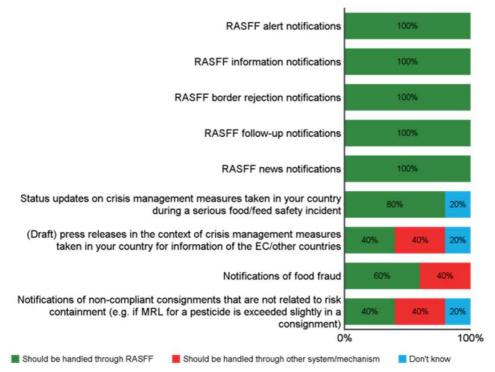
Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N= 34 to 35 (depending on item). Note: Based on respondents that provided an assessment.

Figure 49: "Should the following types of notifications/ messages in the future be handled through RASFF or through another information system (or mechanism)?" (Only National Contact Points)



Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=29-30 depending on item. Note: Based on respondents that provided an assessment.

Figure 50: "Should the following types of notifications/ messages in the future be handled through RASFF or through another information system (or mechanism)?" (Only other stakeholders)



Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=5. Note: Based on respondents that provided an assessment.

Figure 51: "To what extent does the RASFF Portal sufficiently inform professional operators?" (All respondents)

Source: Civic Consulting survey of RASFF National Contact Points and other stakeholders involved in the RASFF, N= 65. Note: Based on respondents that provided an assessment.

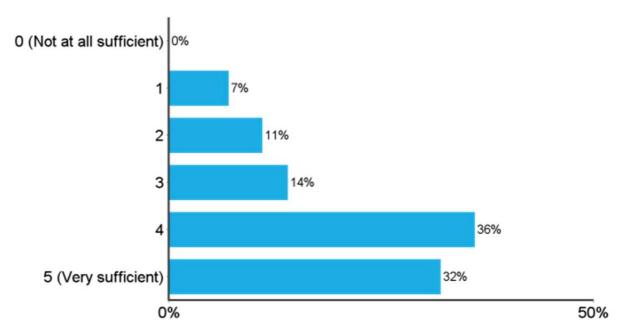


Figure 52: "To what extent does the RASFF Portal sufficiently inform professional operators?" (Only National Contact Points)

Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=28. Note: Based on respondents that provided an assessment.

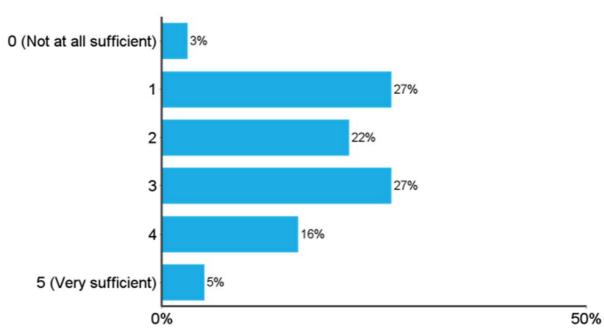


Figure 53: "To what extent does the RASFF Portal sufficiently inform professional operators?" (Only other stakeholders)

Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=37. Note: Based on respondents that provided an assessment.

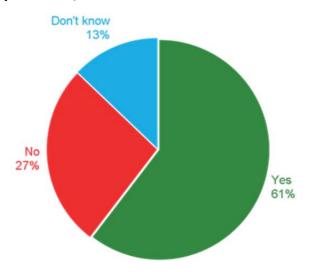


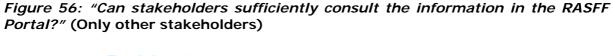
Figure 54: "Can stakeholders sufficiently consult the information in the RASFF Portal?" (All respondents)

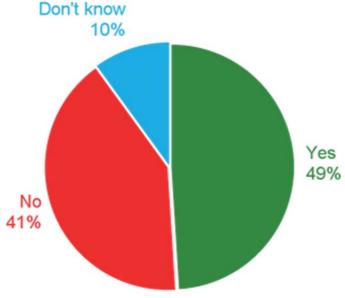
Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N= 71. Note: Based on respondents that provided an assessment.

Don't know
16%
No
9%
Yes
75%

Figure 55: "Can stakeholders sufficiently consult the information in the RASFF Portal?" (Only National Contact Points)

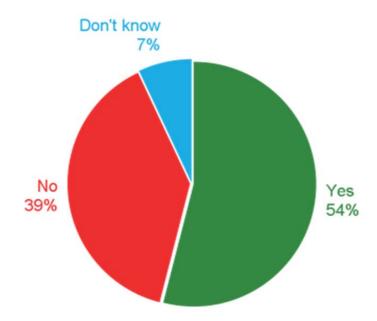
Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=32. Note: Based on respondents that provided an assessment.





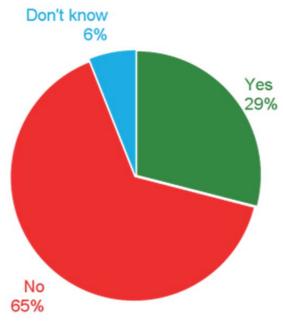
Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=39. Note: Based on respondents that provided an assessment.

Figure 57: "Do you consider there is a need to improve the information flow to stakeholders and professional operators from the RASFF?" (All respondents)



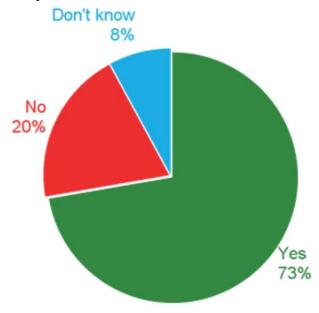
Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N=71. Note: Based on respondents that provided an assessment.

Figure 58: "Do you consider there is a need to improve the information flow to stakeholders and professional operators from the RASFF?" (Only National Contact Points)



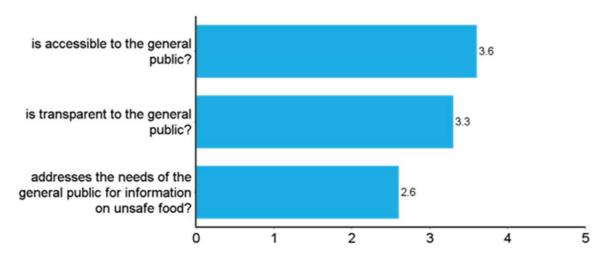
Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=31. Note: Based on respondents that provided an assessment.

Figure 59: "Do you consider there is a need to improve the information flow to stakeholders and professional operators from the RASFF?" (Only other stakeholders)



Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=40. Note: Based on respondents that provided an assessment.

Figure 60: "To what extent the RASFF Portal...?" (All respondents)



Source: Civic Consulting survey of RASFF National Contact Points and other stakeholders involved in the RASFF, N=68 to 71. Note: Based on respondents that provided an assessment.

is accessible to the general public?

is transparent to the general public?

addresses the needs of the general public for information on unsafe food?

0 1 2 3 4 5

Figure 61: "To what extent the RASFF Portal...?" (Only National Contact Points)

Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=30-31 depending on item. Note: Based on respondents that provided an assessment.

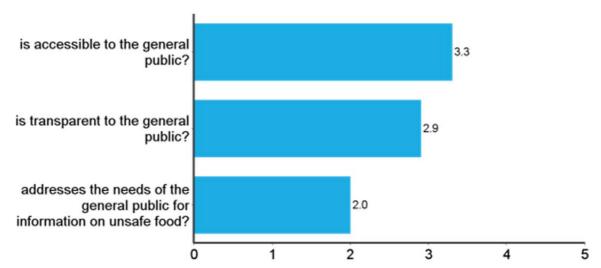
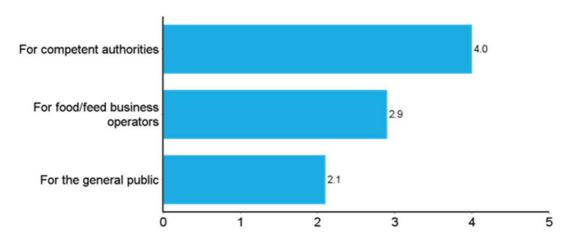


Figure 62: "To what extent the RASFF Portal ...?" (Only other stakeholders)

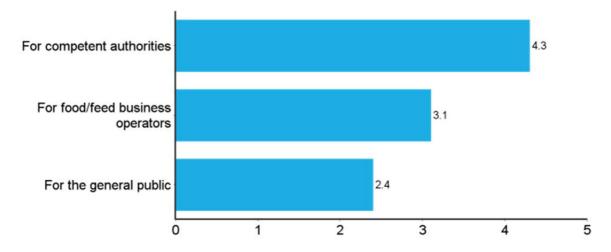
Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=38-40 depending on item. Note: Based on respondents that provided an assessment.

Figure 63: "To what extent is the classification of notifications used (alert notification, information notification, border rejection notification, follow-up notification) clear?" (All respondents)



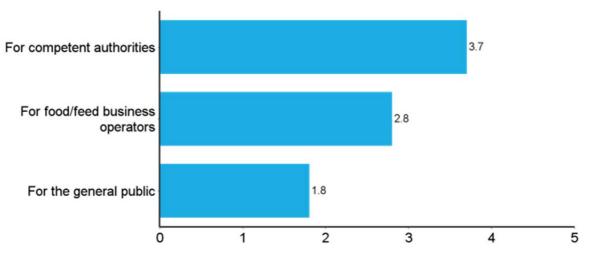
Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and relevant stakeholders, N=54 to 59 (depending on item). Note: Based on respondents that provided an assessment.

Figure 64: "To what extent is the classification of notifications used (alert notification, information notification, border rejection notification, follow-up notification) clear?" (Only National Contact Points)



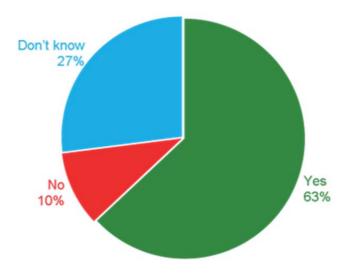
Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=29-31 depending on item. Note: Based on respondents that provided an assessment.

Figure 65: "To what extent is the classification of notifications used (alert notification, information notification, border rejection notification, follow-up notification) clear?" (Only other stakeholders)



Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=23-30 depending on item. Note: Based on respondents that provided an assessment.

Figure 66: "Are the members of the RASFF sufficiently respecting the confidentiality requirements as set in the Regulation 178/2002 (Article 52)?" (All respondents)



Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N= 71. Note: Based on respondents that provided an assessment.

Figure 67: "Are the members of the RASFF sufficiently respecting the confidentiality requirements as set in the Regulation 178/2002 (Article 52)?" (Only National Contact Points)



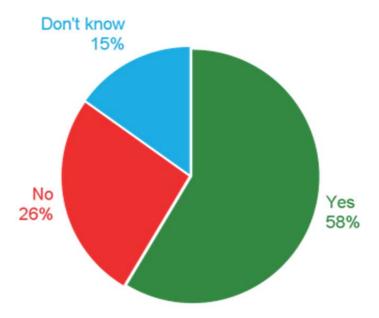
Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=32. Note: Based on respondents that provided an assessment.

Figure 68: "Are the members of the RASFF sufficiently respecting the confidentiality requirements as set in the Regulation 178/2002 (Article 52)?" (Only other stakeholders)



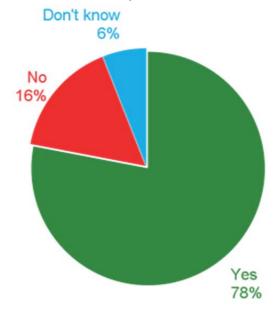
Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=39. Note: Based on respondents that provided an assessment.

Figure 69: "Does the RASFF achieve an adequate balance between confidentiality and information to consumers and stakeholders?" (All respondents)



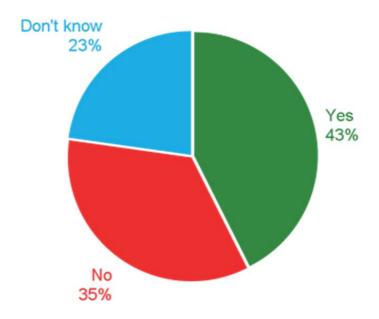
Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N=72. Note: Based on respondents that provided an assessment.

Figure 70: "Does the RASFF achieve an adequate balance between confidentiality and information to consumers and stakeholders?" (Only RASFF National Contact Points)



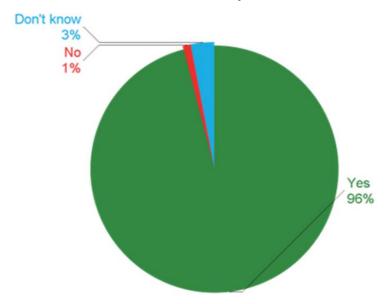
Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=32. Note: Based on respondents that provided an assessment.

Figure 71: "Does the RASFF achieve an adequate balance between confidentiality and information to consumers and stakeholders?" (Only other stakeholders)



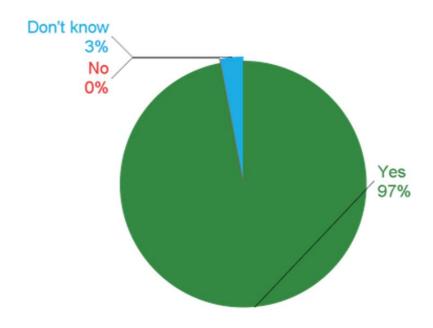
Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=40. Note: Based on respondents that provided an assessment.

Figure 72: "Do you consider that the RASFF has an added value compared to what could be achieved without it?" (All respondents)



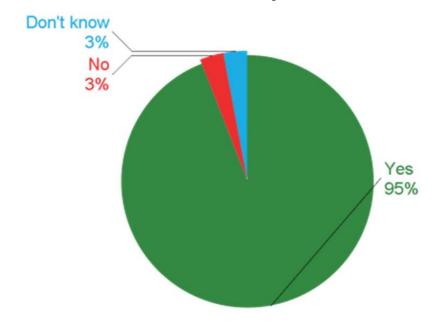
Source: Civic Consulting survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF, N=72. Note: Based on respondents that provided an assessment.

Figure 73: "Do you consider that the RASFF has an added value compared to what could be achieved without it?" (Only National Contact Points)



Source: Civic Consulting survey of RASFF National Contact Points (NCPs), N=32. Note: Based on respondents that provided an assessment.

Figure 74: "Do you consider that the RASFF has an added value compared to what could be achieved without it? " (Only other stakeholders)

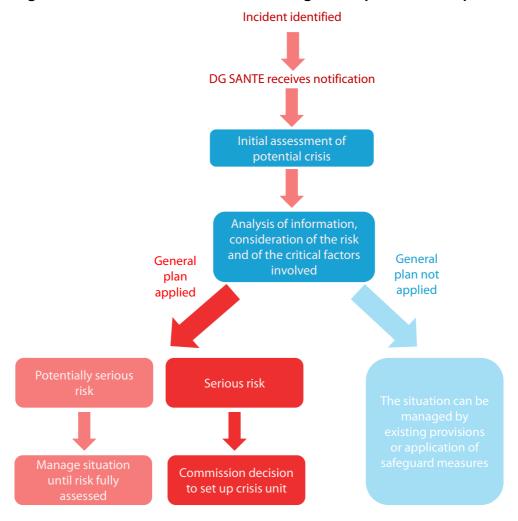


Source: Civic Consulting survey of other stakeholders involved in the RASFF, N=40. Note: Based on respondents that provided an assessment.

## Annex 6: Figures and tables relating to (potential) crisis management

## 6.1 Figures and tables

Figure 75: Flowchart of EU crisis management phases and options



Source: European Commission 2012. Standard Operating Procedures for food/feed crisis management.

Table 2: Crisis management measures in past food safety incidents

Food safety incident	Description of the food safety incident	Selected crisis management measures used (at EU/MS level)	Extent to intended impacts of crisis management were achieved	Assessment of effectiveness by survey respondents
Melamine crisis (2008)	In 2008, melamine was fraudulently added to milk and milk products produced in China to give the appearance of increased protein levels. The high levels of melamine in infant milk resulted in very severe health effects in infants and young children in China. In Europe, the substance was detected in composite products containing milk and soya ingredients, and in sodium bicarbonate.	In response to the crisis, the European Commission issued a request for urgent scientific advice to EFSA, held teleconferences of the Health Security Committee, and adopted three consecutive emergency measures (Commission Decision 2008/757/EC, Commission Decision 2008/798/EC and Commission Decision 2008/921/EC) to prevent the contaminated products from entering the EU market. From the onset of the crisis, the RASFF was used to inform Member States about developments in China and to communicate the results of controls carried out. In some Member States, crisis management measures were also put in place, e.g. the issuing of press releases, providing information to consumers on web pages of competent authorities, and triggering withdrawal procedures for affected products.	Despite the global impact of the melamine crisis, it did not leave any tangible effects on consumer health in the EU. <sup>a</sup> Therefore, although some case study interviewees had difficulties in assessing whether or not the crisis management arrangements achieved their intended impacts at the EU level, others agreed that the coordinated implementation of the most effective measures to contain the risk, efficient management of the incident, and consumer health protection were adequately achieved. There were mixed views among interviewees regarding the extent to which consumer trust was protected; media coverage of the event was cited as a factor hindering its achievement.	Average assessment of effectiveness of crisis management arrangements by survey respondents:  - in own country: 4.3  - at EU level: 4.2  On a scale from 0 (not at all effective) to 5 (very effective)

Food safety incident	Description of the food safety incident	Selected crisis management measures used (at EU/MS level)	Extent to intended impacts of crisis management were achieved	Assessment of effectiveness by survey respondents
Glass fragments in instant coffee (2010)	The incident involved a large food producer (Nestlé) which issued a voluntary recall of three types of glass-packaged instant coffee following the company's own checks. The checks revealed a risk of the presence of small pieces of glass in the instant coffee resulting from damaged jars, probably incurred during transport. These pieces of glass were not visible to consumers prior to consumption due to an opaque film label covering the entire surface of the jar. As a result, the company withdrew and recalled the affected products from 30 markets, including mainly EU Member States and Balkan countries. <sup>b</sup>	At EU level, no specific crisis management measures were put in place, although the RASFF played an important role in the exchange of information and by raising awareness about the recall. The incident was managed primarily by the company, which launched a public recall across all markets to which the product had been distributed, and triggered internal crisis management procedures. At Member State level, the competent authorities of some countries published information about the concerned products on the website of the relevant ministry, or issued public warnings to accelerate the recall process. However, according to interviewees from different Member States, no contingency plans had to be triggered in those countries; the incident was managed using regular procedures.	While there was no need to put EU crisis management measures in place, case study interviewees agreed that the incident was well-managed by the company. The limited effect of the recalled product on consumers indicates that at the very least, consumer health protection was achieved. Moreover, there is no indication suggesting that coordinated implementation of the most effective measures to contain the risk was not achieved.	Average assessment of effectiveness of crisis management arrangements by survey respondents:  - in own country: 4.7  - at EU level: 4.0  On a scale from 0 (not at all effective) to 5 (very effective)

Food safety incident	Description of the food safety incident	Selected crisis management measures used (at EU/MS level)	Extent to intended impacts of crisis management were achieved	Assessment of effectiveness by survey respondents
E.coli outbreak (2011)	The E.coli outbreak was characterised by a high incidence of infections with Shiga toxin-producing Escherichia coli (STEC) of serotype O104:H4, caused by the consumption of fenugreek sprouted seeds. It is the largest known STEC-associated outbreak worldwide, with roughly 900 cases of the life-threatening post-diarrhoeal sequel of haemolytic uremic syndrome (HUS) and 55 deaths. It also caused severe economic damage to the European agricultural sector.	At the EU level, the EC put in place a number of crisis management measures: shortly after the start of the outbreak, the EC began to organise audioconferences between Member States and other relevant bodies (e.g. ECDC, WHO, RKI); it sent a Task Force to Germany composed of experts from the EC, ECDC and EFSA and subsequently mandated EFSA to perform a traceability exercise to identify the source of the outbreak. Once the source was found, the EC adopted Commission Implementing Decision 2011/402/EU. Throughout the incident, the RASFF was used as a tool for information exchange, which contributed significantly to the traceability exercise. In Germany, crisis communication was undertaken by the BfR, RKI and BVL, and a Task Force was set up to manage the crisis. In France, conference calls were used to communicate between relevant ministries; moreover, national instructions were adopted in addition to the emergency measures at EU level.	While some case study interviewees considered that crisis management arrangements achieved coordinated implementation of the most effective measures to contain risk, improved management of serious food/feed safety incidents, and protection of human health, others indicated that the E.coli outbreak was not efficiently managed, and that consumer health could have been better protected. Interviewees generally considered that the limited disruption of the internal market and trade was not achieved (except insofar as it was intentional through the imposition of the ban on import of seeds and beans from Egypt). There was general agreement among interviewees that upholding consumers' trust in food/feed safety was not reached.	Average assessment of effectiveness of crisis management arrangements by survey respondents: - in own country: 4.2 - at EU level: 3.0 On a scale from 0 (not at all effective) to 5 (very effective)

Source: Civic Consulting. Notes: a) Alemanno, Alberto, "The European Food Import Safety Regime Under a 'Stress Test': The Melamine Contamination of the Global Food Supply Chain", Vol. 3, No. 4, 2010. b) RASFF notification 2010.0626. c) Frank, C, D Werber, and A Milde-Bush, "Results of Surveillance for Infections with Shiga Toxin-Producing Escherichia Coli (STEC) of Serotype O104: H4 after the Large Outbreak in Germany, July to December 2011," Eurosurveillance, Vol. 19, No. 14, 2014, pp. 1–6.

Table 3: Emergency measures adopted by the European Commission on basis of Article 53 of Regulation (EC) No 178/2002 (2002-2013)

Year adopted	Emergency measure	Legal instrument	Amended	In force
2002	2002/250/EC: Commission Decision of 27 March 2002 concerning the extension of the protective measures provided by Decision 2001/699/EC, with regard to the fishery and aquaculture products imported from Vietnam	Commission Decision		
2002	2002/247/EC: Commission Decision of 27 March 2002 suspending the placing on the market and import of jelly confectionery containing the food additive E 425 konjac	Commission Decision		
2002	2002/249/EC: Commission Decision of 27 March 2002 concerning certain protective measures with regard to certain fishery and aquaculture products intended for human consumption and imported from Myanmar	Commission Decision		
2002	2002/251/EC: Commission Decision of 27 March 2002 concerning certain protective measures with regard to poultry meat and certain fishery and aquaculture products intended for human consumption and imported from Thailand	Commission Decision	٧	٧
2002	2002/805/EC: Commission Decision of 15 October 2002 concerning certain protective measures with regard to certain products of animal origin for animal nutrition and imported from Ukraine	Commission Decision		٧
2002	2002/794/EC: Commission Decision of 11 October 2002 concerning certain protective measures with regard to poultry meat, poultry meat products and poultry meat preparations intended for human consumption and imported from Brazil	Commission Decision	٧	
2003	2003/477/EC: Commission Decision of 24 June 2003 amending Decision 2002/251/EC to revoke the protective measures with regard to the fishery and aquaculture products imported from Thailand	Commission Decision		
2003	2003/460/EC: Commission Decision of 20 June 2003 on emergency measures regarding hot chilli and hot chilli products	Commission Decision	٧	
2003	2003/493/EC: Commission Decision of 4 July 2003 imposing special conditions on the import of Brazil nuts in shell originating in or consigned from Brazil	Commission Decision		
2004	2004/374/EC: Commission Decision of 13 April 2004 suspending the placing on the market and import of jelly mini-cups containing the food additives E 400, E 401, E 402, E 403, E 404, E 405, E 406, E 407, E 407a, E 410, E 412, E 413, E 414, E 415, E 417 and/or E 418	Commission Decision		
2005	2005/85/EC: Commission Decision of 26 January 2005 imposing special conditions on the import of pistachios and certain products derived from pistachios originating in, or consigned from Iran	Commission Decision		
2005	2005/317/EC: Commission Decision of 18 April 2005 on emergency measures regarding	Commission Decision		

Year adopted	Emergency measure	Legal instrument	Amended	In force
	the non-authorised genetically modified organism Bt10 in maize products			
2006	2006/27/EC: Commission Decision of 16 January 2006 on special conditions governing meat and meat products of equidae imported from Mexico and intended for human consumption	Commission Decision		٧
2006	2006/236/EC: Commission Decision of 21 March 2006 on special conditions governing fishery products imported from Indonesia and intended for human consumption	Commission Decision	٧	٧
2006	2006/504/EC: Commission Decision of 12 July 2006 on special conditions governing certain foodstuffs imported from certain third countries due to contamination risks of these products by aflatoxins <sup>a</sup>	Commission Decision		
2006	2006/578/EC: Commission Decision of 23 August 2006 on emergency measures regarding the non-authorised genetically modified organism LL RICE 601 in rice products	Commission Decision		
2006	2006/694/EC: Commission Decision of 13 October 2006 prohibiting the placing on the market of curd cheese manufactured in a dairy establishment in the United Kingdom	Commission Decision		
2006	2006/698/EC: Commission Decision of 16 October 2006 on emergency measures applying to fishery products imported from Brazil and intended for human consumption	Commission Decision	٧	
2007	2007/82/EC: Commission Decision of 2 February 2007 on emergency measures suspending imports from the Republic of Guinea of fishery products intended for human consumption	Commission Decision		٧
2007	Commission Regulation (EC) No 884/2007 of 26 July 2007 on emergency measures suspending the use of E 128 Red 2G as food colour	Commission Regulation		٧
2007	2007/642/EC: Commission Decision of 4 October 2007 on emergency measures applying to fishery products imported from Albania and intended for human consumption	Commission Decision		٧
2008	2008/289/EC: Commission Decision of 3 April 2008 on emergency measures regarding the unauthorised genetically modified organism Bt 63 in rice products <sup>b</sup>	Commission Decision		
2008	2008/352/EC: Commission Decision of 29 April 2008 imposing special conditions governing guar gum originating in or consigned from India due to contamination risks of those products by pentachlorophenol and dioxins <sup>c</sup>	Commission Decision	٧	
2008	2008/388/EC: Commission Decision of 23 May 2008 imposing special conditions governing the import of sunflower oil originating in or consigned from Ukraine due to contamination risks by mineral oil	Commission Decision		
2008	Commission Regulation (EC) No 601/2008 of 25 June 2008 on protective measures applying to certain fishery products imported from Gabon and intended for human consumption	Commission Regulation		
2008	2008/660/EC: Commission Decision of 31 July 2008 amending Decision 2006/236/EC on special conditions governing fishery products imported from Indonesia and intended for	Commission Decision		٧

Year adopted	Emergency measure	Legal instrument	Amended	In force
	human consumption			
2008	2008/757/EC: Commission Decision of 26 September 2008 imposing special conditions governing the import of products containing milk or milk products originating in or consigned from China <sup>d</sup>	Commission Decision	٧	
2008	2008/866/EC: Commission Decision of 12 November 2008 on emergency measures suspending imports from Peru of certain bivalve molluscs intended for human consumption	Commission Decision	٧	٧
2009	2009/727/EC: Commission Decision of 30 September 2009 on emergency measures applicable to crustaceans imported from India and intended for human consumption or animal feed	Commission Decision		
2009	2009/726/EC: Commission Decision of 24 September 2009 concerning interim protection measures taken by France as regards the introduction onto its territory of milk and milk products coming from a holding where a classical scrapie case is confirmed	Commission Decision		٧
2009	2009/835/EC: Commission Decision of 12 November 2009 on emergency measures imposing special conditions on official controls governing the import of pears originating in or consigned from Turkey due to high residue levels of amitraz	Commission Decision		
2009	Commission Regulation (EC) No 1152/2009 of 27 November 2009 imposing special conditions governing the import of certain foodstuffs from certain third countries due to contamination risk by aflatoxins and repealing Decision 2006/504/EC <sup>a</sup>	Commission Regulation	٧	
2010	Commission Regulation (EU) No 258/2010 of 25 March 2010 imposing special conditions on the imports of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins, and repealing Decision 2008/352/EC <sup>c</sup>	Commission Regulation	٧	
2010	2010/220/EC: Commission Decision of 16 April 2010 on emergency measures applicable to consignments of farmed fishery products imported from Indonesia and intended for human consumption	Commission Decision		
2010	2010/381/EC: Commission Decision of 8 July 2010 on emergency measures applicable to consignments of aquaculture products imported from India and intended for human consumption	Commission Decision	٧	٧
2011	Commission Implementing Regulation (EU) No 297/2011 of 25 March 2011 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station	Commission Implementing Regulation	٧	٧
2011	2011/402/EU: Commission Implementing Decision of 6 July 2011 on emergency measures applicable to fenugreek seeds and certain seeds and beans imported from Egypt	Commission Implementing Decision	٧	٧
2013	Commission Implementing Regulation (EU) No 91/2013 of 31 January 2013 laying down	Commission	٧	

Year adopted	Emergency measure	Legal instrument	Amended	In force
	specific conditions applicable to the import of groundnuts from Ghana and India, okra and curry leaves from India and watermelon seeds from Nigeria and amending Regulations (EC) No 669/2009 and (EC) No 1152/2009 e	Implementing Regulation		
2014	2014/88/EU: Commission Implementing Decision of 13 February 2014 suspending temporarily imports from Bangladesh of foodstuffs containing or consisting of betel leaves ('Piper betle')		٧	٧
2014	Commission Implementing Regulation (EU) No 884/2014 of 13 August 2014 imposing special conditions governing the import of certain feed and food from certain third countries due to contamination risk by aflatoxins and repealing Regulation (EC) No 1152/2009	Commission Implementing Regulation		٧

Source: Data provided by European Commission for this study. Information regarding amendments and status (in force or not) retrieved from http://www.eur-lex.europa.eu. Note: Since the entry into force of the Lisbon Treaty on 1 December 2009, Commission Decisions are now Commission Implementing Decisions and Commission Regulations are now Commission Implementing Regulations. a) While no longer in force, the import of these products is now regulated through Commission Implementing Decision (EU) No 884/2014; b) While no longer in force, the import of these products is now regulated through Commission Implementing Decision (EU) No 2011/884/EU; c) While no longer in force, the import of these products is now regulated through Commission Implementing Regulation (EU) 2015/175; d) While no longer in force, the import of these products is now regulated through Commission Regulation (EU) 885/2014.

Table 4: Availability of contingency plans in the field of food/feed by Member State (as defined in Art. 13 of Regulation (EC) No 882/2004)

Country	A specific national contingency plan for food/feed	A general national contingency plan which also covers food/feed incidents	No national contingency plan, but a set of procedures to be used in case of emergencies in the field of food/feed
Austria	X	$\checkmark$	$\checkmark$
Belgium	X	$\checkmark$	X
Cyprus	$\checkmark$	X	X
Czech Republic	√ <sup>a</sup>	$\checkmark$	:
Denmark	$\checkmark$	$\checkmark$	:
Finland	X	X	$\checkmark$
France <sup>b</sup>	X	X/√	√ <sup>c</sup>
Germany	$\checkmark$	:	$\sqrt{d}$
Greece	$\checkmark$	:	:
Hungary	$\checkmark$	$\checkmark$	:
Ireland	$\checkmark$	$\checkmark$	:
Latvia	X	X	$\checkmark$
Netherlands	$\checkmark$	In development	In development
Poland	$\checkmark$	$\checkmark$	:
Portugal	$\checkmark$	In development	$\checkmark$
Romania	:	$\checkmark$	:
Slovenia	:	In development	:
Spain	$\checkmark$	:	:
Sweden <sup>e</sup>	In development	In development	:
United Kingdom	$\sqrt{f}$	$\checkmark$	:

Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management. Note: V contingency plan/procedures available; X contingency plan/procedures not available; : no answer or 'Don't know'. a) Several contingency plans are available in the Czech Republic - Ministry of Agriculture: Information Support when Handling Extraordinary Events and Crisis Situations in the Field of Food and Feed Safety (2005). Ministry of Health: Standardized Plan for epidemic situations, The Standard Operational Procedure for occurrences of food-borne diseases. Czech Agriculture and Food Inspection Authority: Crisis manual (regularly updated). Central Institute for Supervising and Testing in Agriculture: Emergency Plan (upt. 8/2013). State Veterinary Administration of the Czech Republic: Contingency Plans in the area of large scale animal infections b) In France, two competent authorities manage food/feed crisis incidents. This line summarises the responses provided by both of them. c) Several procedures are available in France - Note de service sur la gestion des alertes et des crises (2007); Guide de gestion des alertes (2005); Protocole d'information, de coordination et de gestion des alertes sanitaires d'origine alimentaire entre les administrations centrales concernées 5dgs, dgccrf, dgal (2007, revised in 2013) d) This refers to procedures in place in Germany's federal states. e) The information was provided by the Swedish NCP for feed. f) Currently under review – the development of a new Incident Management Plan was ongoing at the time of the survey.

Table 5: "Have you carried out systematic review(s) of your crisis preparedness/crisis management arrangements in the field of food/feed on the basis of ..."

Country	past serious food/feed safety incidents?	crisis simulation exercises?	review of organisation of the competent authorities?
Austria	No, never	No, never	No, never
Belgium	Yes, regularly	Yes, regularly	Yes, regularly
Cyprus	No, never	No, never	No, never
Czech Republic	No, never	Yes, sometimes	Yes, sometimes
Denmark	Yes, sometimes	Yes, sometimes	Yes, once
Finland	Yes, sometimes	No, never	No, never
France <sup>a</sup>	Yes, regularly	Yes sometimes / No, never	No, never / Yes, once
Germany	Yes, regularly	Yes, regularly	Yes, sometimes
Greece	Yes, sometimes	No, never	No, never
Hungary	Yes, sometimes	Yes, regularly	Yes, sometimes
Ireland	Yes, regularly	Yes, once	Yes, once
Latvia	Yes, sometimes	No, never	No, never
Netherlands	Yes, regularly	Yes, sometimes	Yes, sometimes
Poland	Yes, regularly	Don't know	No, never
Portugal	Yes, sometimes	No, never	No, never
Slovenia	Yes, once	No, never	Yes, regularly
Spain	No, never	No, never	Yes, sometimes
Sweden	Yes, regularly	Yes, regularly	Don't know
United Kingdom	Yes, regularly	Yes, regularly	Yes, sometimes

Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management. Notes: a) in France, two competent authorities manage food/feed crisis incidents. This line summarises the responses provided by both of them.

Table 6: Estimated costs of selected food/feed safety incidents (2002-2013)

Incident	Affected	Brief description of incident	Direct costs of the food/feed safety incident	Indirect costs (e.g. due to long-term economic impact, loss of market shares or consumer trust, etc.)
MPA contamination (2002)	Feed and Food	In 2002, soft drinks and feed were contaminated with Medroxyprogesterone acetate in the Netherlands. <sup>a</sup>	The direct costs of this incident, including withdrawal costs and the value of affected products and animals are estimated at €43 million. <sup>a</sup>	Indirect costs are estimated at €35 million of lost income to the primary sector and €25 - 50 million as a result of a temporary decline in the production of slaughteries and damage due to export restrictions. <sup>a</sup>
Dioxin contamination Germany (2003)	Food and Feed	The incident, affecting mainly Germany, resulted from a defective drying process at a by-product processing plant in Thuringia. <sup>a</sup>	The direct costs of this incident, including withdrawal costs and the value of affected products and animals is estimated at €0.71 million. <sup>ab</sup>	No data available
Dioxin contamination Ireland (2008)	Feed and Food	In 2008, pork fat and animal feed samples were found to be contaminated by dioxins in Ireland.	Although less than 10% of pork products were products were recalled with an estimated cost	e potentially affected by the contaminated feed, 100% of of €200 million. <sup>c</sup>
Glass fragments in instant coffee (2010)	Food	The incident involved a large producer who issued a voluntary recall of three types of glass-packaged instant coffee following the company's own checks.	Not including costs related to the destruction of the products nor additional indirect costs e.g. related to reputation damage, the cost of the recall is estimated to have reached over €23 million. d	No data available
E.coli outbreak (2011)	Food	The E.coli outbreak was characterised by a high incidence of infections with Shiga toxin-producing Escherichia coli (STEC) of serotype O104:H4, caused by the consumption of fenugreek sprouted seeds.	Costs related to the treatment of patients in Germany have been estimated at €0.1 million per hospital in Northern Germany, reaching approximately €1.7 million in Hamburg and Bremen alone. e	The losses for farmers in the fruit and vegetable sector were estimated at least €812 million in the first two weeks; in addition, a temporary export ban of vegetables to Russia occurred, constituting an annual value of €600 million. €227 million was spent by the EU on market support for the agricultural sector, €0.6 million was spent on a media campaign and €34.1 million allocated to promotional programs for fresh fruits/vegetables. <sup>f</sup>

Source: Civic Consulting, based on: a) Civic Consulting, "Financial Guarantees in the Feed Sector", 2005; b) Covers only the costs reported from Thuringia Ministry of Agriculture, Nature Protection and Environment; c) Houses of the Oireachtas, Report on the Contamination of Irish Pork Products, 2009. d) Estimate calculated by Civic

Consulting according to a model developed for calculating the costs of recalls, (see "Economics of Traceability for Mitigation of Food Recall Costs." Munich Personal RePEc Archive Paper No. 27677, 27 December 2010) and based on RASFF notification 2010.0626 and estimated costs of products. e) Der Spiegel, "Darmkeim Ehec: Seuche kostet Deutschland Millionen", June 2011. f) European Commission, Lessons Learned from the 2011 Outbreak of Shiga Toxin-Producing Escherichia Coli (STEC) O104:H4 in Sprouted Seeds, 2011.

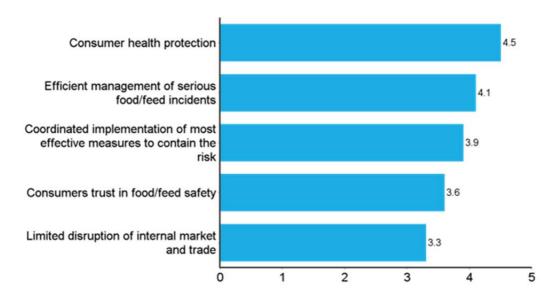
Table 7: Availability of contingency plans in the field of food/feed in Member States

Country	Specific contingency plan for food/feed	General contingency plan - also covers food/feed incidents	No contingency plan, but a set of procedures
Austria	Х	√	√
Belgium	Χ	$\checkmark$	X
Cyprus	$\checkmark$	X	X
Czech Republic	$\sqrt{a}$	$\checkmark$	:
Denmark	$\checkmark$	$\checkmark$	:
Finland	X	X	$\checkmark$
France <sup>b</sup>	X	X/√	√ <sup>c</sup>
Germany	$\checkmark$	:	$\sqrt{d}$
Greece	$\checkmark$	:	:
Hungary	$\checkmark$	$\checkmark$	:
Ireland	$\checkmark$	$\checkmark$	:
Latvia	X	X	$\checkmark$
Netherlands	$\checkmark$	In development	In development
Poland	$\checkmark$	$\checkmark$	:
Portugal	$\checkmark$	In development	$\checkmark$
Romania	:	$\checkmark$	:
Slovenia	:	In development	:
Spain	$\checkmark$	:	:
Sweden <sup>e</sup>	In development	In development	:
United Kingdom	√ <sup>f</sup>	V	:

Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management. Note: V contingency plan/procedures available; X contingency plan/procedures not available; : no answer or 'Don't know'. For additional notes see Table in Section Error! Reference source not found..

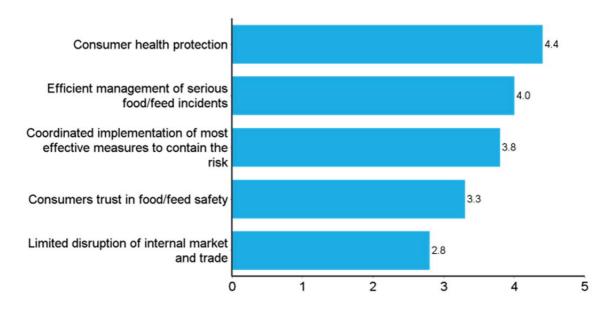
## 6.2 Survey results

Figure 76: "To what extent have the existing crisis management arrangements achieved the following in past serious food/feed safety incidents <u>in [your] country?</u>" (All respondents)



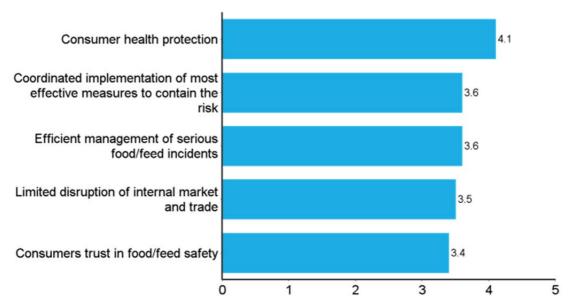
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N= 30 to 33 (depending on item). Note: Based on respondents that provided an assessment.

Figure 77: "To what extent have the existing crisis management arrangements achieved the following in past serious food/feed safety incidents <u>in [your] country?</u>" (Only competent authorities)



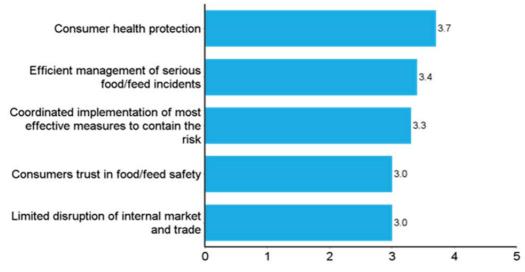
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=19 to 21 depending on item. Note: Based on respondents that provided an assessment.

Figure 78: "To what extent have the existing crisis management arrangements achieved the following in past serious food/feed safety incidents <u>in [your]</u> <u>country</u>?" (Only other stakeholders)



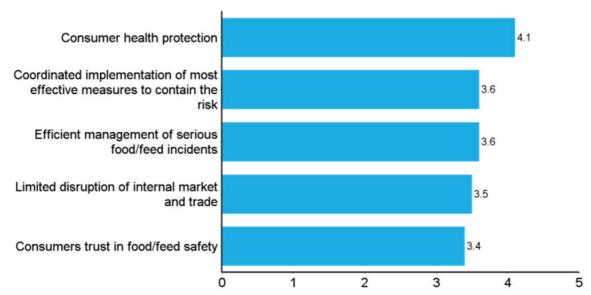
Source: Civic Consulting survey of other stakeholders, N=11 to 12 depending on item. Note: Based on respondents that provided an assessment.

Figure 79: "To what extent have the existing crisis management arrangements achieved the following in past serious food/feed safety incidents (at EU level)?" (All respondents)



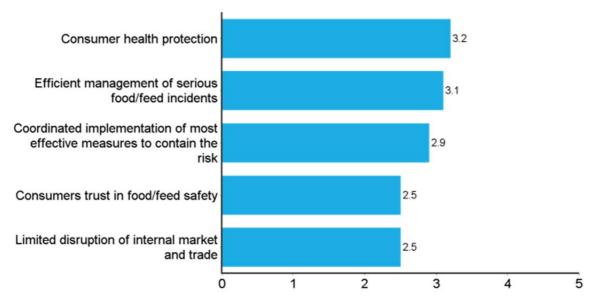
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N= 27 to 31 (depending on item). Note: Based on respondents that provided an assessment.

Figure 80: "To what extent have the existing crisis management arrangements achieved the following in past serious food/feed safety incidents (at EU level)?" (Only competent authorities)



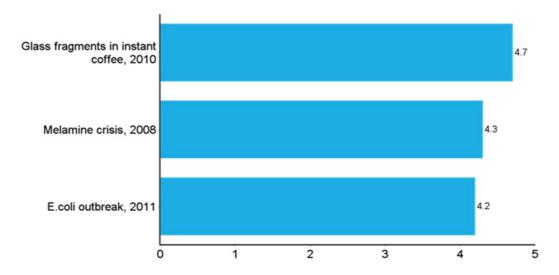
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=14 to 18 depending on item. Note: Based on respondents that provided an assessment.

Figure 81: "To what extent have the existing crisis management arrangements achieved the following in past serious food/feed safety incidents (at EU level)?" (Only other stakeholders)



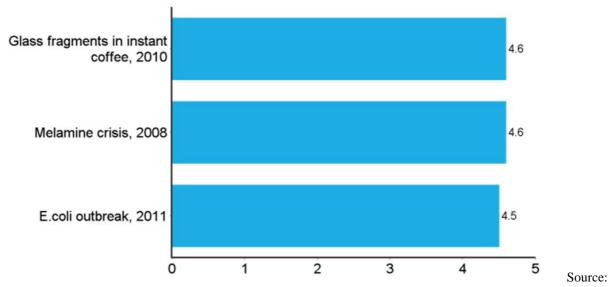
Source: Civic Consulting survey of other relevant stakeholders, N=12 to 13 depending on item. Note: Based on respondents that provided an assessment.

Figure 82: "Please assess the effectiveness of crisis management arrangements [in your country] during the following examples of serious food/feed safety incidents that affected your country." (All respondents)



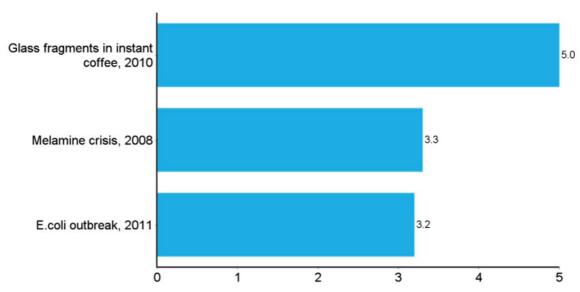
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N= 12 to 23 (depending on item). Note: Based on respondents that provided an assessment.

Figure 83: "Please assess the effectiveness of crisis management arrangements [in your country] during the following examples of serious food/feed safety incidents that affected your country." (Only competent authorities)



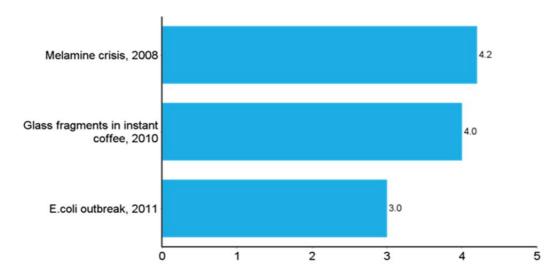
Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=11 to 18 depending on item. Note: Based on respondents that provided an assessment.

Figure 84: "Please assess the effectiveness of crisis management arrangements [in your country] during the following examples of serious food/feed safety incidents that affected your country." (Only other stakeholders)



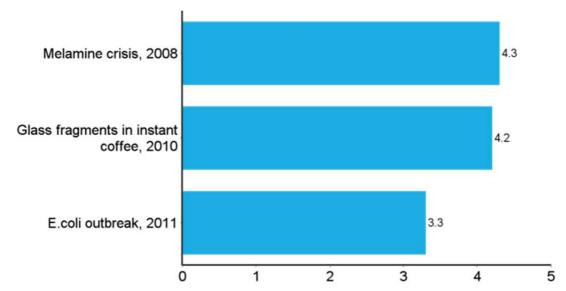
Source: Civic Consulting survey of other relevant stakeholders, N= 1 to 5 depending on item. Note: Based on respondents that provided an assessment.

Figure 85: "Please assess the effectiveness of crisis management arrangements [at EU level] during the following examples of serious food/feed safety incidents that affected your country." (All respondents)



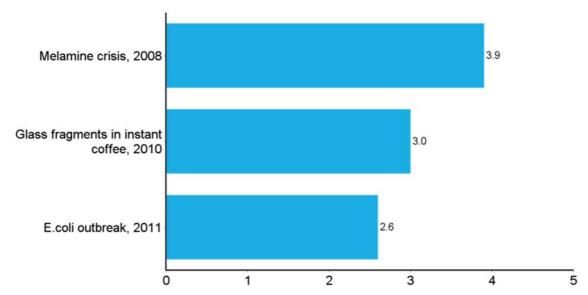
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N=14 to 28 (depending on item). Note: Based on respondents that provided an assessment.

Figure 86: "Please assess the effectiveness of crisis management arrangements during the following examples of serious food/feed safety incidents that affected your country (at EU level)" (Only competent authorities)



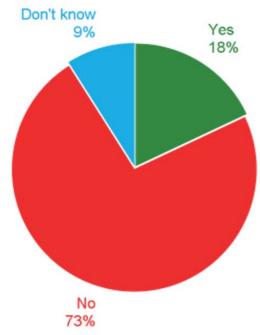
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=12 to 19 depending on item. Note: Based on respondents that provided an assessment.

Figure 87: "Please assess the effectiveness of crisis management arrangements during the following examples of serious food/feed safety incidents that affected your country (at EU level)" (Only other stakeholders)



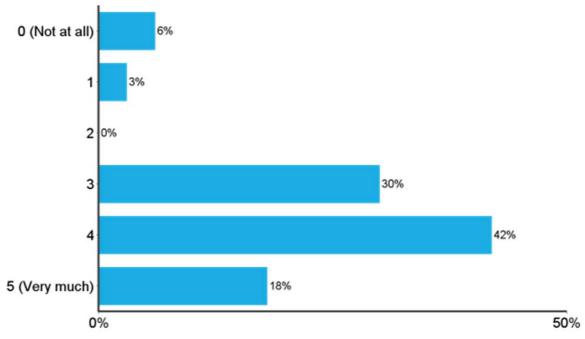
Source: Civic Consulting survey of other relevant stakeholders, N= 2 to 9 depending on item. Note: Based on respondents that provided an assessment.

Figure 88: "Do you use criteria to evaluate the effectiveness of existing crisis management arrangements in your country (e.g. the duration between outbreak detection and containment)?" (Only competent authorities)



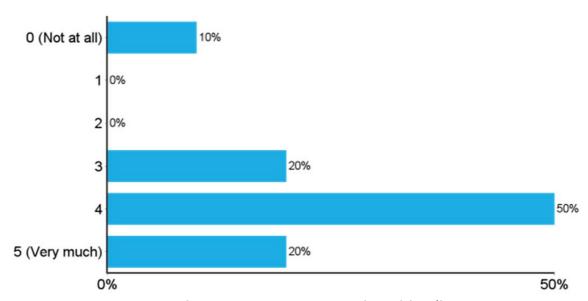
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=22. Note: Based on respondents that provided an assessment.

Figure 89: "The general plan for food/feed crisis management provides for two layers of action (...) In your view, are these two layers of action relevant?" (All respondents)



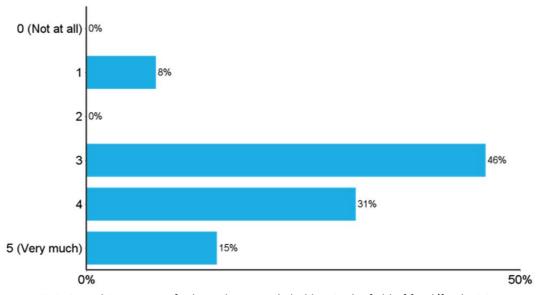
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N=33. Note: Based on respondents that provided an assessment.

Figure 90: "The general plan for food/feed crisis management provides for two layers of action (...) In your view, are these two layers of action relevant?" (Only competent authorities)



Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=20. Note: Based on respondents that provided an assessment.

Figure 91: "The general plan for food/feed crisis management provides for two layers of action (...) In your view, are these two layers of action relevant?" (Only other stakeholders)



Source: Civic Consulting survey of other relevant stakeholders in the field of food/feed crisis management, N=13. Note: Based on respondents that provided an assessment.

0 (Not at all) 6%

1 6%

2 6%

3 19%

45%

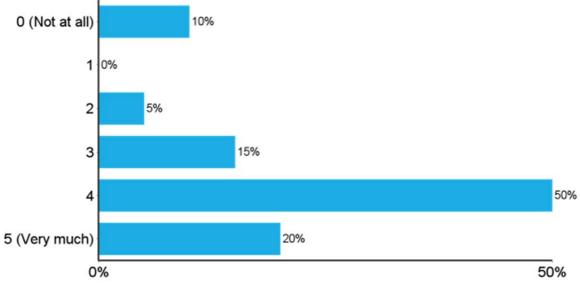
5 (Very much) 16%

Figure 92: "Are these two layers still appropriate for food/feed crisis management?" (All respondents)

Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N=31. Note: Based on respondents that provided an assessment.

Figure 93: "Are these two layers still appropriate for food/feed crisis management?" (Only competent authorities)

0 (Not at all)

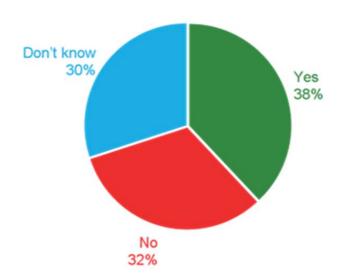


Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=20. Note: Based on respondents that provided an assessment.

Figure 94: "Are these two layers still appropriate for food/feed crisis management?" (Only other stakeholders)

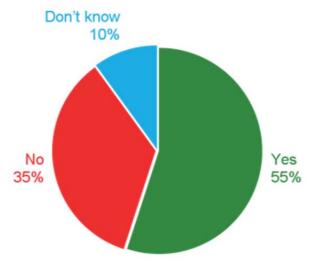
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N=31. Note: Based on respondents that provided an assessment.

Figure 95: "In your view, have the mechanisms foreseen in Sections 2.2 and 6 of Commission Decision 2004/478/EC (where a crisis unit is not set up but adequate provisions are made to ensure effective management) been sufficient for the management of past serious food/feed safety incidents?" (All respondents)



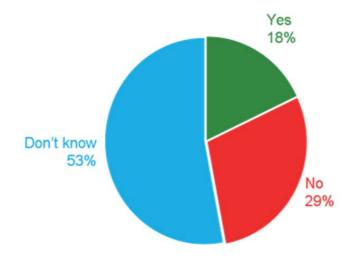
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N=37. Note: Based on respondents that provided an assessment.

Figure 96: "In your view, have the mechanisms foreseen in Sections 2.2 and 6 of Commission Decision 2004/478/EC (where a crisis unit is not set up but adequate provisions are made to ensure effective management) been sufficient for the management of past serious food/feed safety incidents?" (Only competent authorities)



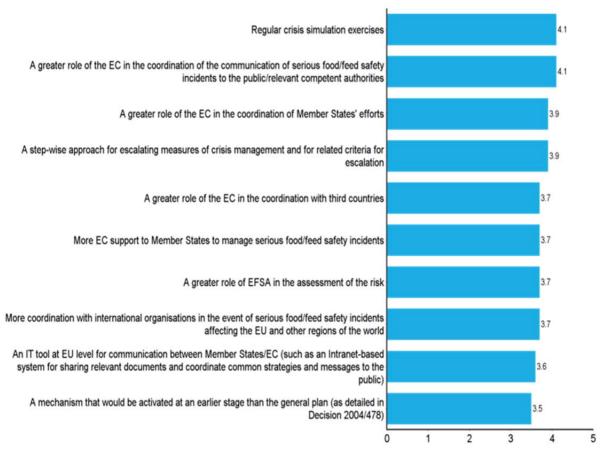
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=20. Note: Based on respondents that provided an assessment.

Figure 97: "In your view, have the mechanisms foreseen in Sections 2.2 and 6 of Commission Decision 2004/478/EC (where a crisis unit is not set up but adequate provisions are made to ensure effective management) been sufficient for the management of past serious food/feed safety incidents?" (Only other stakeholders)



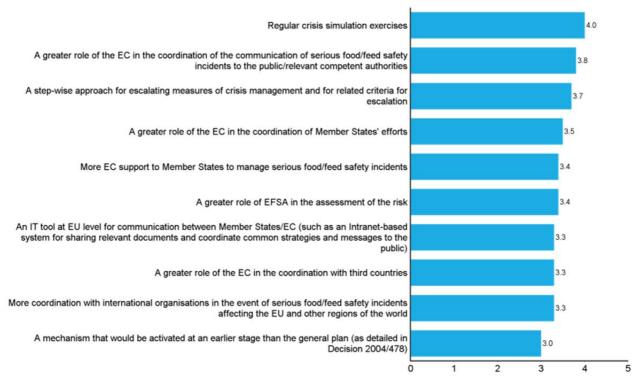
Source: Civic Consulting survey of other relevant stakeholders, N=17. Note: Based on respondents that provided an assessment.

Figure 98: "Please assess whether or not there is a need for the following measures related to crisis management at EU level." (All respondents)



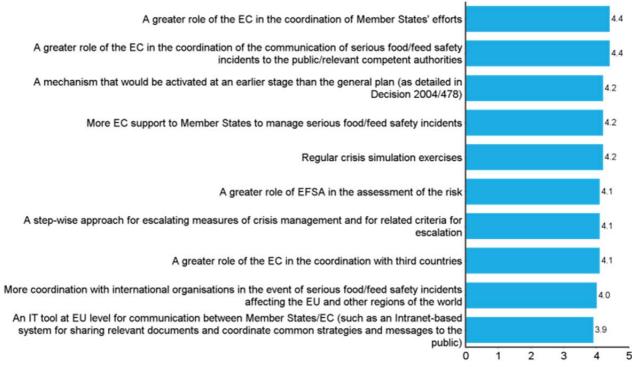
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N=33 to 40 (depending on item). Note: Based on respondents that provided an assessment.

Figure 99: "Please assess whether or not there is a need for the following measures related to crisis management at EU level." (Only competent authorities)



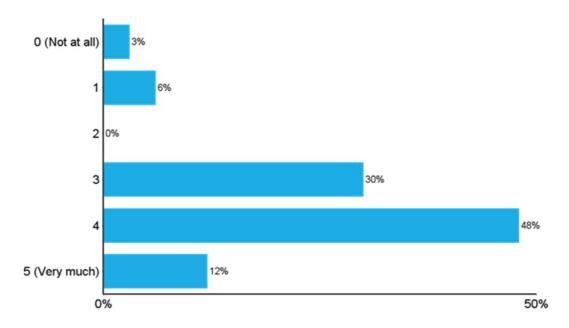
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=16 to 22 depending on item. Note: Based on respondents that provided an assessment.

Figure 100: "Please assess whether or not there is a need for the following measures related to crisis management at EU level." (Only other stakeholders)



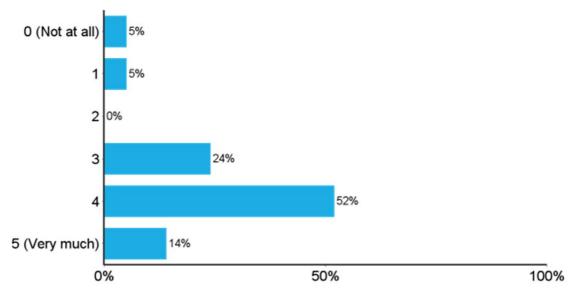
Source: Civic Consulting survey of other relevant stakeholders, N= 14 to 18 depending on item. Note: Based on respondents that provided an assessment.

Figure 101: "To what extent have emergency measures ('safeguard measures'; as defined in Articles 53 and 54 of Regulation (EC) No 178/2002) been effective for the management of past serious food/feed safety incidents?" (All respondents)



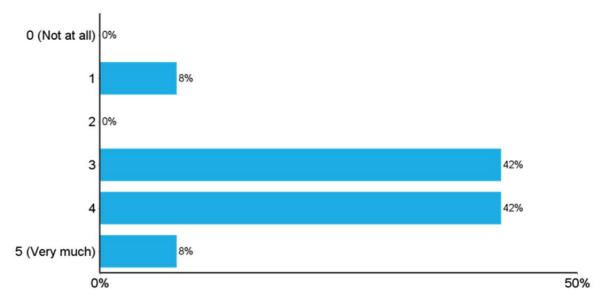
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N=33. Note: Based on respondents that provided an assessment.

Figure 102: "To what extent have emergency measures ('safeguard measures'; as defined in Articles 53 and 54 of Regulation (EC) No 178/2002) been effective for the management of past serious food/feed safety incidents?" (Only competent authorities)



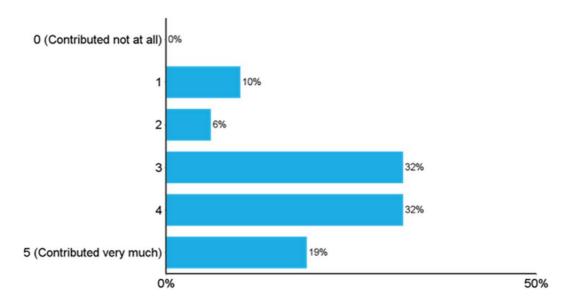
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=21. Note: Based on respondents that provided an assessment.

Figure 103: "To what extent have emergency measures ('safeguard measures'; as defined in Articles 53 and 54 of Regulation (EC) No 178/2002) been effective for the management of past serious food/feed safety incidents?" (Only other stakeholders)



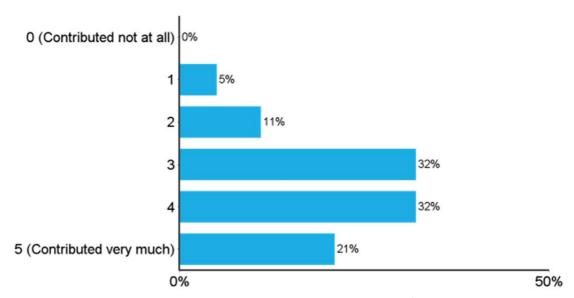
Source: Civic Consulting survey of other relevant stakeholders, N=12. Note: Based on respondents that provided an assessment.

Figure 104: "To what extent has the mechanism of emergency measures provided by Articles 53 and 54 of Regulation (EC) No 178/2002 contributed to avoiding disparities between measures taken by different Member States and to ensuring a consistent approach during past serious food/feed safety incidents?" (All respondents)



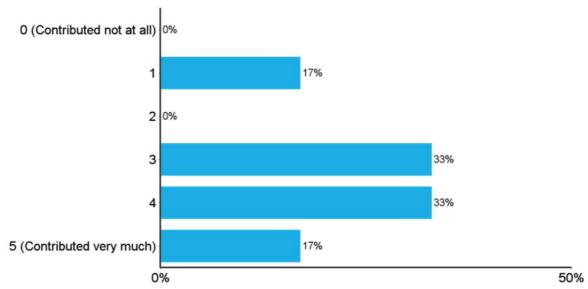
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N=31. Note: Based on respondents that provided an assessment.

Figure 105: "To what extent has the mechanism of emergency measures provided by Articles 53 and 54 of Regulation (EC) No 178/2002 contributed to avoiding disparities between measures taken by different Member States and to ensuring a consistent approach during past serious food/feed safety incidents?" (Only competent authorities)



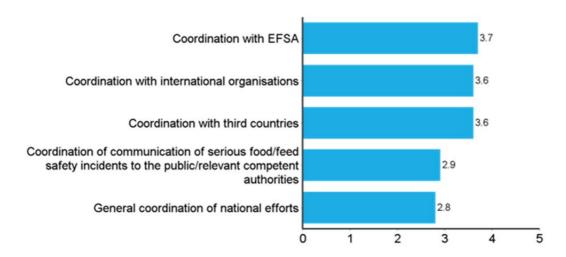
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=19. Note: Based on respondents that provided an assessment.

Figure 106: "To what extent has the mechanism of emergency measures provided by Articles 53 and 54 of Regulation (EC) No 178/2002 contributed to avoiding disparities between measures taken by different Member States and to ensuring a consistent approach during past serious food/feed safety incidents?" (Only other stakeholders)



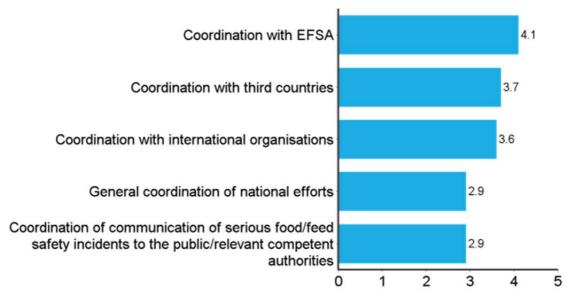
Source: Civic Consulting survey of other relevant stakeholders, N=12. Note: Based on respondents that provided an assessment.

Figure 107: "Overall, to what extent has the EC played the role of coordinator in past serious food/feed safety incidents that affected your country?" (All respondents)



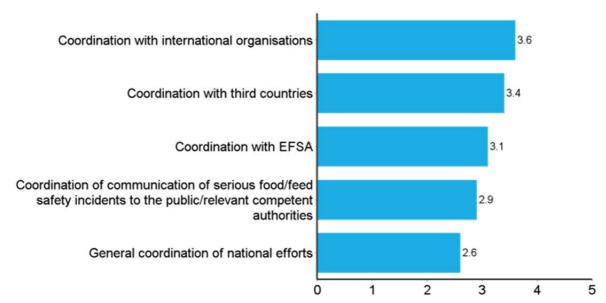
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N=22 to 35 (depending on item). Note: Based on respondents that provided an assessment.

Figure 108: "Overall, to what extent has the EC played the role of coordinator in past serious food/feed safety incidents that affected your country?" (Only competent authorities)



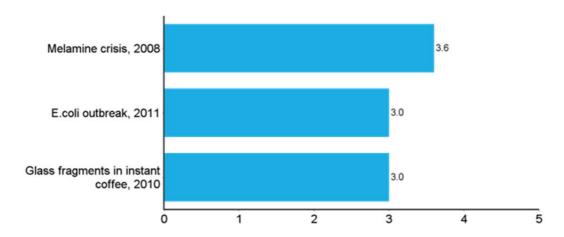
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=13-21 depending on item. Note: Based on respondents that provided an assessment.

Figure 109: "Overall, to what extent has the EC played the role of coordinator in past serious food/feed safety incidents that affected your country?" (Only other stakeholders)



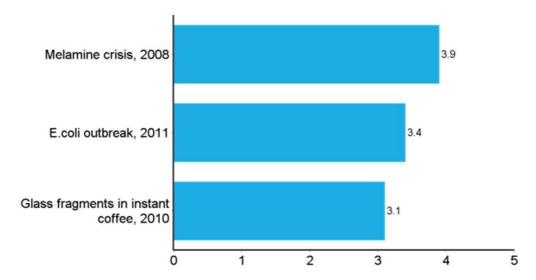
Source: Civic Consulting survey of other relevant stakeholders, N=8-14 depending on item. Note: Based on respondents that provided an assessment.

Figure 110: "More specifically, to what extent has the EC played the role of coordinator during the following examples of serious food/feed safety incidents that affected your country?" (All respondents)



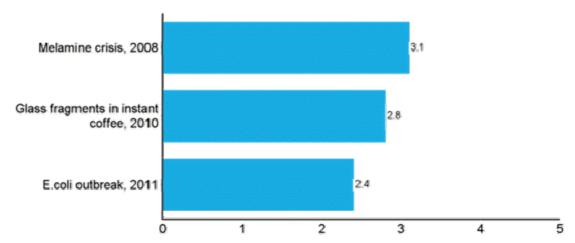
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and stakeholders, N=16 to 28 (depending on example). Note: Based on respondents that provided an assessment.

Figure 111: "More specifically, to what extent has the EC played the role of coordinator during the following examples of serious food/feed safety incidents that affected your country?" (Only competent authorities)



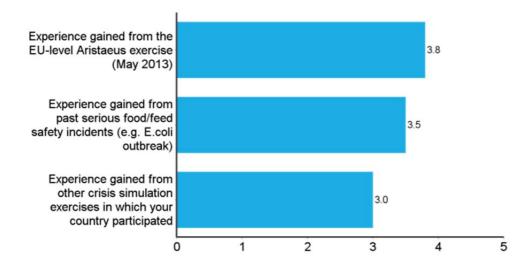
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=12-18 depending on item. Note: Based on respondents that provided an assessment.

Figure 112: "More specifically, to what extent has the EC played the role of coordinator during the following examples of serious food/feed safety incidents that affected your country?" (Only other stakeholders)



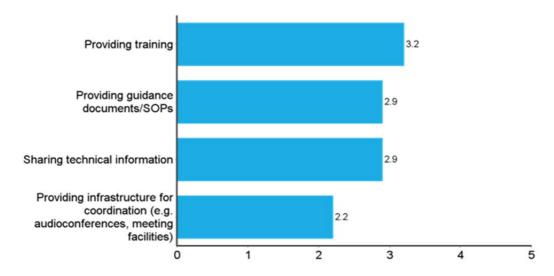
Source: Civic Consulting survey of other relevant stakeholders, N=4-10 depending on item. Note: Based on respondents that provided an assessment.

Figure 113: "To what extent have the following experiences improved current crisis management arrangements <u>at the EU level?</u>" (Only competent authorities)



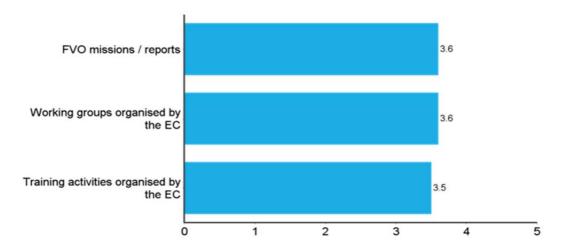
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=8/13/6 (depending on item). Note: Based on respondents that provided an assessment.

Figure 114: "To what extent has the EC contributed to the coordination of national efforts (e.g. in outbreak investigations)?" (Only competent authorities)



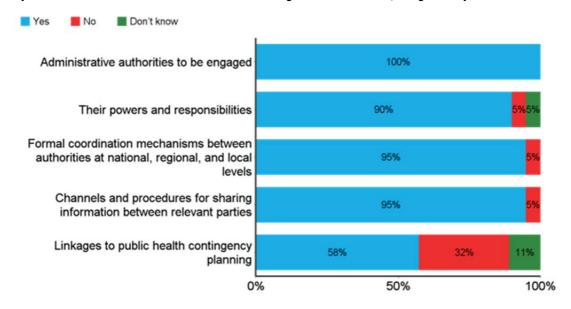
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=18 to 19 (depending on item). Note: Based on respondents that provided an assessment.

Figure 115: To what extent has the EC contributed to the development of best practices for the management of serious food/feed safety incidents (e.g. for the design of contingency plans)? Please assess the contribution to the development of best practices." (Only competent authorities)



Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=11 to 15 (depending on item). Note: Based on respondents that provided an assessment.

Figure 116: "If in your country one of the above listed types of contingency plan/procedures is available, please indicate whether the following items are specified for serious food/feed safety incidents." (Only competent authorities)



Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N= 19 to 20 (depending on item). Note: Based on respondents that provided an assessment.

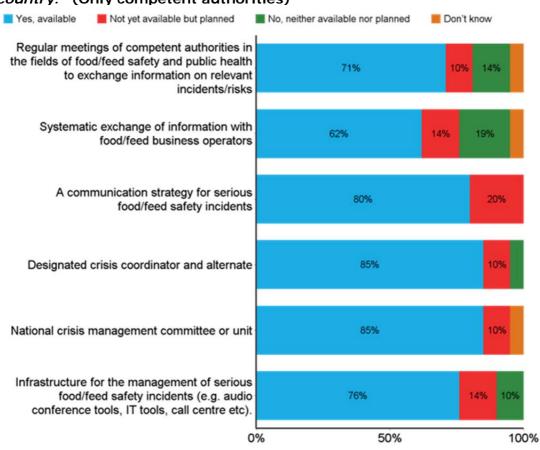


Figure 117: "Besides the elements listed in question 3, please indicate which of the following other elements of crisis management are available in your country." (Only competent authorities)

Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N= 20 to 21 (depending on item). Note: Based on respondents that provided an assessment.

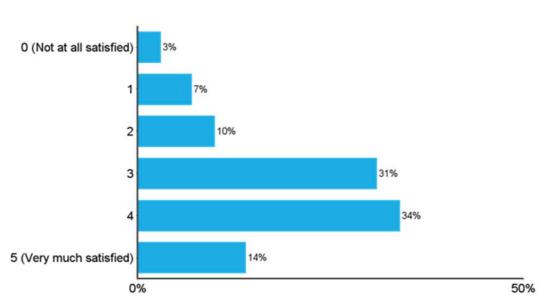
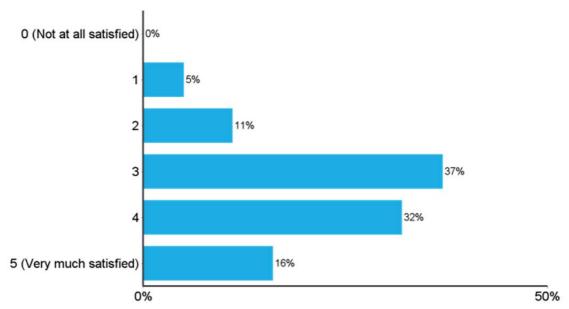


Figure 118: "To what extent are you satisfied with how actively other MS have managed serious food/feed safety incidents that have affected your country?" (All respondents)

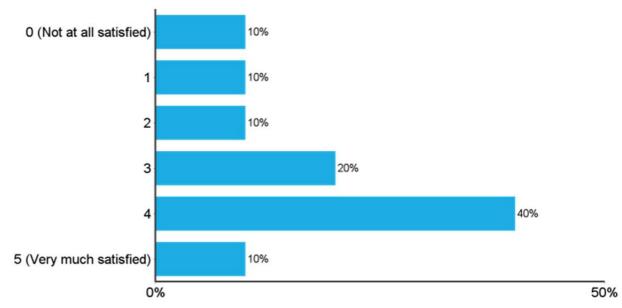
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N= 29. Note: Based on respondents that provided an assessment.

Figure 119: "To what extent are you satisfied with how actively other MS have managed serious food/feed safety incidents that have affected your country?" (Only competent authorities)



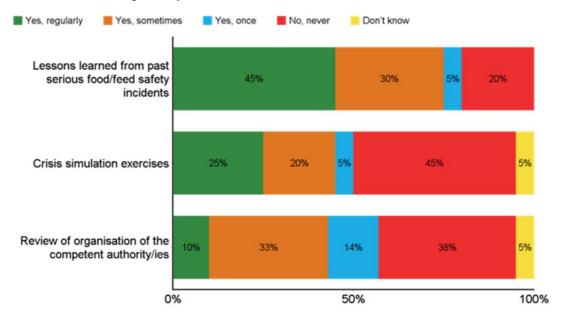
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management , N=19. Note: Based on respondents that provided an assessment.

Figure 120: "To what extent are you satisfied with how actively other MS have managed serious food/feed safety incidents that have affected your country?" (Only other stakeholders)



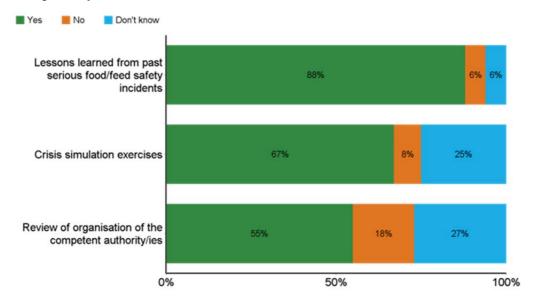
Source: Civic Consulting survey of other relevant stakeholders, N=10. Note: Based on respondents that provided an assessment.

Figure 121: "Have you carried out systematic review(s) of your crisis preparedness/crisis management arrangements in the field of food/feed on the basis of...?" (Only competent authorities)



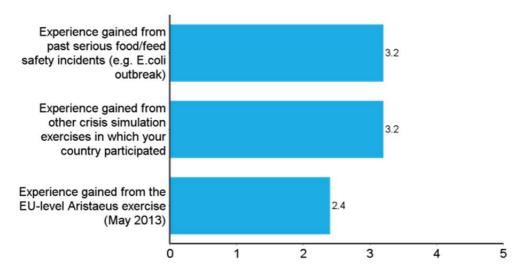
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=20 to 21 (depending on item). Note: Based on respondents that provided an assessment.

Figure 122: "If Yes, please specify whether the review led to improvements." (Only competent authorities)



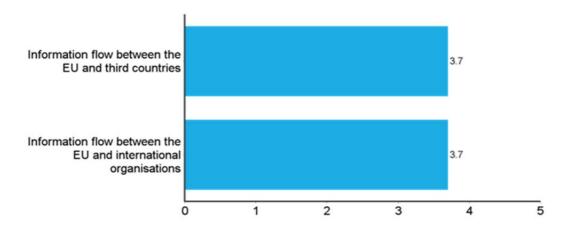
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=11 to 16 (depending on item). Note: Based on respondents that provided an assessment.

Figure 123: "To what extent have the following experiences improved current crisis management arrangements in your country?" (Only competent authorities)



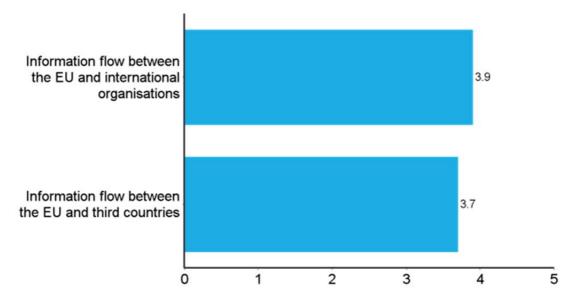
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=21/11/17 (depending on item). Note: Based on respondents that provided an assessment.

Figure 124: "To what extent are you satisfied with the information flow between the EU and third countries/international organisations in past serious food/feed safety incidents that affected your country?" (All respondents)



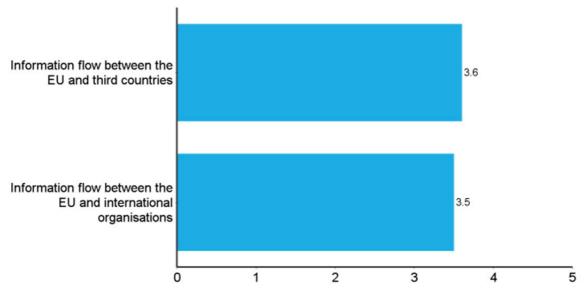
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N= 25 to 27 (depending on item). Note: Based on respondents that provided an assessment.

Figure 125: "To what extent are you satisfied with the information flow between the EU and third countries/international organisations in past serious food/feed safety incidents that affected your country?" (Only competent authorities)



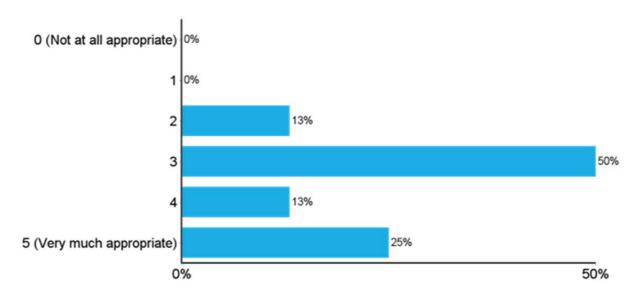
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=13-15 depending on item. Note: Based on respondents that provided an assessment.

Figure 126: "To what extent are you satisfied with the information flow between the EU and third countries/international organisations in past serious food/feed safety incidents that affected your country?" (Only other stakeholders)



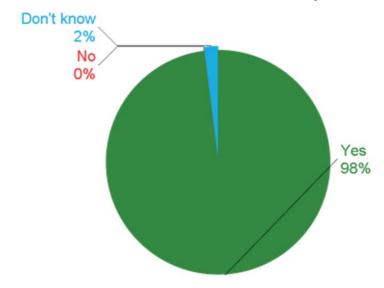
Source: Civic Consulting survey of other relevant stakeholders, N=12. Note: Based on respondents that provided an assessment.

Figure 127: "In your view, has the balance of costs and benefits of crisis management at EU level been appropriate?" (Only competent authorities)



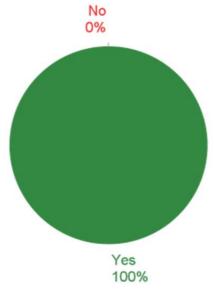
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=8. Note: Based on respondents that provided an assessment.

Figure 128: "Do you consider that there is an added value resulting from the EC coordinating crisis management of the Member States concerning a serious food/feed safety incident compared to what could be achieved if there was no coordination at EU level?" (All respondents)



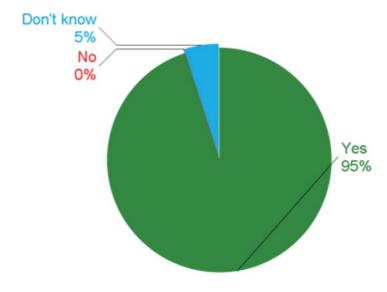
Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management and relevant stakeholders, N=25 to 27 (depending on item). Note: Based on respondents that provided an assessment.

Figure 129: "Do you consider that there is an added value resulting from the EC coordinating crisis management of the Member States concerning a serious food/feed safety incident compared to what could be achieved if there was no coordination at EU level?" (Only competent authorities)



Source: Civic Consulting survey of competent authorities in the field of food/feed crisis management, N=22. Note: Based on respondents that provided an assessment.

Figure 130: "Do you consider that there is an added value resulting from the EC coordinating crisis management of the Member States concerning a serious food/feed safety incident compared to what could be achieved if there was no coordination at EU level?" (Only other stakeholders)



Source: Civic Consulting survey of other relevant stakeholders, N=21. Note: Based on respondents that provided an assessment.

## Annex 7: List of data provided by the EC on the information flow of the RASFF (for reference year 2013)

The following list presents the data on the RASFF information flow which was compiled by the EC for the purposes of this evaluation. Additional key data was retrieved from the 2013 RASFF Annual report.

- The number of original and follow up notifications transmitted with delay, classified by the number of days of delay since reception of the notification;
- Data on the time taken for transmission of notifications to the network (in hours);
- A list of alert notifications that were downgraded;
- A list of notifications proposed for rejection by ECCP which were not reconsidered and were finally rejected from transmission, listed by notifying country;
- A list of emails relating to bilateral issues that were dealt with between NCPs, not related to RASFF notifications.
- The total number of countries with (direct or indirect) access to RASFF Window;
- Emails about notifications sent to INFOSAN and emails from INFOSAN, including an indication specifying whether or not these messages resulted in RASFF notifications;
- Data on the number of notifications and number of transmissions sent to Third Countries;
- Data on the number of follow up notifications submitted per original alert notification; and
- The number of organisations/countries concerned per original alert notifications transmitted.

The analysis of the data is included in the answers to the relevant evaluation questions.

## Annex 8: List of interviews conducted in the course of the evaluation

Organisation	Date of interview	Interview focus	Interview type
European Commission, DG SANTE, Unit G4 – Food, alert system and training	26 September 2014	Cross-cutting issues (crisis management)	Exploratory interview
Spanish Agency for Consumer Affairs, Food Safety and Nutrition (ES)	29 September 2014	Cross-cutting issues (crisis management)	Exploratory interview
Food Drink Europe	30 September 2014	Cross-cutting issues	Exploratory interview
European Commission, DG SANTE, Head of Unit E5 – Enforcement	2 October 2014	Cross-cutting issues	Exploratory interview
European Commission, DG SANTE, Head of Unit G4 – Food, alert system and training	2 October 2014	Cross-cutting issues	Exploratory interview
European Commission, DG SANTE, Unit G4 – Food, alert system and training (RASFF team)	2 October 2014	Cross-cutting issues (RASFF)	Exploratory interview
Spanish Agency for Consumer Affairs, Food Safety and Nutrition (ES)	6 October 2014	Cross-cutting issues (RASFF)	Exploratory interview
Copa-Cogeca	8 October 2014	Cross-cutting issues	Exploratory interview
Food and Veterinary Office (FVO)	9 October 2014	Cross-cutting issues	Exploratory interview
Netherlands Food and Consumer Product Safety Authority (NL)	16 October 2014	Cross-cutting issues	Exploratory interview
Direction générale de l'alimentation/mission des urgences sanitaires (FR)	1 December 2014	E.coli outbreak	Semi-structured interview
Ministry of Health (IT)	3 December 2014	Melamine crisis	Semi-structured interview
Federal Office for Consumer Protection and Food Safety (DE)	5 December 2014	E.coli outbreak	Semi-structured interview
Federal Ministry of Food and Agriculture (DE)	5 December 2014	E.coli outbreak	Semi-structured interview
Spanish Agency for Consumer Affairs, Food Safety and Nutrition (ES)	12 December 2014	E.coli outbreak	Semi-structured interview

Ministry of Agriculture (HR)	16 December 2014	Glass fragments in instant coffee	Semi-structured interview
International Network of Food Safety Authorities (INFOSAN)	8 January 2015	Melamine crisis and cross-cutting issues	Semi-structured interview
European Food Safety Authority (EFSA)	15 January 2015	E.coli outbreak, melamine crisis and cross-cutting issues	Semi-structured interview
Direction générale de la Concurrence, de la Consommation et de la Répression des Fraudes (FR)	16 January 2015	Glass fragments in instant coffee, E.coli outbreak	Semi-structured interview
Hellenic Food Authority (EL)	21 January 2015	Glass fragments in instant coffee	Semi-structured interview
Chief Sanitary Inspectorate (PL)	22 January 2015	Melamine crisis	Semi-structured interview
European Center for Disease Prevention and Control (ECDC)	19 February 2015	E.coli outbreak and cross-cutting issues	Semi-structured interview
Food and Drug Administration (USA)	26 February 2015	Melamine crisis and cross-cutting issues	Semi-structured interview
Nestlé	6 May 2015	Glass fragments in instant coffee	Semi-structured interview
European Commission, DG SANTE, Unit G4 – Food, alert system and training (RASFF team)	19-20 May 2015	Cross-cutting issues (RASFF)	Follow up interview
European Commission, DG SANTE, Unit E3, 003 Contaminants / Residues of veterinary medicinal products	19 May 2015	Cross-cutting issues (RASFF and crisis management)	Follow up interview
European Commission, DG SANTE, Relations with agencies and advisory groups	19 May 2015	Cross-cutting issues (RASFF and crisis management)	Follow up interview
European Commission, DG SANTE, Unit G4 - Food, alert system and training	19 May 2015	Cross-cutting issues (crisis management)	Follow up interview
European Commission, DG SANTE, Head of Unit G4 – Food, alert system and training	20 May 2015	Cross-cutting issues (RASFF and crisis management)	Follow up interview

European Commission, DG SANTE, Unit E5, Enforcement	20 May 2015	Cross-cutting issues (RASFF)	Follow up interview
European Commission, DG SANTE, Unit C3, Health Threats	17 June 2015	E.coli outbreak and cross-cutting issues	Follow up interview
European Commission, DG SANTE, Unit E5, Enforcement	24 June 2015	Cross-cutting issues (RASFF)	Follow up interview
New Zealand Mission to the European Union, NATO and Sweden	25 June 2015	Cross-cutting issues (RASFF and crisis management)	Follow up interview

Source: Civic Consulting. Note: Names of individuals have been deleted to preserve the anonymity of interviewees.

# Annex 9: Chronology of case studies

# Case study: Melamine crisis in food (2008)

## Brief description of food safety incident:

Melamine is a chemical substance rich in nitrogen. As the protein concentration of food is measured by the analysis of nitrogen levels, the fraudulent addition of melamine aims at enhancing the apparent protein content of food and feed products. However, melamine is toxic and can result in severe health effects. In 2008, melamine was fraudulently added to milk and milk products produced in China to give the appearance of increased protein levels. The high levels of melamine in infant milk resulted in very severe health effects in infants and young children in China.

## Chronology of events/overall duration:

11 September 2008 – The World Health Organisation (WHO) identifies the issue of the fraudulent addition of melamine to food products through a local media article in China.

15 September 2008 – The European Commission issues News notification (RASFF News 08-459) containing press reports as regards the presence of melamine in infant formula in China, the resulting health problems affecting 432 infants in China and the death of one infant.

17 September 2008 – The first melamine findings in Chinese milk and milk products outside of China are reported in Singapore. <sup>2</sup> China recalls tons of milk powder produced by a large Chinese producer since March 2008. <sup>3</sup>

19 September 2008 – The European Food Safety Authority (EFSA) receives a request from the European Commission for urgent scientific advice on the risks to human health due to the possible presence of melamine in composite food products imported from China.<sup>4</sup>

21 September 2008 – Chinese authorities report 39,965 cases of kidney stones in infants, including three deaths related to the consumption of melamine contaminated powdered infant formula. On this date, 12,892 patients are hospitalized, 104 with severe illness. Most of these cases (82%) affect children under 2 years of age.<sup>5</sup>

24 September 2008 – The EFSA issues a scientific statement at the request of the Commission which assesses the risks for public health due to the presence of melamine in infant milk and other milk products in China.<sup>6</sup>

25 September 2008 – A teleconference of the Health Security Committee is held. 7

*26 September 2008* – Commission Decision 2008/757/EC imposing special conditions governing the import of products containing milk or milk products originating in or consigned from China is adopted.<sup>8</sup>

1 October 2008 – At the request of the European Commission, the European Centre for Disease Prevention and Control (ECDC) issues a Public Health Impact Assessment on EU citizens of the melamine contamination of dairy products in China.

14 October 2008 – Commission Decision 2008/798/EC imposing special conditions governing the import of products containing milk and milk products originating in or consigned from China and repealing Commission Decision 2008/757/EC is adopted.<sup>9</sup>

<sup>&</sup>lt;sup>1</sup> European Commission, The Rapid Alert System for Food and Feed: 2007 Annual Report, 2007.

<sup>&</sup>lt;sup>2</sup> Gossner, Céline Marie-Elise, Jørgen Schlundt, Peter Ben Embarek, Susan Hird, Danilo Lo-Fo-Wong, Jose Javier Ocampo Beltran, Keng Ngee Teoh, and Angelika Tritscher, "The Melamine Incident: Implications for International Food and Feed Safety.," Environmental Health Perspectives, Vol. 117, No. 12, December 2009, pp. 1803–8. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2799451&tool=pmcentrez&rendertype=abstract.

<sup>&</sup>lt;sup>3</sup> European Centre for Disease Prevention and Control, Provisional ECDC Public Health Impact Assessment, 2008.

<sup>&</sup>lt;sup>4</sup> European Food Safety Authority (EFSA), Scientific Opinion on Melamine in Food and Feed, Vol. 8, Vol. 8, Parma, 2010.

<sup>&</sup>lt;sup>5</sup> European Centre for Disease Prevention and Control, Provisional ECDC Public Health Impact Assessment, 2008.

<sup>&</sup>lt;sup>6</sup> European Food Safety Authority (EFSA), Scientific Opinion on Melamine in Food and Feed, Vol. 8, Vol. 8, Parma, 2010.

<sup>&</sup>lt;sup>7</sup> European Centre for Disease Prevention and Control, Provisional ECDC Public Health Impact Assessment, 2008.

<sup>&</sup>lt;sup>8</sup> European Commission, Commission Decision of 26 September 2008 Imposing Special Conditions Governing the Import of Products Containing Milk or Milk Products Originating in or Consigned from China, 2008.

<sup>&</sup>lt;sup>9</sup> The Commission of the European Communities, "Commission Decision 2008/798/EC Imposing Special Conditions Governing the Import of Products Containing Milk or Milk Products Originating in or Consigned from

*30 October 2008* – The European Commission issues News notification (RASFF News 08-500) informing members of the network about the presence of high levels of melamine in ammonium bicarbonate (used as raising agent in the food industry) produced in China and imported by Taiwan.<sup>10</sup>

*November 2008* – RASFF notifications are issued by several EU Member States regarding the presence of melamine in food containing soya and soya products (e.g. RASFF Alert 2008.1384 and RASFF Information 2008.1451)

*9 December 2008* – Commission Decision 2008/921/EC amending Decision 2008/798/EC is adopted, with existing emergency measures extended to ammonium bicarbonate and to feed and food containing soya and soya products. <sup>11</sup>

## Countries/regions affected:

Imports of milk and milk products, including milk powder, originating from China were not allowed into the EU prior to the melamine incident. However, composite products such as biscuits and confectionary (such as chocolate and bonbons) containing milk ingredients were imported from China into the EU.<sup>12</sup>

- In the EU, Austria, Belgium, the Czech Republic, Germany, Spain, France, Hungary, Ireland, Italy, Malta, Netherlands, Poland, Slovenia, Slovakia and the UK notified the RASFF about the presence of melamine in food/food products from China.<sup>13</sup>
- Outside the EU, Australia, Canada, Hong Kong, Macao, Taiwan, Indonesia, Japan, Malaysia, New Zealand, Nigeria, Republic of Korea, Singapore, Solomon Islands, South Africa, Switzerland, Thailand, Tanzania, and United States reported melamine findings in products originating from China or in products containing ingredients from China. In addition, Bangladesh, Brunei, Burkina Faso, Burundi, Cambodia, Gabon, Ghana, Lebanon, Myanmar, Palau, Philippines, Russian Federation, Seychelles, Viet Nam, and Yemen reported the import of contaminated products or were countries to which the import of contaminated products occurred, as declared by the exporting country. In total, 47 countries received melamine-contaminated products.<sup>14</sup>

# Data on number of persons affected:

On 21 September 2008, Chinese authorities reported 39,965 cases of kidney stones in infants, including three deaths related to the consumption of melamine contaminated powdered infant formula.<sup>15</sup> Updated figures indicate that at least 6 children died from severe kidney failure due to the melamine added to milk powder, more than 200,000 infants and young children were affected by kidney problems, with more than 50,000 infants and young children hospitalised.<sup>16</sup> In the EU, the melamine incident is not considered to have had tangible negative health effects on the population.<sup>17</sup>

**Data on economic impact:** No information on economic impacts of the melamine crisis in food could be identified in the course of the case study.

China, and Repealing Commission Decision 2008/757/EC," Official Journal of the European Union, 2008, pp. 2007–2009.

<sup>&</sup>lt;sup>10</sup> RASFF News notification 08-500.

<sup>&</sup>lt;sup>11</sup> European Commission, Commission Decision of 9 December 2008 Amending Decision 2008/798/EC, 2008.

<sup>&</sup>lt;sup>12</sup> European Commission, The Rapid Alert System for Food and Feed: 2008 Annual Report, 2008.

<sup>&</sup>lt;sup>13</sup> Notifications retrieved from iRASFF.

<sup>&</sup>lt;sup>14</sup> Gossner, Céline Marie-Elise, Jørgen Schlundt, Peter Ben Embarek, Susan Hird, Danilo Lo-Fo-Wong, Jose Javier Ocampo Beltran, Keng Ngee Teoh, and Angelika Tritscher, "The Melamine Incident: Implications for International Food and Feed Safety.," Environmental Health Perspectives, Vol. 117, No. 12, December 2009, pp. 1803–8. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2799451&tool=pmcentrez&rendertype=abstract.

<sup>&</sup>lt;sup>15</sup> European Centre for Disease Prevention and Control, Provisional ECDC Public Health Impact Assessment, 2008.

<sup>&</sup>lt;sup>16</sup> European Commission, The Rapid Alert System for Food and Feed: 2008 Annual Report, 2008.

Alemanno, Alberto, "The European Food Import Safety Regime Under a 'Stress Test': The Melamine Contamination of the Global Food Supply Chain," Vol. 3, No. 4, 2010.

# Case study: Glass fragments in instant coffee (2010)

# Brief description of food safety incident:

The glass fragments case involved a large instant coffee producer, who issued a precautionary voluntary recall of three different types of glass-packaged instant coffee following the company's own checks. The checks revealed a risk of the presence of small pieces of glass in the instant coffee resulting from damaged jars, probably incurred during transport. These pieces of glass were not visible to consumers prior to consumption due to an opaque film label covering the entire surface of the jar and its cap. 19

# Chronology of events/overall duration:

20 May 2010 – The Hellenic Food Authority (EFET) receives a letter from "Nestle Hellas S.A." notifying the precautionary recall of certain glass-packaged instant coffees as a result of the company's own checks [later on, "Nestle Hellas S.A" informed EFET that the own checks had been performed in the parent company in France, not in Greece]. EFET completes and submits a notification to the European Commission (RASFF Information 2010.0620). The Hellenic Food Authority's Regional Directorate of Attica is informed and ordered to monitor the recall;

21 May 2010 – The French Directorate General for Competition, Consumers and Fraud Repression (DGCCRF) submits a notification (RASFF Alert 2010.0626) referring to the same incident and identical products as contained in information notification 2010.0620 submitted the previous day. The European Commission requests EFET to withdraw notification 2010.0620. On the same day, follow up notifications provided by the U.K. and Germany are transmitted through the RASFF, communicating the outcome of investigations carried out in those countries countries (RASFF follow-up 2010.0626-add01 and –add02). The Czech NCP also informs the network about the withdrawal of the product initiated on 20 May 2010, providing the link to the public warning issued by the company (RASFF 2010.0626-inf01);

25 May 2010 – The Greek NCP (EFET) responds positively to the European Commission's request by withdrawing information notification 2010.0620;

26 May 2010 – The European Commission Contact Point incorporates notification 2010.0620 into notification 2010.0626;

27 May 2010 – Cyprus provides information on traceability of the affected product (RASFF follow-up 2010.0626-add04). Norway provides follow up (RASFF follow-up 2010.0626-add05) about the measures taken (public warning, press release and recall);

28 May 2010 – Germany informs the network (RASFF follow-up 2010.0626-add06) that the product has been redistributed to France, and confirms that due to damage during transport, glass particles may enter the product (RASFF follow-up 2010.0626-add07). Spain informs the network through a follow up notification (RASFF follow-up 2010.0626-add08) that the product concerned has been withdrawn from the market, that it is not possible to restrict the recall to a specific lot, and that the product has also been distributed to Andorra;

31 May 2010 – Germany confirms that it is not possible to restriction of recalls to lots according to production code or "use by" date (RASFF follow-up 2010.0626-add09)

04 June 2010 – Greece provides follow up (RASFF follow-up 2010.0626-add10) about the redistribution of affected products to Cyprus.

09 June 2010 – The competent authorities in Bosnia and Herzegovina provide information to the RASFF (RASFF 2010.0626-inf02) about the measures taken.

10 June 2010 — The Greek NCP (EFET) submits a follow-up notification (RASFF follow-up 2010.0626-add11) to the European Commission concerning the distribution of incriminated products to Albania;

15 June 2010 – Sweden informs the network (RASFF 2010.0626-inf03) about the measures taken (controls and withdrawal of the affected product).

18 June 2010 – Poland provides follow up (RASFF follow-up 2010.0626-add12) about distribution of the product to Ireland and the Netherlands.

22 June 2010 – Ireland informs the network (RASFF 2010.0626-inf04) about the outcome of investigations and

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 $<sup>^{18}</sup>$  Rapid Alert System for Food and Feed, 2010 Annual report, p.33.

<sup>&</sup>lt;sup>19</sup> RASFF notification 2010.0626

measures taken by its competent authorities regarding distribution of the affected products by a Polish supplier to Polish shops in Ireland.

30 June 2010 – Lithuania provides follow up to notification 2010.0626 (RASFF follow-up 2010.0626-add13), informing that the product has been redistributed to Latvia and Estonia.

09 July 2010 – Estonia informs the network that the products have been recalled from consumers, and a press release requesting the recall of products from the market was issued by UAB Nestle Baltics Estonia (RASFF follow-up 2010.0626-add14).

13 July 2010 - Lithuania confirms that the relevant products have been recalled from consumers (RASFF followup 2010.0626-add15).

20 August 2010 - Spain provides follow up to original notification 2010.0626 (RASFF follow-up 2010.0626add16), informing the network that company has completed collection of the affected products, which were sent for destruction, with the exception of 98 162 jars which had not been distributed and were sent back to the factory of origin in France. Spain also informs the network about the measures taken in Andorra.

23 September 2010 - Spain confirms via the RASFF (RASFF follow-up 2010.0626-add17) that all relevant lots have been blocked at national level, withdrawn from the market by the supplier or destroyed.

23 November 2010 - 9,152.8 tons of products are destroyed in Greece. 20

08 December 2010 - The French NCP informs the RASFF (RASFF follow-up 2010.0626-add18) about the measures planned by Nestle to recycle the coffee contained in the products recalled with unbroken packaging.

16 March 2011 - Greece informs France via the RASFF (RASFF follow-up 2010.0626-add19) about the re-dispatch of approximately 10.4 tons of product from Greece to France.

# Countries/regions affected:

- In the EU, countries affected included France (issued RASFF notification 2010.0626), Austria, Belgium, the Czech Republic, Germany, Denmark, Spain, Estonia, Finland, United Kingdom, Greece, Croatia, Hungary, Latvia, Lithuania, the Netherlands, , Poland, Portugal, Romania, and Sweden.
- Outside the EU, Andorra, Bosnia and Herzegovina, Switzerland, Norway, Serbia, Russia, Ukraine<sup>21</sup>, Albania, and Canada<sup>22</sup> were affected.

Data on number of persons affected: No known cases of humans affected; however, the company's own-checks were triggered by consumer complaints.

Data on economic impact: According to alert notification 2010.0626, the following volumes of product were recalled in this incident: 249,552 kg of Espresso Original; 794,544 kg of Espresso Doux et Fruite; and 1,037,832 kg of Espresso Puissant et Corse. No additional data on the economic impact has been made available by Nestle.

<sup>&</sup>lt;sup>20</sup> Hellenic Food Authority, Chronology of Events and Key Measures Taken Regarding Notification 2010.0626, 2015.

<sup>&</sup>lt;sup>21</sup> RASFF notification 2010.0626 and follow-ups

<sup>&</sup>lt;sup>22</sup> Canadian Federation of Independent Grocers, "Health Hazard Alert Nescafe Brand Espresso Instant Coffee May Contain Glass Fragments," 2010.

# Case study: E.coli outbreak (2011)

**Brief description of food safety incident:** The E.coli outbreak was a food safety incident characterised by a high incidence of infections with Shiga toxin-producing *Escherichia coli* (STEC) of serotype O104:H4, caused by the consumption of fenugreek sprouted seeds. More than 20% of the recognised outbreak cases developed the lifethreatening post-diarrhoeal sequel of haemolytic uremic syndrome (HUS). The 2011 incident is the largest known STEC-associated outbreak worldwide.<sup>23</sup>

## Chronology of events/overall duration:

The E.coli outbreak occurred first in Germany, starting at the beginning of May and reaching a peak on 22 May 2011. <sup>24</sup> One month later, on 22 June 2011, an outbreak of the same strain was identified in the southwest region of France. On 26 July 2011, the E.coli outbreak was declared to be finished in Germany. <sup>25</sup>

21 May 2011 – The German Robert Koch Institute (RKI)<sup>26</sup> notifies the Bundesinstitut für Risikobewertung (BfR)<sup>27</sup> and BVL (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit)<sup>28</sup> of an increase in the number of HUS and STEC cases reported by the authorities in the federal states of Hamburg and Schleswig-Holstein.<sup>29</sup>

22 May 2011 – The outbreak reaches a peak with 161 new STEC infection cases and 63 new HUS cases in one day. The German Administration communicates the increase of citizens with (HUS) through the Early Warning and Response System (EWRS) for the prevention and control of communicable diseases.<sup>30</sup>

24 May 2011 – Germany launches an urgent inquiry through the ECDC's Epidemic Intelligence Information Sharing System (EPIS). The European Commission (DG SANCO, Unit C3 - Health Threats), asks the ECDC (European Centre for Disease Control) to perform a rapid risk assessment.<sup>31</sup>

25 May 2011 – The European Commission holds the first of several audio conferences with the ECDC, the RKI and Member States' authorities. A team of experts is sent to Hamburg, the epicentre of the outbreak.<sup>32</sup>

26 May 2011 – The European Commission organises another meeting inviting all Member States affected by the outbreak. The WHO is invited to the audio conference, giving its support and providing data on previous outbreaks in third countries.<sup>33</sup> Shortly before the audio conference, the Senator for Health of the Hamburg City-State informs the general public of evidence of STEC pathogens on cucumbers from Spain.<sup>34</sup> The President of the Spanish Agency for Food and Nutrition Security Commission (AESAN)<sup>35</sup> contacts the European Commission for more details, who requests more time to gather information.<sup>36</sup>

<sup>&</sup>lt;sup>23</sup> Frank, C, D Werber, and A Milde-Bush, "Results of Surveillance for Infections with Shiga Toxin- Producing Escherichia Coli (STEC) of Serotype O104: H4 after the Large Outbreak in Germany, July to December 2011," *Eurosurveillance*, Vol. 19, No. 14, 2014, pp. 1–6.

<sup>&</sup>lt;sup>24</sup> European Commission, Lessons Learned from the 2011 Outbreak of Shiga Toxin-Producing Escherichia Coli (STEC) 0104:H4 in Sprouted Seeds, 2011.

<sup>&</sup>lt;sup>25</sup> Appel, Bernd, Gaby-fleur Böl, Matthias Greiner, Monika Lahrssen-wiederholt, Stefan Gross, Petra Hiller, and Oliver Lindtner, EHEC Outbreak 2011: Investigation of the Outbreak along the Food Chain, Berlin, 2012.

<sup>&</sup>lt;sup>26</sup> The Robert Koch Institute (RKI) is the central federal institution in Germany responsible for disease control and prevention.

<sup>27</sup> The Bundesinstitut für Pisikohewertung (RfD) is the scientific accept, in Corrections and the fire and the fire accept in Corrections and the fire acceptance in Co

<sup>&</sup>lt;sup>27</sup> The Bundesinstitut für Risikobewertung (BfR) is the scientific agency in Germany responsible for preparing expert reports and opinions on food and feed safety and on the safety of substances and products.

<sup>&</sup>lt;sup>28</sup> The Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL) is the Federal Office of Consumer Protection and Food Safety in Germany.

<sup>&</sup>lt;sup>29</sup> Appel, Bernd, Gaby-fleur Böl, Matthias Greiner, Monika Lahrssen-wiederholt, Stefan Gross, Petra Hiller, and Oliver Lindtner, EHEC Outbreak 2011: Investigation of the Outbreak along the Food Chain, Berlin, 2012.

Font, Mariola Rodríguez, "The 'Cucumber Crisis ': Legal Gaps and Lack of Precision in the Risk Analysis System in Food Safety," Rivista Di Diritto Alimentare, 2012, pp. 1–15.
 Plachenstainer, Francesco, "Managing Food Safety Emergencies and Crises: A Multilevel Comparative Analysis

of the US and EU Legal Frameworks," 2013. <sup>32</sup> Plachenstainer, Francesco, "Managing Food Safety Emergencies and Crises: A Multilevel Comparative Analysis

of the US and EU Legal Frameworks," 2013.

33 Plachenstainer, Francesco, "Managing Food Safety Emergencies and Crises: A Multilevel Comparative Analysis of the US and EU Legal Frameworks," 2013.

<sup>&</sup>lt;sup>34</sup> Appel, Bernd, Gaby-fleur Böl, Matthias Greiner, Monika Lahrssen-wiederholt, Stefan Gross, Petra Hiller, and Oliver Lindtner, EHEC Outbreak 2011: Investigation of the Outbreak along the Food Chain, Berlin, 2012. COSAN) on 12 December 2014.

Now the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN).

<sup>&</sup>lt;sup>36</sup> Font, Mariola Rodríguez, "The 'Cucumber Crisis ': Legal Gaps and Lack of Precision in the Risk Analysis System in Food Safety," Rivista Di Diritto Alimentare, 2012, pp. 1–15.

*27 May 2011* – Two notifications are transmitted through the RASFF (RASFF Alert 2011.0702 and RASFF Alert 2011.0703) identifying distributors and producers of organic cucumbers in Malaga and Almeria, Spain.<sup>37</sup> The government of Andalusia suspends the consignments of cucumbers of the batch indicated in the RASFF notifications.<sup>38</sup>

*30 May 2011* – The German National Reference Laboratory detects that the findings from the STEC pathogen found in the cucumbers differ from those in the infected patients.<sup>39</sup> The first conference call is held between EU Member States contact points for the EWRS and RASFF networks.<sup>40</sup>

01 June 2011 – One of the two RASFF Alert notifications (2011.0702) issued on 27 May is withdrawn from the RASFF.  $^{41}$ 

03 June 2011 – The ECDC and European Food Safety Authority (EFSA) publish a joint statement providing public health advice on the prevention of diarrhoeal illness with a special focus on Shiga toxin-producing Escherichia coli.

05 June 2011 – A team of seven experts from the European Commission, ECDC and EFSA are sent to Berlin with the aim of providing assistance with the ongoing epidemiology, verifying the results and contributing to the ongoing investigations in order to identify the sources of the contamination.<sup>43</sup>

07 June 2011 – Germany issues a RASFF notification (RASFF Alert 2011.0752) informing the network of the suspected presence of E.coli in a sprouts mixture.<sup>44</sup>

 $08 \, June \, 2011$  – EFSA and the ECDC publish a joint technical report on Shiga toxin/verotoxin-producing Escherichia coli in humans, food and animals in the EU/EEA, with special reference to the German outbreak strain STEC O104.  $^{45}$ 

11 June 2011 – German authorities confirm that sprouts produced by a farm in Bienenbüttel, south of the city of Hamburg are responsible for the E. coli outbreak in Germany. 46

22 June 2011 – Eight cases of HUS or bloody diarrhoea are reported by a hospital to the Cellule interrégionale d'épidémiologie in the Bordeaux region of France.<sup>47</sup>

24 June 2011 – French authorities issue an alert via the RASFF (RASFF Alert 2011.0842) notifying the network of food poisoning suspected to be caused by verotoxin producing Escherichia coli. According to the alert, the same strain of E.coli (O104) as in the German outbreak is determined in two patients, and vegetables for sprouting are indicated as the suspected source of the food poisoning.<sup>48</sup>

26 June 2011 – The European Commission mandates EFSA to perform a tracing back and tracing forward exercise to identify the source of the French and German outbreaks. In response to the request, EFSA subsequently sets

<sup>&</sup>lt;sup>37</sup> RASFF notification 2011.0703 and RASFF Portal Notification details 2011.0702 accessed on 10 March 2015 at https://webgate.ec.europa.eu/rasff-window/portal/index.cfm?event=notificationDetail&NOTIF\_REFERENCE=2011.0702.

<sup>&</sup>lt;sup>38</sup> Font, Mariola Rodríguez, "The 'Cucumber Crisis ': Legal Gaps and Lack of Precision in the Risk Analysis System in Food Safety," Rivista Di Diritto Alimentare, 2012, p.3.

<sup>&</sup>lt;sup>39</sup> Appel, Bernd, Gaby-fleur Böl, Matthias Greiner, Monika Lahrssen-wiederholt, Stefan Gross, Petra Hiller, and Oliver Lindtner, EHEC Outbreak 2011: Investigation of the Outbreak along the Food Chain, Berlin, 2012.

<sup>&</sup>lt;sup>39</sup> RASFF Portal Notification details 2011.0702 accessed on 10 March 2015 at https://webgate.ec.europa.eu/rasff-window/portal/index.cfm?event=notificationDetail&NOTIF\_REFERENCE=2011.0702

<sup>&</sup>lt;sup>40</sup> Angot, Jean-Luc, "E.Coli Crisis: Lessons Learnt," 2011, pp. 1–14.

<sup>&</sup>lt;sup>41</sup> RASFF Portal Notification details 2011.0702 accessed on 10 March 2015 at https://webgate.ec.europa.eu/rasff-window/portal/index.cfm?event=notificationDetail&NOTIF\_REFERENCE=2011.0702.

<sup>&</sup>lt;sup>42</sup> European Food Safety Authority (EFSA), "Public Health Advice on Prevention of Diarrhoeal Illness with Special Focus on Shiga Toxin - Producing Escherichia Coli," 2011. http://efsa.europa.eu/en/press/news/110611.htm.

<sup>43</sup> http://ec.europa.eu/food/food/coli\_outbreak\_germany\_en.htm

<sup>&</sup>lt;sup>44</sup> RASFF Alert notification 2011.0752.

<sup>&</sup>lt;sup>45</sup> European Food Safety Authority, and European Centre for Disease Prevention and Control, "Shiga Toxin/verotoxin-Producing Escherichia Coli in Humans, Food and Animals in the EU/EEA, with Special Reference to the German Outbreak Strain STEC O104.," 2011, p. 23.

<sup>46</sup> http://ec.europa.eu/food/food/coli\_outbreak\_germany\_en.htm

<sup>&</sup>lt;sup>47</sup> Gault, Gaëlle, François-Xavier Weill, Patricia Mariani-kurkdjian, Nathalie Jourdan-da Silva, Lisa King, Bénédicte Aldabe, Martine Charron, et al., "Outbreak of Haemolytic Uraemic Syndrome and Bloody Diarrhoea due to Escherichia Coli O104:H4, South-West France, June 2011," BEHWebt, Vol. 3, No. June, 2011, pp. 22–25. www.invs.sante.fr/ behweb/2011/03/index.htm.

<sup>&</sup>lt;sup>48</sup> RASFF Alert notification 2011.0842, 25 June 2011.

up a Task Force composed of experts from the European Commission, EU Member States, the ECDC, the WHO and  ${\sf FAO.}^{49}$ 

29 June 2011 – EFSA and ECDC publish a joint rapid risk assessment on the outbreak in France, indicating fenugreek, mustard, and rucola sprouts distributed by a UK company as the suspected sources of STEC infections.<sup>50</sup>

05 July 2011 – EFSA publishes a report on tracing fenugreek seeds in relation to the Shiga toxin-producing E.coli outbreaks in Germany and France, linking the outbreaks in both countries to a specific lot of fenugreek seeds imported from Egypt.<sup>51</sup>

06 July 2011 – The European Commission imposes a ban on the import of certain seeds and beans from Egypt (Commission Implementing Decision of 6 July 2011 (2011/402/EU)).

12 July 2011 – French authorities issue national instructions to suspend the placing on the market of all batches of fenugreek seeds imported from Egypt between 2009 and 2011 and to withdraw and destroy those which are already on the market. The national instructions also provide for the suspension of the placing on the market of grains and seeds mentioned in Annex of Commission Implementing Decision 2011/402/EU imported from Egypt before 07 July 2011 until 31 October 2011. 52

26 July 2011 – The RKI announces that no new cases of illness have been reported by the federal states for three weeks and declares the STEC crisis to be finished in Germany.<sup>53</sup>

# Countries/regions affected:

- Germany: all federal states, but especially Hamburg, Schleswig-Holstein, Bremen, Mecklenburg-Western Pomerania and Lower Saxony, with HUS incidence in these states up to 10 cases per 100,000 persons.
- France: Bordeaux (South-West) region.
- A number of countries were affected due to citizens travelling to Germany at the time of the E.coli outbreak. Citizens from the EU, Canada, Switzerland, and the U.S. were affected by the outbreak.

# Data on number of persons affected:

- Germany: 855 cases of HUS, 2987 cases of bloody diarrhoea, 53 deaths;
- France: 15 cases, no deaths;
- Other EU countries: 71 cases of STEC, 41 cases of HUS, 1 death;
- Non-EU countries: 8 cases of STEC, 4 cases of HUS, 1 death.

# Data on economic impact (where available):

- Losses for farmers: €812.6 million in the first two weeks;
- Market intervention: €227 million (total value);
- Media campaign: €0.6 million;
- Promotional programs for fresh fruits and vegetables: €34.1 million;
- Loss related to the temporary export ban of vegetables to Russia: €600 million (annual value).

<sup>&</sup>lt;sup>49</sup> European Food Safety Authority (EFSA), "Tracing Seeds, in Particular Fenugreek (Trigonella Foenum-Graecum) Seeds, in Relation to the Shiga Toxin-Producing E.coli (STEC) 0104:H4 2011 Outbreaks in Germany and France," 2011.

<sup>&</sup>lt;sup>50</sup> European Food Safety Authority, and European Centre for Disease Prevention and Control, EFSA/ECDC Joint Rapid Risk Assessment: Cluster of Haemolytic Uremic Syndrome (HUS) in Bordeaux, France, Vol. 2011, Vol. 2011, Stockholm, 2011.

<sup>&</sup>lt;sup>51</sup> ECDC, "Understanding the 2011 EHEC/STEC Outbreak in Germany," 2011.

<sup>&</sup>lt;sup>52</sup> Lefebvre, Frédéric, Arrêté Du 12 Juillet 2011 Relatif Aux Mesures D'urgence Applicables Aux Graines de Fenugrec et À Certaines Graines et Fèves Importées d'Egypte, 12 July 2011.

<sup>&</sup>lt;sup>53</sup> Appel, Bernd, Gaby-fleur Böl, Matthias Greiner, Monika Lahrssen-Wiederholt, Stefan Gross, Petra Hiller, and Oliver Lindtner, EHEC Outbreak 2011: Investigation of the Outbreak along the Food Chain, Berlin, 2012.

<sup>&</sup>lt;sup>54</sup> Robert Koch Institut, "Final Presentation and Evaluation of the Epidemiological Findings in the EHEC O104: H4 Outbreak," 2011.

<sup>&</sup>lt;sup>55</sup> Robert Koch Institut, "Final Presentation and Evaluation of the Epidemiological Findings in the EHEC O104: H4 Outbreak," 2011.

<sup>&</sup>lt;sup>56</sup> European Commission, Lessons Learned from the 2011 Outbreak of Shiga Toxin-Producing Escherichia Coli (STEC) 0104:H4 in Sprouted Seeds, 2011.

# Annex 10: Intervention logic for the RASFF

**NEEDS** 

Rapid and coordinated response in cases of risks to human health deriving from food/feed

Containment of food/feed safety incidents and prevention of crisis

Prevention of disruptions of the internal market

Effective
national control
including border
control to
ensure
compliance with
EU rules of
products placed
on the EU
market

Consumer confidence in safe food/feed on the EU market

Protection of consumer health

GENERAL OBJECTIVES

Swift exchange of information between MS in cases of risks to human health deriving from food and feed

Information of consumer and industry stakeholders on risks to human health deriving from food/feed <sup>a</sup>

Information of third countries on risks detected to human health deriving from food and feed SPECIFIC OBJECTIVES

Provide a tool for information exchange on direct or indirect risks in relation to food or feed

Inform MS on the follow-up to notified direct or indirect risks

Exchange of information on measures to contain risk

INPUT

EC: staff costs, set up and maintenance of IT platforms including iRASFF, RASFF Window, training costs

NCP and EFSA: staff costs

NCPs: Training costs

OUTPUT

Rapid alert system, including templates, data dictionaries, guidelines, and IT platforms

Trained and qualified personal and infrastructure in MS, TC and EC to operate the system

Coordination throughout the EU and between the concerned actors **RESULTS** 

Rapid availability of information related to risks

Correct information related to the risk/appropriate communication

Availability of information on follow-up by MS and TC

Data on food/feed safety risks/trends

Enhanced emergency/crisis preparedness

Identification of emergencies and crises

**IMPACTS** 

National control plans better focused on frequently occurring and eminent risks

More focused checks at EU borders on frequently occurring and eminent risks

Compliance with EU rules of products placed on the EU market

Disruptions of the internal market are better prevented

More confident consumers through better information on risks to human health deriving from food/feed

Consumer health protection

Source: Civic Consulting. Notes: a) While Regulation (EC) No 178/2002 recognises the need for informing the public on risks to human health posed by food and feed, including product identification, the nature of the risk, and the measure taken, this is not an explicit objective of the RASFF.

# Annex 11: Intervention logic for crisis management procedures

## **NEEDS**

# **GENERAL OBJECTIVES**

## SPECIFIC **OBJECTIVES**

#### **OUTPUT**

## **RESULTS**

## **IMPACTS**

Rapid and coordinated response in cases of risks to human health deriving from food and feed

Containment of food/feed crisis

Mitigate disruptions of the internal market/trade in the event of serious food/feed incident

Consumer confidence in safe food/feed on the EU market

Protection of consumer health

Source: Civic Consulting.

Adequate management of food and feed related serious incidents that cannot be contained by individual

Member States

Procedures that allow for rapid action at EU and MS level for food and feed crisis

Coordinated efforts to determine and implement most effective measures to contain incidents

EC, MS, EFSA: staff costs and expenditures for designated crisis coordination and development of tools for risk management incl. SOPs,

**INPUT** 

Costs for performingthe simulation exercises

contingency

plans

Training costs knowledge building

Risk assessment done by EFSA

General plan for crisis management

Crisis unit

Tested procedures for crisis management, including SOPs by EC

Contingency plans by MS

Trained experienced personnel

Identification and adoption of effective measures to contain the risk

Efficient use of existing resources

Effective communication

Efficient management of serious food/feed incidents

Coordinated implementation of most effective measures to contain the risk

Consumerstrust in food/feed safety

Limited disruption of internal market and trade

Consumer health protection

# Annex 12: Framework for the evaluation of the RASFF and of crisis management procedures

Evaluation issue	Evaluation questions	Judgement criteria	Indicators	Data sources	Details	
Rapid Alert	System for Food and	Feed				
		extent to which the EC fullis	% of MS NCP confirming that EC has always transmitted alert notifications to all members of the network within 24 hours after reception, upon verification	Survey of RASFF National Contact Points	Question 18a: "To what extent does the EC fulfil the following duties of Article 50 of Regulation 178/2002, as specified in detail in Articles 2 to 7 of Regulation 16/2011 laying down implementing measures for the RASFF? a) The EC has transmitted alert notifications to all members of the network within 24 hours after reception, upon verification."	
				% of MS NCP confirming that EC has always transmitted follow-up notifications to alerts to all members of the network within 24 hours	Survey of RASFF National Contact Points	Question 18b: "The EC has transmitted follow-up notifications to alerts to all members of the network within 24 hours."
				Interviews	EC	
			Degree of satisfaction of the MS NCP with the rapidity of the EC's transmission of the information notifications	Survey of RASFF National Contact Points	Question 18c: "The EC has transmitted information notifications to all members of the network without undue delay."	
			% of MS NCP confirming that EC has always	Survey of RASFF National	Question 18d: "The EC has	

				transmitted border rejection notifications to NCPs/border posts	Contact Points	transmitted border rejection notifications to NCPs/border posts."			
			•	Degree of satisfaction of the MS NCP with the quality and rapidity of the validation of notifications by EC	Survey of RASFF National Contact Points	Question 18e: "The validation of notifications by the EC before transmitting them to all members of the network has been rapid and of good quality."			
					Interviews	Selected NCPs			
			•	Degree of satisfaction of TCs with the way the EC has informed them without undue delay when notified products originated from/are distributed to these third countries	Survey of third countries	Question 18f: "The EC has informed our country's contact point without undue delay when notified products originated from or were distributed to our country."			
						•	Identification of cases in which the EC did not fulfil its obligations	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 10
					Glass fragments in instant coffee (2010), question 10				
						Melamine in food crisis (2008), question 10			
	EC played the role of resultin manager and, at the	problems mentioned resulting from the double role of the Commission as manager and participant of	•	Identification of problems originating from the EC's double role as manager and participant of the RASFF	Interviews	EC, selected NCPs			
	of the network?		•	Degree to which respondents assess that the EC's double role as manager and participant of the RASFF has led to problems	Survey of RASFF National Contact Points and other stakeholders	Question 23: "Have there been cases where the double role of the Commission as manager and participant of the RASFF led to problems? If Yes, please specify."			

To what extent has the EC contributed to the coordination of the members of the RASFF and to the development of good and common notification practices?  EC's contribution to the coordination of the members of the RASFF and to the development of good and common notification practices	Assessment of RASFF members regarding the EC's contribution to the coordination of the members of the RASFF and to the development of good and common notification practices	Survey of RASFF National Contact Points	Question 19: "To what extended has the EC contributed to the coordination of the member of the RASFF and to the development of good and common notification practices? If it has not contributed to the coordination of the member of the RASFF, please explain why not."	
			Interviews	Selected NCPs
		Scope for improvement	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 24: "Do you have suggestions how the role o the EC in the RASFF could be improved? If Yes, please specify."
To what extent has the adoption of the Regulation improved the functioning and monitoring of the RASFF have occurred as a result of the adoption of Regulation 178/2002?  RASFF?	functioning and monitoring	Number of countries and food chain areas covered by RASFF over time	Document review	Literature [1]
	as a result of the adoption of	<ul> <li>Number of notifications produced/received over time</li> </ul>	RASFF information flow	Data on the number of notifications produced/received over time.
			Interviews	EC
To what extent have the regular Working Groups organised by	Extent to which the regular RASFF contact point Working Groups organised by the EC contributed to the better	Number of Working Groups organized by the EC	Interviews	EC, selected NCPs
the EC contributed to the better functioning		Assessment by NCPs regarding the contribution of the Working Groups to the better functioning of the	Survey of RASFF National	Question 20: "To what extended have the regular RASFF cor

	of the RASFF? funct	functioning of the RASFF	<ul> <li>RASFF</li> <li>Indication of outcomes of Working Groups that have contributed to the better functioning of the RASFF</li> </ul>	Contact Points	point Working Groups organised by the EC contributed to the better functioning of the RASFF? If the working groups have contributed to a better functioning, please explain which outcomes you consider most relevant"
	To what extent are the guidelines issued by the EC on the functioning of the network clear and	(Standard Operating	Assessment of RASFF NCPs regarding the degree to which the SOPs are clear	Survey of RASFF National Contact Points	Question 21a: "To what extent are the SOPs issued by the EC on the functioning of the network a) clear?"
	helpful?		Assessment of RASFF NCPs regarding the degree to which the SOPs are helpful		Question 21b: "To what extent are the SOPs issued by the EC on the functioning of the network b) helpful?"
		Extent to which the SOPs are consistent with the needs and expectations of the RASFF NCPs	Assessment of RASFF NCPs regarding the degree to which the SOPs are consistent with their needs and expectations	Survey of RASFF National Contact Points	Question 21c: "To what extent are the SOPs issued by the EC on the functioning of the network c) consistent with your needs and expectations?"
Efficiency	RASFF efficient?	Extent to which the benefits of the RASFF have been achieved at an appropriate	% of NCPs assessing that costs incurred by their country for the RASFF have been appropriate when compared with the benefits of the RASFF for them	Surveys of RASFF National Contact Points	Question 41: "Have the costs incurred by your country for the RASFF been appropriate
To what extent can the objectives be achieved at a lower cost with a better	cost	Identification of key benefits		when compared with the benefits of the RASFF for you? Please explain the key benefits for your country."	
	management of the available resources?		<ul> <li>Costs of running the RASFF incurred by the EC (including staff costs, training costs, costs of setting up and maintaining IT platform)</li> </ul>	Financial analysis of the RASFF at EC and NCP level	Data from EC and NCP
		<ul> <li>Costs of running the RASFF NCPs incurred by Member States (staff costs and costs for training of employees)</li> </ul>			

	Extent to which the balance of cost and benefits of the RASFF could be improved	<ul> <li>% of NCPs assessing that the balance of costs and benefits of the RASFF for their country could be improved</li> <li>Areas suggested by respondents in which the balance of costs and benefits of the RASFF could be improved</li> </ul>	Surveys of RASFF National Contact Points	Question 43: "Could the balance of costs and benefits of the RASFF for your country be improved? If Yes, please specify how."
tasks – notably those which are not related to the dissemination of risk related information for the purposes of risk	currently handles (or has ated to handled in the past) certain tasks which should be better	% of notifications which are not related to the dissemination of risk related information for the purposes of risk containment	RASFF information flow	Data on notifications which are not related to the dissemination of risk-related information for the purposes of risk containment
	information systems (or mechanisms)	% of NCPs that consider certain tasks should be better handled through other information systems or mechanisms in the future	Surveys of RASFF National Contact Points	Question 42: "Should the following types of notifications / messages in the future be handled through RASFF or through another information system (or mechanism)? If it should be handled through another information system, please specify.
				<ul><li>a) RASFF alert notifications</li><li>b) RASFF information</li></ul>
				notifications  c) RASFF border rejection notifications
				d) RASFF follow-up notifications
				e) RASFF news notifications
				f) Status updates on crisis management measures taken in your country during a serious food/feed safety incident
				g) (Draft) press releases in the context of crisis management

				measures taken in your country for information of the EC/other countries  h) Notifications of food fraud i) Notifications of non-compliant consignments that are not related to risk containment (e.g. if MRL for a pesticide is exceeded slightly in a consignment) j) Other"	
			Identification of specific tasks that could be handled by other systems	Interviews	EC, selected NCPs
			Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 7a	
				Glass fragments in instant coffee (2010), question 7a	
					Melamine in food crisis (2008), question 7a
Effective- ness	To what extent has the RASFF achieved its objectives?	Extent to which the RASFF has achieved the following objectives:  - Provide a tool for information exchange between members of the network on direct or indirect risks in relation to food or feed  - Inform members of the network on the follow- up to notified direct or indirect risks  - Exchange of information	<ul> <li>% of respondents considering that the following objectives are being achieved:</li> <li>Provide a tool for information exchange between members of the network on direct or indirect risks in relation to food or feed</li> <li>Inform members of the network on the follow-up to notified direct or indirect risks</li> <li>Exchange of information between members of the network on measures to contain risk</li> <li>Information of third countries on risks detected to human health deriving from food and feed</li> <li>Information of consumers on risks detected to human health deriving from food and feed</li> </ul>	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 2: "To what extent is the RASFF achieving the following objectives:  a) Provide a tool for information exchange between members of the network on direct or indirect risks in relation to food or feed b) Inform members of the network on the follow-up to notified direct or indirect risks c) Exchange of information between members of the network on measures to

	between members of the network on measures to contain risk  - Information of third countries on risks detected to human health deriving from food and feed  - Information of consumers on risks detected to human health deriving from food and feed			contain risk d) Information of third countries on risks detected to human health deriving from food and feed e) Information of consumers on risks detected to human health deriving from food and feed."
			RASFF information flow	Data on alert notifications, follow-up notifications and notifications to third countries
To what extent have the initial objectives remained valid?	Extent to which the initial objectives of the RASFF are still relevant	% of respondents considering that the initial objectives have remained valid	Surveys of RASFF National Contact Points and other stakeholders involved in	Question 2: (For each objective) "Does this objective remain valid? If No, please
	Still relevant	Identification of objectives that are no longer valid, if any	the RASFF	explain."
	Extent to which stakeholders suggest additional objectives other than the initial objectives of the RASFF	Identification of additional objectives other than the initial objectives of the RASFF	Surveys of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 3: Considering the objectives in question 2: do you see the need for the RASFF to address any additional objective?
To what extent has the RASFF adapted to the changes in the regulatory framework,	What are changes in the regulatory framework, emerging risk, the market and consumer behaviour to which the RASFF has not adapted?	<ul><li>% of respondents considering the RASFF has not adapted to:</li><li>Changes in the regulatory framework</li></ul>	Surveys of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 4: "Have there been changes to the following areas to which the RASFF has not adapted?
emerging risk, changes in market and consumer behaviour etc.?		<ul> <li>Emerging risks</li> <li>Changes in the market</li> <li>Changes is consumer behavior</li> </ul>		a) Changes in the regulatory framework (e.g. Regulation 16/2011 on implementing measures for the RASFF, major legislation such as the Hygiene Package)?
				b) Changes in emerging risks (e.g. related to more globalised food chains)?

		Identification of changes to which the RASFF has not adapted	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	c) Changes in markets/marketing channels (e.g. e-commerce in food)? d) Changes in consumer behaviour (e.g. increased consumption of processed food)? e) Other changes. Please specify"  Question 4: "If No, please explain the changes to which the RASFF has not adapted."	
				Interviews (follow-up in case changes identified through survey to which the RASFF has not adapted)	EC, selected NCPs
Participa- tion of third	To what extent is the RASFF open to third	F open to third open to the participation of third countries and international organisations cipation?	ipation of organisations with access to the RASFF d	Document review	Literature [1]
countries/	countries' and			Interviews	EC, INFOSAN, selected TCs
inter- national organi-	organisations' participation?			RASFF information flow	Data on RASFF notifications to/from TCs
How can the syste more widely used between the international communities of			% of respondents that consider the RASFF to be open to their participation	Survey of third countries and international organisations	Question 30b: "To what extent is the RASFF <u>open</u> to your participation as a third country/international organisation?"
	between the international	Extent to which the use of the RASFF between the international communities of countries could be extended	Identification of current purposes for using RASFF information by TCs and IOs	Survey of third countries and international organisations	Question 30a: "For which purposes do you use notifications received through the RASFF? i) Preventing affected consignments from being exported to the EU, ii) Preventing affected consignments from being

	countries?	ountries?			imported to my country, iii) To remove any affected consignments from the market in my country, iv) To improve compliance with EU rules of products to be exported, v) To provide information to stakeholders and consumers, vi) Other (please specify)"
			Identification of obstacles to the use of the RASFF by third countries and international organisations (such as language requirements, level of detail requested, confidentiality provisions, legal basis etc.)	Survey of third countries and international organisations	Question 31: "Are there any obstacles for your organisation preventing you to provide more information to the RASFF?"
				Interviews	WHO, selected TCs
			Scope for improvement	Survey of third countries and international organisations	Question 35: "Do you have suggestions how the participation of Third Countries/International Organisations in the RASFF could be improved?"
	To what extent is the reciprocity of information flow between RASFF and the	Extent to which information is shared between members of the RASFF and International Organisations	Number of notifications to/from WHO INFOSAN	RASFF information flow	Data on RASFF notifications to/from INFOSAN
	International Organisations	Extent to which reciprocity of		Interviews	EC and WHO
	appropriate?	information flow is appropriate	during past serious food/feed safety incidents	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 24
					Glass fragments in instant coffee (2010), question 24
					Melamine in food crisis (2008), question 24

How well does the RASFF work together with other systems (at Member State, EU and international levels)?	With which other existing systems (at international level, EU/MS levels) is RASSF working together?	Identification of other systems (at international level, EU/MS levels) with which RASSF is working together	Interviews	EC, WHO, selected NCPs
	Assessment by stakeholders of extent to which the RASFF is complementary to INFOSAN or duplicates it	% of respondents indicating that RASFF is complementary to INFOSAN/ does not duplicate it	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 36a: "To what extent is the RASFF complementary to the following information systems or duplicates them? a) International level: INFOSAN."
		Complementarities or duplications, if any, between RASFF and INFOSAN during past serious food/feed safety incidents	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 8
				Glass fragments in instant coffee (2010), question 8
				Melamine in food crisis (2008), question 8
	Assessment by stakeholders of extent to which the RASFF is complementary to other EU level systems (EWRS, TRACES, RAPEX, ECURIE, EPIS, ARGUS, Administrative Assistance and Cooperation) or duplicates them	% of respondents indicating that RASFF is complementary to other EU level systems (EWRS, TRACES, RAPEX, ECURIE, EPIS, ARGUS, Administrative Assistance and Cooperation) / does not duplicate them	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	<ul> <li>Question 36b: "EU level:</li> <li>i. EWRS (Early Warning and Response System</li> <li>ii. TRACES (TRAde Control and Expert System)</li> <li>iii. RAPEX (Rapid Exchange of Information System)</li> <li>iv. ECURIE (European Community Urgent Radiological Information Exchange)</li> <li>v. ARGUS (General European rapid alert system)</li> <li>vi. Administrative Assistance</li> </ul>

				vii. Other. Please specify."
		Complementarities or duplications between RASFF and EWRS/TRACES during past serious food/feed safety incidents	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 8
				Glass fragments in instant coffee (2010), question 8
				Melamine in food crisis (2008) question 8
	Assessment by stakeholders of how well RASFF works together with national level systems	% of respondents indicating that RASFF is complementary to alert systems at the national level / does not duplicate them	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 36c: "National level: the alert system in your country. Please specify name of system."
	Identification of problem areas that prevent cooperation	Problem areas identified, if any	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 36: "Please explain."
What are the geographic weak points in the food safety map, due to lack of food alert systems or their weak functioning? What could be the role of RASFF there?	Are there regions of the world from which NCPs would need to receive more information through the RASFF?	Number of notifications from third countries	RASFF information flow	Data on the number of notifications from third countries
	Assessment by NCPs of the need for more information from specific regions of the world through RASFF (e.g. Western Balkans, North Africa, Sub-Saharan Africa, Middle East and Arabian Peninsula, Asia, Oceania, Latin America and the Caribbean, North America)	<ul> <li>% of NCPs indicating there is a need for more information from the Western Balkans</li> <li>% of NCPs indicating there is a need for more information from North Africa</li> <li>% of NCPs indicating there is a need for more information from Sub-Saharan Africa</li> <li>% of NCPs indicating there is a need for more information from the Middle East and Arabian Peninsula</li> </ul>	Survey of RASFF National Contact Points	Question 34: "Would you need to receive more information from third countries through the RASFF? If Yes, from which regions of the world as a priority?"

			<ul> <li>information from Asia</li> <li>% of NCPs indicating there is a need for more information from Oceania</li> <li>% of NCPs indicating there is a need for more information from Latin America and the Caribbean</li> <li>% of NCPs indicating there is a need for more information from North America</li> </ul>		
		Areas for improvement	Suggestions identified by NCPs	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 35: "Do you have suggestions how the participation of Third Countries/International Organisations in the RASFF could be improved?"
Information flow to stake-	To what extent does the RASFF [sufficiently] inform involved	Extent to which RASFF sufficiently informs involved	▶ Type of information available in the RASFF Portal for professional operators	RASFF Portal	N/A
holders and profession- nal operators	professional operators?	professional operators	% of respondents that consider the RASFF Portal sufficiently informs professional operators	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 27: "Does the RASFF sufficiently inform professional operators?"
	To what extent can stakeholders [sufficiently] consult the information managed	skeholders  can sufficiently consult the information in the RASFF	% of respondents that consider that they can sufficiently consult information in the RASFF Portal	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 28: "Can stakeholders sufficiently consult the information in the RASFF Portal?"
by the RASFF?	by the KASFF?		Assessment of respondents on the need to improve the information flow to stakeholders and professional operators from the RASFF	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 29: "Do you consider that there is a need to improve the information flow to stakeholders and professional operators in the RASFF?"
Trans- parency and confiden-	parency and RASFF transparent and	Extent to which the RASFF Portal is transparent to the	Identification of information in the RASFF Portal available to the general public	RASFF Portal	N/A
cominden-	accessible to the	general public	Assessments of respondents regarding the	Survey of RASFF National	Question 37a: "To what extent

tiality	general public?		transparency of the RASFF to the general public	Contact Points and other stakeholders involved in the RASFF	is the RASFF Portal transparent to the general public?"
		Extent to which the RASFF Portal is accessible to the general public	Assessments of respondents regarding the accessibility of the RASFF to the general public	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 37b: "To what extent is the RASFF Portal accessible to the general public?"
		Suggestions for improvement	Suggestions of respondents for improving the transparency of the RASFF	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 40a: "Do you have suggestions how the <u>transparency</u> of the RASFF could be improved?"
	To what extent does the RASFF address the needs of the general public for information on unsafe food?	Extent to which the RASFF Portal addresses the needs of the general public for information on unsafe food	Assessments of respondents regarding the extent to which the RASFF Portal addresses the needs of the general public for information on unsafe food	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 37c: "To what extent does the RASFF Portal address the needs of the general public for information on unsafe food?"
RASFF achieve an adequate balance between confident and information to consumers and stakeholders?  To what extent is to classification used	adequate balance between confidentiality and information to consumers and	Extent to which the RASFF achieves an adequate balance between confidentiality and information to consumers and stakeholders	Assessments of stakeholders regarding the extent to which the RASFF achieves an adequate balance between confidentiality and information to consumers and stakeholders	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 39b: "Does the RASFF achieve an adequate balance between confidentiality and information to consumers and stakeholders?"
	To what extent is the classification used pertinent and clear?	Extent to which the classification of notifications used is clear for competent authorities	% of respondents who consider that the classification of notifications used in RASFF (alert notification, information notification, border rejection notification, follow-up notification) is clear for competent authorities	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 38a: "To what extent is the classification of notifications used (alert notification, information notification, border rejection notification, follow-up
		Extent to which the	% of respondents who consider that the		nothication, follow up

		classification of notifications used is clear for the general public  Extent to which the classification of notifications used is clear for food/feed business operators	<ul> <li>classification of notifications used in RASFF (alert notification, information notification, border rejection notification, follow-up notification) is clear for the general public</li> <li>% of respondents who consider that the classification of notifications used in RASFF (alert notification, information notification, border rejection notification, follow-up notification) is clear for food/feed business operators</li> </ul>		notification) clear?  a) For competent authorities  b) For the general public  c) For food/feed business operators"
		Possible unclarities or misunderstandings regarding classifications used	Identification of possible unclarities or misunderstandings regarding classifications used indicated by respondents	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Explanations provided to question 38
	To what extent is the RASFF respecting the confidentiality requirements as set in the Regulation?	Are the confidentiality requirements as set in the Regulation 178/2002 (Article 52) sufficiently respected?	Assessment of respondents regarding the sufficiency of respect by members of the RASFF of the confidentiality requirements as set in the Regulation 178/2002 (Article 52)	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 39a: "Are the members of the RASFF sufficiently respecting the confidentiality requirements as set in the Regulation 178/2002 (article 52)? If No, please explain why."
		Have there been cases in which the confidentiality requirements were not respected by members of the RASFF network?	Cases in which members of the RASFF network did not ensure that the confidentiality requirements were respected as indicated by respondents	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Explanations provided to question 39
	Suggestions for improvement	Suggestions of respondents for improving the confidentiality of the RASFF	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 40b: "Do you have suggestions how the confidentiality of the RASFF could be improved?"	
Risk-based	To what extent are the operations of the RASFF really risk based?	Extent to which the notifications exchanged through the RASFF are based on risk	% of respondents who consider that notifications exchanged through the RASFF are sufficiently risk based	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 10: "Are the notifications exchanged through the RASFF sufficiently risk based? If no, please explain why."

	To what extent is risk accurately evaluated in the RASFF?	Extent to which risk is accurately evaluated in the RASFF (Point of reference is Regulation 16/2011 in which the term risk is understood as: "a direct or indirect risk to human health in connection	<ul> <li>Degree to which respondents consider that risk is accurately evaluated in the RASFF</li> <li>% of alert notifications downgraded to information notifications or rejected</li> </ul>	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF RASFF information flow	Question 11: "To what extent is <u>risk accurately evaluated</u> in the RASFF? Please explain."  Data on downgraded/rejected alert notifications
		with food, food contact material or feed in accordance with Regulation (EC) No 178/2002 or as a	Assessment of stakeholders regarding the extent to which risk was accurately evaluated in the RASFF in past serious food/feed safety incidents	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 11
		serious risk to human health, animal health or the environment in connection			Glass fragments in instant coffee (2010), question 11
	Regular	with feed in accordance with Regulation (EC) No 183/2005."	ith		Melamine in food crisis (2008), question 11
			Identification of suggestions for improving the risk-	Interviews	EC, selected NCPs, EFSA
			based approach of the RASFF	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 12: "Do you have suggestions how the <u>risk-based approach</u> of the RASFF could be improved?"
Role of EFSA	What is the role of EFSA within the RASFF?	Role description of EFSA within the RASFF	Identification of the role of EFSA within the RASFF in legislation	Document review	Literature [1]
	Is EFSA fulfilling its role in RASFF as laid down in	Extent to which EFSA is fulfilling its role in the RASFF as laid down in Article 50 of Regulation 178/2002 (EFSA "may supplement the	Assessment of NCPs and stakeholders who consider that EFSA is fulfilling its role as laid down in Article 50 of Regulation 178/2002 in past serious food/feed safety incidents	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 13

	the Regulation?	notification with any scientific or technical information, which will facilitate rapid, appropriate risk management action by the Member States")  Is EFSA's role in the risk-based approach of RASFF adequate to address the needs of Member States and the EC?	<ul> <li>Assessment of NCPs and stakeholders who consider that EFSA's role in the risk-based approach of the RASFF is adequate to address the needs of Member States and the EC</li> <li>Scope for improvement</li> </ul>	Interviews	Glass fragments in instant coffee (2010), question 13  Melamine in food crisis (2008), question 13  EFSA, EC, selected NCPs
Scope	To what extent is the scope of the RASFF appropriate?	Is the scope of the RASFF appropriate to address the needs of RASFF members? Are there any elements of the RASFF that are not necessary? Are there any needs that are not addressed in the RASFF?	% of NCPs who consider that the scope of the RASFF is appropriate to address their needs	Survey of RASFF National Contact Points	Question 8: "Is the scope of the RASFF <u>appropriate</u> to address your needs?"
			Assessment of degree to which there are elements of the RASFF that are not necessary	Interviews	Selected NCPs, EC
			Assessment of degree to which there are needs not addressed in the RASFF		
	Is the scope of the RASFF sufficiently defined?	sufficiently areas covered and the type	% of respondents who consider that the scope of the RASFF is sufficiently defined	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 7: "Is the scope of the RASFF (i.e. areas covered and the type of information provided) sufficiently defined in Article 50 of Regulation 178/2002? If no, please explain why."
			Scope for improvement	Survey of RASFF National Contact Points and other stakeholders involved in the RASFF	Question 9: "Do you have suggestions how the <u>definition</u> of the scope of the RASFF could be improved?"
Involve- ment of the	To what extent have the MS adapted to meet the requirements	Extent to which Member States adopted national	% of Member States that adopted legislation to implement the RASFF, or are in the process of doing	Interviews	EC, selected NCPs

MS	of the Regulation?  legislation to implement the RASFF to meet the requirements of the Regulation  To what extent have the MS developed their legislation to meet the	SO			
	requirements of the Regulation?			Survey of RASFF National Contact Points	Question 13: "Has your country adopted national legislation to implement the RASFF?"
	To what extent do the MS fulfil their obligations under the RASFF?	Extent to which MS fulfil the duties of Article 50 of Regulation 178/2002, as specified in detail in Articles 2 to 7 of Regulation 16/2011 laying down implementing measures for the RASFF:  - Sending alert notifications to the Commission contact point within 48 hours from the moment the risk was reported to their NCP - Sending information notifications to the Commission contact point without undue delay - Sending border rejection notifications to the Commission contact point without undue delay - Immediately transmitting a follow-up notification to the	Assessment of NCPs regarding the fulfillment by their own country of obligations under the RASFF	Survey of RASFF National Contact Points	Question 14: "To what extent does your country fulfil the following duties of Article 50 of Regulation 178/2002, as specified in detail in Articles 2 to 7 of Regulation 16/2011 laying down implementing measures for the RASFF?"  a) My country has sent alert notifications to the Commission contact point within 48 hours from the moment the risk was reported to the NCP b) My country has sent information notifications to the Commission contact point without undue delay c) My country has sent border rejection notifications to the Commission contact point without undue delay d) Whenever my country has had any additional information relating to the risk or product referred to in an original

- point whenever it has had any additional
- information relating to the risk or product referred to in an original notification
- Ensuring the efficient functioning of the RASFF within its jurisdiction
- Designating one contact point for the RASFF
- Immediately informing the Commission contact point of any changes in the RASFF contact point and of relevant contact details
- Ensuring an effective communication between the RASFF NCP and the Commission contact point
- Setting up up an effective communication network between the RASFF NCP and all relevant competent authorities in their country
- Defining the roles and responsibilities of the RASFF NCP and those of the relevant competent authorities in their country
- Ensuring the availability of an on-duty officer reachable on a 24hour/7-day-a-week basis

- Submitting notifications

- transmitted a follow-up notification to the Commission contact point
- e) My country has ensured the efficient functioning of the RASFF within its jurisdiction
- f) My country has designated one contact point for the RASFF
- g) My country has immediately informed the Commission contact point of any changes in the RASFF contact point for my country and of relevant contact details
- h) My country has ensured an effective communication between the RASFF NCP and the Commission contact point
- i) My country has set up an effective communication network between the RASFF NCP and all relevant competent authorities in my country
- j) My country has defined the roles and responsibilities of the RASFF NCP and those of the relevant competent authorities in my country
- k) My country has ensured the availability of an on-duty officer reachable on a 24hour/7-day-a-week basis
- I) Notifications have been submitted by my country using the templates provided by the

	using the templates provided by the			Commission contact point."	
	Commission contact point	Assessment of NCPs regarding the fulfillment of obligations under the RASFF by other MS	Survey of RASFF National Contact Points	Question 15: "In your view, do other MS fulfil their duties under the RASFF? Please explain."	
		Identification of cases in which MS did not fulfil their obligations in past serious food/feed safety incidents	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 10	
				Glass fragments in instant coffee (2010), question 10	
				Melamine in food crisis (2008), question 10	
To what extent are the MS actively participating in the RASFF?	To which extent MS actively participate in the RASFF by submitting original notifications to the RASFF and by providing follow-up to notifications submitted by other members	Numbers of notifications (including original and follow up notifications) submitted by MS in the RASFF	RASFF information flow	Data on notifications submitted by MS	
NASFF!		and by providing follow-up to notifications submitted by	Assessment of NCPs regarding the extent to which other MS actively submit original notifications to the RASFF	Survey of RASFF National Contact Points	Question 16a: "To what extent are you satisfied with a) how actively other MS submit original notifications to the RASFF."
		Assessment of NCPs regarding the rapidity of follow-up notifications provided by other MS	Survey of RASFF National Contact Points	Question 16b: "To what extent are you satisfied with b) The rapidity of follow-up notifications provided by other MS."	
		Assessment of NCPs regarding the quality of follow- up notifications provided by other MS	Survey of RASFF National Contact Points	Question 16c: "To what extent are you satisfied with c) The quality of follow-up notifications provided by other MS."	
		Scope for improvement	Survey of RASFF National Contact Points	Question 17a: "Do you have suggestions how a) the involvement of Member States	

value resulting from the EU Rapid Alert System for Food and Feed compared to what could be achieved by	Extent to which there is an added value resulting from the EU Rapid Alert System for Food and Feed compared to what could be achieved if there was no mechanism at the EU level	<ul> <li>Assessment by respondents of the added value of the RASFF</li> <li>Assessment of the added value of the RASFF during serious food/feed safety incidents</li> <li>Overall results of the evaluation regarding added value of the RASFF</li> </ul>	Interviews  Survey of RASFF National Contact Points and other stakeholders involved in the RASFF  Interviews  Interviews  All tools used in the RASFF evaluation	into the RASFF could be improved?"  EC, selected NCPs  Question 46: "Do you consider that the RASFF has an added value compared to what could be achieved without it? Please specify."  EC, selected NCPs  EC, selected NCPs
European provisions of Regulation (EC) 178/2002 (Articles 55 to 57) and of relevant secondary legislation (e.g. Commission Decision 2004/478/EC) correspond to the current needs for food/feed crisis coordination?	ment  The general plan for food/feed crisis management provides for two layers of actions: (1) one layer of action related to potential serious risk (Sections 2.2 and 6 of Commission Decision 2004/478/EC), where a crisis unit is not set up but adequate provisions are made to ensure effective management (2) another	<ul> <li>Assessment of responsible EC staff that the two layers of action are relevant and correspond to the current needs for food/feed crisis management</li> <li>Assessment of MS and stakeholders regarding crisis coordination during past serious food/feed safety incidents (see below)</li> </ul>	Interviews  Case studies	EC  Outbreak of Shiga toxin- producing Escherichia coli (2011), question 20a  Glass fragments in instant coffee (2010), question 20a  Melamine in food crisis (2008),

setting up of a crisis unit.  Related judgment criteria include:  - The two layers of action are relevant and still appropriate for food/feed crisis management  - The first layer of action (mechanisms foreseen in Sections 2.2 and 6 of Commission Decision 2004/478/EC, where a crisis unit is not set up but adequate provisions are made to ensure effective management) has been sufficient for the management of past serious food/feed safety incidents	% of respondents assess the two layers of action to be relevant and still appropriate for food/feed crisis management	Survey of competent authorities in the field of food/feed crisis management and stakeholders	Question 30: "The general plan for food/feed crisis management provides for two layers of actions: (1) one layer of action related to potential serious risk (see Sections 2.2 and 6 of Commission Decision 2004/478/EC), where a crisis unit is not set up but adequate provisions are made to ensure effective management (2) another layer of action implying the setting up of a crisis unit  a) In your view, are these two layers of action relevant?  b) Are these two layers still appropriate for food/feed crisis management?"
[as the second layer of action has not yet been used]	The first layer of action has been sufficient for the management of past serious food/feed safety incidents	Survey of competent authorities in the field of food/feed crisis management and stakeholders	Question 31: "In your view, have the mechanisms foreseen in Section 2.2 and 6 of Commission Decision 2004/478/EC (where a crisis unit is not set up but adequate provision are made to ensure effective management) been sufficient for the management of past serious food/feed safety incidents? If no, please specify.
		Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 20b
			Glass fragments in instant coffee (2010), question 20b

				Melamine in food crisis (2008), question 20b
food are i addr plan	d/feed crisis coordination identified that are not ressed by the general for food/feed crisis	Existence of other needs for food/feed crisis coordination which are not addressed by the general plan for food/feed crisis management	Survey of competent authorities in the field of food/feed crisis management and stakeholders	Question 32: "Please assess the need for the following possible future measures related to crisis management at EU level
man	nagement			a) A step-wise approach for escalating measures of crisis management and for related criteria for escalation
				b) A mechanism that would be easier to activate than the general plan (as detailed in Decision 2004/478)
				c) A greater role of the EC in the coordination of Member States' efforts
				d) Regular crisis simulation exercises at EU level
				e) A greater role of EFSA in the assessment of the risk
				f) A greater role of the EC in the coordination of the communication of serious food/feed safety incidents to the public/relevant competent authorities
				g) An IT tool at EU level to facilitate communication between Member States/EC (such as an Intranet-based system for sharing relevant documents and coordinate common strategies and messages to the public)
				h) An improved coordination

				with international organisations in the event of serious food/feed safety incidents affecting the EU and other regions of the world i) A greater role of the EC in the coordination with third countries j) More EC support to Member States to manage serious food/feed safety incidents k) Other needs. Please specify [TF]"
To what extent is the EC fulfilling its obligations deriving from the	Level of EC compliance with obligations under Regulation regarding the general plan	Review of fulfillment of EC obligations under the Regulation in Articles 55 to 57	Document review	Literature [2] (incl. Regulation (EC) No 178/2002, Commission Decision 2004/478/EC)
Regulation (in particular as far as the "general plan" is concerned)?	(Articles 55 to 57 of the Regulation)		Interviews	EC, selected competent authorities in the field of food/feed crisis management
To what extent has the EC played the role of coordinator in a potential	The EC played the role of coordinator in past serious food/feed safety incidents well regarding: - General coordination of national efforts (MS level) - Coordination with EFSA - Coordination of communication of serious food/feed safety incidents to the public/relevant competent authorities	% of MS and stakeholders that are satisfied with the EC's role in past serious food/feed safety incidents regarding general coordination of national efforts	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 12: "Overall, to what extent has the EC played the role of coordinator in past serious food/feed safety incidents that affected your country?"
crisis?		% of MS and stakeholders that are satisfied with the EC's role in past serious food/feed safety incidents regarding coordination with EFSA		
		% of MS and stakeholders that are satisfied with the EC's role in past serious food/feed safety incidents regarding coordination of communication to the public/relevant competent authorities		
	<ul><li>Coordination with international organisations</li><li>Coordination with third countries</li></ul>	% of MS and stakeholders that are satisfied with the EC's role in past serious food/feed safety incidents regarding coordination with international organisations		
		% of MS and stakeholders that are satisfied with the		

			EC's role in past serious food/feed safety incidents regarding coordination with third countries		
			Identification of cases in which EC played the role of coordinator in past serious food/feed safety incidents [not] well	Document review	Literature [2]
				Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 13: "More specifically, to what extent has the EC played the role of coordinator during the following examples of serious food/feed safety incidents that affected your country (you can add additional examples yourself, if you consider them relevant)?  a) E.coli outbreak, 2011 (RASFF 2011.0842) b) Glass fragments in instant coffee, 2010 (RASFF 2010.0626) c) Melamine crisis, 2008 (RASFF News 08-459 and others)"
				Interviews	EC, selected competent authorities in the field of food/feed crisis management and other stakeholders
				Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 21
					Glass fragments in instant coffee (2010), question 21
					Melamine in food crisis (2008), question 21
To	o what extent has the	The experiences gained from	EC and MS have identified lessons learned from	Document review	Literature [2,3,4,5]

	experience gained from previous potential crisis such as the E. coli outbreak in 2011 and crisis exercises improved the crisis preparedness and the current crisis management arrangements?	past serious food/feed safety incidents have improved current crisis management arrangements (at national and EU levels)	past serious food/feed safety incidents	Interviews	EC, selected competent authorities in the field of food/feed crisis management
			Improvements introduced at MS and EU level based on experiences gained from past serious food/feed safety incidents	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 28
					Glass fragments in instant coffee (2010), question 28
					Melamine in food crisis (2008), question 28
				Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 5a: "Have you carried out systematic review(s) of your crisis preparedness/management arrangements in the field of food/feed on the basis of a) Lessons learned from past serious food/feed safety incidents? If Yes, please specify whether the review led to improvements. If improvements were made, please specify which."
		The experiences from crisis simulation exercises (at EU level and national level) have improved current crisis management arrangements	Assessment of MS and stakeholders regarding improvement of current crisis management arrangements (at national and EU levels) as consequence of experiences from crisis simulation exercises (at EU level and national level	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 5b: "Have you carried out systematic review(s) of your crisis preparedness/management arrangements in the field of food/feed on the basis of b) Crisis simulation exercises. If Yes, please specify whether the review led to improvements. If improvements were made, please specify which."

				Question 14 b,c: "To what extent have the following experiences improved current crisis management arrangements? If not, please explain. b) Experience gained from the EU-level Aristaeus exercise (May 2013) c) Experience gained from other crisis simulation exercises in which your country participated. Please specify exercise: [TF]
To what extent has the EC contributed to the coordination of the	Extent to which the EC contributed to the coordination of the national	to the coordination of the national efforts (e.g. in outbreak investigations) during past serious	Document review	Literature [2,3,4,5]
national efforts e.g. in outbreak investigations and to the development of best practices e.g. for the	efforts (e.g. in outbreak investigations)		Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 21
design of contingency plans?				Glass fragments in instant coffee (2010), question 21
				Melamine in food crisis (2008), question 21
		Assessment of MS and stakeholders regarding EC contribution to the coordination of the national efforts (e.g. in outbreak investigations)	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 15: "To what extent has the EC contributed to the coordination of national efforts (e.g. in outbreak investigations)?
				<ul> <li>a) Providing infrastructure for coordination (e.g. audioconferences, meeting facilities)</li> </ul>
				b) Providing training
				c) Sharing technical

		Extent to which the EC contributed to the development of best practices for the management of serious food/feed safety incidents (e.g. for the design of contingency plans), considering the following activities:  - Training activities organised by the EC  - Working groups organised by the EC  - FVO missions/reports  - Other	<ul> <li>Identification of training activities/working groups/FVO missions organised by EC for the development of best practices</li> </ul>	Interviews	information d) Providing guidance documents/SOPs e) Other, please specify" EC (incl. FVO)
			Assessment of MS and stakeholders regarding contribution of the EC to the development of best practices	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Literature [2]  Question 16: "To what extent has the EC contributed to the development of best practices for the management of serious food/feed safety incidents (e.g. for the design of contingency plans)? Please consider the following activities:  a) Training activities organised by the EC  b) Working groups organised by the EC  c) FVO missions / reports d) Other. Please specify."
Emergency procedures	To what extent have the emergency procedures been instrumental for the management of emergencies?	Have emergency measures ('safeguard measures', as defined in Articles 53 and 54 of Regulation 178/2002) been used in the management of past serious food/feed safety incidents?	Identification of instances in which emergency measures were used during past serious food/feed safety incidents	Document review  Case studies	Literature [2,3,4,5]  Outbreak of Shiga toxin-producing Escherichia coli (2011), question 19  Glass fragments in instant coffee (2010), question 19  Melamine in food crisis (2008), question 19
		Extent to which emergency	% of MS and stakeholders that consider emergency	Survey of competent	Question 28: "To what extent

		measures have been effective for the management of past serious food/feed safety incidents	food/feed safety incidents as effective past serious  Identification of cases in which emergency	authorities in the field of food/feed crisis management and other stakeholders	have emergency measures ('safeguard measures'; as defined in Articles 53 and 54 of Regulation 178/2002) been effective for the management of past serious food/feed safety incidents? If not, please explain."
				Interviews	EC, selected competent authorities
	To what extent have the mechanisms provided by Articles 53 and 54 contributed to avoid disparities and ensure a comprehensive and consistent approach to the treatment of a serious risk in relation to food or feed?  To what extent the legal instrument used for the emergency measures (decisions/Regulation) have impacted on the efficiency of the measures?	Extent to which the mechanism of emergency measures provided by Articles 53 and 54 of Regulation 178/2002 contributed to avoiding disparities between measures taken by different Member States and to ensuring a consistent approach during past serious food/feed safety incidents	<ul> <li>% of MS and stakeholders that consider emergency measures for the management of past serious food/feed safety incidents to have contributed to avoiding disparities between measures taken by different Member States</li> <li>Identification of cases in which disparities between measures taken by different MS occurred</li> </ul>	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 29: "To what extent has the mechanism of emergency measures provided by Articles 53 and 54 of Regulation 178/2002 contributed to avoiding disparities between measures taken by different Member States and to ensuring a consistent approach during past serious food/feed safety incidents? If not, please explain"
Efficiency	To what extent can the objectives of crisis management be achieved at a lower cost (particularly in relation to SMEs) with synergies of the available resources?	Extent to which the objectives of crisis management at EU level have been achieved at an appropriate cost	% of MS and stakeholders that consider the benefits of crisis management at EU level have been achieved at an appropriate cost	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 24: "To which extent have the benefits of crisis management at EU level been achieved at an appropriate cost (considering EU expenditures for staff time, communication measures, support measures, etc.)?"
			% of MS and stakeholders that consider the balance of cost and benefits of crisis management at EU	Survey of competent authorities in the field of food/feed crisis	Question 25: "Do you have suggestions how the balance of costs and benefits of crisis

		level could be improved	management and other stakeholders	management at EU level could be improved? If Yes, please specify how."	
			Assessment of the degree to which objectives of crisis management at EU level can be achieved at a lower cost	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 25
					Glass fragments in instant coffee (2010), question 25
					Melamine in food crisis (2008), question 25
				Interviews	EC, relevant competent authorities
		Do potential synergies in the use of the available resources exist?	Identification of potential synergies	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 25
					Glass fragments in instant coffee (2010), question 25
					Melamine in food crisis (2008), question 25
	To what extent certain tasks of crisis management e.g. the dissemination of risk related information or communication issues, should be handled through alternative existing mechanism?	Are there certain elements of EU crisis management which should be better communicated through other information systems (or mechanisms) than RASFF?	Identification of elements of EU crisis management which should be better communicated through other information systems (or mechanisms) than RASFF	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 26: "Are there certain elements of EU crisis management which should be better communicated through other information systems (or mechanisms) than RASFF? If Yes, please specify the tasks and the system (or mechanisms).
Effective- ness	To what extent has the crisis management achieved such objectives in previous potential crisis? Where expectations have	To what extent have the existing crisis management arrangements achieved the following in past serious	% of MS and stakeholders that consider existing crises management arrangements have achieved:  - Coordinated implementation of most effective	Survey of competent authorities in the field of food/feed crisis management and other	Question 7: "To what extent have the existing crisis management arrangements achieved the following in past serious food/feed safety

not been met, what w the factors that hinder their achievement?	nat hindered  ment? - Coordinated  implementation of most  effective measures to	measures to contain the risk  - Efficient management of serious food/feed incidents  - Consumers trust in food/feed safety	stakeholders	incidents? If not, please explain: a) Coordinated implementation of most effective measures to contain
	contain the risk  - Efficient management of serious food/feed incidents  - Consumers trust in	- Consumer health protection - Limited disruption of internal market and trade		the risk b) Efficient management of serious food/feed incidents c) Consumers trust in food/feed safety
	- Consumer health protection			d) Consumer health protection e) Limited disruption of internal market and trade."
	<ul> <li>Limited disruption of internal market and trade</li> </ul>	During past serious food/feed safety incidents, extent to which crisis management arrangements achieved:	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 18
		<ul> <li>Coordinated implementation of most effective measures to contain the risk</li> <li>Efficient management of serious food/feed incidents</li> </ul>		Glass fragments in instant coffee (2010), question 18
		- Consumers trust in food/feed safety  - Consumer health protection  - Limited disruption of internal market and trade		Melamine in food crisis (2008), question 18
			Interviews	EC, selected competent authorities in the field of food/feed crisis management
			Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 8: "Please assess the effectiveness of crisis management arrangements during the following examples of serious food/feed safety incidents that affected your country (you can add additional examples yourself, if you consider them relevant). If 'not effective', please explain.  a) E.coli outbreak, 2011 (RASFF

					2011.0842) b) Glass fragments in instant coffee, 2010 (RASFF 2010.0626) c) Melamine crisis, 2008 (RASFF News 08-459 and others)"
		Were there factors that hindered achievement? If yes, which?	Identification of factors, if any, which have hindered achievements	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 7: "To what extent have the existing crisis management arrangements achieved the following intended outcomes in past serious food/feed safety incidents? If not, please explain."
	Identify tangible and measurable criteria to evaluate effectiveness of existing crisis management arrangements in the EU	Are there other criteria in use to evaluate the effectiveness of existing crisis management arrangements? If yes, what are these criteria?	Other criteria in use to evaluate the effectiveness of existing crisis management arrangements	Survey of competent authorities in the field of food/feed crisis management	Question 9: "Do you use criteria to evaluate the effectiveness of existing crisis management arrangements in your country (e.g. the duration between outbreak detection and containment)? If Yes, please specify criteria in use and link to relevant document, if possible."
Participa- tion of Third Countries/ Interna-	To what extent are the European crisis management mechanisms	ropean crisis  anagement mechanisms  ien to third countries' d international ganisations' rrticipation?  European crisis management mechanisms are open to third countries'/international organisations' participation	Identification of cases in which TCs and international organisations participated in crisis management mechanisms	Interviews	EC, selected competent authorities in the field of food/feed crisis management
tional and international organisation	and international organisations' participation?			Document review	Literature [2]
			Assessment of third countries/international organisations regarding extent to which European crisis management mechanisms are open to them	Survey of selected third countries/international organisations	Question 20: "To what extent are the European crisis management arrangements

					open to your participation as a third country/international organisation?"
		Have there been obstacles for third countries/international organisations preventing them to provide more information to the EC during past serious food/feed safety incidents (such as language requirements, level of detail requested, confidentiality provisions, legal basis etc.)?	Identification of obstacles for third countries/international organisations preventing them to provide more information to the EC	Survey of selected third countries/international organisations	Question 21: "Have there been any obstacles for your organisation preventing you to provide more information to the EC during past serious food/feed safety incidents (such as language requirements, level of detail requested, confidentiality provisions, legal basis etc.). If Yes, please specify obstacles"
				Document review	Literature [2]
	How well is the information flow between to other relevant partners, competent authorities and International	on flow between information flow between the EU and third countries/international organisations (WHO, FAO, satisfactory in past serious	Assessment of information flow between the EU and third countries/international organisations in past serious food/feed safety incidents	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 24
	Organisations (WHO, FAO, INFOSAN, UNIDO)?				Glass fragments in instant coffee (2010), question 24
					Melamine in food crisis (2008), question 24
			Scope for improvement	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 23: "Do you have suggestions how the information flow between the EU and third countries/international organisations could be improved for the management of serious food/feed safety incidents?
Involve- ment of the	To what extent have the MS adapted to meet the	Availability of different types of contingency plans in the	ldentification of types of contingency plans	Survey of competent authorities in the field of	Question 2: "Please indicate the type of contingency plan

EU Member States		food/feed crisis management	(as defined in Article 13 of Regulation (EC) No 882/2004 available in the field of food/feed in your country, if any  a) A specific national contingency plan for food/feed b) A general national contingency plan which also covers food/feed incidents c) No national contingency plan, but a set of procedures to be used in case of emergencies in the field of food/feed"		
				Interviews	EC, selected competent authorities
				Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 16
					Glass fragments in instant coffee (2010), question 16
					Melamine in food crisis (2008), question 16
	To what extent do the MS fulfil their obligations?	Extent to which the national contingency plan/procedures include the following items for serious food/feed safety incidents: - Administrative authorities to be engaged - Their powers and responsibilities - Formal coordination mechanisms between authorities at national,	Identification of elements of contingency plans available in the field of food/feed in MS	Survey of competent authorities in the field of food/feed crisis management	Question 3: "If in your country one of the above listed types of contingency plan/procedures is available, please indicate whether the following items are specified for serious food/feed safety incidents:  a) Administrative authorities to be engaged b) Their powers and

	regional, and local levels - Channels and procedures for sharing information between relevant parties - Linkages to public health contingency planning			responsibilities c) Formal coordination mechanisms between authorities at national, regional, and local levels d) Channels and procedures for sharing information between relevant parties e) Linkages to public health contingency planning."
To what extent have the MS developed their legislation/plans/guides /infrastructure to meet the requirements of the Regulation?	Extent to which other elements of crisis management are available in MS, including: - Regular meetings of competent authorities in the fields of food/feed safety and public health to exchange information on relevant incidents/risks - Systematic exchange of information with food/feed business operators - A communication strategy for serious food/feed safety incidents - Designated crisis coordinator and alternate - Infrastructure for the management of serious food/feed safety incidents (e.g. audio conference tools, IT tools, call centre etc.)	Identification of other elements of crisis management available in MS	Survey of competent authorities in the field of food/feed crisis management	Question 4: "Besides the elements listed in question 3, please indicate which of the following other elements of crisis management are available in your country:  a) Regular meetings of competent authorities in the fields of food/feed safety and public health to exchange information on relevant incidents/risks b) Systematic exchange of information with food/feed business operators c) A communication strategy for serious food/feed safety incidents d) Designated crisis coordinator and alternate e) National crisis management committee or unit f) Infrastructure for the management of serious food/feed safety incidents (e.g. audio conference tools, IT

				tools, call centre etc.). g) Other. Please specify."
actively managing crisis or	How actively have MS managed past serious food/feed safety incidents?	Satisfaction of MS and other stakeholders with how actively other MS have managed serious food/feed safety incidents that affected their country	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 18: "To what extent are you <u>satisfied with how actively other MS have managed serious food/feed safety incidents that have affected your country?"</u>
		manage past serious food/feed safety incidents	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 18: "If not satisfied, please provide examples."
			Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 22
				Glass fragments in instant coffee (2010), question 22
				Melamine in food crisis (2008), question 22
			Interviews	EC, selected competent authorities in the field of food/feed crisis management
		Scope for improvement	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 19: "Do you have suggestions how Member States could improve their crisis management?"
At which point is there an additional value resulting from the EU coordinating crisis management done by different competent authorities or establishing	Extent to which there is an added value resulting from the EC coordinating MS crisis management concerning a serious food/feed safety incident compared to what	Assessment by MS and stakeholders of the added value of the EU coordinating crisis management	Survey of competent authorities in the field of food/feed crisis management and other stakeholders	Question 33: "Do you consider that there is an <u>added value</u> resulting from the EC coordinating crisis management of the Member States concerning a serious

	3	n in the general was no coordination at EU level			food/feed safety incident compared to what could be achieved if there was no coordination at EU level?"
			Identification of instances during past serious food/feed safety incidents in which EU coordination provided added value	Case studies	Outbreak of Shiga toxin- producing Escherichia coli (2011), question 27
					Glass fragments in instant coffee (2010), question 27
					Melamine in food crisis (2008), question 27
				Interviews	EC, selected competent authorities in the field of food/feed crisis management

Source : Civic Consulting.

# **Annex 13 : Terms of Reference**

# Task specifications

### 1. Title of the assignment

The evaluation of the Rapid Alert System for Food and Feed and of crisis management procedures.

Responsible service: DG SANCO unit G4

Evaluation Manager: Enrique BELTRAN POVEDA / Klaus KOSTENZER

### 2. Context of the assignment

2.1. Description of the Policy Area to be evaluated:

The Rapid Alert System for Food and Feed (RASFF) provides a system for the swift exchange of information between member countries in cases of direct or indirect risks to human health deriving from food and feed, so as to enable as much as possible a coordinated response to food safety threats. RASFF enables information to be shared rapidly between food and feed control authorities in Member States and the European Commission where a health risk has been identified. Countries can then act rapidly and in a coordinated manner in order to avert food safety risks before they can harm consumers. It is therefore an important tool for protecting consumer health. The RASFF is managed by the Commission and members of the network include the Member States, the EEA countries and EFSA.

Regulation (EC) N° 178/2002, setting up the rapid alert system for food and feed, also provides for the procedures for crisis management and measures in emergency situations ensuring that all foods, whatever their type and origin, and all feed should be subject to common measures in the event of a serious risk to human health, animal health or the environment.

Regulation (EC) N° 178/2002 also appointed the European Commission as manager of the RASFF network. The Commission receives a RASFF notification through the National Contact Point (NCP) and ensures that it is immediately relayed to all members of the network. Therefore, the Commission, responsible for managing the system, is providing knowledge and a technological platform to facilitate transmission and handling of the RASFF notifications. It receives all notifications from members of the network and performs the following checks on them, prior to making them available to all members of the network:

- a completeness check
- legislative requirements
- > verification if the subject of the notification falls within the scope of the RASFF
- > classification of the notification
- > members of the network flagged for action
- recurrences of similar problems relating to the same professional operator and/or hazard/country of origin.

In this way, the RASFF supports the Member States' actions by allowing the rapid exchange of information on risks posed by food or feed and on measures taken or to be taken to counter such risks.

The Commission must inform a non-member of RASFF (third countries) if a product subject to a notification has been exported to that country or when a product originating from that country has been the subject of a notification. In this way, the country can take corrective measures where needed and appropriate. As mentioned in Article 10 of Regulation (EC) 16/2011, "the Commission contact point shall establish contact with a designated single contact point in the third country, if any, with a view to reinforce communication, including through the use of information technology". With the arrival of RASFF Window, the Commission established a network of contact points in the authorities and embassies of most of these third countries.

Information from RASFF notifications (on occurrences, trends, emerging issues, etc.) is also used as an input to inform risk management decisions such as safeguard measures and reinforced border checks (e.g. according to Directive 97/78/EC, Art. 24 and Regulation (EC) No 669/2009) and in some cases policy developments.

In a more general matter the procedures in place to manage a food or feed crisis that pose a serious (or potentially serious) risk to human health shall be evaluated. Regulation (EC) No 178/2002 envisages complementary tools for risk management in the field of food and feed. In particular, Article 55 provides for the drawing up of a "general plan" for food/feed crisis management which specifies the crisis situations and the practical procedures necessary for managing a crisis, including the principles of transparency to be applied and a communication strategy. Pursuant to Article 55, the Commission adopted the general plan (Commission Decision 2004/478/EC), and drafted SOPs to complement the provisions of said Decision by establishing modalities and internal working arrangements in order to respond to food/feed crisis situations of such complexity that they are not likely to be prevented, eliminated or reduced to an acceptable level by existing provisions or adequately managed solely by way of application of Articles 53 and 54 of Regulation (EC) No 178/2002 (safeguard measures).

Furthermore, for the implementation of the "general plan" and in accordance with Articles 4 and 13 of Regulation (EC) No 882/2004, the Member States shall put in place operational contingency plans with measures to be implemented without delay when feed and food is found to pose a serious risk to humans or animals either directly or through the environment.

These crisis management procedures (both at EU and national level) should be reviewed as appropriate, in the light of first-hand experiences and lessons learned, including experience gained from simulation exercises.

## 2.2. Specific and operational objectives of the activity/action.

The main objective of the RASFF is to ensure that information available to the competent authorities in a Member State indicating that food or feed is likely to constitute a risk is swiftly shared with all members of the network, so as to enable measures to contain such risk to be taken as rapidly and as effectively as needed. The system thus enables adequate prevention and management of emergencies in order to prevent that they develop into crises.

Food safety incidents have demonstrated the need to establish appropriate measures in emergency situations ensuring that all foods, whatever their type and origin, and all feed should be subject to common measures in the event of a serious risk to human health, animal health or the environment. The prevention and better management of crisis involved the creation of new tools, in particular the obligation of traceability, the requirement that food/feed business operators withdraw/recall food/feed at risk and notify public authorities, an improved and broader RASFF allowing for adequate transmission of information regarding potential risks for health, and the establishment of procedures for emergencies/crises.

The RASFF is set up as a network involving the MS, the Commission and EFSA. The members of the network shall immediately notify the Commission when a serious risk for human health deriving from food or feed is identified, and of any measure, recommendation or rejection related to it. The Commission shall immediately transmit the information to the network, and also any supplementary information received.

Surveillance, monitoring and investigation of food-borne pathogens and contaminants are a crucial point to coordinate the Member States in their obligation to investigate foodborne outbreaks in line with Article 8 of Directive 2003/99/EC. Procedures should be put in place at national and EU level to cover the different phases of a food/feed crisis (alerting /evaluation / management phase) as well as a set of "tools" intended to facilitate the handling of the crisis such as general model questionnaires, risk assessment models and templates, guides with who is doing what and how etc. Furthermore, a comprehensive coordination of all internal and external communication should be in place (communication strategy). This includes the channels of communication within the Commission and its agencies, but also the communication with the different stakeholders of the involved sectors (feed, food safety, public health), with other public institutions, and with the Member States and their agencies. Furthermore, a description of the operational modalities and linkages between the different existing crisis/alert systems at EU level should be in place (for example RASFF, EWRS, EPIS, ARGUS, etc.).A comprehensive approach to emergency food safety measures should allow effective risk management actions to be taken and avoid artificial disparities in the treatment of a serious risk in relation to food or feed. Food crises have also shown the benefits to the Commission of having properly adapted, more rapid procedures for crisis management. These organisational procedures should make it possible to improve coordination of effort and to determine the most effective measures on the basis of the best scientific information.

### 2.3. Legal basis, budget and duration of the activity/action

- Articles 50 to 57 of Regulation (EC) No 178/2002;
- Article 4 and 13 of Regulation (EC) No 882/2004,
- Commission Regulation (EU) No 16/2011,
- Commission Decision 2004/478/EC.

## 2.4. Instruments of the activity/action

The RASFF was established to provide the control authorities with an effective tool for exchange of information on direct or indirect risks to human health resulting from food or feed and which might require rapid action in other Member States. The legal basis of the RASFF is Regulation (EC)  $N^{\circ}$ 

178/2002. Article 50 of this Regulation establishes the rapid alert system as a network involving the Member States (EU + EFTA/EEA), the Commission and the European Food Safety Authority (EFSA).

Whenever a member of the network has any information relating to the existence of a serious direct or indirect risk to human health, this information is immediately notified to the Commission under the RASFF. The Commission immediately transmits this information to the members of the network.

Article 50.3 of the Regulation requires Member States to notify the network of certain measures taken in specific situations, without prejudice to other Community legislation:

- 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;
- 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.

When a crisis arises on the national or EU level, effective crisis management is crucial and therefore emergency preparedness is to be regularly reviewed. This will depend on various crisis situations e.g. major outbreaks of foodborne pathogens and the practical procedures necessary for managing a crisis, including the principles of transparency to be applied and a communication strategy.

### 3. Description of the assignment

### 3.1. Purpose and objective of the evaluation

To assess whether the regulatory framework established by Articles 50 to 57 of Regulation (EC) No 178/2002, hereafter referred to as "the Regulation" (as complemented by Regulation (EC) No 16/2011), is effective and efficiently working and providing added value to its stakeholders. This entails

- examining whether the mentioned articles have been implemented in full and are achieving
  objectives, in an effective and complete way, and if not, what factors have hindered their
  achievement;
- checking whether the regulatory framework meets policy goals at minimum cost, achieving the benefits that only EU legislation can bring, as well as the relevance in delivering EU-added value, the coherence with EU wider policy priorities and the focus on simplification and the reduction of regulatory costs and burdens;
- assessing the relationship between the RASFF and other mechanisms (whether computerised or not) through which Member States are required to exchange information in relation to the results of official controls performed along the food chain; particular attention should be paid in this context to the obligations resulting from the provisions of Title IV of Regulation (EC) No 882/2004 (administrative assistance and cooperation), to the provisions of the Commission proposal which aims at modifying that Regulation (COM(2013 265 final) and to ongoing

initiatives aimed at establishing an IT system for the administrative assistance and cooperation exchanges in the EU;

- considering, in line with the orientation adopted by the Commission in the legislative proposal referred to above, how RASFF should operate in an efficient and harmonised way with various functionalities of the IMSOC system referred to in Article 130 of the Commission proposal.
- considering how to ensure that the RASFF main function (i.e. the handling of risk related information and data) is delivered in a manner that allows it to focus on the efficient prioritisation of remedial actions on the basis of risk.
- assessing the roles and responsibilities of each competent authority/institution (both at EU and national level) in an emergency or a crisis situation taking into account the current regulatory framework, the "general plan", the SOPs, the contingency plans and their actual performance in real situations or crisis exercises;
- describing the mechanisms of crisis management with a view on the appropriate coordination between the relevant partners.
- assessing the operational modalities and linkages between the different existing crisis/alert systems at EU level (for example RASFF, EWRS, EPIS, ARGUS, etc.).
- NOTE: an evaluation of the General Food Law Regulation is ongoing in parallel to this evaluation and the contractor might be requested to coordinate works with the team working on the General Food Law Regulation evaluation.

## 3.2. Evaluation issues to be addressed

- The role of the European Commission in a food/feed crisis and as manager of the EU rapid alert system, the efficiency of maintaining the system and the capacity to keep the members interacting should be considered in the evaluation.
- It is important to evaluate the participation of third countries, international organisations and other stakeholders in RASFF,
- Effectiveness: to what extent were the objectives set out in the regulation achieved?
- Efficiency: were the outputs and effects achieved at a reasonable cost? Or to what extent were the time and efforts taken well used to disseminate information related to health risks with a view to enable a coordinated approach to the containments of such risks?
- EU-added value: what is the additional value resulting from the EU rapid alert system and from an EU crisis management compared to what could be achieved by Member States at national and/or regional levels?
- Complementarity: how well the RASFF system and the different existing crisis/alert systems at EU level for the crisis management work with other systems (administrative assistance exchanges, TRACES, national systems, international systems, etc.), and in particular identify potential overlap, if it exists, with other EU mechanisms?

### 3.3. Scope of the evaluation (operational, temporal, geographical...)

As Regulation (EU) N° 178/2002 was adopted in 2002, the scope will be 2002-2013, and covering the 28 EU MS, Switzerland and also the EEA countries: Norway, Liechtenstein and Iceland.

#### 3.4. Evaluation questions

- Rapid Alert System for Food and Feed:
  - 1. Role of the European Commission:
    - a. To what extent is the EC fulfilling its obligations deriving from the Regulation?
    - b. To what extent has the EC played the role of manager and, at the same time, participant of the network?
    - c. To what extent has the adoption of the Regulation improved the functioning and monitoring of the RASFF?
    - d. To what extent has the EC contributed to the coordination of the members of the RASFF and to the development of good and common notification practices?
    - e. To what extent have the regular Working Groups organised by the EC contributed to the better functioning of the RASFF?
    - f. To what extent are the guidelines issued by the EC on the functioning of the network clear and helpful?

### 2. Efficiency:

- a. Identify tangible and measurable criteria to evaluate efficiency notably in relation to its core task.
- b. To what extent is the RASFF efficient?
- c. To what extent can the objectives be achieved at a lower cost with a better management of the available resources?
- d. To what extent certain tasks notably those which are not related to the dissemination of risk related information for the purposes of risk containment which are currently handled by the RASFF should be better handled through other existing mechanism (computerised or not)?

#### 3. Effectiveness:

- a. Identify tangible and measurable criteria to evaluate effectiveness.
- b. To what extent has the RASFF achieved its objectives?
- c. To what extent have the initial objectives remained valid?
- d. To what extent has the RASFF adapted to the changes in the regulatory framework, emerging risk, changes in market and consumer behaviour etc.?

### 4. Participation of Third Countries/ International Organisations:

- a. To what extent is the RASFF open to third countries' and international organisations' participation?
- b. How can the system be more widely used between the international communities of countries?
- c. To what extent is the reciprocity of information flow between RASFF and the International Organisations (WHO, FAO, INFOSAN, UNIDO ...) appropriate?
- d. How well does the RASFF work together with other systems (at Member State, EU and international levels)?
- e. What are the geographic weak points in the food safety map, due to lack of food alert systems or their weak functioning? What could be the role of RASFF there?

## 5. Information flow to stakeholders and professional operators:

- a. To what extent does the RASFF inform involved professional operators?
- b. To what extent can stakeholders consult the information managed by the RASFF?

#### 6. Transparency and confidentiality:

- a. To what extent is the RASFF transparent and accessible to the general public?
- b. To what extent is the classification used pertinent and clear?
- c. To what extent is the RASFF respecting the confidentiality requirements as set in the Regulation?

### 7. Risk-based:

a. To what extent are the operations of the RASFF really risk based?

b. To what extent is risk accurately evaluated in the RASFF?

#### 8. Role of EFSA:

- a. What is the role of EFSA within the RASFF?
- b. Is EFSA fulfilling its role in RASFF as laid down in the Regulation?

## 9. Scope:

- a. To what extent is the scope of the RASFF appropriate?
- b. Is the scope of the RASFF sufficiently defined?
- 10. Involvement of the EU Member States (MS):
  - a. To what extent have the MS adapted to meet the requirements of the Regulation?
  - b. To what extent do the MS fulfil their obligations under the RASFF?
  - c. To what extent are the MS actively participating in the RASFF?
  - d. To what extent have the MS developed their legislation to meet the requirements of the Regulation?
  - e. What is the additional value resulting from the EU Rapid Alert System for Food and Feed compared to what could be achieved by Member States at national and/or regional levels if there would not be a RASFF?
- Crisis and potential crisis Management:
  - Role of the European Commission:
    - a. To what extent the provisions of Regulation (EC) No 178/2002 (Articles 55 to 57) and of relevant secondary legislation (e.g. Commission Decision 2004/478/EC) correspond to the current needs for food/feed crisis coordination?
    - b. To what extent is the EC fulfilling its obligations deriving from the Regulation (in particular as far as the "general plan" is concerned)?
    - c. To what extent has the EC played the role of coordinator in a potential crisis?
    - d. To what extent has the experience gained from previous potential crisis such as the *E. coli* outbreak in 2011 and crisis exercises improved the crisis preparedness and the current crisis management arrangements?

e. To what extent has the EC contributed to the coordination of the national efforts e.g. in outbreak investigations and to the development of best practices e.g. for the design of contingency plans?

## • Emergency procedures

a. To what extent have the emergency procedures been instrumental for the management of emergencies? To what extent have the mechanisms provided by Articles 53 and 54 contributed to avoid disparities and ensure a comprehensive and consistent approach to the treatment of a serious risk in relation to food or feed? To what extent the legal instrument used for the emergency measures (decisions/Regulation) have impacted on the efficiency of the measures?

## • Efficiency:

- a. To what extent can the objectives of crisis management be achieved at a lower cost (particularly in relation to SMEs) with synergies of the available resources?
- b. To what extent certain tasks of crisis management e.g. the dissemination of risk related information or communication issues, should be handled through alternative existing mechanism (RASFF or other systems, audio-conferences, etc.)?

#### • Effectiveness:

- a. Identify tangible and measurable criteria to evaluate effectiveness of existing crisis management arrangements in the EU.
- b. To what extent has the crisis management achieved such objectives in previous potential crisis? Where expectations have not been met, what were the factors that hindered their achievement?

## • Participation of Third Countries/ International Organisations :

- a. To what extent are the European crisis management mechanisms open to third countries' and international organisations' participation?
- b. How well is the information flow between to other relevant partners, competent authorities and International Organisations (WHO, FAO, INFOSAN, UNIDO ...)?

#### • Involvement of the EU Member States (MS):

- a. To what extent have the MS adapted to meet the requirements of the Regulation?
- b. To what extent do the MS fulfil their obligations?

- c. To what extent are the MS actively managing crisis or dealing with incidents such as foodborne outbreaks?
- d. To what extent have the MS developed their legislation/plans/guides/infrastructure to meet the requirements of the Regulation?
- e. At which point is there an additional value resulting from the EU coordinating crisis management done by different competent authorities or establishing a crisis management as foreseen in the general plan itself rather than national actions?

## 3.5. Methodology

The methodology of this evaluation must be drawn up by the tenderer taking into account the objectives and scopes outlined above as well a good mix of different evaluation tools including the following case studies:

#### Case studies:

The RASFF system has helped respond to, and mitigate, several serious foodborne outbreaks in recent years such as dioxin and E. coli crises. In 2010 and 2011 RASFF played a role in managing two major food safety incidences: glass fragments in instant coffee and E. coli in sprouts. They should be examined in detail.

- o The E. coli crisis was one of the most serious foodborne outbreaks in EU history with more than 50 casualties, mainly in Germany. On 21 May 2011, Germany reported an ongoing outbreak of Shiga toxin-producing Escherichia coli (STEC), serotype O104:H4. On 24 June 2011, French authorities reported an E. coli outbreak in the region of Bordeaux. The phenotypic and genotypic characterisation of the E. coli O104:H4 indicated that the isolates from the French and German outbreaks were common to both incidents. From initial epidemiological investigations, the German outbreak was associated with the consumption of fresh salad vegetables. Subsequent investigations showed that the risk of infection was specifically associated with the consumption of fresh sprouted seeds. Approximately 3 000 cases with bloody diarrhoea, more than 850 cases of HUS (Hemolytic-Uremic Syndrome) and more than 50 deaths linked to this outbreak have been reported to the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO), making it one of the largest foodborne outbreaks reported in Europe in decades. In the initial stages of the outbreak, EFSA provided background information on the internalisation of enteric pathogens in plant material (EFSA; Urgent advice on the public health risk of Shigatoxin producing Escherichia coli in fresh vegetables. EFSA Journal 2011; 9(6):2274). In addition, and at EFSA's initiative, a report summarising available data on STEC and particularly STEC O104 serotype in humans, food, animals, previously reported in Europe was compiled jointly with the ECDC. In addition ECDC and EFSA published a joint rapid risk assessment, with a further update provided later by ECDC.
- o Presence of glass fragments in instant coffee from France. A notification was received on 21 May 2010 by France on a large recall of a well-known instant coffee brand for the possible

presence of small pieces of glass in the product. As it happens, the same day, information had been received from Croatia on similar findings in the product and the notification could be linked to a notification from Greece which appeared to concern the same brand and flavours of the product. The same day, the contact points from the United Kingdom and from Germany could already report on their investigations into traceability and cause of the problem. It appeared that damage to the glass jars was probably incurred during transport and led to insertion of small fragments of glass in the product. Because of the nature of the problem, a restriction to particular production codes or best before dates was not possible leading to a substantial traceability and recall exercise of the products concerned in order to remove them from the market. Recall notices were issued by the company in all countries involved. In total 30 countries were concerned, mostly EU Member States and countries in the Balkan region.

Submissions should explain possible limitations due to insufficient data or number of events.

### 3.6. Expertise required from the evaluation team

Experience in evaluation of systems in the area of food safety, crisis management, official controls and in particular on rapid alert systems or other reporting systems.

University degree and 5 years of relevant experience in the food safety field.

University degree and 5 years of experience in evaluations of legislation and public policies.

### 3.7. Reporting and deliverables

The reports shall be provided electronically in MS-Word format, and in PDF format as requested. In addition, the contractor is expected to deliver a series of presentations on the current status of the work as well as a final PowerPoint presentation together with the Final report (up to 4 presentations in total). The reports shall be written in English, and be clear, concise and comprehensive. A structured and precise elaboration of add-ons to previous reports shall be included. An indicative size for each report, excluding annexes, is:

• inception report: 20 to 30 pages

• interim report: 40 to 60 pages

• final report: 80-100 pages

More precisely, the following reports and presentations shall be delivered:

#### Kick-off meeting report

Members of the contractor's evaluation team will attend a kick-off meeting with the Steering Group. The purpose of this meeting is to verify:

- the team's understanding of the Task Specifications;
- the proposed general approach to the work (methodology, scope, etc.);

• the composition of the full evaluation team.

## <u>Inception report</u> – within 2 months of signing the contract

The inception report completes the structuring phase of the evaluation. It aims to describe the organisation of the work, and to adapt and substantiate the overall approach, the methodology required for each evaluation question and the work plan outlined in the proposal. It should set out in detail how the proposed methodology will be implemented, and in particular lay out clearly in tabular form how the method allows each evaluation question to be answered The report may supplement and/or suggest additional evaluation questions the contractors consider suitable. As such, this document will provide an opportunity to make a final check on the feasibility of the method proposed and the extent to which it corresponds with the task specifications.

The inception report will be submitted to the Steering Group which will discuss on this basis with the contractor and may request changes and improvements. The final versions of evaluation questions suggested by the contractor and the evaluation indicators to be used will be validated by the Steering Group at this stage. After the meeting the contractor will submit a final version.

### <u>Interim report</u> – 5 months after the inception report

This report will provide information on the initial analysis of data collected. The evaluator should already be in a position to provide preliminary findings and answers to the evaluation questions.

The report will provide the evaluation manager and the Steering Group with an opportunity to check whether the evaluation is on track and whether it has focused on the specified information needs.

The contractor will submit a final interim report with the necessary updates after discussion with the Steering Group in a specific meeting. At this meeting, the contractor will define in agreement with the evaluation manager and the Steering Group the table of contents and structure of the draft final report. A document outlining the latter must be submitted in advance of the meeting by the contractor. It will serve as a basis for the discussion.

## <u>Draft final report</u> –8 months after the interim report

This document will provide the preliminary conclusions of the evaluator in respect of the evaluation questions in the task specifications. These will be based on evidence generated through the evaluation. Any judgements provided should be clear and explicit. The draft final report should also contain substantiated recommendations made on the basis of the conclusions reached by the evaluator. It will also provide a technical overview of the evaluation process, highlighting limitations and possible bias therein.

The draft final report should be structured along the lines of common Evaluation Standards and include a draft one-page summary on the Key Messages (conclusions and recommendations in bullet form) of the evaluation, an executive summary of not more than 10 pages (factual data concerning the implementation of the Programme and summary of analyses and conclusions), the main report (presenting the results of the analyses in full, conclusions and recommendations) and technical annexes (one of which will be the Task Specifications)..

<u>Final report</u> – to be submitted 1 month after communication of comments made by the SG on the draft final report

The final report should have the same structure as the draft final report. It will take account of the results of the comments and discussions with the Steering Group regarding the draft final report insofar as they do not interfere with the autonomy of the evaluators in respect of their conclusions.

It is essential that all the reports be clear, unambiguous and comprehensive. They should also be understandable for non-specialists. The reports should be provided to the European Commission in Word format with the charts in Excel. They should be accompanied, where requested, by appropriate annexes. All reports and presentations are to be submitted in electronic format in accordance with the deadlines set in the time-schedule specified below.

The contractor should provide the final report in both MS-Word and Adobe Acrobat (PDF) respecting the Commission Visual Identity and in 45 hard copies. The contractor should also provide a PowerPoint presentation of key aspects and findings of the study, together with speaking notes. At the request of the Commission, the contractor should provide a maximum of two presentations to interested stakeholder groups. The Commission will hold the copyright of the reports.

The executive summary must be translated in DE and FR, being not longer than 6 pages. A 200-word abstract should be provided in EN.

### 3.8. Organisation and timetable

The duration of the assignment is 9 months.

### 3.9. Budget

The Maximum budget for this assignment is EUR 80.000.

### 3.10. Special requirements

(e.g. confidentiality, conflict of interests, IT and communication techniques)

### 4. References

- 4.1. Other existing documentation/data and how to access it (reports / publications from Member States
  - White paper on Food Safety (12/01/2000) COM (1999) 719 final; http://www.cc.cec/sg\_vista/cgibin/repository/getdoc/COMM\_PDF\_COM\_1999\_0719\_F\_EN\_ACTE.pdf
  - Annual Reports of the Rapid Alert System for Food and Feed: http://ec.europa.eu/food/food/rapidalert/rasff\_publications\_en.htm
  - Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed; http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:006:0007:0010:EN:PDF
  - Guidance on the implementation of Articles 11, 12, 14, 17, 18, 19 and 20 of Regulation (EC) N° 178/2002 on General Food Law;
     http://ec.europa.eu/food/food/foodlaw/guidance/guidance\_rev\_8\_en.pdf
  - Draft version "Standard operating procedures of the Rapid Alert System for Food and Feed"

#### 4.2. Useful web-links

- SANCO-RASFF web page: http://ec.europa.eu/food/food/rapidalert/index\_en.htm
- RASFF Portal:

https://webgate.ec.europa.eu/rasff-window/portal/?event=SearchForm&cleanSearch=1

• European Food Safety Authority (EFSA) web page:

http://www.efsa.europa.eu/

• The European Centre of Disease Prevention and Control (ECDC) web page:

http://www.ecdc.europa.eu/en/Pages/home.aspx

• The Rapid Alert System for non-food products posing a serious risk (RAPEX):

http://ec.europa.eu/consumers/safety/rapex/index\_en.htm

