



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

*Presentation of draft final report
Part I: Introduction & Rapid Alert System for Food and Feed*

For the Expert Group on the General Food Law by the Food Chain Evaluation Consortium (FCEC)

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Structure of presentation

- Purpose and scope of the evaluation
- Overview of work conducted
- Results of the evaluation Rapid Alert System for Food and Feed
- Results of the evaluation Crisis management procedures (Part II)

Purpose and scope of the evaluation

- The purpose of the evaluation is to assess whether the regulatory framework established by Articles 50 to 57 of Regulation (EC) No 178/2002 is effective and efficiently working and providing added value to its stakeholders.
- Evaluation period: between 2002 (year of adoption of Regulation (EU) No 178/2002) and 2013.
- Evaluation covers the 28 EU MS, Switzerland and the EEA countries (Norway, Liechtenstein and Iceland).

Overview of work conducted /1

- Elaboration of intervention logic of the RASFF and of crisis management procedures;
- Extensive literature review covering over 180 documents with help of dedicated software;
- Two complementary surveys:
 - RASFF national contact points and other stakeholders involved in the RASFF (75 responses);
 - Competent authorities in the field of food/feed crisis management and relevant stakeholders (47 responses).

Overview of work conducted /2

- Exploratory interviews with broad range of stakeholders;
- Case studies conducted of three food safety incidents based on interviews and document review;
- Complementary in-depth interviews, including with EFSA, the ECDC, INFOSAN, and the U.S. FDA;
- Additional follow-up interviews with EC and third country;
- Data on information flow, financial analysis of the RASFF, and data concerning economic impacts of selected food/feed safety incidents.

Part I

The Rapid Alert System for Food and Feed

Effectiveness /1

- The intervention logic elaborated in the course of this evaluation in close cooperation with the EC identifies the following four objectives of the RASFF:
 - 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 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.

Effectiveness /2

- RASFF achieves well its core objectives related to information exchange between members, reflected in the large number of notifications handled by the system: 3,137 original notifications and 5,158 follow-up notifications, with third countries having been informed 2,373 in reference year 2013;
- Less than 3% of notification rejected by ECCP, indicating that more than 97% of submitted notifications are considered to be of sufficient quality for circulation to network members (in terms of completeness and scope of notification);
- NCPs and other stakeholders involved in the RASFF have also provided positive assessments regarding achievement of these objectives (rating between 3.7 and 4.4 on a scale of 0 to 5).

Effectiveness /3

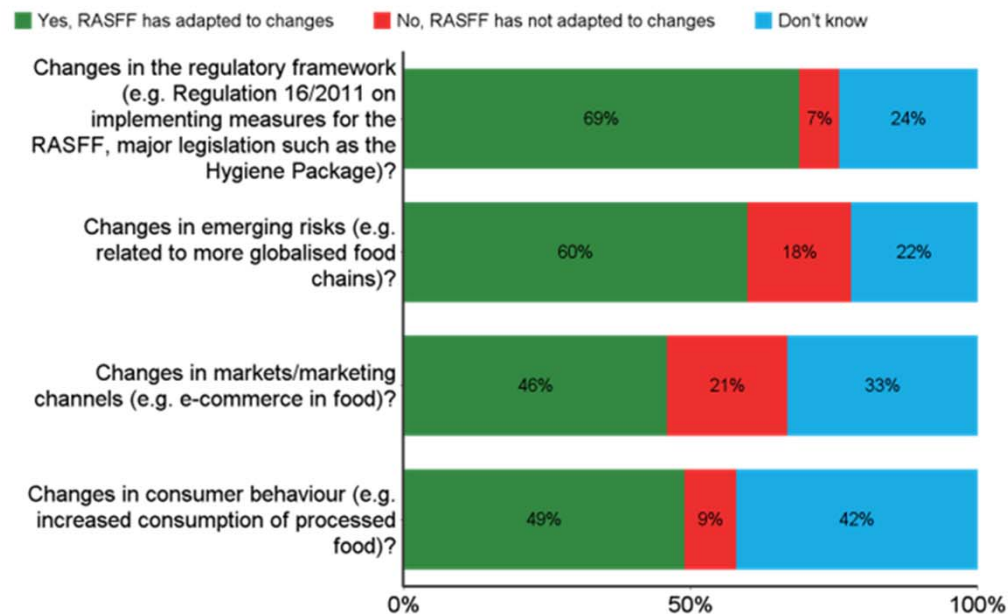
- In all three serious food/feed safety incidents that were studied in depth, the RASFF has played an important role as a tool for information exchange;
- The use of alert notifications and the significant number of follow-up notifications transmitted demonstrate that the system was used to communicate information about risks deriving from food, and that it allowed members to be informed about the follow up to those risks, including measures taken to contain it;
- Moreover, in each of the incidents examined, the system was also used to exchange information with at least one third country.

Effectiveness /4

- Since the adoption of Regulation 178/2002, more than a decade has passed during which a series of changes have altered the landscape of food/feed safety, including:
 - in the legal framework (e.g. Regulation 16/2011 on implementing measures for the RASFF, Hygiene Package)
 - emerging risks (e.g. related to more globalised food chains)
 - markets/marketing channels (e.g. ecommerce in food)
 - consumer behaviour (e.g. increased consumption of processed food)
- RASFF NCPs and other stakeholders largely consider that the RASFF has adapted to changes in the regulatory framework and changes in emerging risks.

Effectiveness /5

“Have there been changes to the following areas to which the RASFF has not adapted?”



While most respondents also considered RASFF has adapted to changes in markets and consumer behaviour, e-commerce in food stands out as posing significant challenges not only for RASFF, but for carrying out official controls and the enforcement of food safety legislation in general

Effectiveness: recommendations

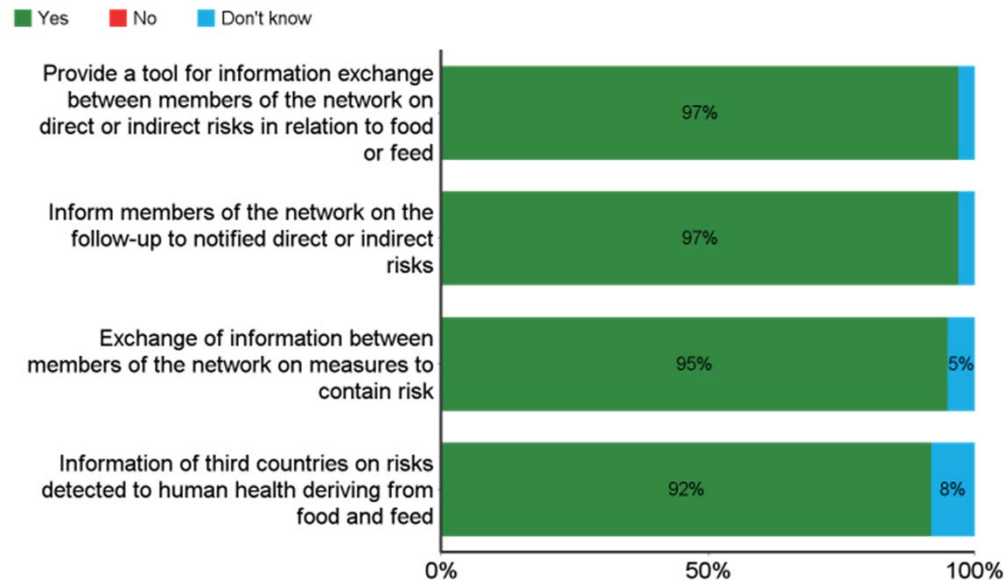
- RASFF is increasingly relevant as a tool for information exchange in light of rapid growth of trade in food and feed and the increasing complexity of related supply chains, and as a source of information on trends in risks, affected food and feed products/materials, and measures taken;
- Therefore further develop the RASFF as a cornerstone of the EU food/feed safety system and collect additional data for monitoring purposes (see relevance, next section);
- Further recognise the role of RASFF in crisis management (e.g. by reviewing and formalising practices such as daily updates during serious food/feed safety incidents and incident reports at the closure of an incident).

Relevance /1

- The level of globalisation of trade is increasing, and with it the complexity of supply chains. From 2000 to 2010, imports from developing countries to the EU grew at an average annual rate of 5.4%.
- In 2013, EU countries imported agricultural products worth €101.8 billion. This represents a 64 % increase compared to 2004.
- This increasing level of globalisation of trade in food and feed and the increasing complexity of the food supply chain reinforce the need for a mechanism to rapidly exchange information on risks related to food/feed, allowing food safety authorities (and business operators) to address the risks identified through appropriate measures.

Relevance /2

“Does this objective remain valid?”



The objectives of RASFF as a tool for information exchange on risks in relation to food and feed and on related measures between members of the network (and with third countries) are considered to remain valid by a very large majority.

Relevance /3

- Suggestions for additional potential objectives of RASFF identified include using the system as a tool for aggregating data on food/feed safety incidents, and to contribute to a wider EU food and feed safety strategy by providing analysis of trends in risks and related measures taken.
- In the future, it could contribute to a wider system of safeguarding food and feed safety by capitalising on the data which it collects e.g. on risks detected, affected food and feed products/materials and traceability information.

Relevance: recommendations

- Convene a working group of NCPs and independent food safety experts to discuss the scope of data collection through the RASFF as a monitoring tool for food and feed safety trends (e.g. by collecting data on amount of affected food/feed in notifications/lot sizes, or sales channel of affected products).
- This working group could also consider whether it would be useful to structure notifications according to the incident or source to which they relate (e.g. through the use of a unique identifier) to allow users to more easily identify relations between notifications and to have a better understanding of individual incidents and their development.

Coherence and scope /1

- Results of this evaluation confirm that the scope of the RASFF appropriately addresses the needs of RASFF members. A majority of National Contact Points and other stakeholders also finds the scope of the RASFF sufficiently defined in the legislation.
- All other notification systems considered are potentially complementary to the RASFF (EWRS, TRACES, RAPEX, ECURIE, EPIS, ARGUS, AAC, IMSOC and INFOSAN).
- Some instances of potential duplications can be noted, though they are partly unavoidable.

Coherence and scope /2

- In other cases where potential duplications between notifications systems may exist, they are already reduced or (planned to be) minimised to some extent through:
 - Alignment of procedures (INFOSAN and RASFF);
 - Partial linkages between systems (TRACES and RASFF);
 - Planned software links for data transfer between systems (AAC and RASFF).
- The creation of the envisaged IMSOC (Information Management System for Official Controls) could further attenuate potential duplications by facilitating data exchange between systems.

Coherence and scope: recommendations

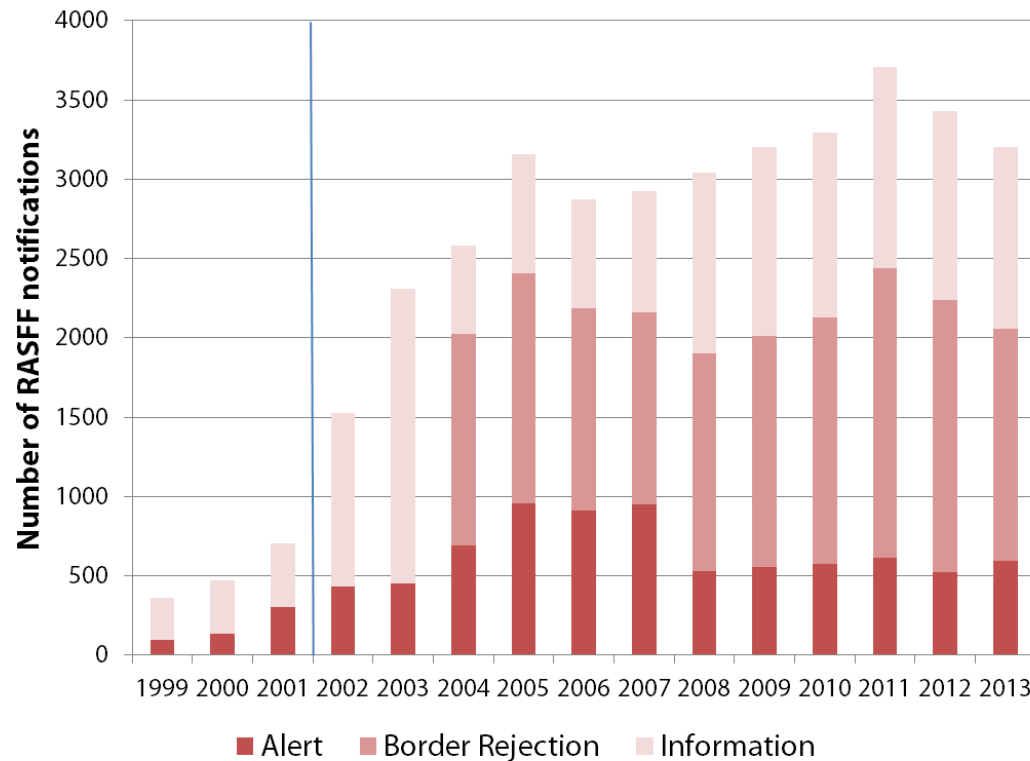
- In instances where there is potential duplication between systems (e.g. RASFF and AAC), it is important to explicitly define the scope of the relevant systems and to communicate them clearly to members of the network.
- Recommended to provide guidance and training to RASFF NCPs once the scope of each system has been clarified in SOPs/guidance documents, in order to avoid misunderstandings and minimise potential duplications

Legal basis and role of the EC /1

- The adoption of Regulation (EC) No 178/2002 provided a legal basis for the RASFF and formalised its procedures.
- It improved the functioning of the system in several ways:
 - Transformed practices followed by its members into specific obligations to be fulfilled by MS and the ECCP;
 - The requirements in the Regulation provided additional impetus for members to create the structures essential for running the RASFF at the national level.
- Combined with a growing awareness of MS about risks related to food /feed, these effects contributed to improving the functioning and monitoring of the RASFF.

Legal basis and role of the EC /2

- It also led to a sharp increase in the number of original notifications and follow-up notifications transmitted:

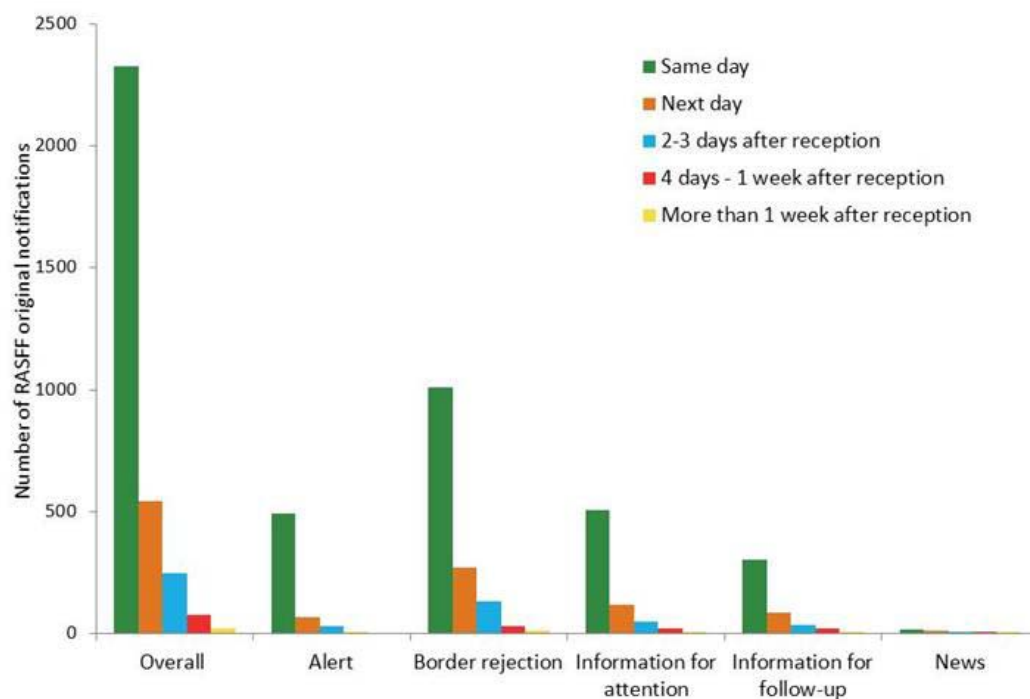


Legal basis and role of the EC /3

- The EC has largely fulfilled its duties deriving from the RASFF legal basis during the evaluation period concerning organisational aspects and the verification and transmission of notifications.
- In reference year 2013 about 19 in 20 original alert notifications and 7 in 8 follow-up notifications were transmitted by the ECCP to RASFF members on the same/following day.
- Additional data provided by EC confirms that approximately 94% of alert notifications are transmitted within 24 hours.

Legal basis and role of the EC /4

Original notifications according to time of transmission (2013)



Where delays occurred, notifications have typically been forwarded in advance to NCPs of countries concerned, pending translation.

Legal basis and role of the EC /5

- Contribution of EC to the coordination of RASFF members and to the development of good and common notification practices is viewed very positively by NCPs.
- The Working Groups have contributed to the better functioning of the RASFF, and the SOPs on the functioning of the network are considered helpful, clear and consistent with needs and expectations.
- However: question arises whether the current centralised structure of the RASFF with ECCP as gatekeeper for all notifications is sufficiently future proof.
- It could be considered to decentralise the RASFF to some extent by allowing bilateral information flow amongst members.

Legal basis and role of the EC: recommendations

- Given the significant increase in the number of notifications in recent years, the ECCP should focus its resources on priority areas (particularly the verification and transmission of alert notifications and their follow up).
- A working group of the ECCP and NCPs could consider possible solutions, e.g. some decentralisation of the system by allowing MS to communicate directly through the RASFF under specific conditions.
- This would require amending the current legislative framework and adapting the iRASFF system.

Risk basis and role of EFSA /1

- Risk: “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.”
- Legislation foresees that EFSA be included in the network as a member to provide its input, where needed, for assessing those risks.
- In practice, the risk evaluation of notifications takes place in two sequential stages: first at NCP level and then at ECCP.

Risk basis and role of EFSA /2

- No consensus among stakeholder groups concerning the extent to which notifications exchanged through the RASFF are sufficiently risk-based: two-thirds of NCPs consider that this is the case, while an almost similar majority of other stakeholders disagree.
- While some split of opinion regarding the accuracy of evaluation of risks in the RASFF, 62% of stakeholders other than NCPs provided a rating of 3 or higher.
- In 2013, 230 notifications were rejected by ECCP and 8 alert notifications downgraded: demonstrates role of ECCP as gatekeeper of the system.

Risk basis and role of EFSA /3

- Some factors that contribute to differences in the evaluation of risk:
 - RASFF members responsible for assessing risk: can lead to some grey areas;
 - Guidance documents available to a limited extent (for pesticide residues).
- On some occasions, more involvement of EFSA could be helpful, specifically when the risk involved is less well known, or as a way to harmonise diverging approaches of RASFF NCPs to assess risk.

Risk basis and role of EFSA: recommendations

- Contribution of EFSA to the RASFF could be reinforced to provide the system with a mechanism allowing the ECCP to obtain a rapid (e.g. within 48 hours) feedback when a risk is not well known or cannot be easily assessed using existing guidelines or precedents.
- Feedback could be based on EFSA in-house expertise in the form of an initial review of available information.
- Further guidance to assist NCPs with identification and classification of risks could be developed jointly by the EFSA and the ECCP (already planned) e.g. for contaminants or other hazard categories.

Involvement of EU Member States /1

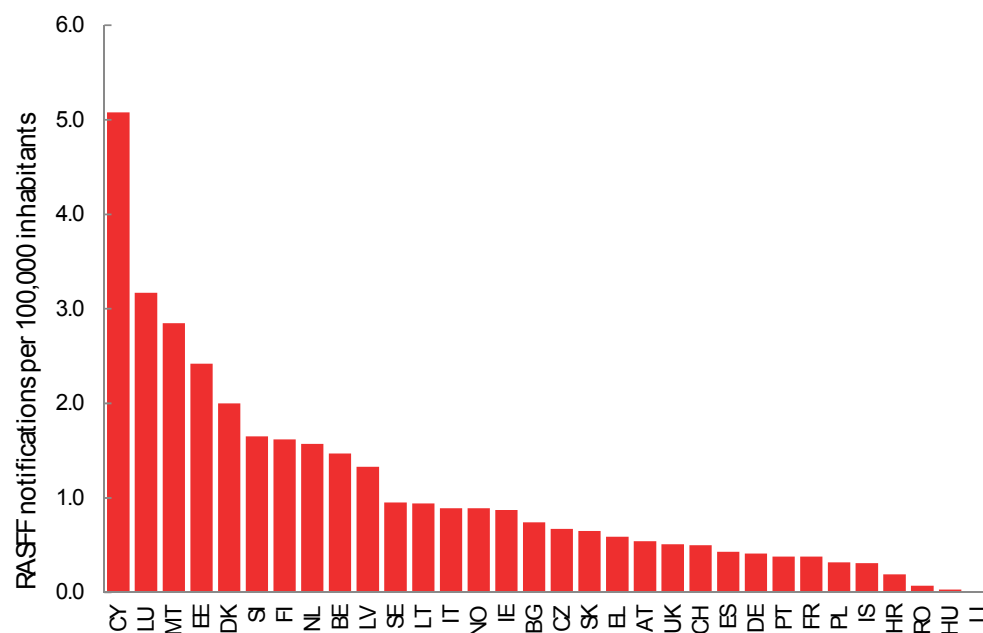
- According to their peers, self-assessment and assessment of the ECCP, RASFF member countries largely fulfil their duties under the RASFF as required by the legislation. Duties include:
 - Designation of a contact point for the RASFF;
 - Availability of an on-duty officer reachable on a 24/7 basis;
 - Sending alert notifications to ECCP within 48 hours upon reception and other notifications without undue delay.
- Evidence collected in case studies of three serious food/feed safety incidents largely supports this assessment.

Involvement of EU Member States /2

- Approximately half of RASFF member countries have adopted national legislation to implement the RASFF, the others have implemented RASFF without legislative changes.
- No clear link between having/not having national legislation and the running of the system when considering the staffing of the NCP, and number of original notifications transmitted in the reference year.
- Also no clear link between the adoption of national legislation and the quality of notifications a country submits (considering number of rejected notifications).

Involvement of EU Member States /3

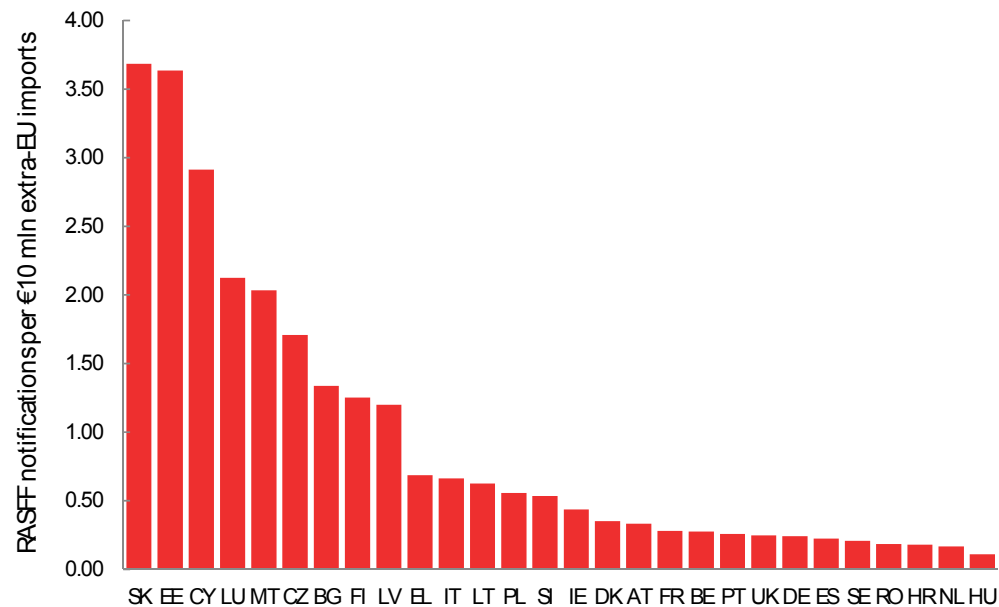
Number of RASFF original notifications submitted by members of the network according to population size (2013)



The extent to which member countries submit notifications varies significantly, from none to over 500 original notifications in 2013. When population size of the notifying country is considered, differences between countries remain.

Involvement of EU Member States /4

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



Similarly, when trade activity in terms of imports from third countries is considered, differences in the rate at which member countries submit notifications remain.

Involvement of EU Member States /5

- These differences could be caused by particular national approaches concerning certain risks, differences in national legislation and enforcement of EU legislation, and country-specific administrative structures/procedures.
- Possible other explanations for low notification rates include different notification standards and weak/infrequent official controls, as well as insufficient information flow between the bodies implementing official controls and the RASFF NCP.

Involvement of EU Member States: recommendations

- Future audits of the national food and feed safety systems conducted by the Food and Veterinary Office could further explore the reasons for differences in the level of activity in detail, in those countries with exceptionally low notification rates.

Efficiency /1

- Estimated cost of running the RASFF during normal operation (i.e. in absence of a serious food/feed safety incident) approximately €7.4 million.
- Inputs to be considered are mainly staff costs (at EU and NCP levels), IT infrastructure and training costs.
- On average, MS employ 2.4 FTE professional staff members and 1.0 FTE administrative/support staff (in total about 97 FTE).
- In addition, cost for EC's contact point and IT staff. Plus expenditures for infrastructure, development and corrective maintenance of RASFF (€727,000 in the reference year 2013).

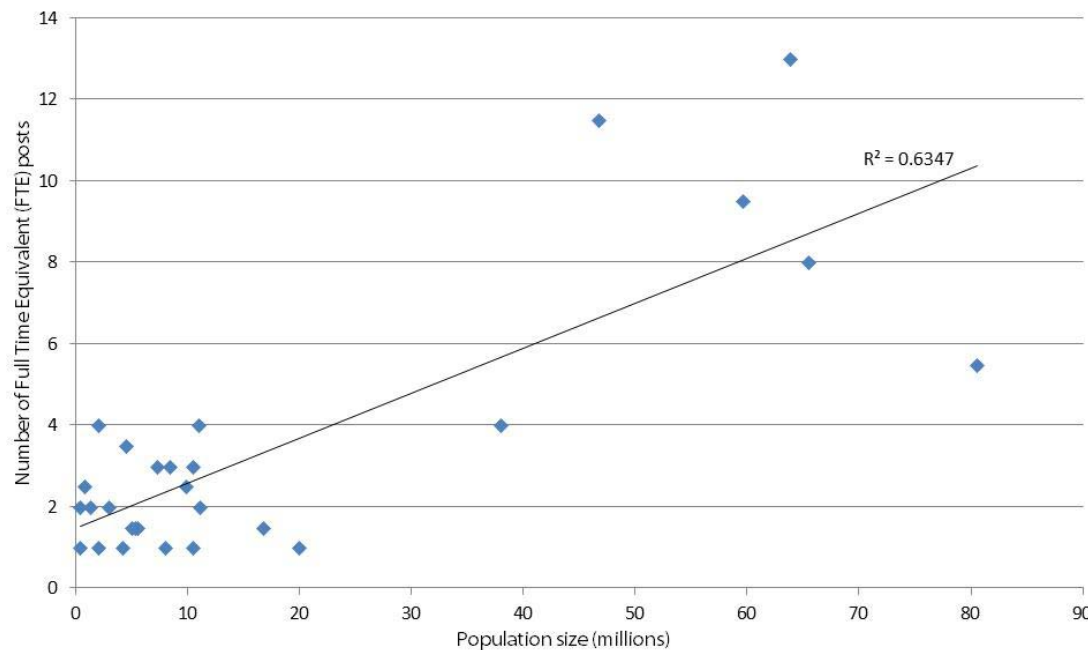
Efficiency /2

Organisation level	Cost category	Cost
Costs at member country level	Staff costs (RASFF National Contact Points)	€ 5,817,418
	Reported training costs	€ 54,522
	<i>Total costs Member States</i>	€ 5,871,940
Costs of EFTA Surveillance Authority (ESA)	Staff costs	€ 209,632
	Reported training costs	€ 1,300
	<i>Total costs ESA</i>	€ 210,932
Costs of European Commission	Costs of IT systems (incl. costs related to staff, infrastructure, development and corrective maintenance)	€ 727,000
	Coordination costs (RASFF European Commission Contact Point)	€ 533,797
	Reported training costs ^a	€ 0
	<i>Total costs European Commission</i>	€ 1,260,797
Costs of European Food Safety Authority (EFSA)	Staff costs	€ 12,528
	Reported training costs	€ 0
	<i>Total costs EFSA</i>	€ 12,528
Total costs of running the RASFF		€ 7,356,197

Equivalent to a cost of roughly €690 per information item (original and follow-up notifications and information to third countries). Given that most notifications concern multiple countries, the cost per notified country are substantially lower.

Efficiency /3

Scatterplot of member countries population size and NCP staff posts



While population size is an important factor in determining NCP staffing, significant differences exist between countries of similar sizes. This is likely to depend on further country specific differences, e.g. relevance of trade.

Efficiency /4

- Overall, costs appear to be reasonable, even though they cannot directly be compared to the resulting benefits.
- Objectives of the RASFF are considered by NCPs to have been achieved at an appropriate or very appropriate cost when compared with the benefits of the RASFF for their country.
- Main benefits identified related to the speed of information and communication exchange, the management of food/feed safety incidents, as well as the protection of consumer health.
- Several options to achieve efficiency gains by transferring certain tasks and functionalities to other systems/mechanisms were identified in the course of the evaluation.

Efficiency: recommendations

- Upgrading the iRASFF application to centralise information from all RASFF notifications into a single IT system.
- Consider to handle border rejection notifications only through TRACES or ensure a direct IT link between TRACES and iRASFF.
- Consider to transmit information on non-compliances not directly related to risk containment through the AAC system, to reduce the quantity of information exchanged through the RASFF.
- Efficiency of the RASFF could further be increased by allowing bilateral exchanges to be made between members without requiring verification and intervention of ECCP.

Participation of Third Countries

- RASFF is accessible to third countries via RASFF Window, an IT tool that currently allows 107 third countries outside the EU/EFTA to access notifications that relate to their country.
- In 2013, third countries were informed 329 times about a product that had been distributed to them and 2,231 times about notifications which concerned a product originating from their country.
- A majority of NCPs suggest they need to receive more information from third countries through the RASFF, especially from Asia and the Western Balkans. The ECCP has confirmed that while it frequently informs third countries about notifications that are relevant to them, the response from those countries is less consistent (e.g. follow up or measures taken).

Participation of International Organisations

- INFOSAN is the main international partner system of the RASFF.
- Information flow with INFOSAN is most relevant in times of large international food/feed safety incidents, such as the 2008 melamine crisis.
- According to both the ECCP and INFOSAN, the reciprocity of the information flow is appropriate, and is helped by an alignment of procedures and membership of RASFF and INFOSAN in recent years.
- Cooperation between the two systems continues to occur on a case by case basis.

Third Countries/ International Organisations: recommendations

- The EC could continue to emphasise the importance of providing follow up to RASFF notifications in bilateral meetings with third countries that concern food / feed safety. In its audits of third countries, the FVO could also identify which follow up actions or measures were taken by competent authorities in response to relevant RASFF notifications, and identify reasons for limited follow up provided to the ECCP.
- Cooperation between the RASFF and INFOSAN should be furthered; if possible, this could be done by establishing an (IT) link between the two systems.

Stakeholder information, transparency and confidentiality /1

- Professional operators and stakeholders are indirectly involved in the RASFF: main information channel between the RASFF and industry/consumer stakeholders is through the use of IT tools.
- RASFF Portal and Consumers' Portal: enables users to find notifications using a search function, but the name of the company producing or distributing the given product, and brand name of product are not provided (in contrast to RAPEX).
- Websites of national food safety authorities may provide additional information.

Stakeholder information, transparency and confidentiality /2

- No consensus regarding the extent to which the RASFF sufficiently informs professional operators and other stakeholders. RASFF NCPs tend to consider that professional operators and other stakeholders are sufficiently informed, other respondents to our survey tend to disagree.
- Overall, a majority of respondents see a need for improving the information flow to stakeholders and professional operators, though NCPs see this need to a lesser degree than other stakeholders.

Stakeholder information, transparency and confidentiality /3

“Do you consider there is a need to improve the information flow to stakeholders and professional operators from the RASFF?”



To improve the information flow, respondents suggested providing more information on follow up action taken, and information whether a notification has been closed or remains open.

Stakeholder information, transparency and confidentiality /4

- Survey results suggest that while the classification of notifications may be clear for competent authorities and food/feed business operators, it is rather unclear for the general public.
- Our case studies also indicate a lack of clarity of confidentiality requirements. E.g. in the 2011 E.coli outbreak it was not fully known to members of the RASFF which information could be disclosed to non-members.
- Also, confidentiality requirements may be interpreted differently by different member countries, particularly regarding which type of information is covered by professional secrecy.

Stakeholder information, transparency and confidentiality: recommendations /1

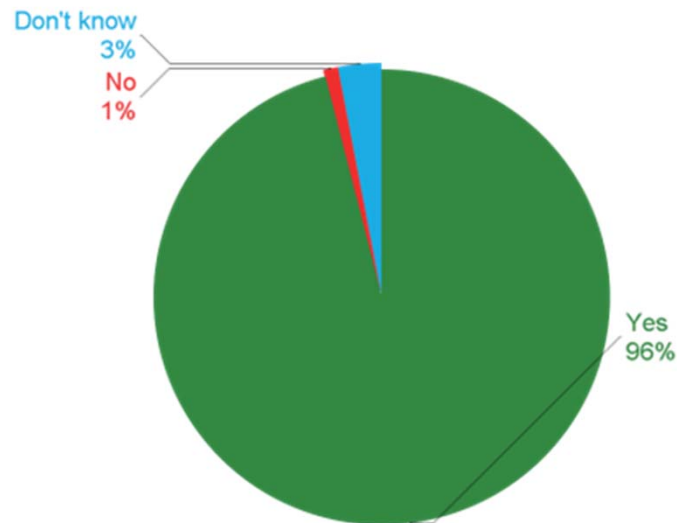
- The RASFF Portal and Consumers' Portal could provide additional details on the products involved in a notification, e.g. about the status of a notification.
- An explicit legend containing the definition of notification types and accompanying examples could be clearly displayed on the main webpages.
- The EC could actively promote and support the development of national consumer websites in order to complement the information provided by the RASFF Consumers' Portal with pictures, brand names, and details about distribution.

Stakeholder information, transparency and confidentiality: recommendations /2

- The SOPs could further elaborate on the confidentiality requirements of the RASFF by providing examples and conditions in which the need for transparency prevails over the requirement of confidentiality.
- In addition, a Working Group of RASFF NCPs could be dedicated to this topic in order to create a common understanding of the confidentiality requirements across all RASFF members.

Added value /1

“Do you consider that the RASFF has an added value compared to what could be achieved without it? “



Almost all respondents to this question (i.e. 96%) considered that RASFF has an added value compared to what could be achieved without it. Two indicated that they did not know, while 1 respondent (business organisation) considered that RASFF had no added value. No explanation for this assessment was provided.

Added value /2

- The evidence collected suggests that the RASFF provides a significant added value to its members by enabling the rapid communication between Member States regarding food and feed safety risks identified that is essential in a single market.
- Areas of added value provided by the RASFF are considered to be numerous and far-reaching in their positive impact, including the prevention of food/feed crisis and an increased consumer trust in food and feed safety.