



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

Final report

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Civic Consulting - Agra CEAS Consulting - Arcadia International - Van Dijk Management Consultants





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ABSTRACT

The evaluation of the Rapid Alert System for Food and Feed and of crisis management procedures led by Civic Consulting of the Food Chain Evaluation Consortium aims 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. Based on the data collected through a literature review, surveys, three case studies of past food safety incidents, in-depth interviews, an analysis of the RASFF information flow and a financial analysis of the RASFF as well as data concerning the economic impacts of the selected food safety incidents, the evaluation analyses the effectiveness, relevance, coherence, efficiency, and added value of the interventions. The assessment reveals that while the RASFF has functioned effectively throughout the reference period (2002-2013), there is scope for enhancing its role as a cornerstone of the EU system for food/feed safety. Moreover, although some aspects of crisis management have been successful, the effectiveness of crisis management has varied throughout the reference period. The findings also point to a need for reviewing Commission Decision 2004/478/EC. The report presents the answers to 52 evaluation questions, and provides key conclusions and recommendations, where relevant.

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LIST OF ABBREVIATIONS

AAC	Administrative Assistance and Cooperation
ArfD	Acute Reference Dose
ARGUS	EU General rapid alert system
BIP	Border Inspection Post
COPA – COGECA	Committee of Professional Agricultural Organisations - General Committee for Agricultural Cooperation in the European Union
DG SANTE	Directorate General for Health and Food Safety
EC	European Commission
ECCP	European Commission Contact Point
ECDC	European Centre for Disease Control
ECURIE	European Community Urgent Radiological Information Exchange
EFSA	European Food Safety Authority
EFTA	European Free Trade Association
EMRISK	EFSA Emerging Risks Unit
EPIS	Epidemic Intelligence Information System
EU	European Union
EU – RLs	European Reference Laboratories
EWRS	Early Warning and Response System
FVO	Food and Veterinary Office
FAO	Food and Agriculture Organisation
IMSOC	Information Management System for Official Controls
INFOSAN	International Food Safety Authorities Network
IT	Information Technology
IO	International Organisation(s)
MS	Member State(s)
MRL	Maximum Residue Limit
NCP	National Contact Point
PAFF	Standing Committee on Plants, Animals, Food and Feed
RAPEX	Rapid Alert System for Non-Food Products
RASFF	Rapid Alert System for Food and Feed
SCOFCAH	Standing Committee on Food Chain and Animal Health
SOP	Standard Operating Procedures
STEC	Shiga toxin-producing Escherichia coli
TC	Third Country
TOR	Terms of Reference
TRACES	Trade Control and Expert System
WHO	World Health Organisation

1. KEY MESSAGES

The evaluation of the Rapid Alert System for Food and Feed (RASFF) and of crisis management procedures has led to a number of conclusions and recommendations. The following points summarise the main findings concerning the RASFF:

- The overarching conclusion of the evaluation is that on the whole, the RASFF has functioned effectively throughout the evaluation period in light of its objectives. The system is strongly appreciated by its addressees (the RASFF National Contact Points in member countries) and a large quantity of actionable information is transmitted through the system, allowing Member States and international partner countries to react swiftly to risks detected in food and feed. However, while the system as a whole is considered to function well, there remains some scope for enhancing its role as a cornerstone of the EU system for food/feed safety. In particular, more guidance on different risks as well as increased support from EFSA in certain cases could contribute to improving the risk-based approach of the system.
- Since its conception in 1979, the RASFF remains highly relevant. The increasingly globalised trade in food and feed, as well as the deepening of the European single market reinforce the need for an effective way of transmitting information on risks detected and measures taken by individual Member States. The objectives pursued by the RASFF are largely considered to correspond to these needs, with some potential additional objectives identified that could be taken on board in the future, such as using the RASFF as a tool for analysing trends in food/feed safety risks, and recognising its key role in crisis management.
- The RASFF is largely coherent with a number of other notification systems, both at EU level and with its main international partner system INFOSAN. Where overlaps do occur, certain measures have been planned or have already been taken in order to minimise duplications.
- In terms of efficiency, the costs of the RASFF appear to be reasonable, although they cannot be directly compared with the benefits of the system. Nonetheless, there is some scope for improving its efficiency in the future, specifically by upgrading the iRASFF application, moving certain tasks to other notification systems, further improving linkages between the RASFF and relevant systems, and allowing for a degree of de-centralisation of the system in specific cases.
- There is nearly unanimous consensus that the RASFF provides added value compared to what could be achieved without it by Member States acting at the national level. This conclusion is also confirmed by the results relating to previous criteria, in particular those pointing to the high relevance and effectiveness of the system.

The following points summarise the main findings concerning crisis management procedures:

- Emergency measures adopted at EU level are broadly considered to have been effective and successful in ensuring a consistent response to past food/feed safety incidents by Member States. However, results of the evaluation suggest that the overall effectiveness of crisis management has differed in the reference period, depending on the food/feed safety incident and the objectives considered. The evidence also suggests that the EC has played the role of coordinator in the management of past incidents, although the extent to which this was the case and the satisfaction of

competent authorities and other stakeholders with the EC's role vary, depending on the specific coordination aspect and incident considered.

- The two layers of action provided for in Commission Decision 2004/478/EC are considered by competent authorities and other stakeholders responding to our survey to be (in principle) relevant and still appropriate for food/feed crisis management. However, the second layer of action was never used, i.e. a crisis unit has never been set up, in spite of the fact that major food/feed safety incidents with significant impacts on consumer health occurred during the evaluation period. Regarding the first layer of action, the evaluation concludes that it has not always been sufficient for the management of previous food/feed safety incidents; moreover, during more complex crisis situations like the E.coli outbreak, a clearer crisis management structure within the European Commission would have been considered beneficial by key stakeholders involved. Finally, there is strong support by competent authorities and other stakeholders for additional measures to be taken for crisis management at EU level. As a result, one of the key outcomes of this evaluation is that there is a need to review Commission Decision 2004/478/EC in order to adapt it more closely to the current needs.
- The efficiency of EU crisis management has also varied depending on the case studied. While overall, costs of crisis management are considered to be appropriate, in some cases, the economic impact of a food/feed safety incident may have been higher than the unavoidable minimum. The evaluation concludes that a way to safeguard an improved balance of costs and benefits of crisis management is to focus on actions related to contingency planning and emergency preparedness, including training and simulation exercises. The evaluation identifies several suggestions for improving the balance of costs and benefits at EU and Member State levels. These include a regular review of contingency plans, especially following serious food/feed incidents, and organising crisis simulation exercises and trainings. Finally, it is recommended to implement measures/procedures at all levels to safeguard clear and effective communication during future incidents.
- Similarly to the RASFF, there is unanimous agreement that there is an added value in the crisis management and coordination by the EC compared with what could be achieved by Member States acting individually.

2. EXECUTIVE SUMMARY

As part of its Regulatory Fitness (REFIT) programme, the European Commission designated the food chain as a pilot project for a fitness check, with the General Food Law (Regulation (EC) No 178/2002) identified as a key candidate for undergoing a REFIT evaluation. In 2014, the EC launched an evaluation of Articles 50-57 of the Regulation, which include the provisions relating to the Rapid Alert System for Food and Feed (RASFF), emergency measures and crisis management. The evaluation was led by Civic Consulting of the Food Chain Evaluation Consortium.¹

With its conception dating back to 1979, the Rapid Alert System for Food and Feed (RASFF) is one of the few elements of the European food safety framework predating the White Paper on Food Safety in 2000 that is still in place today. Acting as a key component of this framework, the RASFF provides a system for the swift exchange of information between its members in cases of direct or indirect risks to human health deriving from food and feed, to enable as much as possible a coordinated response of its members to food/feed safety threats. As it currently functions, the RASFF is composed of several IT tools or platforms providing access to notifications which are tailored for different stakeholder groups. Through these developments, it has emerged as an essential element of the European food safety system, providing an EU-wide network for food/feed risk communication and a valuable source of information for competent authorities and business operators. The 32 members of the network have transmitted over 3,100 original notifications in 2014, equivalent to an average of more than 8 original notifications per day.² These have given rise to 5,910 follow-up notifications, and more importantly perhaps, the information transmitted between users of the RASFF has allowed for numerous products presenting a risk to be removed from or denied access to the EU market.

The RASFF thus plays a central role in the prevention and management of risks detected in food and feed, allowing Member States to take national measures for countering those risks, in line with the subsidiarity principle. However, when national actions undertaken by Member States acting individually are not sufficient to contain a risk, additional measures and procedures may need to be put in place. Articles 53 to 57 of Regulation (EC) No 178/2002 outline and establish the tools that are at the disposal of the European Commission for the coordinated management of food/feed safety incidents affecting the EU, including emergency measures, the drawing up of a general plan for crisis management, and the establishment of a crisis unit.

The evaluation of the RASFF and crisis management procedures has aimed 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. Specific aspects of the RASFF that were examined include its relevance, coherence and scope, its legal basis and the role of the European Commission as manager of the system, the risk-basis of its operations and the role of EFSA, the involvement of EU Member States, the participation of Third Countries and International Organisations, and the information provided by the RASFF to stakeholders, including the transparency and confidentiality of the system. Crisis management procedures were also assessed with respect to their relevance, the role of the European Commission, the involvement of EU Member States, and the participation of Third Countries and International Organisations.

¹ A complementary study on the evaluation of Regulation (EC) No 178/2002 ("the General Food Law Regulation") – which does not consider Articles 50 to 57 – was led by Agra CEAS Consulting of the Food Chain Evaluation Consortium.

² European Commission, RASFF - for Safer Food: The Rapid Alert System for Food and Feed 2014 Annual Report, 2015.

A range of methodological tools were employed for answering the 52 evaluation questions listed in the Terms of Reference. These tools included a literature review, two surveys of competent authorities and other stakeholders, three case studies of past serious food safety incidents and complementary in-depth interviews. In addition, a financial analysis of the RASFF and an analysis of the information flow generated through the system were conducted. Additional data on the estimated costs of food/feed safety incidents that occurred within the reference period was collected to inform the discussion about the efficiency of crisis management procedures and to complement the case studies. The primary and secondary evidence collected through these methodological tools forms the basis of the answers to the evaluation questions provided in this report. This evaluation presents a number of key conclusions on the RASFF and crisis management arrangements in the EU, providing recommendations for improvement, where needed.

2.1. RASFF

The overarching conclusion of the evaluation is that on the whole, the RASFF has functioned effectively throughout the evaluation period in light of its objectives. The system is strongly appreciated by its addressees (the RASFF National Contact Points in member countries) and a large quantity of actionable information is transmitted through the system, allowing Member States and international partner countries to react swiftly to risks detected in food and feed. Partly, the effectiveness of the RASFF can be attributed to the role of the European Commission as manager of the network. This evaluation concludes that the EC has largely fulfilled its duties deriving from the RASFF legal basis during the evaluation period concerning organisational aspects, and, most importantly, the verification and transmission of notifications. Its contribution to the coordination of the members of the RASFF and to the development of good and common notification practices is also viewed very positively by National Contact Points. The Working Groups of the RASFF NCPs have contributed to the better functioning of the RASFF, and the Standard Operating Procedures on the functioning of the network are considered to be helpful, clear and consistent with needs and expectations.

Although the legislation assigns the role of coordinator to the European Commission, member countries have a crucial role to play in ensuring the effective functioning of the RASFF as members of the network and its primary beneficiaries. Some key obligations relating to the RASFF derive directly from the legislation, but the active participation of members depends on a range of other factors and varies significantly from country to country. According to their peers and self-assessment, as well as the assessment of the EC Contact Point, RASFF member countries largely fulfil their duties under the RASFF as required by Regulation (EC) No 178/2002 and Commission Regulation (EU) No 16/2011. The evidence collected in case studies of three serious food/feed safety incidents largely supports this assessment. On the other hand, the extent to which member countries submit notifications through RASFF varies significantly, ranging from none to over five hundred original notifications in the reference year 2013. Even when population size and trade activity of the notifying country are considered, differences between countries in notification numbers remain.

The effectiveness of the RASFF also depends on the degree to which its operations are risk-based, i.e. the extent to which the notifications transmitted through the system adequately reflect the risks to food and feed involved, as intended by its legal basis. The extent to which notifications exchanged through the RASFF are considered to be *sufficiently* risk based varies among stakeholder groups, with two thirds of RASFF National Contact Points stating that this is the case, while an almost similar majority of other stakeholders – mainly food business operators and their organisations – disagree. However, 62% of those stakeholders provided a positive rating when considering the extent to which risk is *accurately* evaluated in the RASFF. While the ECCP contributes to the harmonisation of approaches for risk evaluation, there remain

factors that may potentially lead to differences in how risk is evaluated. These include that RASFF members have the responsibility for deciding whether or not there is a risk involved in non-compliant food/feed (and subsequently whether the risk is such as to require the notification to the RASFF), which may lead in some cases to a "grey area" for risk evaluation, if RASFF members come to different conclusions under similar circumstances. Also, detailed guidance documents that may lead to a more harmonised evaluation of the risk across Member States are only available to a limited extent, e.g. in the area of pesticides.

Nonetheless, since its conception in 1979, the RASFF remains highly relevant. The increasingly globalised trade in food and feed, as well as the deepening of the European single market reinforce the need for an effective way of transmitting information on risks detected and measures taken by individual Member States. The objectives pursued by the RASFF are largely considered to correspond to these needs, with some potential additional objectives identified that could be taken on board in the future, such as using the RASFF as a tool for analysing trends in notified food/feed safety risks, and recognising its key role in crisis management. In addition, the RASFF is largely coherent with a number of other notification systems, both at EU level and with its main international partner system INFOSAN. Where overlaps do occur, certain measures have been planned or have already been taken in order to minimise duplications.

In terms of efficiency, the costs of the RASFF appear to be reasonable, although they cannot be directly compared with the benefits of the system. This is because the information exchange through the system is not a benefit in itself, but rather contributes to benefits that accrue as a result of measures taken on the basis of RASFF notifications. However, comparing total costs to the quantity of information transmitted provides some insight on the efficiency of the RASFF: for the reference year 2013, the costs amounted to 690 Euro per information item transmitted to RASFF members. Considering that most notifications concern multiple countries, the cost per notified country is substantially lower. Nonetheless, there is some scope for improving its efficiency in the future.

Finally, there is nearly unanimous consensus that the RASFF provides added value compared to what could be achieved without it by Member States acting at the national level. This conclusion is also confirmed by the results relating to previous criteria, in particular those pointing to the high relevance and effectiveness of the system.

2.2. Crisis management procedures

A key element of crisis management procedures in the EU relates to the possibility of adopting emergency measures in response to food or feed originating in the European Union or imported from a third country that is likely to constitute a serious risk to human health, animal health, or the environment. A large number of food/feed safety incidents have been contained and managed by the European Commission on this basis. Emergency measures have also been used as instruments for the management of two of the three past serious food safety incidents scrutinised in depth in this evaluation, the melamine crisis and the E.coli outbreak. In both incidents, the measures are considered to have been effective, although in the E.coli outbreak the emergency measure was adopted towards the end of the crisis once the source of the outbreak had been identified and it therefore mainly consolidated protective measures taken.

While emergency measures adopted at EU level are broadly considered to have been effective and successful in ensuring a consistent response to past food/feed safety incidents by Member States, results of the evaluation suggest that the overall effectiveness of crisis management has differed in the reference period, depending on

the food/feed safety incident and the objectives considered. In particular, while consumer health protection, the efficient management of the incident and coordinated implementation of most effective measures to contain the risk in past serious food/feed safety incidents are mostly considered to have been achieved, crisis management arrangements were less effective for protecting consumers' trust in food/feed safety and ensuring a limited disruption of internal market and trade, especially in the 2011 E.coli outbreak. The evidence also suggests that the EC has played the role of coordinator in the management of past incidents, although the extent to which this was the case and the satisfaction of competent authorities and other stakeholders with the EC's role vary, depending on the specific coordination aspect and incident considered.

Commission Decision 2004/478/EC provides for two layers of action related to crisis management at EU level: one layer of action related to potential serious risk, where a crisis unit is not set up but adequate provisions are made to ensure effective management, and another layer of action implying the setting up of a crisis unit according to Article 56 of Regulation (EC) No 178/2002. Both layers are considered by competent authorities and other stakeholders responding to our survey to be (in principle) relevant and still appropriate for food/feed crisis management. However, the second layer of action was never used, i.e. a crisis unit has never been set up, in spite of the fact that major food/feed safety incidents with significant impacts on consumer health occurred during the evaluation period. Regarding the first layer of action, the evaluation concludes that it has not always been sufficient for the management of previous food/feed safety incidents; moreover, during more complex crisis situations like the E.coli outbreak, a clearer crisis management structure within the European Commission would have been considered beneficial by key stakeholders involved. Finally, there is strong support by competent authorities and other stakeholders for additional measures to be taken for crisis management at EU level. As a result, one of the key outcomes of this evaluation is that there is a need to review Commission Decision 2004/478/EC in order to adapt it more closely to the current needs.

Mirroring the results of the evaluation concerning the effectiveness of crisis management, the efficiency of EU crisis management has varied depending on the case studied. While overall, costs of crisis management are considered to be appropriate, in some cases, the economic impact of a food/feed safety incident may have been higher than the unavoidable minimum. The evaluation concludes that a way to safeguard an improved balance of costs and benefits of crisis management is to focus on actions related to contingency planning and emergency preparedness, including training and simulation exercises. While the EC made significant efforts following the E.coli outbreak – including a cross-border simulation exercise, drafting of SOPs, training courses and conducting fact-finding missions on emergency preparedness planning in Member States – the evaluation identifies additional suggestions for improving the balance of costs and benefits at EU and Member State levels.

Similarly to the RASFF, there is unanimous agreement that there is an added value in the crisis management and coordination by the EC compared with what could be achieved by Member States acting individually.

2.3. Key recommendations

Drawing on the conclusions presented above, the evaluation has developed recommendations that may serve to correct some of the shortcomings identified, or to enhance the added value of the RASFF and crisis management arrangements. A selection of key recommendations concerning the RASFF include the following:

Firstly, given the increasing relevance of the RASFF, it is recommended to **further develop the system** as a cornerstone of the EU food and feed safety system and to

improve the collection of additional data on notified risks. For example, currently a large number of notifications regarding a specific risk does not allow one to conclude that the risk is more relevant in terms of affected food and feed than other risks. A higher number of notifications could simply be caused by smaller lot sizes. If RASFF members provided the amount of affected food/feed consistently in notifications, distortions due to the number of notifications regarding a specific risk could be avoided. Also, if the sales channel were consistently provided regarding notified food and feed products that have reached the final consumer, it would be possible to identify trends by sales channel, and to take measures if an increasing number of notifications relate to one specific sales channel (such as e commerce).

Secondly, the **contribution of EFSA to the RASFF** provided for by Article 50(3) of Regulation (EC) No 178/2002 could be **better implemented** by providing the system with a mechanism allowing the ECCP to obtain a rapid (e.g. within 48 hours) feedback from EFSA when a risk is not well known or cannot be easily assessed using existing guidelines or precedents. Rapid feedback provided by EFSA could be based on in-house expertise and have the form of an initial review of available risk information by an EFSA scientist. While the role of EFSA is not to provide scientific assistance to the RASFF on a daily basis, its readiness to occasionally supplement notifications with scientific or technical information – particularly on less well-known risks – would likely serve to improve the risk-based operation of the RASFF. **Further guidance to assist NCPs with evaluation of risks**, similar to the document currently available concerning pesticide residues, should be developed jointly by the EFSA and the ECCP, as is already planned.

To improve the efficiency of the RASFF, the European Commission Contact Point 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, including a degree of decentralisation of the system by allowing Member States to communicate directly through the RASFF under certain specific conditions. Future developments in this direction would require amending the current legislative framework and adapting the architecture of the iRASFF system accordingly. In addition, **upgrading the iRASFF application** to centralise information from all RASFF notifications into a single IT system and thereby replacing RASFF Window would increase the efficiency of the operation, as two parallel database systems would no longer have to be maintained by the ECCP for RASFF. Efficiency could also be improved by developing **linkages between information systems and further reducing overlaps**, e.g. between RASFF and TRACES. In the future, the transmission of information on non-compliances which are not directly related to risk containment through the AAC system, to reduce the quantity of information exchanged through the RASFF, could also be considered. In this case, a direct link between the AAC and the RASFF should also be envisaged.

Finally, given the effectiveness of the RASFF as a platform for information exchange between member countries during previous serious food/feed safety incidents, the **RASFF's role in crisis management** is central and should **be recognised**. Relevant practices should be reviewed and formalised. This includes, for example, the transmission of daily updates on serious food/feed safety incidents by the ECCP, or the compilation of a short incident report at the closure of the incident, to summarise key facts such as the amount of food/feed affected, the impact in terms of consumer safety, the measures taken and their results.

A number of recommendations have also been developed with relation to crisis management procedures. Results of this evaluation suggest that the current legal framework is less functional for addressing more complex crisis situations such as the E.coli outbreak in 2011. **Commission Decision 2004/478/EC** should therefore **be reviewed and updated**. Issues that this review could address include: a) the extent to which the existing workflow at DG SANTE could be gradually reinforced when serious food/feed safety incidents have to be managed, preferably through a step-wise

escalation which allows additional (staff and technical) resources to be dedicated progressively as an incident develops; b) the effective linking of food/feed safety and public health emergency procedures at EU level in case serious food/feed safety incidents, mainly foodborne diseases, affect public health; c) the use of the term 'crisis unit' – a more neutral term such as 'task force' could reduce possible public concerns in case additional resources have to be assigned to incident management under a step-wise escalation approach; d) the role of the network of crisis coordinators. It is recommended that the revised Decision (and, if applicable, related SOPs) should be short, unambiguous and build to the extent possible on procedures that have proven to work well during previous crisis, and on best practices used in crisis management at Member State level. In addition, it is recommended to implement measures/procedures at local, regional, national and union level to **safeguard clear and effective communication** during serious food/feed safety incidents.

Concerning crisis management arrangements in the Member States, it is recommended that the FVO continues its **review of contingency plans/procedures** for serious food/feed safety incidents at the national level, and that the European Commission (with the involvement of affected Member States) conducts dedicated evaluations of crisis management procedures after a serious food/feed safety incident has been closed, to identify possible deficiencies of arrangements or measures taken, and lessons learnt (as has been the case after the E.coli outbreak). It is also recommended that Member States themselves review their contingency planning for serious food/feed safety incidents in regular intervals, and specifically after a serious food/feed incident in their country has been closed. While approaches for contingency planning at Member State level currently differ significantly, FVO reports on contingency planning and reports of Member States working groups, including of the Heads of European Food Safety Agencies, could provide a basis for **harmonisation of approaches and identification of best practices**.

Finally, it is recommended to continue and reinforce EU measures to improve crisis management procedures and crisis preparedness as well as to test them on a regular basis during **EU crisis simulation exercises**, which should at least involve key contact points in Member States, both for handling crisis management measures and communications. It is also recommended that Member States organise complementary crisis simulation exercises and training courses. These should take place on a regular basis and include, where possible, multiple sectors (such as health, food safety), different levels of government (such as national and regional) and neighbouring countries, where feasible.

3. SYNTHÈSE

Dans le cadre de son programme pour une réglementation affûtée et performante (REFIT), la Commission européenne (CE) a désigné la chaîne alimentaire comme projet pilote pour un bilan de qualité, la législation alimentaire générale (Règlement (CE) n° 178/2002) étant identifiée comme un candidat clé à soumettre à une évaluation REFIT. En 2014, la CE a lancé une évaluation des articles 50-57 du règlement, lesquels incluent les dispositions relatives au Système d'alerte rapide pour les denrées alimentaires et les aliments pour animaux (RASFF), aux mesures d'urgence et à la gestion des crises. L'évaluation a été réalisée par Civic Consulting, du Consortium d'évaluation de la chaîne alimentaire (Food Chain Evaluation Consortium).³

De par sa conception remontant à 1979, le Système d'alerte rapide pour les denrées alimentaires et les aliments pour animaux (RASFF) constitue l'un des quelques éléments du cadre de sécurité des aliments européen précédant le Livre blanc sur la sécurité alimentaire de 2000 toujours en place à l'heure actuelle. Composant clé de ce cadre, le Système RASFF offre un système d'échange rapide d'informations entre ses membres en cas de risques directs ou indirects pour la santé humaine dérivés d'aliments destinés à l'alimentation humaine et animale, afin de permettre autant que possible une réponse coordonnée de ses membres face à des menaces de sécurité sanitaire dans ce domaine. Dans son fonctionnement actuel, le Système RASFF est composé de plusieurs outils ou plateformes TI fournissant un accès aux notifications adaptées aux différents groupes d'acteurs. Au cours de ces développements, il s'est imposé comme un élément essentiel du système européen de sécurité des aliments, offrant un réseau au niveau européen pour la communication sur les risques liés aux aliments destinés à l'alimentation humaine et animale ainsi qu'une source précieuse d'informations pour les autorités compétentes et exploitants. Les 32 membres du réseau ont transmis plus de 3100 notifications initiales en 2014, soit une moyenne de plus de 8 notifications initiales par jour.⁴ Celles-ci ont donné lieu à 5910 notifications de suivi, et ce qui importe sans doute plus, les informations transmises entre les utilisateurs du Système RASFF ont permis soit le retrait de nombreux produits présentant un risque, soit l'interdiction d'accès de ceux-ci sur le marché de l'Union européenne (UE).

Le Système RASFF joue donc un rôle central en matière de prévention et de gestion des risques détectés pour les aliments destinés à l'alimentation humaine et animale, permettant aux États membres de prendre des mesures au niveau national contrant ces risques, conformément au principe de subsidiarité. Lorsque les actions nationales entreprises par des États membres agissant à titre individuel ne suffisent pas à maîtriser un risque, il peut toutefois s'avérer nécessaire de mettre en place des mesures et procédures supplémentaires. Les articles 53 à 57 du Règlement (CE) n° 178/2002 énoncent et définissent les outils à disposition de la Commission européenne pour la gestion coordonnée des incidents compromettant la sécurité des aliments destinés à l'alimentation humaine et animale touchant l'UE, incluant des mesures d'urgence, l'élaboration d'un plan général pour la gestion des crises, et la mise en place d'une cellule de crise.

L'évaluation du Système RASFF et des procédures de gestion des crises avait pour objectif d'évaluer si le cadre réglementaire établi par les articles 50 à 57 du Règlement (CE) n° 178/2002 est efficace, s'il fonctionne bien, et s'il offre une valeur ajoutée à ses acteurs. Parmi les aspects spécifiques du Système RASFF examinés, on

³ Une étude complémentaire concernant l'évaluation du Règlement (CE) n° 178/2002 ("législation alimentaire générale"), ne considérant pas les articles 50 à 57, a été menée par Agra CEAS Consulting du Consortium d'évaluation de la chaîne alimentaire.

⁴ Commission européenne, RASFF - pour des denrées alimentaires plus sûres : Système d'alerte rapide pour les denrées alimentaires et les aliments pour animaux Rapport annuel 2014, 2015.

trouve sa pertinence, sa cohérence, son champ d'application, sa base légale, et le rôle de la Commission européenne comme gestionnaire du système, mais également son fonctionnement axé sur les risques et le rôle de l'EFSA (Autorité européenne de sécurité des aliments), l'implication des États membres de l'UE, la participation des pays tiers et des organisations internationales, et les informations fournies par le Système RASFF aux acteurs, dont la transparence et la confidentialité du système. Les procédures de gestion des crises ont également été évaluées en ce qui concerne leur pertinence, le rôle de la Commission européenne, l'implication des États membres de l'UE, la participation des pays tiers et des organisations internationales.

Un ensemble d'outils méthodologiques a été utilisé pour répondre aux 52 questions d'évaluation reprises dans les termes de référence. Ces outils comprenaient une revue de la documentation, deux enquêtes d'autorités compétentes et d'autres acteurs, trois études de cas relatives à des incidents de sécurité des aliments graves passés, ainsi que des entrevues approfondies complémentaires. En outre, une analyse financière du Système RASFF et une analyse du flux d'informations généré par le biais du système ont été réalisées. Des données supplémentaires sur les coûts estimés des incidents ayant compromis la sécurité des aliments destinés à l'alimentation humaine et animale survenus dans la période de référence ont été recueillies afin d'étoffer la discussion quant à l'efficacité des procédures de gestion des crises et de compléter les études de cas. Les preuves primaires et secondaires recueillies à l'aide de ces outils méthodologiques constituent la base des réponses aux questions d'évaluation fournies dans le présent rapport. Cette évaluation présente un certain nombre de conclusions clés sur le Système RASFF et les mécanismes de gestion des crises au sein de l'UE, formulant le cas échéant des recommandations d'amélioration.

3.1. Système RASFF

La principale conclusion de l'évaluation est que le Système RASFF a fonctionné dans l'ensemble efficacement sur la totalité de la période d'évaluation du point de vue des objectifs à atteindre. Le système est très apprécié de ses destinataires (les points de contact nationaux (NCP) du Système RASFF dans les États membres), et une grande quantité d'informations pouvant donner lieu à une action sont transmises par le biais du système, ce qui permet aux États membres et pays partenaires internationaux de réagir rapidement face aux risques détectés dans les aliments destinés à l'alimentation humaine et animale. Dans une certaine mesure, l'efficacité du Système RASFF peut être attribuée au rôle de la Commission européenne en tant que gestionnaire du réseau. Cette évaluation conclut que la CE a largement respecté ses obligations dérivant de la base légale du Système RASFF durant la période d'évaluation en ce qui concerne les aspects organisationnels, mais surtout pour la vérification et la transmission des notifications. Sa contribution à la coordination des membres du Système RASFF et le développement de bonnes pratiques de notifications communes sont également considérés comme très positifs par les points de contact nationaux. Les groupes de travail des NCP du RASFF ont contribué au meilleur fonctionnement du Système RASFF, et les modes opératoires normalisés (SOP) sur le fonctionnement du réseau sont considérés comme utiles, clairs et conformes aux besoins et attentes.

Bien que la législation assigne le rôle de coordinateur à la Commission européenne, les États membres ont eux aussi un rôle crucial à jouer pour assurer le fonctionnement efficace du Système RASFF en tant que membres du réseau et principaux bénéficiaires. Si certaines obligations clés relatives au Système RASFF sont directement dérivées de la législation, la participation active des membres dépend d'un certain nombre d'autres facteurs et varie significativement d'un pays à l'autre. D'après leurs pairs, leur auto-évaluation ainsi que l'évaluation du point de contact CE, les États membres du Système RASFF respectent largement leurs obligations dans le cadre du Système RASFF conformément aux exigences du Règlement (CE) n° 178/2002 et du Règlement (UE) de la Commission n° 16/2011. Les preuves recueillies dans les études de cas de trois incidents graves compromettant la sécurité

des aliments destinés à l'alimentation humaine et animale confirment largement cette évaluation. Par ailleurs, la mesure dans laquelle les États membres soumettent des notifications par le biais du Système RASFF varie significativement, allant de zéro à plus de cinq cents notifications initiales dans l'année de référence 2013. Ces différences entre pays quant au nombre de notifications demeurent même après prise en considération de la taille de la population et de l'activité commerciale du pays auteur de la notification.

L'efficacité du Système RASFF dépend également du degré selon lequel son fonctionnement est axé sur les risques, c'est-à-dire de la mesure dans laquelle les notifications transmises par le biais du système reflètent de manière appropriée les risques pour les aliments destinés à l'alimentation humaine et animale impliqués, comme prévus par sa base légale. La mesure dans laquelle des notifications échangées par le biais du Système RASFF sont considérées comme *suffisamment* axées sur les risques varie parmi les groupes d'acteurs, deux-tiers des points de contact nationaux RASFF confirmant que ceci est bien le cas, tandis qu'une majorité quasiment similaire d'autres acteurs, principalement des exploitants de produits alimentaires et leurs organisations, sont en désaccord sur ce point. Toutefois, 62% de ces acteurs ont fourni une note positive pour la considération de la mesure dans laquelle le risque a été évalué de manière correcte dans le Système RASFF. Tandis que le point de contact de la Commission européenne (ECCP) contribue à l'harmonisation des approches en matière d'évaluation des risques, il reste certains facteurs pouvant potentiellement conduire à des différences quant à la manière d'évaluer les risques. Parmi ceux-ci, les membres du RASFF sont responsables de décider s'il existe ou non un risque concernant un aliment destiné à l'alimentation humaine et animale non conforme (et donc si le risque est tel qu'il requiert une notification au Système RASFF), ceci pouvant conduire dans certains cas à une "zone grise" d'évaluation des risques, si des membres du système arrivent à des conclusions différentes pour des circonstances similaires. De plus, les documents d'orientation détaillés qui pourraient contribuer à une évaluation plus harmonisée du risque dans l'ensemble des États membres ne sont disponibles que de manière limitée, par exemple dans le domaine des pesticides.

Néanmoins, depuis sa création en 1979, le Système RASFF a conservé un haut niveau de pertinence. La globalisation toujours croissante du commerce des aliments destinés à l'alimentation humaine et animale ainsi que la consolidation du marché unique européen réaffirment le besoin d'un mode efficace de transmission des informations sur les risques détectés et des mesures prises par les États membres individuels. Les objectifs poursuivis par le Système RASFF sont largement pris en compte pour répondre à ces besoins, certains objectifs supplémentaires potentiels ayant été identifiés, lesquels pourraient être rajoutés à l'avenir, tels que l'utilisation du Système RASFF comme outil d'analyse des tendances en matière de risques notifiés pour la sécurité des aliments destinés à l'alimentation humaine et animale et la reconnaissance de son rôle clé dans la gestion des crises. En outre, le Système RASFF est en grande partie en accord avec un certain nombre d'autres systèmes de notification, tant au niveau de l'UE que de son principal partenaire international, le Réseau international des autorités de sécurité sanitaire des aliments (INFOSAN). Dans le cas de chevauchements, certaines mesures ont été prévues, voire ont déjà été prises, afin de minimiser la duplication des tâches.

En termes d'efficacité, les coûts du Système RASFF s'avèrent raisonnables, bien qu'ils ne puissent être comparés directement avec les avantages du système. Ceci est dû au fait que l'échange d'informations par le biais du système ne constitue pas un avantage en soi, mais contribue plutôt à l'obtention d'avantages issus de la prise de mesures reposant sur des notifications RASFF. Toutefois, la comparaison entre les coûts totaux et la quantité d'informations transmises donne une indication sur l'efficacité du Système RASFF : pour l'année de référence 2013, les coûts s'élevaient à 690 EUR par information transmise aux membres RASFF. Si l'on considère que la plupart des notifications concernent plusieurs pays, le coût par pays notifié s'avère donc

sensiblement inférieur. Il serait néanmoins possible d'améliorer cette efficacité à l'avenir.

Enfin, il existe un consensus quasi-unanime selon lequel le Système RASFF offre une réelle valeur ajoutée, comparé à ce qui serait obtenu sans lui si les États membres agissaient au niveau national. La présente conclusion est également confirmée par les résultats liés aux critères précédents, en particulier ceux signalant la pertinence et l'efficacité élevées du système.

3.2. Procédures de gestion des crises

Un élément clé des procédures de gestion des crises dans l'UE concerne la possibilité d'adopter des mesures d'urgence en réaction à des aliments destinés à l'alimentation humaine ou animale provenant de l'Union européenne ou importés d'un pays tiers constituant probablement un risque grave pour la santé humaine, la santé animale ou l'environnement. Un grand nombre d'incidents compromettant la sécurité des aliments destinés à l'alimentation humaine et animale ont pu être maîtrisés et gérés par la Commission européenne sur cette base. Des mesures d'urgence ont également été utilisées comme instruments pour la gestion de deux des trois incidents graves de sécurité alimentaire passés examinés en détail dans cette évaluation : la crise de mélamine et l'épidémie de E. coli. Pour ces deux incidents, les mesures sont considérées comme ayant été efficaces, bien que dans le cas de l'épidémie d'E. coli, la mesure d'urgence ait été adoptée vers la fin de la crise après identification de l'origine, ne venant donc que consolider les mesures préventives prises.

Tandis que les mesures d'urgence adoptées au niveau européen sont généralement considérées comme ayant été efficaces et réussies pour ce qui est d'apporter une réponse cohérente aux incidents graves passés compromettant la sécurité des aliments destinés à l'alimentation humaine et animale par les États membres, les résultats de l'évaluation suggèrent que l'efficacité d'ensemble de la gestion des crises a différé au cours de la période de référence, en fonction de l'incident et des objectifs considérés. Notamment, tandis que les objectifs en matière de protection de la santé des consommateurs, de gestion efficiente de l'incident et de mise en œuvre coordonnée des mesures les plus efficaces pour maîtriser le risque dans les incidents graves passés compromettant la sécurité des aliments destinés à l'alimentation humaine et animale sont principalement considérés comme en grande partie atteints, les mécanismes de gestion des crises sont eux moins efficaces quand il s'agit, d'une part, de préserver la confiance des consommateurs envers la sécurité des aliments destinés à l'alimentation humaine et animale et, d'autre part, d'assurer une interruption limitée du marché et du commerce intérieur, notamment lors de l'épidémie d'E. coli de 2011. Les preuves suggèrent également que la CE a joué le rôle de coordinateur pour la gestion des incidents passés, bien que la mesure dans laquelle cela a été le cas et la satisfaction des autorités compétentes et autres acteurs quant au rôle de la CE varient, en fonction de l'aspect de coordination et de l'incident spécifiques pris en considération.

La décision 2004/478/CE de la Commission prévoit deux couches d'action liée à la gestion des crises au niveau européen : une couche d'action liée au risque grave potentiel, où il n'y a pas de mise en place de cellule de crise mais des dispositions appropriées prises pour assurer une gestion efficace, et une autre couche d'action impliquant la mise en place d'une cellule de crise conformément à l'article 56 du Règlement (CE) n° 178/2002. Les autorités compétentes et autres acteurs ayant répondu à notre enquête considèrent (en principe) ces deux couches comme pertinentes et encore appropriées pour la gestion des crises des aliments destinés à l'alimentation humaine ou animale. Toutefois, la seconde couche d'action n'a jamais été utilisée, à savoir qu'aucune cellule de crise n'a jamais été mise en place, malgré la survenue d'incidents majeurs compromettant la sécurité des aliments destinés à l'alimentation humaine et animale ayant des retombées significatives sur la santé des

consommateurs durant la période d'évaluation. Concernant la première couche d'action, l'évaluation conclut que celle-ci n'a pas toujours été suffisante pour la gestion des incidents passés compromettant la sécurité des aliments destinés à l'alimentation humaine et animale ; en outre, durant les situations de crise plus complexes telles que l'épidémie d'E. coli, une structure de gestion des crises plus claire au sein de la Commission européenne aurait été considérée comme un atout par les acteurs clés impliqués. Enfin, les autorités compétentes et autres acteurs sont très favorables à la prise de mesures supplémentaires pour une gestion des crises au niveau européen. Par conséquent, un des résultats clés de cette évaluation est qu'il existe un besoin de réexaminer la décision 2004/478/CE de la Commission et de mieux l'adapter aux besoins actuels.

Reflétant les résultats de l'évaluation concernant l'efficacité de la gestion des crises, l'efficacité de la gestion des crises de l'UE a varié en fonction du cas étudié. Tandis que les coûts liés à la gestion des crises sont considérés dans l'ensemble comme appropriés, l'impact économique d'un incident compromettant la sécurité des aliments destinés à l'alimentation humaine et animale peut, dans certains cas, être bien plus élevé que le minimum inévitable. L'évaluation conclut que pour sauvegarder un équilibre amélioré entre coûts et avantages en matière de gestion des crises, mieux vaut se concentrer sur les actions liées à la planification des mesures d'urgence, notamment la formation et les exercices de simulation. Tandis que la CE a fait des efforts significatifs suite à l'épidémie d'E. coli (dont un exercice de simulation transfrontalier, la rédaction de SOP, des séances de formation et la réalisation de missions d'étude sur la planification des mesures d'urgence dans les États membres), l'évaluation identifie des suggestions supplémentaires destinées à améliorer l'équilibre entre coûts et avantages au niveau de l'UE et des États membres.

Comme pour le Système RASFF, le fait que la gestion des crises et la coordination par la CE constitue une valeur ajoutée comparé à ce que l'on obtiendrait par une action individuelle des États membres fait consensus.

3.3. Recommandations clés

S'appuyant sur les conclusions présentées plus haut, l'évaluation a formulé des recommandations qui pourraient servir à corriger certains des insuffisances identifiés, ou à renforcer la valeur ajoutée du Système RASFF ainsi que des mécanismes de gestion des crises. Parmi les recommandations clés concernant le Système RASFF, on peut sélectionner les points repris ci-après.

Tout d'abord, étant donné la pertinence croissante du Système RASFF, il est recommandé de **développer davantage ce système** comme clé de voûte du système de sécurité des aliments destinés à l'alimentation humaine et animale pour l'UE et d'améliorer la collecte d'informations supplémentaires sur les risques notifiés. Par exemple, à l'heure actuelle, un grand nombre de notifications concernant un risque spécifique ne permettent pas de conclure si ce risque est plus pertinent en termes d'aliments destinés à l'alimentation humaine et animale affectés que d'autres risques. Un plus grand nombre de notifications pourraient simplement être provoquées par des tailles de lot plus petites. Si les membres du RASFF indiquaient de manière systématique la quantité d'aliments destinés à l'alimentation humaine et animale affectés dans les notifications, il serait possible d'éviter les distorsions liées au nombre de notifications concernant un risque spécifique. De même, si les canaux de distribution étaient indiqués de manière systématique concernant les produits alimentaires notifiés destinés à l'alimentation humaine et animale ayant atteint le consommateur final, il serait possible d'identifier des tendances par canal de distribution, et de prendre des mesures si un nombre croissant de notifications concernaient un canal spécifique (comme par exemple le commerce électronique).

Ensuite, la **contribution de l'Autorité européenne de sécurité des aliments (EFSA) au Système RASFF**, prévue par l'article 50(3) du Règlement (CE) n° 178/2002 pourrait bénéficier d'une **meilleure mise en œuvre** si l'on dotait le système d'un mécanisme permettant au ECCP d'obtenir un retour rapide (par exemple dans les 48 h) émanant de l'EFSA lorsqu'un risque n'est pas bien connu ou ne peut pas être évalué facilement à l'aide des lignes directrices existantes ou de la jurisprudence. Un retour rapide fourni par l'EFSA pourrait reposer sur une expertise en interne et se présenter sous la forme d'un examen initial des informations de risques disponibles par un scientifique de l'EFSA. Bien que le rôle de l'EFSA ne soit pas de fournir une assistance scientifique au Système RASFF sur une base quotidienne, sa capacité à compléter occasionnellement des notifications par des informations scientifiques ou techniques, notamment sur des risques moins bien connus, contribuerait probablement à améliorer le fonctionnement axé sur les risques du Système RASFF. Un **guide supplémentaire assistant les NCP dans l'évaluation des risques**, similaire au document actuellement disponible concernant les résidus de pesticides, devrait être développé de manière conjointe par l'EFSA et l'ECCP, comme cela a déjà été planifié.

Afin d'améliorer l'efficacité du Système RASFF, le point de contact de la Commission européenne devrait **concentrer ses ressources sur les zones prioritaires** (notamment la vérification et la transmission des notifications d'alerte et leur suivi). Un groupe de travail rassemblant ECCP et NCP pourrait prendre en compte les solutions possibles, dont un degré de décentralisation du système en permettant aux États membres de communiquer directement par le biais du Système RASFF dans certaines conditions spécifiques. Des progrès futurs dans cette direction nécessiteraient l'amendement du cadre législatif actuel et, de manière correspondante, l'adaptation de l'architecture du système iRASFF. En outre, la **mise à niveau de l'application iRASFF** afin de centraliser les informations de toutes les notifications RASFF en un système informatique unique, remplaçant de ce fait la fenêtre RASFF, augmenterait l'efficacité d'exploitation, la maintenance des deux systèmes de base de données parallèles ne devant plus être effectuée par l'ECCP pour le Système RASFF. L'efficacité pourrait également être améliorée en développant des **couplages entre les systèmes informatiques et en réduisant encore les chevauchements**, par exemple entre le Système RASFF et le Système TRACES. À l'avenir, la transmission d'informations sur les non-conformités qui ne sont pas directement liées à la maîtrise des risques par le biais du système d'assistance administrative et de coopération (AAC) pourrait également être prise en considération, afin de réduire la quantité d'informations échangées par le biais du système RASFF. Dans ce cas, une liaison directe entre l'AAC et le Système RASFF pourrait également être envisagée.

Enfin, étant donné l'efficacité du Système RASFF en tant que plateforme d'échange d'informations entre les États membres durant les précédents incidents graves compromettant la sécurité des aliments destinés à l'alimentation humaine et animale, **le rôle du Système RASFF dans la gestion des crises s'avère central et devrait être reconnu**. Les pratiques pertinentes devraient être réexaminées et formalisées. Ceci comprend par exemple la transmission de mises à jour quotidiennes concernant les incidents compromettant la sécurité des aliments destinés à l'alimentation humaine et animale par l'ECCP, ou la compilation d'un court rapport d'incident à la clôture de ceux-ci, afin de résumer les éléments clés, tels que la quantité d'aliments destinés à l'alimentation humaine et animale affectée, l'impact en termes de sécurité des consommateurs, les mesures prises et leurs résultats.

Un certain nombre de recommandations ont également été préparées en ce qui concerne les procédures de gestion des crises. Les résultats de cette évaluation suggèrent que le cadre légal actuel est moins fonctionnel pour traiter des situations de crise plus complexes telles que l'épidémie de E. coli de 2011. La **décision 2004/478/CE de la Commission** devrait par conséquent **être réexaminée et actualisée**. Les points sur lesquels ce réexamen pourraient porter sont les suivants :

a) la mesure dans laquelle la gestion du travail actuelle au niveau de la DG SANTE pourrait être graduellement renforcée lorsque des incidents graves compromettant la sécurité des aliments destinés à l'alimentation humaine et animale doivent être gérés, de préférence suivant un schéma d'intervention par paliers permettant d'assigner des ressources supplémentaires (en personnel et moyens techniques) progressivement suivant l'évolution de l'incident ; b) le couplage efficace entre la sécurité des aliments destinés à l'alimentation humaine et animale et les procédures d'urgence de santé publique au niveau européen dans le cas d'incidents graves compromettant la sécurité des aliments destinés à l'alimentation humaine et animale, principalement les intoxications alimentaires, a une influence sur la santé publique ; c) Utilisation du terme "cellule de crise" : un terme plus neutre tel que "comité de réflexion" pourrait réduire les éventuelles inquiétudes du public en cas d'attribution de ressources supplémentaires pour la gestion d'incidents dans le cadre d'une stratégie d'intervention par paliers, et d) le rôle du réseau de coordinateurs de crise. Il est recommandé que la décision révisée (ainsi que, le cas échéant, les SOP connexes) demeure courte, non ambiguë et qu'elle s'appuie dans la mesure du possible sur des procédures ayant fait leurs preuves lors de crises précédentes et sur les meilleures pratiques utilisées en matière de gestion des crises au niveau des États membres. Il est en outre recommandé de mettre en place des mesures/procédures aux niveaux local, régional, national et européen afin de **sauvegarder une communication claire et efficace** lors d'incidents graves compromettant la sécurité des aliments destinés à l'alimentation humaine et animale.

En ce qui concerne les mécanismes de gestion des crises au sein des États membres, il est recommandé que l'Office alimentaire et vétérinaire (OAV) poursuive son réexamen des procédures/planifications des mesures d'urgence pour les incidents graves compromettant la sécurité des aliments destinés à l'alimentation humaine et animale au niveau national, et que la Commission européenne (en impliquant les États membres touchés) réalise des évaluations spécifiques des procédures de gestion des crises après clôture d'un tel incident grave, afin d'identifier les carences éventuelles concernant les mécanismes ou mesures appliqués et d'en tirer leçons (comme cela a été le cas après l'épidémie d'E. coli). Il est également recommandé que les États membres réexaminent eux-mêmes leur planification des mesures d'urgence en cas d'incident grave compromettant la sécurité des aliments destinés à l'alimentation humaine et animale à intervalles réguliers, et spécifiquement après clôture d'un incident grave concernant les aliments destinés à l'alimentation humaine ou animale dans leur pays. Tandis que les approches en matière de planification des mesures d'urgence sont actuellement significativement différentes au niveau des États membres, l'OAV fait mention d'une planification des mesures d'urgence et de l'existence de groupes de travail d'États membres, impliquant des responsables à la tête d'autorités de sécurité des aliments nationales, qui pourraient fournir une base pour **l'harmonisation des approches et l'identification des meilleures pratiques**.

Enfin, il est recommandé de continuer à développer et à renforcer des mesures de l'UE afin d'améliorer les procédures de gestion et de planification des crises, ainsi que de les tester de manière régulière lors **d'exercices de simulation de crise à l'échelle européenne**, lesquels devraient au moins impliquer les points de contact clés dans les États membres, tant pour le traitement des mesures de gestion des crises que pour la communication. Il est également recommandé que les États membres organisent des exercices de simulation de crise complémentaires ainsi que des formations à ce sujet. Ceci pourrait avoir lieu sur une base régulière et comprendre dans la mesure du possible divers secteurs (tels que la santé, la sécurité des aliments), différents niveaux de gouvernements (tels que national et régional) et des pays voisins lorsque cela est réalisable.

4. ZUSAMMENFASSUNG

Im Rahmen ihres Programms zur Gewährleistung der Effizienz und Leistungsfähigkeit der Rechtsetzung (REFIT) hat die Europäische Kommission die Lebensmittelkette als Pilotprojekt einer diesbezüglichen Überprüfung ausgewählt und das Allgemeine Lebensmittelrecht (Verordnung (EG) Nr. 178/2002) zum Schwerpunkt einer REFIT-Evaluierung gemacht. 2014 brachte die Kommission eine Evaluierung der Artikel 50 bis 57 der genannten Verordnung auf den Weg, die Regelungen für das Schnellwarnsystem für Lebensmittel und Futtermittel (RASFF), für Sofortmaßnahmen in Notfällen und für das Krisenmanagement beinhalten. Durchgeführt hat diese Evaluierung Civic Consulting vom Konsortium zur Evaluierung der Lebensmittelkette (Food Chain Evaluation Consortium).⁵

Das bereits 1979 konzipierte Schnellwarnsystem für Lebensmittel und Futtermittel (RASFF) ist eines der wenigen Elemente des Europäischen Rahmenwerk für Lebensmittelsicherheit, das älter ist als das im Jahr 2000 veröffentlichte Weißbuch zur Lebensmittelsicherheit und heute noch immer Bestand hat. Das RASFF ist ein wesentlicher Bestandteil dieses Rahmens; bei unmittelbaren oder mittelbaren Risiken für die menschliche Gesundheit, die von Lebensmitteln oder Futtermitteln ausgehen, ermöglicht dieses System den zügigen Austausch von Informationen zwischen den RASFF-Mitgliedern mit dem Ziel, angesichts der Gefährdung der Lebens- und Futtermittelsicherheit eine bestmöglich koordinierte Reaktion der Mitglieder zu gewährleisten. In seiner derzeitigen Form stellt das RASFF verschiedene IT-Instrumente bzw. -Plattformen bereit, die den Zugriff auf Meldungen speziellen Zuschnitts für unterschiedliche Akteure erlauben. Auf dieser Grundlage entwickelte sich das RASFF zu einer wesentlichen Komponente des Europäischen Systems für Lebensmittelsicherheit und bietet ein EU-weites Netz für die Kommunikation über Risiken im Zusammenhang mit Lebensmitteln und Futtermitteln sowie eine wertvolle Informationsquelle für die zuständigen Behörden und die gewerbliche Wirtschaft. 2014 übermittelten die 32 Netzwerkmitglieder über 3100 Originalmeldungen; dies entspricht im Durchschnitt mehr als acht Originalmeldungen pro Tag.⁶ Diese gaben Anlass zu 5910 Folgemeldungen. Vielleicht noch entscheidender ist, dass es anhand der zwischen den RASFF-Nutzern ausgetauschten Informationen möglich wurde, zahlreiche Produkte, die ein Risiko darstellen, vom Markt zu nehmen bzw. diesen die Marktzulassung in der EU zu verwehren.

Das RASFF spielt also eine wichtige Rolle beim Schutz vor und bei der Bewältigung von Risiken durch Lebens- und Futtermittel und versetzt die Mitgliedstaaten in Übereinstimmung mit dem Subsidiaritätsprinzip in die Lage, einzelstaatliche Maßnahmen zu ergreifen, um diesen Risiken zu begegnen. Ist eine Risikobegrenzung anhand einzelstaatlicher Maßnahmen der allein handelnden Mitgliedstaaten nicht möglich, so kann sich die Einführung zusätzlicher Maßnahmen und Verfahren als erforderlich erweisen. Artikel 50 bis 57 der Verordnung (EG) Nr. 178/2002 umreißen und definieren die Instrumente, auf die sich die Europäische Kommission für ein koordiniertes Vorgehen zur Bewältigung von die EU betreffenden Vorfällen im Zusammenhang mit der Lebens- und Futtermittelsicherheit stützen kann; dies umfasst Sofortmaßnahmen in Notfällen, die Erstellung eines allgemeinen Plans für das Krisenmanagement sowie die Einrichtung eines Krisenstabes.

Zweck der Evaluierung der im Rahmen des RASFF und des Krisenmanagements zur Anwendung kommenden Verfahren war es, untersuchen, ob das durch die Artikel 50

⁵ Agra CEAS Consulting, ebenfalls Mitglied des Konsortiums zur Evaluierung der Lebensmittelkette (FCDC), führte eine ergänzende Studie zur Evaluierung der Verordnung (EG) Nr. 178/2002 (der "Lebensmittelbasisverordnung") durch, bei der die Artikel 50 bis 57 allerdings ausgespart wurden.

⁶ Europäische Kommission, RASFF: "for Safer Food: The Rapid Alert System for Food and Feed 2014 Annual Report" (Für sicherere Lebensmittel: Jahresbericht 2014 des Schnellwarnsystems für Lebens- und Futtermittel), 2015.

bis 57 der Verordnung (EG) Nr. 178/2002 geschaffene Regelwerk seine Funktion wirksam und effizient erfüllt und seinen Stakeholdern einen zusätzlichen Nutzen bietet. Besonderes Augenmerk galt bei der Evaluierung des RASFF der Relevanz, der Kohärenz, der Bandbreite und den Rechtsgrundlagen des Systems, der Rolle der Europäischen Kommission bei der Verwaltung und Steuerung des Systems, den Risiken, auf denen die Arbeitsweise des Systems beruht, und der Rolle der EFSA, der Einbeziehung der EU-Mitgliedstaaten und der Beteiligung von Drittländern und internationalen Organisationen sowie den Informationen, die das RASFF für die verschiedenen Akteure bereitstellt, Transparenz und Vertraulichkeit des Systems eingeschlossen. Auch die Krisenmanagementverfahren wurden im Hinblick auf ihre Relevanz, die Rolle der Europäischen Kommission, die Einbeziehung der EU-Mitgliedstaaten und die Beteiligung von Drittländern und internationalen Organisationen untersucht.

Zur Beantwortung der 52 in der Aufgabenbeschreibung aufgeführten Evaluierungsfragen kam eine ganze Reihe von methodischen Instrumenten zum Einsatz. Dies umfasste eine Auswertung verfügbarer Literatur, zwei Umfragen bei zuständigen Behörden und anderen Akteuren, drei Fallstudien über vergangene ernste Vorfälle im Zusammenhang mit Lebensmittelsicherheit sowie ergänzende vertiefende Interviews. Zudem wurden die finanziellen Modalitäten des RASFF sowie der im Rahmen des Systems generierte Informationsfluss eingehend untersucht. Zwecks fundierter Erörterung der Effizienz von Krisenmanagementverfahren sowie zur Ergänzung der Fallstudien wurden zusätzliche Daten zu den geschätzten Kosten der Vorfälle im Zusammenhang mit der Lebens- und Futtermittelsicherheit erhoben, die sich im Bezugszeitraum ereignet hatten. Die anhand dieses methodischen Instrumentariums zusammengetragenen wissenschaftlichen Primär- und Sekundärdaten bildeten dann die Grundlage für die in diesem Bericht formulierten Antworten auf die Evaluierungsfragen. Die vorliegende Evaluierung enthält eine Reihe grundlegender Schlussfolgerungen zu den Vorkehrungen im Zusammenhang mit dem RASFF und dem Krisenmanagement in der EU und – wo dies nötig erscheint – Empfehlungen für mögliche Verbesserungen.

4.1. RASFF

Insgesamt gesehen belegt die Evaluierung, dass das RASFF im Evaluierungszeitraum seine Aufgaben nach Maßgabe der Zielsetzungen wirksam erfüllt hat. Das System wird von den Adressaten (den Nationalen RASFF-Kontaktstellen in den Mitgliedstaaten) sehr geschätzt und eine Vielzahl sachdienlicher und verwertbarer Informationen wird durch das System übermittelt, anhand derer die Mitgliedstaaten und internationale Partnerländer zügig auf Risiken reagieren können, die bei Lebensmitteln und Futtermitteln festgestellt wurden. Teilweise ist die Effektivität des RASFF der Tatsache zuzuschreiben, dass das Netzwerk von der Europäischen Kommission verwaltet wird. Wie die Evaluierung zeigt, hat die Europäische Kommission, was die organisatorischen Aspekte und insbesondere die Überprüfung und Übermittlung von Meldungen betrifft, die ihr aus der Rechtsgrundlage des RASFF erwachsenden Aufgaben im Evaluierungszeitraum weitestgehend erfüllt. Ihr Beitrag zur Koordinierung der RASFF-Mitglieder und zur Erarbeitung bewährter und gemeinsamer Verfahrensweisen bei der Meldung wird auch von den Nationalen Kontaktstellen höchst positiv bewertet. Die Arbeitsgruppen der Nationalen RASFF-Kontaktstellen trugen zu einer verbesserten Arbeitsweise des RASFF bei und die Standardarbeitsanweisungen zur Funktion des Netzwerks werden als hilfreich, nachvollziehbar und bedarfsgerecht betrachtet.

Gemäß den Rechtsvorschriften kommt zwar der Europäischen Kommission die Funktion des Koordinators zu, aber auch die Mitgliedsstaaten sind als Mitglieder des Netzwerks und als dessen vorrangige Nutznießer entscheidend für ein effektives Funktionieren des RASFF verantwortlich. Einige entscheidende Verpflichtungen in Bezug auf das RASFF leiten sich unmittelbar aus den Rechtsvorschriften ab, aber die aktive Beteiligung der Mitglieder hängt auch von verschiedenen anderen Faktoren ab

und ist in den einzelnen Ländern sehr unterschiedlich. Nach den Angaben ihrer Partner, laut Selbstbewertung und laut Einschätzung der Kontaktstelle der Europäischen Kommission erfüllen die RASFF-Mitgliedstaaten die ihnen gemäß Verordnung (EG) Nr. 178/2002 sowie gemäß Verordnung (EU) Nr. 16/2011 der Kommission im Rahmen des RASFF obliegenden Verpflichtungen weitestgehend. Diese Einschätzung wird durch die Informationen untermauert, die im Rahmen von Fallstudien zu drei ernsten Vorfällen im Zusammenhang mit Lebens- und Futtermittelsicherheit erhoben wurden. Betrachtet man den Umfang, in dem das RASFF zur Übermittlung von Meldungen genutzt wird, dann zeigen sich jedoch extreme Unterschiede zwischen den Mitgliedstaaten: Im Bezugsjahr 2013 wurde in einem Fall nicht eine einzige Originalmeldung übermittelt, in einem anderen Fall dagegen waren es mehr als 500 Originalmeldungen. Selbst wenn Bevölkerungszahl und Handelsaktivität des meldenden Landes berücksichtigt werden, zeigen sich bezüglich der Meldezahlen weiterhin Unterschiede zwischen den Ländern.

Die Effektivität des RASFF hängt auch davon ab, in welchem Maß seine Tätigkeit risikobasiert ist, d.h. inwieweit die durch das System übermittelten Meldungen den betreffenden Risiken für Lebensmittel und Futtermittel wie in der Rechtsgrundlage des Systems vorgesehen angemessen Rechnung tragen. Bei den verschiedenen Akteuren gehen die Auffassungen darüber auseinander, inwieweit die über das RASFF ausgetauschten Meldungen *ausreichend* risikobasiert sind: Während zwei Drittel der Nationalen RASFF-Kontaktstellen feststellen, dies sei der Fall, vertritt eine nahezu vergleichbare Mehrheit der Akteure – vor allem Unternehmen aus der Lebensmittelindustrie und deren Organisationen – eine gegenteilige Auffassung. Jedoch äußerten sich 62% dieser Akteure positiv in Bezug auf die Frage, inwieweit ein Risiko im Rahmen des RASFF *korrekt* bewertet wird. Zwar trägt die Kontaktstelle der Europäischen Kommission zur Harmonisierung der Risikobewertungsansätze bei, es gibt jedoch nach wie vor Faktoren, die potenziell zu Unterschieden bei der Bewertung von Risiken führen können. Dazu gehört, dass es in der Zuständigkeit der RASFF-Mitglieder liegt, zu entscheiden, ob verbunden mit nicht ordnungsgemäßen Lebensmitteln oder Futtermitteln ein Risiko besteht oder nicht (und in der Folge darüber, ob dieses Risiko eine Meldung via RASFF erforderlich macht); dies kann in manchen Fällen zu einer "Grauzone" bei der Risikobewertung führen, weil RASFF-Mitglieder unter vergleichbaren Umständen möglicherweise zu unterschiedlichen Schlussfolgerungen kommen. Außerdem stehen nur selten Leitfäden zur Verfügung, die zur besseren Harmonisierung der Risikobewertung in den Mitgliedstaaten beitragen könnten, wie dies zum Beispiel bei Pflanzenschutzmitteln der Fall ist.

Gleichwohl ist das RASFF seit Konzeption des Systems 1979 unverändert von großer Bedeutung. Angesichts der zunehmenden Globalisierung des Lebensmittel- und Futtermittelhandels und angesichts der Vertiefung des Europäischen Binnenmarktes erscheint ein wirksam organisierter Informationsaustausch über die von den Mitgliedstaaten festgestellten Risiken und ergriffenen Maßnahmen notwendiger denn je. Die Zielsetzungen, die dem RASFF zugrundeliegen, tragen dieser Notwendigkeit weitgehend Rechnung, allerdings konnten einige zusätzliche Ziele herausgearbeitet, die künftig im Rahmen des Systems Berücksichtigung finden könnten, beispielsweise die Nutzung des RASFF als Analyseinstrument zur Ermittlung von Trends bei den gemeldeten Risiken im Zusammenhang mit der Lebens- und Futtermittelsicherheit und die Anerkennung der entscheidenden Funktion, die dem System beim Krisenmanagement zukommt. Darüber hinaus weist das RASFF ein hohes Maß an Kohärenz mit verschiedenen anderen Meldesystemen auf, sowohl mit Systemen auf EU-Ebene als auch mit dem INFOSAN-System, dem wichtigsten internationalen RASFF-Partnersystem. Wo Überschneidungen auftreten, sind Maßnahmen zur Minimierung von Doppellungen bzw. Doppelarbeit geplant oder wurden bereits eingeleitet.

Was Effizienz anbelangt, so erscheinen die Kosten des RASFF gerechtfertigt, auch wenn ein direkter Vergleich mit dem Nutzen des Systems nicht möglich ist. Dies ist der Tatsache geschuldet, dass der Informationsaustausch über das System als solcher

selbst keinen Nutzen darstellt, sondern durch die auf der Grundlage von RASFF-Meldungen ergriffenen Maßnahmen zu einem gesteigerten Nutzen beiträgt. Dennoch vermittelt ein Vergleich der Gesamtkosten und der insgesamt übermittelten Informationsmenge einen Eindruck von der Effizienz des RASFF: Im Bezugsjahr 2013 beliefen sich die Kosten pro Informationseinheit, die an die RASFF-Mitglieder übermittelt wurde, auf 690 Euro. Berücksichtigt man, dass die meisten Meldungen mehrere Länder betreffen, dann liegen die Kosten pro gemeldetem Land deutlich darunter. Nichtsdestotrotz besteht Raum für eine künftige Steigerung der Effizienz des Systems.

Nahezu einmütig besteht Konsens darüber, dass das RASFF – verglichen mit dem, was die Mitgliedstaaten ohne dieses System durch Maßnahmen allein auf nationaler Ebene erreichen könnten – einen zusätzlichen Nutzen bietet. Diese Feststellung stützen auch die Ergebnisse in Zusammenhang mit den vorgenannten Kriterien, insbesondere die Ergebnisse, die auf die hohe Relevanz und Effektivität des Systems verweisen.

4.2. Krisenmanagementverfahren

Ein wesentliches Element der Krisenmanagementverfahren in der EU ist die Fähigkeit, durch Sofortmaßnahmen auf eine Situation zu reagieren, in der ein Lebensmittel oder Futtermittel mit Ursprung in der Europäischen Union oder ein aus einem Drittland eingeführtes Lebensmittel oder Futtermittel wahrscheinlich ein ernstes Risiko für die Gesundheit von Mensch oder Tier oder für die Umwelt darstellt. Die Europäische Kommission konnte auf dieser Grundlage eine Vielzahl von Vorfällen im Zusammenhang mit der Lebens- und Futtermittelsicherheit bewältigen und deren Auswirkungen minimieren. Sofortmaßnahmen waren auch das Instrument zur Bewältigung von zwei der drei ernstesten Vorfälle im Zusammenhang mit der Lebensmittelsicherheit, die im Rahmen dieser Evaluierung eingehend untersucht wurden, namentlich die Melamin-Krise und der EHEC-Ausbruch. In beiden Fällen ist zu konstatieren, dass sich diese Maßnahmen als wirksam erwiesen haben, allerdings wurden die Sofortmaßnahmen bei dem EHEC-Ausbruch erst gegen Ende der Krise ergriffen, nachdem die Quelle des Ausbruchs ermittelt werden konnte, und konnten so vor allem bereits ergriffene Schutzmaßnahmen flankieren.

Zwar werden die auf EU-Ebene ergriffenen Sofortmaßnahmen insgesamt als wirksam betrachtet und als erfolgreich darin, einheitliche und systematische Reaktionen der Mitgliedstaaten auf Vorfälle im Zusammenhang mit der Lebens- und Futtermittelsicherheit zu gewährleisten, aber die Evaluierungsergebnisse deuten auch darauf hin, dass die Effektivität des Krisenmanagements insgesamt im Bezugszeitraum unterschiedlich war, abhängig vom jeweiligen Vorfall im Zusammenhang mit der Lebens- und Futtermittelsicherheit und den jeweiligen Zielsetzungen. Während es nach allgemeiner Auffassung zumeist gelang, den gesundheitlichen Verbraucherschutz, die effiziente Bewältigung des Vorfalls und eine koordinierte Umsetzung der meisten effektiven Maßnahmen zur Begrenzung des Risikos bei vergangenen ernstesten Vorfällen im Zusammenhang mit der Lebens- und Futtermittelsicherheit sicherzustellen, erwiesen sich die Krisenmanagementvorkehrungen zum Schutz des Vertrauens der Verbraucher in die Lebens- und Futtermittelsicherheit und zur Beschränkung von Marktstörungen als weniger effektiv, insbesondere bei dem EHEC-Ausbruch im Jahr 2011. Das Datenmaterial veranlasst zudem zu der Feststellung, dass die Europäische Kommission bei der Bewältigung vergangener Vorfälle als Koordinator fungierte; inwieweit sie diese Funktion übernahm und wie zufrieden die zuständigen Behörden und andere Akteure mit der Rolle der Europäischen Kommission waren, ist jedoch davon abhängig, welchen Aspekt der Koordinierung und welchen Vorfall man betrachtet.

Der Beschluss 2004/478/EG der Kommission sieht für das Krisenmanagement auf EU-Ebene zwei generelle Handlungsoptionen vor: eine Handlungsoption, bei der zwar ein potenziell ernstes Risiko besteht und kein Krisenstab eingerichtet wird, aber

angemessene Vorkehrungen getroffen werden, um ein effektives Krisenmanagement zu gewährleisten, und eine zweite Handlungsoption, bei der gemäß Artikel 56 der Verordnung (EG) Nr. 178/2002 ein Krisenstab eingerichtet wird. Beide Optionen betrachten die von uns befragten zuständigen Behörden und sonstigen Akteure als für das Krisenmanagement im Zusammenhang mit Lebens- und Futtermitteln (grundsätzlich) relevant und nach wie vor angemessen. Die zweite Handlungsoption kam jedoch bislang nie zum Einsatz, d.h. trotz der Tatsache, dass sich im Evaluierungszeitraum schwere Vorfälle im Zusammenhang mit der Lebens- und Futtermittelsicherheit mit erheblichen Auswirkungen für die Gesundheit der Verbraucher ereigneten, wurde noch nie ein Krisenstab eingerichtet. Wie die Evaluierung ergab, erwies sich die erste Handlungsoption zur Bewältigung von vergangenen Vorfällen im Zusammenhang mit der Lebens- und Futtermittelsicherheit nicht immer als ausreichend; darüber hinaus hätten die betroffenen Hauptakteure für komplexere Krisensituationen wie den EHEC-Ausbruch klarere Strukturen für das Krisenmanagement bei der Europäischen Kommission als nützlich erachtet. Und schließlich sprachen sich zuständige Behörden und andere Akteure deutlich dafür aus, dass für das Krisenmanagement auf EU-Ebene zusätzliche Maßnahmen ergriffen werden. Als entscheidende Feststellung ergibt sich aus dieser Evaluierung daher die Notwendigkeit, den Beschluss 2004/478/EG der Kommission zu überarbeiten, um diesen den aktuellen Erfordernissen besser anzupassen.

Analog zu den Ergebnissen der Evaluierung zur Effektivität des Krisenmanagements wurden auch mit Blick auf die Effizienz des EU-Krisenmanagements abhängig vom jeweils untersuchten Fall Unterschiede deutlich. Zwar werden die Kosten des Krisenmanagements insgesamt gesehen als angemessen betrachtet, in einigen Fällen jedoch übertrafen die wirtschaftlichen Folgen eines Vorfalls im Zusammenhang mit der Lebens- und Futtermittelsicherheit jedoch vermutlich das unvermeidliche Mindestmaß. Wie die Evaluierung ergibt, ließe sich das Kosten-Nutzen-Verhältnis beim Krisenmanagement dadurch optimieren, dass Notfallplanung und Notfallvorsorge ausgebaut werden, unter anderem durch Schulungsmaßnahmen und Simulationsübungen. Zwar hat die Europäische Kommission in Folge des EHEC-Ausbruchs erhebliche Anstrengungen unternommen – zu nennen sind u.a. eine grenzüberschreitende Simulationsübung, die Formulierung von Standardarbeitsanweisungen, Schulungen sowie Erhebungen über die konkrete Notfallplanung in den Mitgliedstaaten –, im Rahmen der Evaluierung konnten jedoch weitere Vorschläge zur Verbesserung des Kosten-Nutzen-Verhältnisses auf EU-Ebene und auf Ebene der Mitgliedstaaten erarbeitet werden.

Ähnlich wie im Falle des RASFF besteht auch im Hinblick auf das Krisenmanagement und die Koordinierung durch die Europäische Kommission einmütig die Auffassung, dass es hier einen zusätzlichen Nutzen im Vergleich zu dem gibt, was die Mitgliedstaaten jeweils allein erreichen können.

4.3. Wichtige Empfehlungen

Auf Grundlage der oben dargelegten Schlussfolgerungen wurde im Rahmen der Evaluierung eine Reihe von Empfehlungen formuliert, die geeignet erscheinen, verschiedene festgestellte Defizite zu beheben bzw. den zusätzlichen Nutzen der Vorkehrungen in Zusammenhang mit dem RASFF und dem Krisenmanagement zu verbessern. Eine Auswahl der wichtigsten Empfehlungen in Bezug auf das RASFF umfasst Folgendes:

Angeichts der zunehmenden Bedeutung des RASFF wird zunächst vorgeschlagen, **das System** als Eckpfeiler des EU-Systems der Lebens- und Futtermittelsicherheit **weiter auszubauen** und die Zusammenstellung zusätzlicher Daten über gemeldete Risiken zu verbessern. So ist es beispielsweise derzeit in vielen Fällen nicht möglich, bei Meldungen zu einem bestimmten Risiko festzustellen, ob dieses Risiko mit Blick auf die betroffenen Lebens- und Futtermittel von größerer Tragweite ist als andere Risiken.

Höhere Meldezahlen können einfach auch auf kleinere Losgrößen zurückzuführen sein. Enthielten die Meldungen der RASFF-Mitglieder auch systematische Angaben zur Menge der betroffenen Lebens- und Futtermittel, so könnte dies Verzerrungen durch die Anzahl von Meldungen zu einem bestimmten Risiko verhindern. Und anhand systematischer Angaben zu den Vertriebskanälen, durch die gemeldete Lebens- und Futtermittelprodukte den Endverbraucher erreicht haben, wäre es möglich, nach Vertriebskanälen aufgeschlüsselte Trends zu ermitteln und Maßnahmen zu ergreifen, wenn die Meldungen zunehmen, die einen bestimmten Vertriebskanal betreffen (beispielsweise den E-Commerce).

Des Weiteren ließe sich der in Artikel 50 Ziffer 3 der Verordnung (EG) Nr. 178/2002 vorgesehene **Beitrag der EFSA zum RASFF besser strukturell verankern und umsetzen**; dazu müsste das System durch einen Mechanismus ergänzt werden, der eine zügige (d.h. innerhalb von 48 Stunden erfolgende) Rückmeldung der EFSA an die Kontaktstelle der Europäischen Kommission gewährleistet, wenn zu einem Risiko wenig bekannt ist oder ein Risiko nicht problemlos anhand von bestehenden Leitlinien oder Präzedenzfällen zu bewerten ist. Die zügige Rückmeldung seitens der EFSA könnte gestützt auf den behördenintern verfügbaren Sachverstand erfolgen, beispielsweise anhand einer ersten Durchsicht der verfügbaren Informationen zu dem betreffenden Risiko durch einen Wissenschaftler der EFSA. Es ist nicht Aufgabe der EFSA, dem RASFF systematisch wissenschaftliche Hilfestellung zu leisten; wenn aber die EFSA bereit wäre, Meldungen gegebenenfalls mit wissenschaftlichen Fakten oder Fachinformationen – insbesondere zu weniger bekannten Risiken – zu ergänzen, ließe sich dadurch die risikobasierte Arbeit des RASFF sicherlich verbessern. Wie bereits geplant sollten die EFSA und die Kontaktstelle der Europäischen Kommission außerdem gemeinsam **weitere Leitfäden zur Unterstützung der Nationalen Kontaktstellen bei der Risikobewertung** erarbeiten, und zwar nach dem Muster des bereits verfügbaren einschlägigen Dokuments über Pflanzenschutzmittelrückstände.

Um die Effizienz des RASFF zu verbessern, sollte die Kontaktstelle der Europäischen Kommission **ihre Ressourcen auf bestimmte Schwerpunktbereiche konzentrieren** (insbesondere auf die Prüfung und Übermittlung von Alarmmeldungen und diesbezüglichen Folgemaßnahmen). Eine von der Kontaktstelle der Europäischen Kommission und den Nationalen Kontaktstellen eingerichtete Arbeitsgruppe könnte mögliche Lösungen erörtern und prüfen, beispielsweise eine gewisse Dezentralisierung des Systems, die es den Mitgliedstaaten ermöglichen würde, unter klar definierten Voraussetzungen über das RASFF unmittelbar miteinander zu kommunizieren. Künftige Entwicklungen in diese Richtung würden eine Änderung des derzeitigen Rechtsrahmens und eine entsprechende Anpassung des iRASFF-Systems erfordern. Zudem ließe sich die Effizienz der Arbeit auch durch die **Verbesserung und Modernisierung der iRASFF-Anwendung** zwecks einheitlicher Erfassung der Informationen aller RASFF-Meldungen in einem einzigen IT-System und die damit verbundene Abschaffung von RASFF-Window optimieren, denn die Kontaktstelle der Europäischen Kommission müsste dann nicht länger zwei parallele Datenbanksysteme für das RASFF betreiben. Auch der Ausbau von **Verknüpfungen zwischen den Informationssystemen und die weitere Minimierung von Überschneidungen**, beispielsweise zwischen dem RASFF und dem TRACES-System, können zur Effizienzsteigerung beitragen. Zudem könnte man erwägen, Informationen über Verstöße, die nicht unmittelbar zur Risikobegrenzung in Bezug stehen, im Rahmen des Systems für Amtshilfe und Zusammenarbeit ("AAC-System") zu übermitteln und auf diese Weise den Informationsfluss über das RASFF zu entlasten. In einem solchen Fall sollte auch die Schaffung einer direkten Verbindung zwischen dem AAC-System und dem RASFF angestrebt werden.

Wie die Effektivität des RASFF als Plattform für den Informationsaustausch zwischen den Mitgliedsstaaten bei vergangenen ernsten Vorfällen im Zusammenhang mit der Lebens- und Futtermittelsicherheit belegt, **spielt das RASFF auch beim Krisenmanagement eine entscheidende Rolle, der Rechnung getragen werden**

sollte. Die diesbezüglichen Verfahrensweisen sollten überprüft und in eine systematische Form gebracht werden. Dies beinhaltet beispielsweise die Übermittlung von täglich aktualisierten Informationen über ernste Vorfälle im Zusammenhang mit der Lebens- und Futtermittelsicherheit durch die Kontaktstelle der Europäischen Kommission oder auch die Erstellung eines kurzen Berichts über einen solchen Vorfall nach dessen Bewältigung, der die wesentlichen Fakten zusammenfasst: Menge der betroffenen Lebens- und Futtermittel, Auswirkungen in Bezug auf die Verbrauchersicherheit, ergriffene Maßnahmen und deren Ergebnisse usw.

Auch bezüglich der Krisenmanagementverfahren konnte eine Reihe von Empfehlungen erarbeitet werden. Die Evaluierungsergebnisse sprechen dafür, dass der aktuelle Rechtsrahmen für die Bewältigung komplexerer Krisensituationen wie beispielsweise den EHEC-Ausbruch im Jahr 2011 nicht optimal geeignet ist. Daher **erscheint eine Überarbeitung und Aktualisierung des Beschlusses 2004/478/EG der Kommission angeraten.** Bei der Überarbeitung könnten folgende Aspekte berücksichtigt werden: a) die Frage, inwieweit die bestehenden Arbeitsabläufe bei der GD SANTE allmählich forciert werden können, wenn ernste Vorfälle im Zusammenhang mit der Lebens- und Futtermittelsicherheit zu bewältigen sind, vorzugsweise durch einen schrittweisen Ausbau, der die sukzessive Zuweisung zusätzlicher (personeller und technischer) Ressourcen in Abhängigkeit von der Entwicklung des jeweiligen Vorfalls ermöglicht; b) die effektive Verknüpfung von Notfallverfahren im Bereich der Lebens- und Futtermittelsicherheit einerseits und der öffentlichen Gesundheit andererseits auf EU-Ebene, wenn ernste Vorfälle im Zusammenhang mit der Lebens- und Futtermittelsicherheit, vor allem lebensmittelbedingte Erkrankungen, die öffentliche Gesundheit betreffen; c) die Verwendung des Begriffs "Krisenstab": wenn im Rahmen eines Konzepts des schrittweisen Ausbaus zur Bewältigung eines Vorfalls zusätzliche Ressourcen bereitgestellt werden müssen, könnte ein neutralerer Begriff wie z.B. "Arbeitsgruppe" (bzw. "Task Force") mögliche Befürchtungen in der Öffentlichkeit dämpfen; d) die Rolle des Netzes von Krisenkoordinatoren. In diesem Zusammenhang ist Folgendes zu empfehlen: Der überarbeitete Kommissionsbeschluss (sowie gegebenenfalls entsprechende Standardarbeitsanweisungen) sollte(n) kurz und bündig sowie eindeutig formuliert sein und sich möglichst umfassend auf Verfahren stützen, die sich bereits in früheren Krisen als geeignet erwiesen haben, sowie auf bewährte Verfahrensweisen, die im Krisenmanagement auf Ebene der Mitgliedstaaten zum Einsatz kommen. Darüber hinaus wird empfohlen, auf lokaler, regionaler, nationaler und EU-Ebene Maßnahmen bzw. Verfahren zu implementieren, die bei ernstesten Vorfällen im Zusammenhang mit der Lebens- und Futtermittelsicherheit eine **klare und wirksame Kommunikation sicherstellen.**

Im Hinblick auf die Krisenmanagementvorkehrungen in den Mitgliedstaaten wird empfohlen, dass das Lebensmittel- und Veterinäramt (FVO) die **Überprüfung der Notfallpläne und -maßnahmen** für ernste Vorfälle im Zusammenhang mit der Lebens- und Futtermittelsicherheit auf nationaler Ebene weiterführt und dass die Europäische Kommission (unter Beteiligung der betroffenen Mitgliedstaaten) nach der Bewältigung eines ernstesten Vorfalls im Zusammenhang mit der Lebens- und Futtermittelsicherheit eine entsprechende Evaluierung der Krisenmanagementverfahren vornimmt, um mögliche Defizite der getroffenen Vorkehrungen oder Maßnahmen festzustellen und gewonnene Erkenntnisse herauszuarbeiten (wie dies nach dem EHEC-Ausbruch der Fall war). Außerdem wird empfohlen, dass die Mitgliedstaaten selbst ihre Notfallplanung für ernste Vorfälle im Zusammenhang mit der Lebens- und Futtermittelsicherheit in regelmäßigen Abständen und insbesondere nach Bewältigung eines solchen Vorfalls im betreffenden Land einer Überprüfung unterziehen. Angesichts der Tatsache, dass die Notfallplanung auf Ebene der Mitgliedstaaten derzeit auf sehr unterschiedlichen Ansätzen fußt, können die FVO-Berichte über die Notfallplanung sowie die Berichte der Arbeitsgruppen der Mitgliedstaaten und auch der Leiter der Europäischen Behörden für Lebensmittelsicherheit als Grundlage für **die Harmonisierung der Ansätze und die Ermittlung bewährter Verfahrensweisen** dienen.

Und schließlich wird vorgeschlagen, die EU-Maßnahmen zur Verbesserung der Krisenmanagementverfahren und der Krisenvorsorge weiterzuführen und auszubauen und sie in regelmäßigen Abständen im Rahmen von **Krisensimulationsübungen der EU** zu erproben, bei denen zur Durchführung von Krisenbewältigungsmaßnahmen sowie zur Krisenkommunikation die wichtigsten Kontaktstellen in den Mitgliedstaaten einbezogen werden. Darüber hinaus wird vorgeschlagen, dass die Mitgliedstaaten ergänzende Krisensimulationsübungen organisieren und Schulungsangebote bereitstellen. Diese sollten in regelmäßigen Abständen angeboten werden und – soweit möglich – verschiedene Sektoren (Gesundheitswesen, Lebensmittelsicherheit usw.), unterschiedliche Regierungsebenen (zum Beispiel die nationale und regionale Ebene) und – wo dies machbar ist – auch die Nachbarländer einbeziehen.

5. DESCRIPTION OF THE STUDY

This final report is the last deliverable of the Evaluation of the Rapid Alert System for Food and Feed (RASFF) and of crisis management procedures for the Directorate General for Health and Food Safety (DG SANTE) of the European Commission. The evaluation was led by Civic Consulting of the Food Chain Evaluation Consortium (FCEC).

In line with the Terms of Reference (TOR), the final report takes into account 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 the conclusions established. The report presents the answers to the evaluation questions provided in the TOR based on the judgment criteria and indicators agreed upon in the inception phase of the evaluation, as well as the conclusions and recommendations resulting from those answers. It also provides a technical overview of the evaluation process, highlighting limitations and possible bias therein.

This report is structured as follows:

- Section 3 (this section) presents the purpose and the scope of the evaluation;
- Section 6 provides the background of the study, including the legislative framework of the RASFF and crisis management procedures and key contextual information necessary for understanding the subject of the evaluation;
- Section 7 discusses the evaluation questions addressed in this report;
- Section 8 outlines the method followed throughout the evaluation, including a brief overview of the tasks completed, the methodological tools used, and the challenges and limitations faced;
- Section 9 presents the findings and answers to the evaluation questions related to the RASFF;
- Section 10 presents the findings and answers to the evaluation questions related to crisis management procedures; and
- Section 11 contains the conclusions and resulting recommendations developed on the basis of the answers to the evaluation questions for the RASFF and crisis management procedures.

The annexes contain the detailed list of evaluation questions, an updated list of documents used in the literature review, the questionnaires developed for the two complementary surveys, as well as a table listing the organisations of survey participants and figures and tables relating to the Rapid Alert System for Food and Feed and crisis management, together with survey results differentiated by stakeholder groups. Additional annexes contain a list of data provided by the EC concerning the information flow of the RASFF, a list of interviews conducted in the course of the evaluation, a detailed chronology of the food safety incidents covered in the selected case studies, the intervention logic for the RASFF and for crisis management procedures, the analytical framework for the study as developed in the inception phase, and the Terms of Reference of the evaluation.

5.1. Purpose of the evaluation

According to the Terms of Reference, 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.

5.2. Scope of the evaluation

The focus of the evaluation is the period between 2002 (year of adoption of Regulation (EC) No 178/2002) and 2013. The evaluation covers the 28 EU MS, Switzerland and the EEA countries (Norway, Liechtenstein and Iceland).

6. BACKGROUND TO THE INITIATIVE

6.1. Economic context

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%. Among developing countries, China was the most important trade partner.⁷ Moreover, in 2013, EU countries imported agricultural products worth €101.8 billion. This figure represents a 64 percent increase compared to 2004.⁸

International trade in food and feed is expected to continue to rise significantly in order to nourish the increasing global population.⁹ Food and feed trade networks are also expected to become increasingly complex, as products and ingredients pass through a number of different countries at various stages of the food supply chain. Seven countries – five EU countries, as well as the United States and China – formed the core of the international agro-food trade network in 2007, each trading with over three quarters of all the countries in the world.¹⁰ Expanding globalisation allows more and new types of food and feed to be traded, but with this comes a greater risk of food safety problems crossing borders. These developments reinforce the need for a mechanism to rapidly exchange information on risks related to food and feed, allowing food safety authorities, business operators, and the European Commission, when needed, to address the risks identified through appropriate measures.

6.2. The Rapid Alert System for Food and Feed

6.2.1. Background

Coordinated action to ensure food safety at a European level has a long history, often driven by crises. After the “Orange terrorism” incident in 1978, which involved oranges from Israel injected with mercury,¹¹ food control authorities from a number of Member States responded to the large-scale concern amongst the general public with the creation of a rapid alert system – the Rapid Alert System for Food and Feed, or RASFF. The RASFF provides a system for the swift exchange of information between its members in cases of direct or indirect risks to human health deriving from food and feed, to enable as much as possible a coordinated response of its members to food safety threats (in coordination with third countries, where relevant). With the first agreement regarding a rapid alert exchange system reached in 1979, the legal basis of the RASFF was originally found in the Proposal for Council Decision (COM/79/725 Final) and subsequently in Council Decision 84/133/EEC, Council Decision 89/45/EEC and Council Directive 92/59/EEC. The RASFF is therefore one of the few elements of the European food safety framework predating the White Paper on Food Safety in 2000 that is still in place.¹²

The White Paper was a key milestone, and outlined the way to a harmonised framework through horizontal legislation, most notably Regulation (EC) No 178/2002

⁷ European Commission, Sustainable Development in the European Union 2011 Monitoring Report of the EU Sustainable Development Strategy, 2011th ed., European Commission, 2011.p.314.

⁸ European Commission, Directorate-General for Agricultural and Rural Development based on Eurostat Comext data: http://ec.europa.eu/agriculture/statistics/trade/2013/eur28ch/page_002.pdf

⁹ European Commission, New Challenges for Agricultural Research: Climate Change, Food Security, Rural Development, Agricultural Knowledge Systems, European Commission, 2009. p.18.

¹⁰ Ercsey-Ravasz M, Toroczka Z, Lakner Z, Baranyi J (2012) Complexity of the International Agro-Food Trade Network and Its Impact on Food Safety. PLoS ONE 7(5): e37810. doi:10.1371/journal.pone.0037810.

¹¹ European Commission, RASFF: 30 Years of Keeping Consumers Safe, 2009.

¹² European Commission, White Paper on Food Safety COM (1999) 719 Final, 2000.

of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (the "General Food Law Regulation").¹³ Regulation (EC) No 178/2002 defined in Articles 50, 51 and 52 the scope and procedures of RASFF, and consolidated the tasks that had been adopted by the RASFF over time. Thus Regulation (EC) No 178/2002 and the complementary Commission Regulation (EU) No 16/2011 of 10 January 2011 laying down implementing measures for the Rapid alert system for food and feed¹⁴ provide the current legal framework and formalised procedures for the system.¹⁵

As it currently functions, the RASFF is composed of several IT tools or platforms providing access to notifications which are tailored for different stakeholder groups. The *iRASFF* is a direct online notification system for RASFF members. *RASFF Window* provides non-members limited access to notifications; in addition, the *RASFF Portal* and *Consumers' Portal* serve to inform industry and consumer stakeholders about notified products. These components of the RASFF are explored in more detail in the relevant evaluation questions.

Through these developments, the RASFF has emerged as an essential element of the European food safety system, providing an EU-wide network for food/feed risk communication and a valuable source of information for food/feed safety authorities and business operators. The latest data indicates that the 32 members of the network have transmitted over 3,100 original notifications in the course of the past year, equivalent to an average of more than 8 original notifications per day.¹⁶ These have given rise to 5,910 follow-up notifications, and more importantly perhaps, the information transmitted between users of the RASFF has allowed for numerous products presenting a risk to be removed from or denied access to the EU market.

6.2.2. *The scope of the RASFF*

While Article 50 of the Regulation (EC) No 178/2002 originally intended the RASFF as a tool for the notification of direct or indirect risks to human health deriving from food or feed, several years later Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene¹⁷ extended the notion of risk to include serious risks to animal health and to the environment resulting from feed. Thus, Commission Regulation (EU) No 16/2011 laying down the implementing measures for the RASFF defines risk 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."

6.2.3. *Notifications in the RASFF*

Article 1 of Commission Regulation (EU) 16/2011 laying down implementing measures for the RASFF defines three main types of notifications:

¹³ OJ L 31, 1.2.2002, p. 24.

¹⁴ OJ L 6, 11.1.2011, p.7.

¹⁵ Article 51 of Regulation (EC) No 178/2002 provides for implementing measures for the RASFF, which were adopted through Commission Regulation (EU) No 16/2011. The drafting of the implementing measures was significantly delayed through various factors, including the need to first refine procedures to manage the rapidly increasing number of notifications, and then through the so called "Bowland case" (Case T-212/06, Bowland Dairy Products Ltd v. Commission), which concerned the RASFF and was decided by the Court of Justice of the European Union (former European Court of Justice) in favour of the Commission. The adoption of the Commission Regulation (EU) No 16/2011 did not significantly affect the functioning of the RASFF. However, it provided precise time limits for the duties of its members, requiring member countries and the ECCP to transmit alert notifications within 48 hours and 24 hours respectively.

¹⁶ European Commission, RASFF Preliminary Annual Report 2014, 2015.

¹⁷ OJ L 35, 8.2.2005, p. 22.

- *Alert notification* – a notification of a risk that requires or might require rapid action in another member country;
- *Information notification* – a notification of a risk that does not require rapid action in another member country, with this type of notification being further subdivided into *information notification for follow-up* and *information notification for attention*;
- *Border rejection notification* – a notification of a rejection of a batch, container or cargo of food or feed as referred to in Article 50(3)(c) of Regulation (EC) No 178/2002.

In addition, the legislation distinguishes between *original notifications* and *follow-up notifications* which contain additional information in relation to an original notification. More details concerning the classification of notifications are presented under Section 9.4.1.

6.2.4. *The role of the European Commission in the RASFF*

Paragraph 1 of Article 50 of Regulation (EC) No 178/2002 defines the role of the European Commission in the RASFF. First, along with Member States and the European Food Safety Authority (EFSA), the Commission is involved in the RASFF and is required to designate a contact point, “which shall be a member of the network”. The paragraph concludes that “The Commission shall be responsible for managing the network”. Thus, the European Commission is both a member and the manager of the RASFF.

In addition to its responsibilities as participant of the network, the Commission must fulfil a series of obligations as the network’s manager. These obligations are derived from Regulation (EC) No 178/2002 and are specified in Articles 2 to 10 of Commission Regulation (EU) No 16/2011. The key obligations with regards to RASFF notifications include:

- The Commission contact point shall transmit alert notifications to all members of the network within 24 hours after reception, upon verification as referred to in Article 8 of the same Regulation (Article 3(2));
- The Commission contact point shall transmit information notifications to all members of the network without undue delay upon verification as referred to in Article 8 (Article 4 (2));
- The Commission contact point shall transmit border rejection notifications to border inspection posts as defined in Council Directive 97/78/EC [...] and to designated points of entry as referred to in Regulation (EC) No 882/2004 (Article 5(2));
- The Commission contact point shall transmit follow-up notifications to all members of the network without undue delay and within 24 hours for follow-up notifications to alerts (Article 6 (5)).

Article 8 (Verification of a notification) and Article 10 (Exchange of information with third countries) of Commission Regulation (EU) 16/2011 outline the additional duties of the Commission with respect to its role as manager of the network. In particular, the Commission must verify notifications in light of their completeness, legibility, correctness, etc. prior to transmitting them to all members of the network. Regarding third countries, the Commission must inform them if a notified product originates from or is distributed to it; moreover, it shall establish contact points in third countries in order to reinforce communication.

These responsibilities of the Commission are mirrored by the responsibilities of National Contact Points (NCPs) in all RASFF member countries regarding the in-country notification process, which are described below. The notification process within

the RASFF network therefore follows a number of defined steps, in which the Commission (DG SANTE) has a crucial position as gatekeeper, because it has to validate all notifications before submission to other network members (see Figure 1 in the Annex to this report).

6.2.5. *The duties of members of the RASFF*

The obligations of the members of the RASFF are set out in Article 50 of Regulation (EC) No 178/2002, and specified in detail in Articles 2 to 7 of Commission Regulation (EU) No 16/2011 laying down implementing measures for the RASFF.

Article 50 of Regulation (EC) No 178/2002 sets out the following obligations for members of the network:

- Members of the network are required to immediately notify through the RASFF any information they have relating to the existence of a serious direct or indirect risk to human health deriving from food and feed (Article 50(2));
- Member States shall immediately notify the Commission through the RASFF of any measure they adopt 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 (Article 50(3));
- Moreover, they shall immediately notify the Commission through the RASFF of 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 (Article 50 (3));
- Member States shall immediately notify the Commission through the RASFF of 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 (Article 50(3));
- Such notifications must be accompanied by a detailed explanation of the reasons for the action taken by the competent authorities of the Member State in which the notification was issued, and the explanation shall be followed, in good time, by supplementary information, in particular where the measures on which the notification is based are modified or withdrawn (Article 50(3));
- Finally, Member States are required to immediately inform the Commission of the action implemented or measures taken following the receipt of notifications and supplementary information transmitted through the RASFF (Article 50(5)).

The main obligations deriving from the implementing measures related to the organisation of the National Contact Points are as follows:

- Members of the network are required to ensure the efficient functioning of the RASFF within their jurisdiction (Article 2(1));
- Members are required to designate one contact point which will be a member of the network. They must communicate the designated contact point, the person responsible for it, and the relevant contact details to the European Commission Contact Point using the contact point information template (Article 2(2));
- They must inform the Commission contact point of any changes in the national contact point and contact details (Article 2(3));

- Members must ensure an effective communication between their contact point the Commission contact point, set up an effective communication network between the NCP and all relevant competent authorities in their country, and define the roles and responsibilities of the NCP and those of the relevant competent authorities in their country (Article 2(5)); and
- The contact points must ensure the availability of an on-duty officer reachable outside office hours for emergency communications on a 24-hour/7-day-a-week basis (Article 2(6)).

Regarding the transmission of notifications, members of the network are required to:

- Send alert notifications to the Commission contact point within 48 hours from the moment the risk is reported to their NCP (Article 3(1));
- Send information notifications to the Commission contact point without undue delay (Article 4(1));
- Send border rejection notifications to the Commission contact point without undue delay (Article 5(1));
- Immediately transmit a follow-up notification to the Commission contact point whenever the NCP has any additional information relating to the risk or product referred to in an original notification (Article 6(1));

Moreover, the above-mentioned notifications should be submitted to the Commission using the templates provided (Article 7(1)).

6.2.6. *Confidentiality rules of the RASFF*

Article 52 of Regulation (EC) No 178/2002 defines the confidentiality rules for the RASFF. The following key provisions apply:

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

Some clarification of these requirements is provided in the RASFF Standard Operating Procedures (SOPs), which address confidentiality rules for RASFF, among other key issues concerning the network and its members. The confidentiality provisions of the RASFF are further analysed in Section 9.9.

6.2.7. *The role of EFSA in the RASFF*

In addition to providing the legal basis for the RASFF, Regulation (EC) No 178/2002 established the European Food Safety Authority (EFSA) in 2002 as an independent source of scientific advice and communication on risks associated with the food chain.

The Regulation includes provisions regarding the role of the newly established Authority within the RASFF system. In the legislation, the following points define the role of EFSA in the RASFF:

- Along with the National Contact Points of Member States and the Commission contact point, the contact point designated by EFSA is a member of the RASFF (Article 50(1));
- When information is notified from a member of the network to the Commission regarding a serious direct or indirect risk to human health deriving from food or feed, EFSA may supplement the notification with any scientific or technical information that will facilitate rapid and appropriate risk management (Article 50(2)).

The role of EFSA in the RASFF, and particularly the extent to which it fulfils the obligations stemming from the legislation, is analysed under Section 9.5.

6.3. Crisis management procedures

6.3.1. Background

The RASFF plays a central role in the prevention and management of risks detected in food and feed, allowing Member States to take national measures for countering those risks, in line with the subsidiarity principle. However, when national actions undertaken by Member States acting individually are not sufficient to contain a risk, additional measures and procedures may need to be put in place. According to Article 13 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules,¹⁸ Member States are required to draw up national contingency plans to be activated in cases of serious risk, and Articles 53 to 57 of Regulation (EC) No 178/2002 outline and establish the tools that are at the disposal of the European Commission for the coordinated management of food/feed safety incidents affecting the EU. These are explained in more detail in Section 6.3.2 and Section 6.3.3 below.

6.3.2. Emergency procedures

A key element of crisis management procedures in the EU relates to the possibility of adopting emergency measures in response to food or feed originating in the European Union or imported from a third country that is likely to constitute a serious risk to human health, animal health, or the environment. If the product is of European Union origin and if the risk cannot be contained satisfactorily by measures taken by the Member States concerned, the Commission, by way of Article 53 of Regulation (EC) No 178/2002, may suspend the placing on the market of the food/feed in question, lay down special conditions for the food/feed in questions, or apply any other appropriate interim measure. For products imported into the EU, the Commission may suspend the imports, lay down special conditions for the product in question, or adopt any other appropriate interim measure.

Article 54 of the Regulation provides for the possibility of Member States to adopt interim protective measures if the Commission does not act according to Article 53. However, the Commission must then review the emergency measure put in place by the Member State within 10 working days in order to extend, amend or abrogate the given national measures. Emergency measures have been regularly used to ensure a

¹⁸ OJ L 165, 30.4.2004, p. 1.

harmonised approach of the EU in terms of containing risks related to food and feed. They are explored in more detail under Section 10.3.1.

6.3.3. *The legal basis of crisis management procedures*

Regulation (EC) No 178/2002 foresees that when a relevant risk cannot be contained satisfactorily by the Commission or by the Member State(s) concerned through the use of the mechanisms described above, emergency measures may be complemented by a general plan for crisis management in the field of the safety of food and feed (Article 55) and a crisis unit (Articles 56 and 57). The general plan and the role of the crisis unit were outlined in the Annex to Commission Decision of 29 April 2004 concerning the adoption of a general plan for food/feed crisis management (2004/478/EC).¹⁹

Figure 75 in the Annex to this report presents a flow chart which graphically represents the options available to the EC for managing a crisis or potential crisis. Before discussing in more details the legislative provisions for the general plan and the crisis unit, we will first describe the management of a potential crisis in the area of food and feed at EU level without the application of the general plan.

Crisis management using existing provisions and emergency measures

Crisis management at EU level requires cooperation between EU institutions in the field of risk assessment and risk management. In practice, the following four steps are taken in the event of a crisis related to food safety that does not require the general plan to be triggered:²⁰

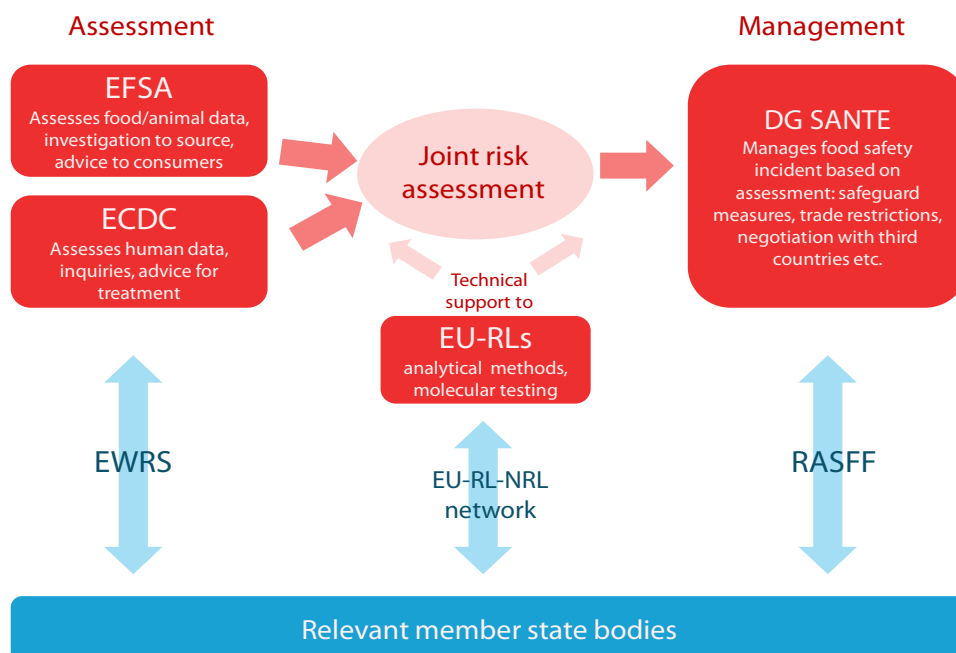
Step 1: Alerting phase. Possible sources of information on the existence of a risk related to food or feed may be FVO audits, rapid alert notifications from the RASFF, information from Member States or from the European Food Safety Authority (EFSA), or information obtained through the media, consumer groups, third countries and other stakeholders. DG SANTE officials who receive information on a potential risk are required to report to their Head of Unit, who performs an initial rapid assessment of the potential crisis and informs the Director of the relevant Directorate of DG SANTE (responsible for the risk in question).

Step 2: Evaluation phase. If the risk is judged to contain a serious direct or indirect risk to human health or a potential serious risk, the Director calls a food/feed crisis evaluation meeting, in which the tasks related to the risk are allocated. A request may be made to EFSA, the primary point of contact, for an urgent scientific opinion on the risk. In response to an 'urgent request' by the Commission, EFSA issues a recommendation. The European Centre for Disease Prevention and Control (ECDC), and the services of the network of EU Reference Laboratories (EU-RLs) may also be mobilised. Together, these elements form a risk assessment that is sent, along with a recommendation from the food/feed crisis evaluation meeting to DG SANTE for appropriate action. The figure below graphically depicts the cooperation between the respective EU institutions in the field of risk assessment and risk management for the example of foodborne disease outbreaks.

¹⁹ OJ L 160, 30.4.2004, p. 60.

²⁰ This description of steps follows to a large extent the procedures outlined in the Standard Operating Procedures for Food/Feed Crisis Management issued by the European Commission.

Figure 1: Cooperation between EU institutions in the field of risk assessment and management of foodborne disease outbreaks, and the role of MS bodies and alert systems



Source: Adapted from Poudelet, E., The role of MS and European institutions in the event of crisis, Bundesinstitut für Risikobewertung, 2012.

The figure illustrates the separation at EU level between risk assessment and risk management in a foodborne disease outbreak, and again emphasises the multi-level nature of the response. The coordination at national level may involve a large number of actors that interact both with the relevant EU level institutions, and with their partner organisations in other affected countries.

Step 3: Management phase. In line with the principle of subsidiarity, the primary responsibility for the containment of risk deriving from food or feed falls upon the Member States. In cases where the risk cannot be contained satisfactorily through measures taken by Member States, however, the Commission may adopt emergency measures, such as the ban of a product or an import from third countries, on the basis of Article 53 of Regulation (EC) No 178/2002. Moreover, when products from a third country are involved, or affected products have been exported, information is provided to the third countries in question in order to avoid general bans on EU products. In addition, the competent authorities in the affected Member States are supported by the Commission in their response to the crisis situation, e.g. through the provision of scientific expertise or recommendations, that ensure uniform implementation of regulations in the different Member States.

Step 4: Concluding phase. At the end of the incident, the Commission informs all parties (including third countries) on the successful containment of the emergency, with the aim of reaching an end to measures such as specific bans of third countries put in place due to the incident.

General plan for crisis management and crisis unit

Article 55 of Regulation (EC) No 178/2002 requires that the "Commission shall draw up, in close cooperation with the Authority and the Member States, a general plan for crisis management in the field of the safety of food and feed (hereinafter referred to as the 'general plan')". Moreover, the Regulation specifies that the general plan shall include "the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Article 53 and 54" as well as the procedures to be undertaken to manage a crisis, including "the principles of transparency to be applied and a communication strategy."

Articles 56 and 57 introduce the notion of the crisis unit and outline its responsibilities. Article 56 also states that "[...] where the Commission identifies a situation involving a serious direct or indirect risk to human health deriving from food and feed, and the risk cannot be prevented, eliminated, or reduced by existing provisions or cannot adequately be managed solely by way of application of Articles 53 and 54, it shall immediately notify the Member States and the Authority."

The Annex to Commission Decision 2004/478/EC describes the procedures to be taken for setting up a crisis unit (see table below).

Table 1: General Plan for food/feed crisis management in setting up a crisis unit

Stage of procedure	Description
1. Information received leading to the application of the general plan and if necessary setting up of crisis unit	On the basis of the assessment of all relevant information available, the Commission shall determine whether a crisis situation involving a serious direct or indirect risk to human health requires the application of the general plan and the setting up of a crisis unit.
2. Establishment of the crisis unit	If conditions are met, the Commission shall set up a crisis unit composed of designated crisis coordinators and shall immediately inform the Member States and EFSA that this crisis unit has been set up. The crisis unit shall be responsible for gathering and evaluating all the relevant data and identifying the options available for managing the crisis. It shall also have the role of informing the public about the risks in question and the measures taken so far. However, each Member State shall continue to be responsible for the management of official controls on its territory.
3. Actions taken by the crisis unit	In accordance with Article 57, the crisis unit will: <ul style="list-style-type: none"> – Collect relevant scientific data and information in order to manage risk; – Evaluate information available, where necessary use technical support from EURL for analytical aspects; – Identify options available for reducing to an acceptable level the risk to human health; – Communicate to the public on the risks involved and the measures taken.
4. Resolution of crisis	Procedures will remain in place until the crisis unit is dissolved. When the Commission considers, after consulting the crisis unit and in close collaboration with the Member States through the Standing Committee on the Food Chain and Animal Health, that the work of the crisis unit is completed because the risk has been brought under control, it may dissolve the crisis unit.
5. Post-crisis assessment	An overall post-crisis assessment, involving the stakeholders, shall be undertaken. A meeting of the crisis coordinators shall be held after the resolution of the crisis in order to improve operational procedures in light of the post-crisis assessment and experienced gained.

Source: Civic Consulting, based on Commission Decision of 29 April 2004, concerning the adoption of a general plan for food/feed crisis management (2004/478/EC).

Commission Decision 2004/478/EC also lays down management procedures where the risk is potential but could evolve into a serious risk which is unlikely to be prevented, eliminated or reduced by existing provisions or solely by way of application of Articles 53 and 54. In this case, a crisis unit will not be set up but adequate provisions will be made to ensure effective management of this type of situation. If the risk is considered to be serious and if the Commission considers that the relevant conditions have been met, a crisis unit shall be set up and the procedures indicated in the table above shall apply. If the risk is not considered to be serious, the existing normal provisions for the management of risk shall apply.

In order to allow for the implementation of the general plan for crisis management, Member States are also required to draw up their own contingency plans to apply in emergency situations, as mentioned above. According to Article 13 of Regulation (EC) No 882/2004 these contingency plans must outline the national administrative authorities to be engaged in crisis management, and their respective powers and responsibilities, as well as the channels and procedures for communication between

the relevant actors. The national contingency plans must be reviewed and updated by Member States, particularly in response to experience gained from crisis simulations.

In conclusion, where an identified risk develops into a (potential) food or feed crisis, the Commission has a number of tools at its disposal. These include emergency measures, a general plan for crisis management and setting up a crisis unit, Standard Operating Procedures complementing the general plan, as well as the possibility to differentiate between crisis and potential crisis. However, Member States retain the responsibility of implementing their own emergency measures via national contingency plans which they are required to draw up and review.

7. EVALUATION QUESTIONS

In addition to outlining the purpose of the evaluation, the TOR provide a list of detailed evaluation questions (EQs), which are separately provided for the *Rapid Alert System for Food and Feed* (evaluation area 1, 36 EQs) and for *Crisis and potential crisis management* (evaluation area 2, 20 EQs). Where relevant, these evaluation questions have been grouped together under common headings. Section 6 of this report presents the evidence and answers to the evaluation questions concerning the RASFF, which relate to the following areas:

- Effectiveness;
- Relevance;
- Coherence and scope of the system;
- Legal basis and the role of the European Commission;
- Risk-based operations of the RASFF and the role of EFSA;
- Involvement of EU Member States;
- Participation of Third Countries and International Organisations;
- Efficiency;
- Stakeholder information, transparency and confidentiality; and
- Added value.

Similarly, Section 7 on crisis management provides evidence and answers to evaluations questions related to the following aspects:

- Effectiveness;
- Relevance;
- Role of the European Commission, including the use of emergency measures;
- Involvement of EU Member States;
- Participation of Third Countries and International Organisations;
- Efficiency; and
- Added value.

A detailed list of evaluation questions is provided in Annex 1 of this report. Moreover, Section 8 presents the conclusions and recommendations deriving from the evaluation questions according to key evaluation criteria.

8. METHODOLOGY, CHALLENGES AND LIMITATIONS

This evaluation is based on data collected with the following methodological tools:

- In-depth document review;
- Two complementary surveys;
- Three case studies of serious food safety incidents;
- Exploratory interviews, in-depth interviews and follow-up interviews;
- Analysis of the RASFF information flow;
- Financial analysis of the RASFF;
- Data on economic impacts of food/feed safety incidents.

This section summarises the process of the evaluation – from structuring to answering the evaluation questions – providing a brief description of the key tasks conducted, and the methodological tools used. The key challenges of the evaluation, as well as resulting limitations, if any, are also presented below.

8.1. Methodology

8.1.1. *Structuring phase*

A total of ten exploratory interviews were conducted with EC staff members and key stakeholders in the structuring phase of the study. The interviews allowed the evaluation team to clarify the evaluation questions, to update the intervention logic for both interventions (see below) and to refine the planned methodological tools. For additional details regarding the interviews conducted, please refer to the table provided in Annex 8 of this report. During this stage, we also informed key stakeholder organisations at both EU and national levels about the evaluation and the two surveys planned in the framework of the study.

The intervention logic of the RASFF and of crisis management was refined on the basis of the initial document review, the discussion with the Commission, and the interviews with stakeholders. The updated intervention logic for both the RASFF and crisis management procedures are presented in Annex 8 and Annex 9 of this report. Based on the updated intervention logic and the information reviewed during the structuring phase, we finalised the analytical framework, including evaluation questions, judgement criteria and indicators (see Annex 10).

Based on the results of the structuring phase, the evaluation team confirmed the applicability of the methodological approach and prepared the methodological tools. The survey questionnaires as developed by the FCEC and approved by the Commission are presented in Annex 2 of this report.

8.1.2. *Collecting primary and secondary evidence*

During the in-depth document review, over 200 documents were identified, collected, and catalogued in dedicated bibliographic reference management software and reviewed. The in-depth document review continued throughout the study as new data, information and evidence became available. An updated list of documents is provided in the Annex of this report.

Two complementary surveys were conducted in the framework of the study, targeting (1) RASFF national contact points and other stakeholders involved in the RASFF; and (2) relevant competent authorities in the field of food/feed crisis management and

relevant stakeholders. Stakeholders that were consulted (in addition to the RASFF national contact points and the relevant competent authorities in the field of food/feed crisis management) included the Administrative Assistance and Cooperation (AAC) contact points in Member States, EU and international organisations, relevant government bodies in third countries, organisations of food/feed business operators and consumer organisations in the EU. The surveys were launched on 19 December 2014 and closed on 27 February 2015. In total, 75 national contact points and other stakeholders participated in the RASFF survey and 47 competent authorities and relevant stakeholders participated in the survey on crisis management. Annex 3 lists the organisations that responded to the survey. Throughout this report, when a distinction is made between National Contact Points/competent authorities and “other stakeholders”, the latter refers to the groups listed above, i.e. AAC contact points, EU/international organisations, third countries, food/feed business operators, etc. When the term “respondents” is used, this refers to all groups who answered to the survey.

In addition to the surveys, three case studies focusing on serious food safety incidents were conducted by the evaluation team. These concerned the outbreak of Shiga toxin-producing *Escherichia coli* – STEC – serotype O104:H4 in 2011, an incident involving glass fragments in instant coffee in 2010 and the melamine crisis of 2008. The three case studies covered different hazard categories (pathogenic micro-organism, foreign body, chemical) and different geographical areas (within the EU/globally). They also allowed for different aspects of the functioning of the RASFF and of crisis management arrangements to be investigated. The table below presents the three case studies, including the main features of each food safety incident covered. Further details on the incidents such as the measures taken at EU and MS level and their effectiveness, or the involvement of Third Countries and International Organisations are provided in the sections related to the corresponding evaluation questions.

Table 2: Overview of case studies

Food safety incident	Description of food safety incident	Hazard category
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.	Chemical
Glass fragments in instant coffee (2010)	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. 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. ^a	Foreign body
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.	Pathogenic micro-organism

Source: Civic Consulting. Notes : a) RASFF notification 2010.0626. A detailed chronology for the food safety incidents examined in each of the three case studies is provided in Annex 3.

The case studies consisted of a review of relevant documents as well as in-depth interviews at EU level and in at least three countries affected by the incident. Key stakeholders consulted for the case studies included the RASFF NCPs and competent authorities involved in the management of the incidents. All interviews were based on semi-structured questionnaires which were developed for the different stakeholder groups. The case study interviews provided valuable insight and information, allowing the evaluation team to obtain a detailed overview of each incident and the issues that were identified in relation to both RASFF and crisis management.

The in-depth evaluation interviews conducted during the case studies were complemented by additional in-depth interviews, including with the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC), and INFOSAN. Moreover, the evaluation team received a list of selected non-EU countries with first-hand experience in using the RASFF. As the United States is a key trading partner in food and drink products of the European Union, the U.S. Food and Drug Administration (FDA) was selected for consultation in an in-depth evaluation interview. This was complemented by an interview with the food safety authority of a second non-EU country (New Zealand) during the follow-up interviews (see below). These in-depth interviews related to past food/feed safety incidents, while also focusing on cross cutting issues of RASFF and crisis management that were crucial for answering the evaluation questions. The table in Annex 4 presents a full list of the interviews that were conducted.

During the structuring phase of the study, it was agreed with the Commission to focus the analysis of the RASFF information flow mainly on a series of indicators for the reference year 2013. A full list of data provided by the European Commission for the purposes of this evaluation is presented in the Annex to this report. The analysis of this data is included in the answers to the relevant evaluation questions in this report.

Moreover, the financial analysis of the RASFF focused on the costs of running the system during normal operation (i.e. in absence of a serious food/feed safety incident) at EU and NCP levels for the reference year 2013. Through the survey of RASFF National Contact points, data on the number of FTE (Full-Time Equivalent)²¹ posts at the NCPs directly involved in the running of the RASFF at national level was collected (distinguishing between professional and administrative/support staff), as well as costs that were incurred by NCPs for training staff of relevant competent authorities at sub-national level in 2013. 28 of the 32 members of the RASFF provided data for the financial analysis. For the remaining countries, data provided by other Member States was extrapolated, to provide a full picture. Data received from the European Commission presented details of the budget received and amount committed in 2013 for running the RASFF at the European level.

Finally, data concerning the economic impacts of the selected food safety incidents was identified and reviewed, where such data was available. Moreover, the relevant dimensions of these impacts were explored during the case study interviews, focusing specifically on the extent to which some of these economic impacts could have been avoided or reduced. As only very limited data on economic impacts regarding two of the three case studies incidents could be identified, complementary research on the (direct and indirect) costs of other food/feed safety incidents that occurred throughout the reference period was conducted (see Section 10.6).

8.1.3. *Validation, triangulation and synthesis of evidence*

Throughout the study, the evaluation team verified the information collected and compared processed information with the source documents in order to safeguard the integrity of data and provide a sound evidence base for the further evaluation process. This process also allowed the evaluation team to identify gaps and contradictions in the data, which were subsequently addressed in follow up interviews and correspondence with staff from the EC and other key stakeholders.

The interim report submitted in the course of the study presented the initial findings and preliminary answers to the evaluation questions, based on the evidence available at that stage of the evaluation. It included results from both surveys and case study/in-depth interviews, which were partially completed. It also provided an initial analysis of the information flow and financial data available.

8.1.4. *Answering the evaluation questions*

Follow-up interviews were conducted with staff from DG SANTE in May and June 2015 (see Annex for a full list of interviews conducted). In addition, to strengthen the evidence base for evaluation questions related to the participation of Third Countries in the RASFF and crisis management procedures, another interview was held with the competent authority of an additional third country. New Zealand was identified as a country with substantial experience in working with the RASFF and as a result, the competent authorities were expected to be able to provide constructive feedback and well-informed answers to the interview questions. The follow up interviews served to clarify certain aspects of the RASFF and crisis management, to close gaps in the data collected, and to discuss preliminary conclusions. The results of these interviews have been included in the analysis presented in this report.

²¹ A full-time equivalent staff member (FTE) is defined as full-time staff member working 40 hours per week. Part-time staff member/staff member 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).

On the basis of the final dataset, the answers to the specific evaluation questions were refined, where necessary, to reflect the final view of the evaluation team and to present evidence (both quantitative and qualitative) in a clear and structured way, and key conclusions were identified. Based on these conclusions, the evaluation team developed draft recommendations for the improvement of the RASFF and crisis management procedures addressing the main evaluation criteria, namely effectiveness, relevance, coherence, efficiency and EU added value. Members of the expert advisory group were asked to review and provide comments concerning these recommendations, which were refined and are presented in this report.

In addition, the evaluation team has presented the findings of the evaluation in Brussels to the Expert Group on the General Food Law (composed of representatives from Member States) and to the Advisory Group Working Group on the Fitness Check of Regulation (EC) No 178/2002 (composed of stakeholders). On both occasions, the presentations were positively received by the participants of the meetings.

8.2. Challenges and limitations

8.2.1. Limited availability of literature for certain aspects

In spite of the large number of documents identified for the in-depth document review of the evaluation, there were significant gaps regarding specific aspects. For example, the documentation regarding the case study related to glass fragments in instant coffee was limited, and data concerning the economic impacts was only available for one of the three incidents considered. To address this limitation, interviews and additional research were used to complement the available information. For instance, to identify the costs related to crisis management, additional past serious food/feed safety incidents were examined for which the relevant data is available.

8.2.2. Interviewees in case studies

In most case studies, the interviewees consulted were directly involved in the management of the incident. In some cases, however, persons who had directly participated in the management of the incident could not be interviewed because they were no longer working in the relevant administrations (this was especially the case for the melamine crisis). In these cases, interviewees based their responses on the written documentation available in their administration and on their general experience in the RASFF or crisis management arrangements.

8.2.3. Establishing the counterfactual

Some evaluation questions – in particular those related to efficiency and added value of the interventions – require establishing a counterfactual, i.e. *what would have occurred in the absence of the RASFF or crisis management procedures?* or *Could the costs be lower while achieving the same objectives?* Such an exercise aims to compare the current situation with a hypothetical one in order to draw conclusions about the impacts achieved by the intervention. In this evaluation, establishing the counterfactual for the RASFF and crisis management arrangements has been particularly challenging. This is due to the complex nature of food/feed safety incidents and the large number of factors influencing their developments. The fact that the existence of the RASFF precedes the adoption of Regulation (EC) No 178/2002 also does not allow for the period prior to 2002 to be used as a baseline. To address this challenge, we have drawn on the experience of key stakeholders involved in the RASFF and crisis management at EU and national level and asked them to provide qualitative assessments concerning relevant aspects of the evaluation in our survey, and have used complementary evidence collected through the in-depth interviews and the three case studies to triangulate the results. Moreover, for certain aspects, we

have adopted a more systemic view of the RASFF and crisis management arrangements, focusing on an examination of *how* an incident was managed in practice and to which extent the actions taken were consistent with the legislation, Standard Operating Procedures, and other guidance currently in place (see also Section 7.1.2)

8.2.4. *Assessing the effectiveness of the RASFF*

In the analytical framework constructed in the inception phase, evaluation questions concerning the effectiveness of the RASFF relied on key indicators related to the information flow of the RASFF, i.e. data on the *quantity* of notifications transmitted through the system. However, in the course of the evaluation it became clear that additional indicators concerning the *quality* of the information passing through the RASFF are needed. As a result, answers to the evaluation questions related to the effectiveness of the RASFF draw on a number of additional indicators, particularly related to the extent to which notifications are useful to the network and allow for action to be taken.

8.2.5. *Quantifying and monetising costs and benefits*

Evaluation questions related to efficiency have required examining the balance of costs and benefits of the RASFF and crisis management. While the benefits provided by both interventions have been clearly identified, they are not easily quantified and monetised. On one hand, this is due to the difficulty in establishing counterfactual scenarios to determine benefits as avoided costs in the absence of RASFF/crisis management. On the other hand, some of the benefits provided are intangible, or not directly observable. For instance, a long term improvement of public health due to lower exposure to harmful substances may not be attributed to the RASFF and emergency measures that enabled the withdrawal of contaminated products from the EU market; indeed, this key benefit may even go unnoticed. The challenge of quantification and monetisation holds true also for the costs of the interventions. While the financial analysis of the RASFF conducted in the course of the evaluation has allowed for an estimate of the costs of running the system in the reference year, no such data exists for crisis management procedures. Moreover, a key challenge has been to demarcate the costs of crisis management, i.e. to establish to what extent the economic impacts of a crisis can be linked to the way in which it was managed.

To overcome the challenges related to the quantification and monetisation of costs and benefits, the evaluation has focused on identifying cost and benefit categories, factors that impact the balance between the two, and ways in which costs can be reduced and benefits maximised, drawing on past serious food/feed safety incidents. Therefore, while no final value of costs and benefits could be reasonably determined in this evaluation, our approach has enabled a discussion of the efficiency of the RASFF and crisis management arrangements and allowed recommendations to be developed for its improvement.

8.2.6. *Limited evidence from Third Countries*

Both the sections on the RASFF and on crisis management arrangements include evaluation questions concerning the involvement of third countries in the respective systems. As mentioned above, due to resource limitations only two non-member countries were consulted via case study and in-depth interviews, and several more contributed to the surveys (see Annex 4 for a list of survey respondents' organisations). However, it should be noted that the small sample size of third countries provides only limited insight on the broader experience of the EU's international partners with the RASFF and crisis management arrangements. It is possible that additional issues could emerge in a wider consultation of the 107 non-member countries with access to RASFF notifications (see Sections 9.7 and 10.4).

9. ANSWERS TO THE EVALUATION QUESTIONS: THE RAPID ALERT SYSTEM FOR FOOD AND FEED

9.1. Effectiveness

9.1.1. *To what extent has the RASFF achieved its objectives?*

The intervention logic elaborated in the course of this evaluation in close cooperation with the European Commission (see Annex 8) identifies the following four objectives of the RASFF:

- I. Provide a tool for information exchange between members of the network on direct or indirect risks in relation to food or feed;
- II. Inform members of the network on the follow-up to notified direct or indirect risks;
- III. Exchange of information between members of the network on measures to contain risk;
- IV. Information of third countries on risks detected to human health deriving from food and feed.

The objectives listed above refer to various dimensions of the RASFF as a tool for information exchange. At a quantitative level, the number of notifications transmitted can serve as an indicator for the degree of information exchange through the system. As is detailed in Section 9.4.1 below, a large number of original notifications (objective I) and follow-up notifications (objectives II and III) were transmitted through the RASFF in recent years (in total 3,137 original notifications and 5,158 follow-up notifications in the reference year 2013)²². Regarding objective IV, data provided by the EC indicates that in the same year information was transmitted to third countries 2,373 times about products originating from or distributed to their country. The figure is lower than the overall number of notifications, as not all risks identified and notified through the RASFF relate to consignments received from or sent to third countries.

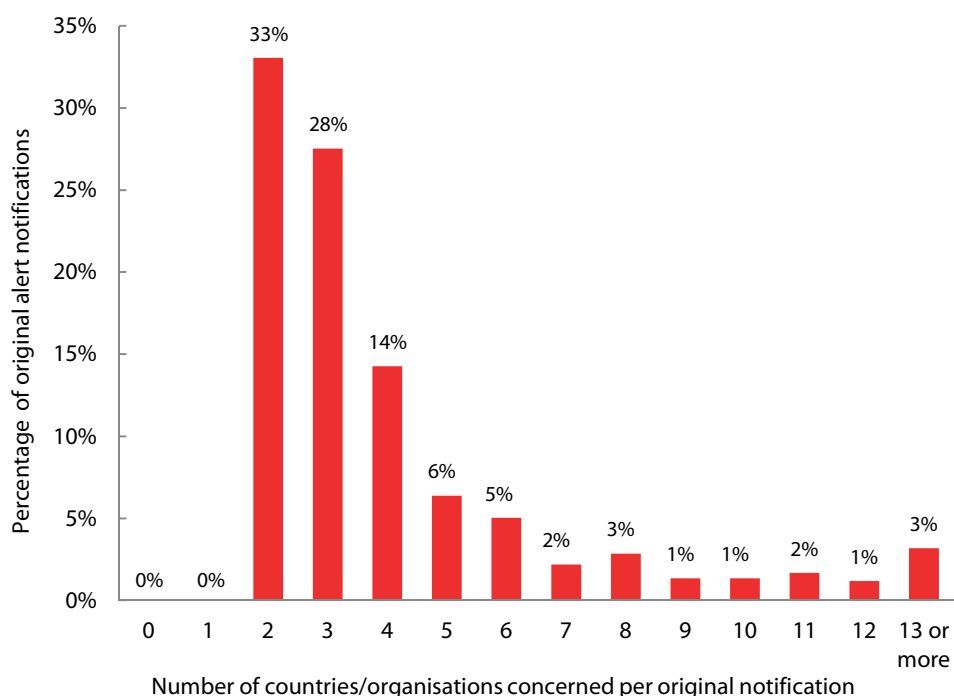
While the number of notifications transmitted through the network provides an overview of the quantity of information exchanged by members of the RASFF, the quality of notifications also has to be considered. As discussed in Section 6.2.4, an obligation of the European Commission Contact Point is to verify notifications prior to their transmission. This process entails verifying elements such as completeness and legibility, use of appropriate data from dictionaries, the correctness of the legal basis, and whether the information contained in the notification is provided in a language that is easily understandable by all members of the network. When these expectations of quality are not met, the ECCP may reject a notification, make small changes (in line with Article 8 of Regulation (EU) No 16/2011), or contact the National Contact Point of the notifying country to obtain the additional information necessary to complete the notification. The numbers of notifications transmitted through the network in the reference year (provided above) include only those which were verified and approved by the ECCP, thereby suggesting that they were of sufficient quality for the purposes of the network. In contrast, the number of rejected notifications was 230 in 2013, or less than 3 percent of all notifications. This indicates that, while there is some limited scope for improvement, the overall quality of notifications transmitted by members of

²² The 2013 RASFF Annual Report cites 3205 original notifications transmitted in the reference year; in the same report, 3137 original notifications are reported to have been transmitted in the same year. While the first number reflects all original notifications transmitted, the second one does not include notifications that were subsequently withdrawn from the system.

the network is mostly sufficient for the transmission to other members of the network, if the standard of the ECCP for the verification of notifications is taken as a benchmark.

Other indicators providing insight on the quality and effectiveness of information transmitted through the RASFF relate to the extent to which the information is *useful for* and *acted upon* by the members of the network for the containment of risks deriving from food and feed. At a first level, the *usefulness* of RASFF notifications to its members can be measured by examining notifications with regards to the number of countries or organisations concerned in one way or another by the original notification. As Figure 2 shows, all original alert notifications transmitted in the reference year 2013 concerned at least two countries/organisations, with nearly one quarter (24%) concerning five or more countries or organisations.

Figure 2: Number of countries/organisations concerned per original alert notification (2013)

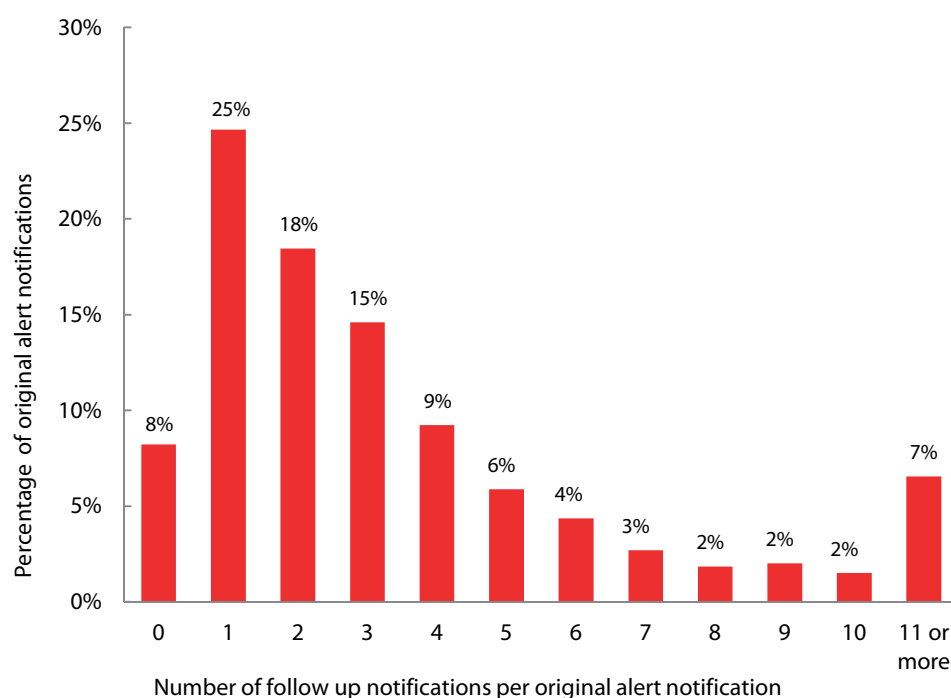


Source: Civic Consulting based on data provided by the European Commission for this study.

At a second level, the extent to which members of the network *react* to information transmitted through the RASFF should be considered. As described in Section 6.2.3, original notifications are those that were not previously notified through the system. Members of the network may then react to original notifications by submitting follow-up notifications, which refer to the same consignments or add information e.g. on hazards, product traceability or measures taken. To the extent that a follow-up notification signifies a reaction from another member of the network in addressing the risk identified, it can serve as an indicator for the effectiveness of the RASFF not only as a tool for information exchange, but for contributing to the safety of food and feed in the EU. In this sense, the more follow up notifications are submitted, the greater the *reactivity* of the members of the network to the risks identified. Of course, reactivity also depends on the seriousness of the risk involved, and therefore a lower number of follow up notifications may also relate to other factors (e.g. that the risk has already largely been contained etc.).

Data from the reference year 2013 indicates that approximately 92% of original alert notifications gave rise to at least one follow up notification, with only 8% of alert notifications receiving no reaction or additional information, as shown in the figure below. Moreover, a majority of original alert notifications led to the transmission of two or more follow up notifications; in some cases more than 30 follow-ups related to a single original alert notification.

Figure 3: Number of follow up notifications submitted per original alert notification (2013)



Source: Civic Consulting based on data provided by the European Commission for this study.

Data concerning the information flow of the RASFF discussed in this section indicates that information is transmitted very frequently through the system, generally of sufficient quality for transmission and tends to be useful for its members. Moreover, in a large majority of cases, the notifications transmitted by one member of the RASFF have led to a reaction from other members. Finally, as discussed in more detail in Section 9.4.2, a large majority of alert notifications (both original and follow-up) have been transmitted by the European Commission Contact Point (ECCP) within the time limit specified by the Regulation. This indicates an effective functioning of the RASFF.

This is confirmed by the assessment of National Contact Points and other stakeholders involved in the RASFF. When asked to assess the extent to which the RASFF has achieved each of the four objectives outlined above, average ratings were notably positive.²³ The objective with the highest average rating was “Provide a tool for information exchange between members of the network on direct or indirect risks in relation to food or feed” (4.4), followed by “Inform members of the network on the follow-up to notified direct or indirect risks” (4.2), “Exchange of information between

²³ All items received an assessment of more than 2.5 on a scale of 0 to 5, with 0 indicating “achieved not at all well” and 5 “achieved very well”.

members of the network on measures to contain risk" (3.8), and "Information of third countries on risks detected to human health deriving from food and feed" (3.7).²⁴

The data on information exchange presented above and the assessment of National Contact Points (NCPs) and other stakeholders involved in the RASFF refer to the overall achievement of the objectives of the system. In this evaluation we also assessed how effective the information exchange through RASFF was during three selected past serious food safety incidents. The table below presents the three case studies considered and outlines the way in which the RASFF was used in each incident, the number of alert notifications and corresponding follow-up notifications submitted, the member countries which submitted these notifications, and the third countries that were informed through the RASFF about the relevant product notified.

²⁴ With respect to the latter objective, the assessment of the three third countries that participated in the survey is of interest: according to their view, the objective to inform third countries was well reached (average assessment 3.3).

Table 3: Use of the RASFF in past serious food safety incidents

Food safety incident	Description of use of the RASFF in the food safety incident	Number of relevant alert notifications transmitted	Number of follow ups to alert notifications transmitted	RASFF member countries notifying or providing follow up	Third countries notified
Melamine crisis (2008)	In the melamine crisis, the RASFF was used by members to confirm the presence of melamine in composite products containing milk ingredients and to notify the illegal import of milk and milk products from China. As member countries were requested to report unfavourable results of controls through the RASFF, the resulting notifications were instrumental for reassessing and adapting the emergency measures in place, by extending them to other food products which were found to contain melamine. The RASFF was also used to transmit data compiled by INFOSAN of findings received from competent authorities around the world.	19 alert notifications ^a	70 follow up notifications	Netherlands, Malta, Austria, Germany, Spain, U.K., Belgium, Greece, France, Portugal, Italy, Switzerland, Luxembourg, Finland, Poland, Hungary, Czech Republic	China, Lebanon
Glass fragments in instant coffee (2010)	In this incident, the RASFF was used to inform members of the network and third countries about the results of the company's own-checks and the decision to withdraw the brands of instant coffee. Information was transmitted about the (re)distribution of the product to the various member countries and third countries and about the measures taken to contain the risk (including inspections, issuing of press releases, withdrawal and destruction or redispach of the product).	1 alert notification ^b	23 follow up notifications	France, U.K., Germany, Czech Republic, Greece, Cyprus, Norway, Spain, Sweden, Poland, Ireland, Lithuania, Estonia	Albania, Andorra, Bosnia and Herzegovina, Croatia, Russia, Serbia, Ukraine
E.coli outbreak (2011)	In the E.coli outbreak, the RASFF was used to transmit information about the source of the outbreak, to track the distribution of fenugreek seeds in member countries, and to exchange information about the measures taken by competent authorities, such as the issuing of press releases and the withdrawal and destruction of products. It was also used to transmit the analytical results of samples taken and to inform the network about the outcome of epidemiological investigations.	2 alert notifications ^c	107 follow up notifications	France, U.K., Italy, Germany, Poland, Austria, Spain, Norway, Bulgaria, Denmark, Czech Republic, Estonia, Sweden, Finland, Greece, Belgium, Netherlands, Lithuania, Latvia, Switzerland, Slovenia, Portugal, Luxembourg, Hungary, Finland	Egypt

Source: Civic Consulting, on the basis of data available in RASFF Window. Notes : a) This number takes into account alert notifications concerning melamine in food transmitted between 11 September and 9 December 2008; b) this does not include notification 2010.0620; c) this does not include notifications 2011.0702 and 2011.0703.

As shown above, the RASFF played a key role as a tool for transmitting information in each of the food safety incidents considered. The use of alert notifications and the significant number of follow-up notifications transmitted by members of the network clearly 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.

The assessment of interviewees during case studies/in-depth interviews largely supports this factual data. In both the melamine crisis and the incident in which glass fragments were found in instant coffee, there was strong agreement among the officials and stakeholders interviewed that the RASFF had achieved the first three objectives. In the case of the E.coli outbreak, key persons involved in the incident pointed to the wider range of uses for which the RASFF was used (e.g. the state of play reports communicated to summarise the situation). A majority of interviewees considered that the first three objectives of RASFF were reached in this incident. Regarding the fourth objective (informing third countries), across all three case studies most interviewees had insufficient information to provide an assessment; those who did considered the objective to have been reached.

9.1.2. *To what extent has the RASFF adapted to changes in the regulatory framework, emerging risks, changes in market and consumer behaviour, etc. ?*

Since the adoption of Regulation (EC) No 178/2002, more than a decade has passed during which a series of changes - including in the legal framework, emerging risks, markets, and consumer behaviour - have altered the landscape of food/feed safety. In order to evaluate the adaptability of the RASFF, survey respondents were asked to assess whether or not in their view the system had adapted to changes in the regulatory framework (e.g. Commission Regulation (EU) No 16/2011 and major legislation such as the Hygiene package), to changes in emerging risks (for instance, related to more globalised food chains), changes in the market and marketing channels (e.g. the use of e-commerce for the distribution of food products), as well as changes in consumer behaviour (including the increased consumption of processed foods). More than two thirds of respondents that answered this question agreed that the RASFF had adapted to changes in the regulatory framework, while only a small minority disagreed. Regarding the adaptation to changes in emerging risks, a majority of respondents considered that the RASFF had adapted to these changes, while almost one fifth of respondents indicated that this was not the case. However, less than half of the respondents affirmed that the RASFF had adapted to changes in the markets/marketing channels and to changes in consumer behaviour although only a minority considered that this was not the case, with a large share of respondents indicating that they did not know.²⁵

Regarding the changes to which respondents considered that the RASFF had least adapted to, several key comments referred to increasing and evolving e-commerce in food, which poses significant challenges not only for the RASFF, but for carrying out official controls and the enforcement of food safety legislation in general.

²⁵ See Figure 10 in Annex 5. 69% of respondents that answered this question agreed that the RASFF had adapted to changes in the regulatory framework, 7% disagreed. 60% of respondents considered that the RASFF had adapted to changes in emerging risks, 18% disagreed. 46% affirmed that the RASFF had adapted to changes in the markets/ marketing channels; 21% disagreed. 49% considered it had adapted to changes in consumer behaviour and 9% disagreed. All remaining respondents who answered this question selected "don't know".

9.1.3. *Identify tangible and measurable criteria to evaluate the effectiveness of the RASFF*

As mentioned before, the number of notifications transmitted through the RASFF provides insights into the effectiveness of the system as a tool for information exchange between members of the network (and with third countries). To validate the criteria used and to identify complementary criteria for the evaluation of the RASFF's effectiveness, participants of our stakeholder survey were asked to assess the relevance of selected criteria. The criterion evaluated to be most relevant was the number of follow-up notifications sent through the RASFF (3.6), followed by the number of original notifications sent through the RASFF (3.5) and the number of notifications sent to third countries (3.3). Other criteria suggested by respondents included the number of notifications withdrawn from the system and the reaction time (e.g. the time between the occurrence of an incident and the transmission of its corresponding notification through the RASFF). The possible criteria have been scrutinised by the evaluation team, and the following conclusions can be drawn:

- The *number of notifications withdrawn* from the system depends upon a series of factors, including new information emerging after a notification has been submitted, which renders it unfounded thereafter. For instance, if the results of an analysis carried out on a counter-sample contradict initial results contained in a notification, it may be withdrawn after agreement with the notifying member. As such, this would not be an appropriate indicator for evaluating the effectiveness of the system;
- The *reaction time* could in principle be a relevant indicator, as it would allow for an assessment of the extent to which the RASFF is indeed a rapid alert system. In practical terms this would concern the time lag between the detection of a relevant risk by food safety authorities in a member country (e.g. during an official control), and the transmission of the corresponding notification through the RASFF. This data would need to be provided by NCPs on a self-reporting basis (i.e. it could be included as an information item in the original notification).

Based on this discussion, it can be concluded that the following indicators could be considered for future reporting on effectiveness of the system:

- Number of original notifications sent through the RASFF (number per year);
- Number of follow-up notifications sent through the RASFF (number per year) and the distribution of follow-up notifications per original notification;
- Number of notifications sent to third countries (number per year);
- The number of countries/organisations concerned per original notification;
- Self-reported time lag between detection of a relevant risk by food safety authorities in a member country, and the transmission of the corresponding original notification by the NCP through the RASFF (hours).

These indicators are relevant for evaluating the effectiveness of the RASFF from the perspective of the quantity and quality of notifications transmitted. On one hand, the absolute number of (original and follow-up) notifications allows for comparisons across time in the evolution of information transmitted. On the other hand, the distribution of follow-up notifications per original notification and the number of countries/organisations concerned by original notifications serve as indicators of the extent to which the notifications transmitted are useful and acted upon by RASFF members, as discussed above. Moreover, to some extent at least, these indicators reflect the quality of notifications, given that the ECCP is required to verify and transmit those notifications which fulfil the conditions outlined in Article 8 of the implementing measures.

Data regarding these indicators have been considered in this evaluation. The data necessary for the remaining (fourth) indicator is not available in the current format of RASFF notifications. Relevant data would need to be reported by the NCPs for each notification, if this indicator was to be used for future monitoring of the system.

9.1.4. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section the answers to the evaluation questions concerning effectiveness of the RASFF are as follows:

- ▶ This evaluation concludes that the RASFF achieves its core objectives related to information exchange between members well. This is reflected in the large number of original notifications (objective I) and follow-up notifications (objectives II and III) handled by the system: in total 3,137 original notifications and 5,158 follow-up notifications in the reference year 2013. These statistics refer to notifications which were verified by the European Commission Contact Point and subsequently transmitted to the network, indicating that they were of sufficient quality if the ECCP's verification standards are used as a benchmark. Moreover, notifications tend to be useful for the members of the network, and in a large majority of cases, the notifications transmitted by one member of the RASFF have led to a reaction from other members. Finally, National Contact Points and other stakeholders involved in the RASFF have also provided a positive assessment regarding the achievement of these objectives.
- ▶ Also, 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 objective of the RASFF to inform third countries on risks detected to human health deriving from food and feed (objective IV) has also been largely achieved during the evaluation period, with third countries having been informed 2,373 times about products originating from or distributed to their country in the reference year.
- ▶ RASFF National Contact Points and other stakeholders largely agree that the RASFF has adapted to changes in the regulatory framework and changes in emerging risks. While there is also mostly agreement that the RASFF has adapted to changes in markets and consumer behaviour, e-commerce in food stands out as an area of concern, where further adaptation (e.g. in terms of reaction time) may be needed.

9.2. Relevance

9.2.1. *To what extent have the initial objectives remained valid?*

As described in Section 6.1, developments in the globalised trade of food and feed underline the need for a mechanism to rapidly exchange information on risks detected in order to allow competent authorities and business operators to address them through appropriate measures. As such, survey respondents were asked to assess to what extent the four objectives of the RASFF still remain valid. Unsurprisingly, more than 90% of those respondents who provided an answer considered that these objectives remain valid. None of the respondents disagreed.

Respondents to our survey were also asked whether further, additional objectives for the RASFF are needed. More than half of the respondents providing an answer did not think an additional objective was needed, while over one third disagreed. Among RASFF National Contact Points, the trend towards *not* adding an objective was stronger than the average, with three quarters of respondents not seeing the need for an additional

objective.²⁶ Among additional objectives to be addressed by the RASFF, survey respondents suggested that the system could be used as a tool for aggregating data on food/feed safety incidents or non-compliance, or that it could contribute to a wider EU emergency strategy by providing analysis of trends, risks and causes of alerts. These suggestions are further considered in Section 11.1 of this report.

9.2.2. *Answers to evaluation question*

Based on the evidence collected and the summary of findings presented in this section, the answer to the evaluation question concerning the relevance of the RASFF is as follows:

- ▶ **The 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 and feed between member countries, allowing food safety authorities (and business operators) to address the risks identified through appropriate measures. This argument is strongly supported by the assessment of RASFF member countries and other stakeholders: the objectives of the RASFF that relate to its character 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 practically all National Contact Points and other stakeholders involved in the RASFF, with no opposing views among respondents to our survey.**
- ▶ **Suggestions from stakeholders in regard to additional potential objectives of the RASFF include to use 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 causing alerts and related measures taken (see also Section 11.1).**

9.3. Coherence and scope

9.3.1. *How well does the RASFF work together with other notification systems (at Member State, EU and international levels)?*

The evaluation questions above relate to the effectiveness and relevance of the RASFF as a stand-alone system. However, a key criterion in evaluating the RASFF relates to its capacity to work with other relevant notification systems, including INFOSAN, EU-level systems (particularly those related to public health, official controls, food and product safety, and early warning) and other alert systems at the Member State level. If a notification system provides distinct data which can complement the information from another notification system, without providing the same or largely overlapping information, these two systems can be considered to be *complementary* to one another. In contrast, *duplication* occurs when two notification systems provide the same data (or largely overlapping information) to their respective network members which may require network members to input data into them separately, effectively increasing the time and/or effort spent to transmit the information. While duplication should typically not occur, it may in some instances be unavoidable, e.g. when the relevant data and information that are provided through the systems are used by authorities with distinct competences and information needs.

Table 1 in the Annex provides a brief description of the EU and international systems considered in this evaluation question, including an analysis of the areas of potential

²⁶ 55% of the respondents providing an answer did not think an additional objective was needed, 37% disagreed and 7% did not know. For RASFF National Contact Points, 75% of respondents did not see the need for an additional objective, 21% of respondents considered an additional objective necessary.

complementarity and duplication. The table shows that all listed systems are potentially complementary to the RASFF. In practice, INFOSAN, the EWRS, and TRACES were key complementary systems during past serious food/feed safety incidents, as indicated by the results of our case studies.

Results from our survey largely confirm this analysis of potential complementarities. Respondents were asked to rate the extent to which the RASFF is complementary to these and the other relevant information systems. The highest average ratings were provided for EWRS (4.3) and INFOSAN (4.1).²⁷ These were closely followed by EPIS, the AAC and TRACES, all of which received an average rating of 3.9. Slightly lower average ratings (but still clearly above the midpoint of 2.5 which separates a negative from a positive assessment) were provided for ARGUS, national level alert systems, ECURIE (all 3.3) and RAPEX (3.2).

The table in the Annex also lists potential duplications that exist in several cases. As mentioned above, these are partly unavoidable, e.g. in cases a risk relates to a product containing both a food and a non-food component (and is therefore notified through RASFF and RAPEX), or to a radiological or nuclear accident affecting food/feed safety, as was the case in the aftermath of the Fukushima accident (where Member States were required to report the results of their controls through both the RASFF and ECURIE). Cases such as these relate to the specific characteristics of the type of product or risk involved, and are therefore exceptional in nature. Furthermore, the authorities involved are typically not the same, so that the use of both information systems safeguards that the information is distributed through a wider network of relevant authorities. Potential overlaps with the RASFF also exist in the case of INFOSAN and TRACES:

- Regarding INFOSAN, duplications may occur for third countries that receive requests for information from both INFOSAN and RASFF. Since the melamine incident in 2008, however, an alignment of procedures and membership of RASFF and INFOSAN has taken place, and this has reportedly reduced the duplication between the two systems.²⁸
- As TRACES allows data to be transferred into the RASFF, duplication between the two systems is minimised. When a border rejection notification is made in TRACES, it is extracted and uploaded into RASFF Window after verification by the RASFF ECCP.²⁹ However, if a border inspection post chooses to upload data into iRASFF first (e.g. in order to receive follow-up from other members), it may be required to also enter data into TRACES thereafter. In this context it is notable that the TRACES IT tool is in the process of being updated, and a software link between the systems, which would increase the efficiency of the data transfer, is envisaged by the RASFF team for the future.

Another area of potential duplication identified relates to the Administrative Assistance and Cooperation system, for which the IT tool is currently under development.³⁰ While its scope has not yet fully been finalised, there are indications that overlaps could occur e.g. in the area of food fraud, if a case of fraud would also involve a direct or indirect risk to human health. In this case, a notification could be transmitted through both the RASFF and the AAC system. Another potential area in which overlap may occur is in cases where information is transmitted between Member States' competent authorities concerning a risk which does not require rapid action. While such cases are currently communicated through the RASFF as information notifications, if they involve a non-compliance they could, in the future, be transmitted through the AAC. The RASFF SOPs provide for the possibility for procedures involving information notifications to evolve, which may help in

²⁷ On a scale from 0 to 5 with 0 indicating "not at all" and 5 "very much".

²⁸ International Food Safety Authorities Network, INFOSAN Activity Report 2011-2012, 2012.

²⁹ See also European Commission, Standard Operating Procedures of the Rapid Alert System for Food and Feed.

³⁰ The IT tool for the AAC system was launched on 18 November 2015.

clarifying the potential duplication.³¹ Moreover, as both the iRASFF and the AAC IT tool are implemented on the same software platform, it is expected that in the future a software link between the systems can be established, which would avoid double entry of data. Section 9.8 of this report further elaborates on ways in which the efficiency of the RASFF can be improved by increasing the links between different IT tools or transferring certain tasks to more appropriate systems.

Results from the survey of RASFF National Contact Points (NCPs) and other stakeholders involved in the RASFF confirm that in practice duplication with other notification systems is not a major concern.³² It can be concluded that, while potential duplications between notifications systems may exist, they are already reduced or (planned to be) minimised 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), which will integrate the various systems used for official controls, could further attenuate potential duplications through further facilitating data exchange between systems (although this will depend on the details of its implementation).

9.3.2. *To what extent is the scope of the RASFF appropriate? Is the scope of the RASFF sufficiently defined?*

According to the intervention logic developed in the inception phase of the evaluation, the RASFF responds to the following needs:

- A rapid and coordinated response in cases of risks to human health deriving from food and feed;
- The containment of food/feed safety incidents and the prevention of crisis;
- Prevention of disruptions of the internal market;
- Effective national controls, including border controls, to ensure the compliance with EU rules of products placed on the EU market;
- Consumer confidence in safe food/feed on the EU market; and
- Protection of human health.

In our survey, RASFF National Contact Points considered the need for “A rapid and coordinated response in cases of risks to human health deriving from food and feed” to be most appropriately addressed within the scope of the RASFF (average rating of 4.8), followed by “Protection of consumer health” (4.6) and “The containment of food/feed safety incidents and prevention of crisis” (4.4).³³ The following three needs received relatively lower (but still very high) ratings: “Effective national control including border control to ensure compliance with EU rules of products placed on the EU market” (4.1), “Consumer confidence in safe food/feed on the EU market” (4.0) and “Prevention of disruptions of the internal market due to food/feed safety incidents” (3.7).

³¹ European Commission, Standard Operating Procedures of the Rapid Alert System for Food and Feed, n.d. pp. 20-21.

³² On a scale of 0 (no duplication at all) to 5 (very much duplication) the highest average rating was provided for national level alert systems, followed by the AAC (1.7), INFOSAN (1.6), TRACES (1.5) and ARGUS (1.0). A number of information systems received an average rating of less than 1.0, specifically the EWRS (0.9), ECURIE (0.7), RAPEX (0.5) and EPIS (0.3).

³³ On a scale from 0 to 5, with 0 indicating “Not at all appropriate” and 5 indicating “Very appropriate”.

Case studies and in-depth interviews support the view that the scope of the RASFF appropriately addresses needs of RASFF members. Neither in the case study on melamine nor in the case study on glass fragments did interviewees identify unnecessary elements in the RASFF, or any needs that were not addressed by the RASFF. There were more diverging views regarding the E.coli outbreak, where some interviewees indicated that the RASFF was overburdened with (non-risk related) status updates, while others considered that all the information handled by the RASFF was appropriate.

In addressing the second evaluation criteria related to the scope of the RASFF, respondents were first asked whether they consider the scope of the RASFF to be sufficiently defined in Article 50 of Regulation (EC) No 178/2002.

A majority of respondents who answered this question agreed that the scope of the RASFF is sufficiently defined in the legislation, although more than one third considered the opposite to be true. A slightly higher proportion of RASFF National Contact Points provided a positive answer than other stakeholders.³⁴ Among respondents who considered the scope of the RASFF to be insufficiently defined in Article 50 of Regulation (EC) No 178/2002, some pointed out that it does not include food contact materials, nor serious risks to animal health or to the environment in relation to feed. While serious risks to animal health or to the environment deriving from feed are covered by Regulation (EC) No 183/2005, food contact material is not specifically mentioned in Article 50 of Regulation (EC) 178/2002, although it is included in recital 11 and explicitly in Regulation (EU) No 16/2011. Several respondents considered that it would be useful to harmonise the definitions as provided in the two regulations.

To examine the potential ways for further clarifying the scope of the RASFF, survey respondents were also asked to provide suggestions as to how the definition of the scope (as defined in Article 50 of Regulation (EC) No 178/2002) of the RASFF could be improved. 40% indicated they have suggestions for improving the scope of the RASFF. The suggested improvements provided by respondents included to clarify what constitutes a serious risk, and to provide more information to food business operators.

9.3.3. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section the answers to the evaluation questions concerning coherence and scope of the RASFF are as follows:

- ▶ **This evaluation confirms that overall the RASFF works together well with other information systems, such as the TRAdE Control and Expert System (TRACES), the Early Warning and Response System (EWRS) and the International Network of Food Safety Authorities (INFOSAN). The RASFF is considered to be complementary to them, as well as the other information systems considered: the General European rapid alert system (ARGUS), the Epidemic Intelligence Information System (EPIS), the European Community Urgent Radiological Information Exchange (ECURIE), and the Rapid Alert system for non-food dangerous products (RAPEX).**
- ▶ **While the RASFF is generally not considered to duplicate any of these systems, some instances of potential duplications have been noted. They are partly unavoidable and may be necessary when a product concerns two or more networks covering distinct scopes. For instance, when a risk relates to a product containing both a food and a non-food component, it must be notified through both RASFF and RAPEX. When a risk relates to or a radiological or nuclear accident affecting food/feed safety, as in the aftermath of the Fukushima accident, it may require Member States to report the**

³⁴ 57% of the respondents who answered this question agreed that the scope of the RASFF is sufficiently defined in the legislation, while 36% of the respondents considered the opposite to be true, and 7% did not know. Among RASFF National Contact Points, 63% provided a positive answer, compared to 53% of other stakeholders.

results of their controls through both the RASFF and ECURIE. 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) and planned software links for data transfer between systems (AAC and RASFF). The creation of the envisaged IMSOC (Information Management System for Official Controls), which will integrate the various systems used for official controls, could further attenuate potential duplications by further facilitating data exchange between systems (although this will depend on the details of its implementation).



Results of this evaluation confirm that the scope of the RASFF appropriately addresses 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.

9.4. Legal basis and role of the European Commission

9.4.1. *To what extent has the adoption of Regulation (EC) No 178/2002 improved the functioning and monitoring of the RASFF?*

As described in Section 6.1, the existence of the RASFF precedes the adoption of Regulation (EC) No 178/2002, its conception and initial legal basis dating to 1979. In that year, the system was comprised of food authorities from just nine countries: Belgium, Denmark, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, and the United Kingdom.³⁵ By 1995, nine further countries were covered by the RASFF, bringing the number of RASFF member countries to 18. With the expansions of the EU since 2004, new countries (mainly from Central and Eastern Europe) joined the network, bringing to the total number of RASFF member countries to 32, including all EU Member States and the EFTA countries.³⁶ Current network members are as follows:

- 28 EU Member States (Croatia being the newest member of the RASFF since 2013);
- European Commission (as manager and coordinator);
- European Food Safety Authority (EFSA);
- Iceland, Liechtenstein, and Norway, via the Agreement on the European Economic Area (EEA);
- EFTA Secretariat (coordinates the input from the EEA countries);
- Switzerland (partial member of RASFF for products of animal origin since 2009).³⁷

The areas covered by the RASFF have changed significantly since the system's origins more than three decades ago. In the beginning, the RASFF was relatively broad and flexible in its scope. Moreover, before the creation of RAPEX in 2004, the initial legal basis referred to a community system for rapid exchange of information on dangers arising from both food and non-food products.³⁸ Over time, the scope of the RASFF has

³⁵ European Commission, RASFF: 30 Years of Keeping Consumers Safe, 2009.

³⁶ This figure does not include third countries that are not considered to be members of RASFF. 107 countries outside the EU/EFTA had access to RASFF notifications provided through RASFF Window, see below, Section 9.6.1.

³⁷ All member organisations of the RASFF are listed on the following RASFF web page: http://ec.europa.eu/comm/food/food/rapidalert/members_en.htm.

³⁸ European Commission, RASFF: 30 Years of Keeping Consumers Safe, 2009.

become more focused and notifications are intended to be risk-based, rather than hazard-based.³⁹

By providing a legal basis for the RASFF, the adoption of Regulation (EC) No 178/2002 improved the functioning of the system in several ways. The provisions concerning RASFF provided in Articles 50 to 52 of the Regulation transformed the practices followed by its members into specific obligations to be fulfilled by both Member States and the European Commission Contact Point (ECCP). Transmitting information about the existence of a serious direct or indirect risk became a duty for RASFF members. Moreover, transmitting border rejection notifications became mandatory. Secondly, the requirements contained in the Regulation (e.g. the obligation to designate a contact point) provided additional impetus for member countries to create the structures essential for running the RASFF at the national level. Finally, Regulation (EC) No 178/2002 defined the scope of the RASFF as transmitting information concerning "a serious direct or indirect risk to human health deriving from food and feed". This represented a broader scope compared to the previous legal basis (the Product Safety Directive had referred to a "serious and immediate risk"), thereby encouraging the exchange of information concerning a wider variety of risks deriving from food and feed.⁴⁰ These effects, combined with a growing awareness of Member States about risks related to food and feed, contributed to improving the functioning and monitoring of the RASFF. It also led to a significant increase in the number of notifications transmitted through the system.

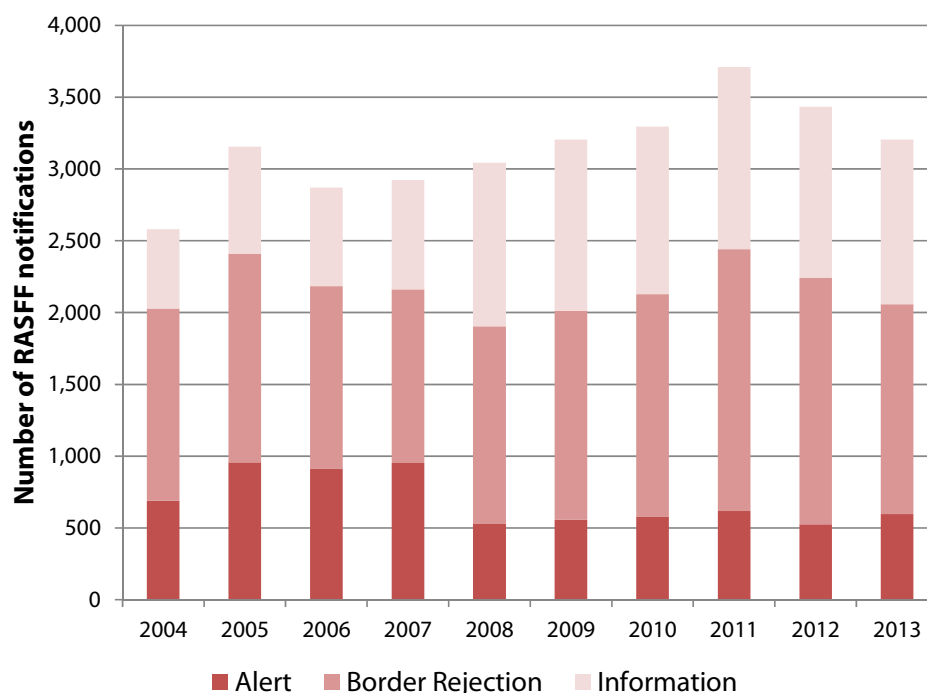
Prior to 1992, approximately 10 notifications were sent through the RASFF annually. In 2001, this figure had increased to 1,567 notifications.⁴¹ By contrast, in 2002, i.e. after the adoption of Regulation (EC) No 178/2002, the number of notifications nearly doubled to over 3,000.⁴² The numbers of notifications reached a peak of about 3,800 original notifications in 2011. Since then, the number has stabilised to just over 3,200 in 2013, as can be seen in the figure below. In this figure, it can also be observed that the number of alert notifications was almost halved between 2007 and 2008 while the number of information notifications increased by 50% in this period. This is explained by the introduction of a stricter classification of alerts in 2008, depending on the seriousness of the risk.

³⁹ However, the system has continued to be used sporadically for other uses not necessarily linked to risk, as illustrated by the horsemeat (food fraud) scandal as recently as 2013. European Commission, *The Rapid Alert System for Food and Feed: 2013 Annual Report*, 2013.

⁴⁰ Subsequently, Commission Regulation (EU) No 1672/2011 laying down implementing measures for the RASFF extended this scope to include also serious risks to human health, animal health or the environment in connection with feed, in accordance to Regulation (EC) No 1831/2003.

⁴¹ European Commission, *RASFF: 30 Years of Keeping Consumers Safe*, 2009.

⁴² European Commission, "The Rapid Alert System for Food and Feed: Report for the Year 2002", 2002.

Figure 4: Trend in RASFF original notifications

Source: Civic Consulting, from data provided in RASFF Annual Report, 2013 and RASFF Annual Report, 2009. 2013 figures according to EC press release of 13 June 2014. The distinction between “information for attention” and “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 “information” notification.

The figure above provides the number of original notifications by category. Commission Regulation (EU) No 16/2011 distinguishes between notifications requiring rapid action (*alert notification*), and other notifications (*information notifications* and *border rejection notifications*). A RASFF notification referring to one or more consignments of a food, feed or food contact material that were not previously notified to the RASFF is defined as an *original notification*. Original notifications can give rise to *follow-up notifications*, which refer to the same consignments and which add information to the original notification such as information on hazards, product traceability or measures taken. Not surprisingly, the rise in the number of original notifications was accompanied by a similar increase in transmission of follow-up notifications. Initially referred to as “additions” to alert or information notifications, in 1999 these amounted to a total of 338 notifications, increasing to 859 in 2001 and to 1,498 in 2002. The number of additions continued to increase following the adoption of Regulation (EC) No 178/2002 and in 2008, these notifications – now renamed as “follow-up notifications” reached 3,975. In 2013, the number of follow-up notifications amounted to 5,158. Figure 2 in Annex 5 illustrates this trend.

9.4.2. To what extent is the EC fulfilling its obligations deriving from the Regulation?

According to Article 50 of Regulation (EC) No 178/2002, as specified in Articles 2 to 10 of Commission Regulation (EU) No 16/2011 laying down implementing measures for the RASFF, the European Commission has to fulfil the following duties:

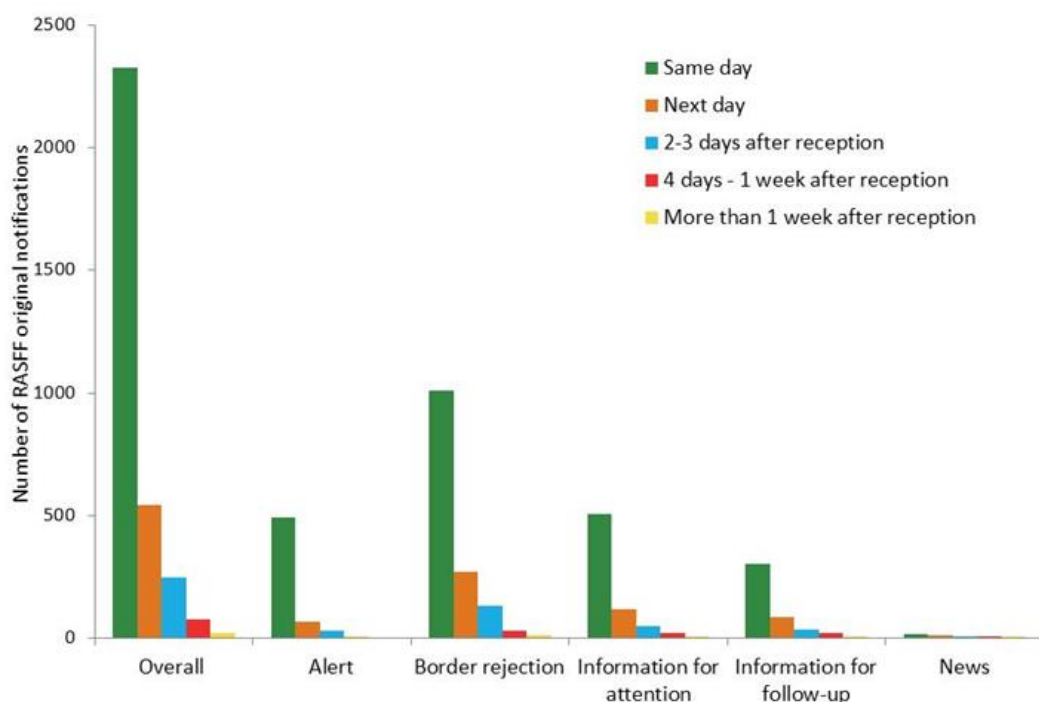
- Maintaining and updating the list of contact points and making it available to all members of the network;
- Ensuring the availability of an on-duty officer reachable outside office hours for emergency communications on a 24-hour/7 day a week basis;
- Transmitting alert notifications and their follow-up to all members of the network within 24 hours after reception, upon verification;

- Informing members of the network flagged for follow-up in alert notifications (or follow-up) by a telephone call to their emergency phone numbers outside of office hours;
- Transmitting information notifications and their follow-up to all members of the network without undue delay;
- Transmitting border rejection notifications to border inspection posts on products entering the Community from third countries and to designated points of entry;
- Verifying notifications and correctly classifying them before transmission;
- Amending/withdrawing notifications at the request of a member of the network;
- Informing third countries when a notified product originates from or is distributed to it.

The first two duties of the RASFF European Commission Contact Point (maintaining and updating the list of RASFF contact and ensuring the availability of an on-duty officer) are essential for any rapid alert system. According to the information available, the EC has ensured that an on-duty officer is available outside of office hours by organising a weekly rotation in which one member of the ECCP staff is responsible for receiving telephone calls informing about a notification and informing the countries concerned on a 24-hour/7-day-a-week basis. Similarly, the EC confirms to have fulfilled the obligation to maintain and update the list of National Contact Points, and there is no indication which would contradict this self-assessment.

Regarding the duty to rapidly transmit alert notifications and follow-up notifications, statistical data is available for the reference year 2013. The following figure examines the delay incurred by the EC in transmitting original notifications by type of notification.

Figure 5: Original notifications according to time of transmission (2013)



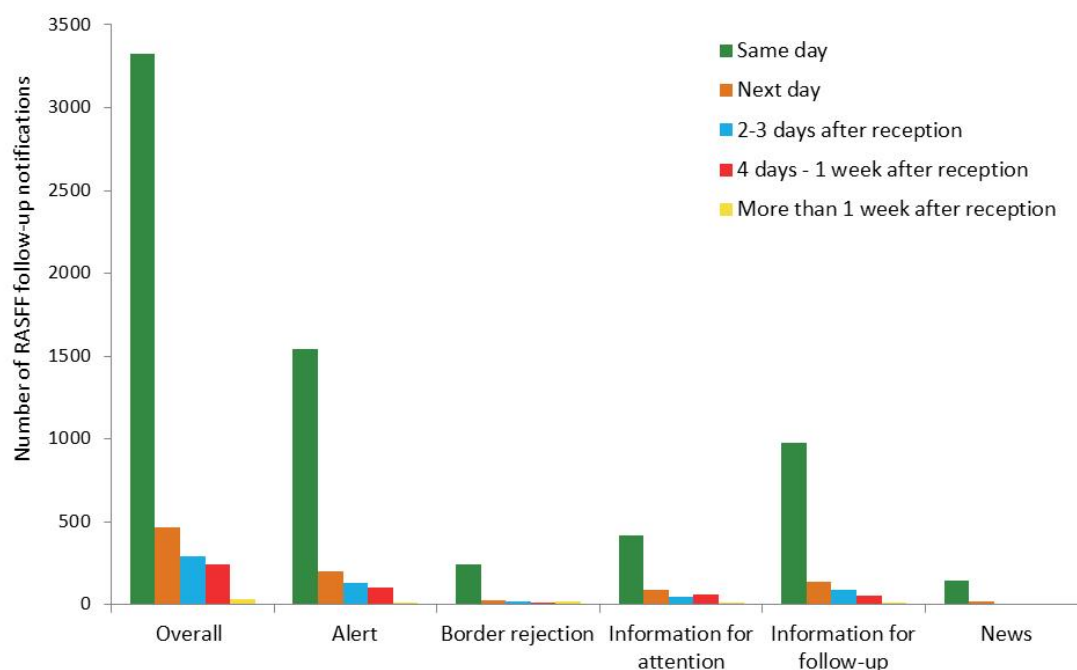
Source: Civic Consulting based on data provided by the European Commission for this study.

The 24-hour deadline for transmission provided in the legal basis only applies to original alert notifications and follow-up notifications to alerts. They are processed with priority. The data presented in the figure above is based on the date of receipt of a notification

and the date of its transmission to network members after verification and (where relevant) translation into English. As a transmission on the following day can be in line with the 24-hour period foreseen in the legislation, only a delay of two or more days is clearly beyond that limit. As indicated in the figure, alert notifications are typically transmitted on the same day (as is the case for all other types of notifications). 95% of alert notifications are transmitted by the ECCP to RASFF members on the same or the following day. Only 5% of alert notification are transmitted on the second day after receipt or later, according to the data provided. Additional data provided by the EC compares the time at which a notification is submitted by an NCP with the time at which the ECCP notifies countries by e-mail about the transmission of the notification to the network, providing an estimate of the time for transmission in hours. This data confirms that approximately 94% of alert notifications are transmitted within 24 hours.

In a large majority of cases, the reason for delay is related to the requirement to translate notifications into English, which typically takes 48 hours to complete. However, in cases where translation is necessary, notifications are advance-forwarded to the relevant countries to ensure that the transmission of information to them is not delayed.⁴³ The following figure provides similar data for follow-up notifications.

Figure 6: Follow-up notifications according to time of transmission (2013)



Source: Civic Consulting based on data provided by the European Commission for this study.

The figure above shows that for follow-up notifications to alerts (for which the 24-hour limit also applies), a higher percentage of notifications with some delay in transmission is noted. While still 88% of follow-up notifications to alerts are transmitted by the ECCP to RASFF members on the same or the following day, 12% of such notifications are transmitted on the second day after reception or later, according to the data provided.

To complement the statistical data, RASFF National Contact Points also provided an assessment regarding the fulfilment of the EC's main obligations deriving from the legislation described above. In our survey, the NCPs of RASFF member countries were asked to indicate whether the 24 hour time limit imposed for the transmission of alert

⁴³ The data on delay provided by the ECCP refers to the official transmission as a notification in the system. It does not consider that some notifications have been forwarded in advance to NCPs of countries concerned, pending an advice or a translation.

notifications and follow up notifications to alerts to all members of the network was (according to their experience) always, mostly, sometimes, or never fulfilled by the EC Contact Point. A large majority of RASFF NCPs consider that the EC Contact Point has always fulfilled both of these duties.⁴⁴

Another survey question further examined the EC's fulfilment of duties deriving from the legislation. More specifically, RASFF NCPs were asked to assess whether the EC has transmitted information notifications to all members of the network without undue delay and whether it had transmitted border rejection notifications to NCPs/border posts. Finally, NCPs were asked to consider the extent to which the EC Contact Point had fulfilled its duties deriving from Article 8 of the implementing measures (i.e. relating to the verification of notifications). Respondents were asked to broadly assess the quality and rapidity with which notifications have been validated by the EC before transmission, by indicating whether the verification has been rapid and of good quality always, often, sometimes, or never. A large majority of NCPs also consider that the EC Contact Point has always fulfilled these duties.⁴⁵

Separate indicators relevant for answering this evaluation question examine the satisfaction of member countries' NCPs with the quality and rapidity of the EC's verification of notifications in specific previous food/feed safety incidents, and explore the degree to which the EC fulfilled its obligations during these incidents. The evidence collected in the case study/in-depth interviews confirms a generally positive view of EC verification of notifications, although some dissent was also noted in one of the case studies:

- *Melamine crisis (2008)*: Throughout the melamine crisis, the RASFF was used extensively to inform Member States about information regarding the situation in China via INFOSAN, and for transmitting information regarding the products containing melamine, the measures taken in Member States, and the results of controls carried out across countries. Interviewees were satisfied with the quality and rapidity with which the Commission validated RASFF notifications during the melamine incident.
- *Glass fragments in instant coffee (2010)*: In the glass fragments case, the RASFF was used to inform the network about the results of the company's own-checks and the subsequent decision to recall the product in question, to transmit information about the countries to which the product in question had been exported or re-exported and to inform members of the network about the measures taken (e.g. recall, destruction of the product, etc.). Interviewees expressed satisfaction with the quality and rapidity with which the Commission validated RASFF notifications during the glass fragments incident.
- *E.coli outbreak (2011)*: In the E.coli outbreak, the RASFF was used by the Member States to input and receive notifications on the risks detected and to provide information on the suspected and contaminated products. The system was also used to communicate „state of play“ reports. Finally, the system played an important role in linking the outbreaks in Germany and France. One of the interviewed authorities criticised the quality with which the Commission validated RASFF notifications during the E.coli outbreak, and more specifically,

⁴⁴ See Figure 23 in Annex 5. 73% of those respondents providing an opinion confirmed that the EC “always” transmits alert notifications within 24 hours, while 17% stated that the EC fulfilled the duty “mostly” within 24 hours. 67% confirmed that the EC “always” transmits follow-up notifications to alerts within the set time limit, while 23% would consider the EC fulfilling it “mostly” within 24 hours. In both questions, 10% of the respondents chose the answer option “don’t know”.

⁴⁵ 73% of NCPs that provided a response consider that the EC has always transmitted information notifications without undue delay, 17% indicated that this is “often” the case. In regard to the speed and quality of the verification of notifications by the EC before transmission to members of the network and to the transmission of border rejection notifications to NCPs/border-posts, in all cases around two thirds of respondents to this question considered that the EC “always” fulfils its duties (67%, 62% and 63%, respectively), and another 13% to 28% considered that the EC “often” fulfilled its related duties.

pointed out that the initial notifications which identified E.coli in Spanish cucumbers (RASFF Alert 2011.0702 and RASFF Alert 2011.0703) did not provide laboratory results.⁴⁶ However, while including laboratory results in an original notification is considered to be good practice, this is not a specific requirement contained in the legislation.⁴⁷ The Standard Operating Procedures of the RASFF, published more recently, instruct members to provide the risk evaluation on which a notification is based together with the notification in cases where the risk involved is not straightforward. However, they provide for the possibility of providing the risk evaluation as a follow up in urgent cases.⁴⁸ In the E.coli outbreak, the laboratory results were not attached to the original notifications at the time of their transmission, but were subsequently provided in the course of the same day (27 May 2011).⁴⁹

In terms of informing third countries, Article 50(6) of Regulation (EC) No 178/2002 foresees that participation in the RASFF may be opened up to applicant third countries. However, this has not been implemented in practice, mainly due to the complex procedure that would be required to achieve this implementation, and also due to the problem that third countries operate in a different legal framework for food safety, which would complicate uniform notification practices and measures. Instead, informing third countries has mainly taken place through the use of RASFF Window. Currently, 107 third countries receive information through RASFF Window (directly, through country desks at the European External Action Service, or through EC Delegations to those countries) and can view original and follow up notifications concerning products originating from or distributed to their country. According to data provided by the EC, in the reference year 2013 third countries were informed 2,373 times about products originating from or distributed to their country. To obtain a third country perspective on the EC's fulfilment of its obligations, a selection of third country contact points were included in our survey and asked to provide their assessment of whether the EC has informed their country's contact point without undue delay when notified products originated from or were distributed to their country. Of the three non-member contact points who provided an answer to the question, two indicated that the EC had "always" informed them without undue delay when notified products originated from or were distributed to their country. The remaining third country contact point indicated that this was "mostly" the case. Two interviewees from non-member countries confirmed the majority opinion, i.e. they reported the EC had always informed them without undue delay when notified products originated from or were distributed to their country.

9.4.3. *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 EC contributed to the coordination of the members of the RASFF and to the development of good and common notification practices?*

As described in the background section to this report, the legislation assigns a double role to the Commission with regards to the functioning of the RASFF. On the one hand, it is a participant of the network. The EC Contact Point may act like member countries or the European Food Safety Authority by e.g. inputting RASFF notifications. On the other hand, in its function as manager of the RASFF, the Commission has additional prerogatives such as verifying and transmitting notifications, or withdrawing and amending them, under certain conditions. In addition, the EC's role as manager of the RASFF entails management of the relevant IT systems, promoting harmonisation among Member States in how risk is assessed through the correct classification of notifications,

⁴⁶ It was mentioned by the same authority that subsequently one of the two notifications was withdrawn from the RASFF, as the laboratory analysis of the counter sample taken did not confirm the original findings. This topic is discussed in the context of the risk-based approach of the RASFF in Section 9.5 below.

⁴⁷ See also 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.

⁴⁸ European Commission, Standard Operating Procedures of the Rapid Alert System for Food and Feed, n.d.

⁴⁹ RASFF 2011.0703-add01.

and verifying and monitoring activities of the members to ensure that all countries which were flagged for follow-up in a notification have provided it accordingly. Thus, although formally the Commission is both participant and manager of the network, it *de facto* acts primarily as manager of the network; its input as a participant is minor compared to the coordinating and managing role it ensures (in the reference year 2013, the RASFF transmitted only 1 notification inputted by the EC itself).⁵⁰

A judgment by the Court of First Instance in the so-called Bowland case in 2009 sheds some light on the double role of the EC as manager and member of the network and the distinct obligations and rights under those two roles. According to the judgment of the Court, in the context of the RASFF network, the Member States are to notify the Commission of the measures listed in (a) to (c) of the first subparagraph of Article 50(3), in addition to supplementary information, pursuant to the second paragraph of Article 50(3), in particular where the measures on which the notification is based are modified or withdrawn. The Commission must immediately transmit to members of the network notifications and supplementary information received under the first and second subparagraphs of Article 50(3) of Regulation (EC) No 178/2002 in its quality as manager of the RASFF. However, as a member of the RASFF and in line with Article 50(2), the Commission may also transmit any information it has relating to the existence of a serious direct or indirect risk to human health deriving from food or feed. Therefore, as the Court ruled, the competent authority of the Member State concerned has sole responsibility for drafting the notifications under Article 50(3) of Regulation No 178/2002, and also for transmitting them to the Commission for communication to the other members of the network. As a member of the network, the Commission may express an opinion, even in a case which is a matter for the national authorities. The opinion has no legal effects, however, and is not binding upon those authorities.⁵¹

In our survey, participants were asked to indicate whether this double role had led to problems in the past. Just over half of respondents to this question indicated that there have never been cases where the double role of the Commission as manager and participant of the RASFF had led to problems; nearly half selected “don’t know”.⁵² When broken down by stakeholder group, it becomes clear that RASFF National Contact Points were more likely to indicate that there had not been cases where the double role of the Commission as manager and participant of the RASFF led to problems, while other stakeholders were more likely to select “don’t know”.

The following indicator for this evaluation relates to the Commission’s role as manager of the network, and more specifically, considers the extent to which the EC has contributed to the coordination of the members of the RASFF and to the development of good and common notification practices to ensure its effective functioning. RASFF National Contact Points were asked to assess the degree to which the Commission had contributed to both of these areas. Survey results show that the EC’s contribution to the coordination of the members of the RASFF and to the development of good and common notification practices is viewed very positively by RASFF NCPs. In regard to both aspects, the NCPs who provided an opinion gave an average rating of 4.6.⁵³

9.4.4. *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*

⁵⁰ European Commission, The Rapid Alert System for Food and Feed: 2013 Annual Report, 2013.

⁵¹ Bowland Dairy Products Ltd v Commission of the European Communities, Case T-212/06 [2009] II-0473, paras. 39-41.

⁵² See Figure 25 in Annex 5. 53% of respondents to this question indicated that there have never been cases where the double role of the Commission as manager and participant had led to problems, 45% selected “don’t know”, and one respondent (a RASFF NCP) considered that notifications are sometimes upgraded or downgraded without consultation and that the influence of the stakeholders is not transparent. 74% of NCPs, compared to only 34% among other stakeholders who answered this question, selected “No”. Other stakeholders were more likely to select “don’t know” (this was the case for 66% of respondents from this group).

⁵³ On a scale of 0 to 5 with 0 representing “not at all” and 5 “very much”.

guidelines issued by the EC on the functioning of the network [SOPs] clear and helpful?

The working groups of the RASFF National Contact Points are organised twice per year by DG SANTE. The NCPs were asked to assess the extent to which these regular working groups have contributed to the better functioning of the RASFF. Those NCPs who expressed an opinion tended to give a positive assessment of the contribution of the working groups to the better functioning of the RASFF, with nearly sixty percent providing the highest rating possible (5). On average, respondents gave a rating of 4.5. No respondents provided a negative rating (i.e. 2 or lower).⁵⁴

Respondents from the National Contact Points were also asked to indicate the outcomes of the working groups that were most relevant to the contribution of a better functioning of the system. A key outcome identified related to the elaboration of the Standard Operating Procedures on the functioning of the RASFF and the accompanying Working Instructions (in preparation), as well as discussions relating to IT developments such as the iRASFF. Moreover, some respondents considered the opportunity provided by the working groups for getting to know members of other NCPs and exchanging information and views with colleagues from other countries to be particularly relevant.

The following indicators for this evaluation question refer to the Standard Operating Procedures (SOPs) of the RASFF that have been developed in the working groups. The aim of the SOPs is to “codify the experience gained over the years by the members of the network” on the basis of the existing legal framework.⁵⁵ A recent edition (version 1, revision 4) of this document from 2014 provides NCPs with guidelines in the following areas related to the RASFF:

- SOP 1: Best practices for NCPs;
- SOP 2: Scope of RASFF – Criteria to determine when a notification to the RASFF is required;
- SOP 3: Preparing an original notification;
- SOP 4: Preparing a follow-up notification;
- SOP 5: Transmitting a notification to the ECCP;
- SOP 6: ECCP verification and distribution of RASFF notifications transmitted by the NCPs;
- SOP 7: Distribution of RASFF notifications received from the ECCP;
- SOP 8: Assessing a notification received from the ECCP;
- SOP 9: Archiving and consulting RASFF notifications and related information;
- SOP 10: Confidentiality rules for the RASFF.

The RASFF National Contact Points were asked to assess to what extent the SOPs issued by the EC on the functioning of the network are clear, helpful and consistent with their needs and expectations. Respondents who expressed an opinion again provided high average ratings for each of these aspects: 4.4 for “helpful”, 4.2 for “clear” and 4.1 for “consistent with your needs and expectations”. Although the small number of respondents who provided a lower score regarding the consistency of the SOPs with their needs and expectations did generally not elaborate on reasons for their rating, one respondent suggested that further work on SOP 2 (scope of RASFF) would be required to clarify the criteria for notification and expectations regarding the initial risk assessment of Member States. The request for further guidance on the scope of the RASFF and risk-

⁵⁴ On a scale of 0 to 5 with 0 representing “not at all” and 5 “very much”.

⁵⁵ European Commission, Standard Operating Procedures of the Rapid Alert System for Food and Feed, n.d.

basis is likely to be addressed in the planned guidance for risk evaluation, to be developed by the EC and EFSA (see Section below).

9.4.5. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section the answers to the evaluation questions concerning the legal basis and the role of the European Commission in the RASFF are as follows:

- ▶ 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: the Regulation transformed the practices followed by its members into specific obligations to be fulfilled by both Member States and the European Commission Contact Point (ECCP). Also, the requirements contained in the Regulation provided additional impetus for members to create the structures essential for running the RASFF at the national level. Finally, the scope of the RASFF became broader with the Regulation in comparison to the previous legal basis, encouraging the exchange of information concerning a wider variety of risks deriving from food and feed. These effects, combined with a growing awareness of Member States about risks related to food and feed, contributed to improving the functioning and monitoring of the RASFF. It also led to a sharp increase in the number of original notifications and follow-up notifications transmitted through the system. With the expansion of the EU the number of member countries has also gradually grown, from nine countries in 1979 to 32 since the accession of Croatia in 2013.
- ▶ This evaluation concludes that the EC has largely fulfilled its duties deriving from the RASFF legal basis during the evaluation period concerning organisational aspects and, most importantly, the verification and transmission of notifications. Alert notifications and their follow-up have to be transmitted by the EC to all members of the network within 24 hours after reception, upon verification. In the reference year 2013, about 19 in 20 original alert notifications and 7 in 8 follow-up notifications to alerts were transmitted by the ECCP to RASFF members on the same or the following day. Where delays occurred, notifications have typically been forwarded in advance to NCPs of countries concerned, pending translation. A large majority of RASFF National Contact Points confirm that the EC largely fulfils its duties concerning the transmission and verification of notifications.
- ▶ The double role of the EC as manager of and participant in the RASFF is unproblematic, and in practice the EC mainly acts as manager of the system. Its contribution to the coordination of the members of the RASFF and to the development of good, common notification practices is also viewed very positively by National Contact Points. The working groups of the RASFF National Contact Points have contributed to the better functioning of the RASFF, and the Standard Operating Procedures on the functioning of the network are considered to be helpful, clear and consistent with needs and expectations.

9.5. Risk-based operations of the RASFF and the role of EFSA

9.5.1. *To what extent are the operations of the RASFF really risk based? To what extent is risk accurately evaluated in the RASFF?*

According to Article 50 of Regulation (EC) No 178/2002, the RASFF is a system for the notification of a direct or indirect risk to human health deriving from food or feed. Commission Regulation (EU) No 16/2011 laying down the implementing measures for the RASFF elaborated further on the risks covered within the scope of the RASFF 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 1831/2003.” The RASFF is thus intended for notifying not only cases where a serious risk to human health, animal health or the environment is involved, but also other cases where a risk to human health of lesser gravity or urgency is identified.

As described in Section 6.1, notifications are classified in the RASFF depending on the risk involved. Alert notifications are those in which rapid action is required or might be required in order to counter the risk, and they are handled with priority. Cases involving a risk which does not require a rapid action in another member country are classified as information notifications. This category is subdivided into the following two types of notifications:

- Information for follow-up – for information notifications related to a product that is or may be placed on the market in another member country;
- Information for attention – for information notifications related to a product that is present only in the notifying member country, has not been placed on the market, or is no longer on the market.

In addition, border rejection notifications are transmitted when a batch, container or cargo of food or feed is rejected by a competent authority at a border post of the EU. News notifications are used to exchange information related to food or feed safety which has not been transmitted through one of the above-mentioned notification types, but is considered to be of interest to competent authorities in member countries.⁵⁶

In practice, the risk evaluation of notifications takes place in two sequential stages. The first stage occurs at the NCP level. A key component of original notifications transmitted by NCPs to the ECCP is the risk section, which must be duly completed before submission. NCPs must also indicate the proposed classification of the notification (alert, information for attention, information for follow-up, or border rejection) based on the risk and availability of the product to consumers, and it must include information on which the risk evaluation is based if the seriousness of the risk is not straightforward. Alternatively, in urgent cases, the risk evaluation can be made subsequently as a follow-up to the notification.⁵⁷

In a second stage, the ECCP verifies notifications submitted by NCPs and their respective classifications. If a notification includes a risk for which no evaluation has been provided and past relevant evaluations are not available, the ECCP should request EFSA to provide a full risk assessment, according to the SOPs. In practice, in cases where ECCP staff have doubts about the correct classification of a notification, or there are indications that a notification may not fall within the scope of the RASFF (implying a proposal for its rejection), internal meetings are held in order to discuss the risk-basis and reach a consensus about the correct classification, before considering whether or not to involve EFSA. When the classification according to the ECCP differs from that of the NCP submitting the notification, or when a notification has been proposed for rejection, the ECCP contacts the NCP in order to seek additional information and to reach a common understanding of the risk involved.

This involvement of the ECCP may serve to improve the accuracy of risk evaluation in the RASFF. For instance, in 2009, a member country transmitted a large number of border rejection notifications concerning the presence of semicarbazide in shrimps. It was found that these notifications did not reflect a risk to human health given that the chemical compound occurs naturally in the skeleton of shrimps and is not necessarily, as was originally considered, a marker for the banned nitrofurantoin nitrofurazone.⁵⁸ After the EC

⁵⁶ European Commission, The Rapid Alert System for Food and Feed: 2013 Annual Report, 2013.

⁵⁷ European Commission, Standard Operating Procedures of the Rapid Alert System for Food and Feed, n.d. p. 21.

⁵⁸ McCracken R, Hanna B, Ennis D, Cantley L, Faulkner D, Kennedy DG (2013) « The occurrence of semicarbazide in the meat and shell of Bangladeshi fresh-water shrimp », *Food Chemistry* 136(3-4) pp. 1562-1567.

recommended the country to correct its analytical method by performing controls on the peeled product, the number of notifications was significantly reduced.⁵⁹

Data on the information flow for the reference year 2013 provides additional insight on the evaluation of risk in the second stage of the process: according to EC data, in this year a total of 230 notifications submitted by RASFF members were rejected by the ECCP. In addition, 8 alert notifications were downgraded to information notifications. While this data does not provide an indication regarding the quality of the risk assessment, it at least shows a considerable involvement of the ECCP as gatekeeper of the system, with a likely influence on consistency of the ways risks are assessed. The number of rejected notifications in 2013 was higher than in the two previous years (94 rejected notifications in 2011⁶⁰ and 67 rejected notifications in 2012⁶¹) due to a more systematic verification of notifications based on Commission Regulation (EU) No 16/2011 and the Standard Operating Procedures, which were already substantially developed. In 2014, the number of rejected notifications fell again to 111, suggesting that the more stringent verification procedure initiated in 2013 had a positive impact on the transmission of risk-based notifications by member countries.⁶²

To examine whether the process described above ensures that only notifications involving a risk are transmitted through the network, RASFF National Contact Points and other stakeholders involved in the RASFF were asked to provide their assessment about whether the notifications exchanged through the RASFF are *sufficiently* risk-based. Answers were almost evenly split between yes and no: 46% of respondents to this question affirmed that notifications exchanged through the RASFF are sufficiently risk based, while 44% of respondents rejected this statement. One tenth (10%) of all those providing a response to the question did not have an opinion.

Differentiating responses between RASFF National Contact Points and other stakeholders shows a very significant variation in opinion between stakeholder groups. While amongst RASFF National Contact Points two thirds (65%) of the respondents agreed that notifications exchanged through the RASFF are sufficiently risk based, almost two thirds of respondents amongst other stakeholders (60%) disagree. Among those respondents who considered notifications transmitted through the RASFF to be insufficiently based on risks, the comments provided by stakeholders shed some light on the reasons for their negative assessment. In particular, several considered that differences in notifications issued by Member States indicated that there is no harmonised approach to risk among members of the network. Others pointed out that the risk-based approach of the RASFF was limited due to a lack of involvement of food business operators.

The second indicator to inform the answer to this evaluation question is the extent to which the risk is *accurately* evaluated in the RASFF. The information obtained from the case studies/in-depth interviews served to scrutinise concrete examples of risk evaluation in the RASFF. In two of the case studies, there was a general agreement that risk was accurately evaluated in the RASFF. However, in the case of the E.coli outbreak there was no agreement in this respect. Key aspects of the case studies that are relevant for answering this evaluation question include:

- *Melamine crisis (2008)*: Evidence suggests that risk was accurately evaluated in the RASFF throughout the melamine incident. It was indicated that the risk assessment was initially based on the WHO's international early risk assessment, which was updated several times throughout the incident.
- *Glass fragments in instant coffee (2010)*: Interviewees considered that the risk was accurately evaluated in the RASFF in the glass fragments case.

⁵⁹ European Commission, The Rapid Alert System for Food and Feed: 2010 Annual Report, 2010.

⁶⁰ European Commission, The Rapid Alert System for Food and Feed: 2011 Annual Report, 2011.

⁶¹ European Commission, The Rapid Alert System for Food and Feed: 2012 Annual Report, 2012.

⁶² European Commission, RASFF Preliminary Annual Report 2014, 2014.

- *E.coli outbreak (2011)*: There was disagreement noted among interviewees whether or not the evaluation of the risk in RASFF was accurate, specifically with reference to the first two notifications (RASFF Alert 2011.0702 and RASFF Alert 2011.0703) regarding the detection of *E.coli* in Spanish cucumbers. During the further investigation, fenugreek sprouted seeds originating in Egypt were identified as the source of the outbreak. Previously, it was clarified that one of the two notifications (RASFF Alert 2011.0703) referred to another strain of *E.coli* (which was confirmed through a counter sample). The other notification (RASFF Alert 2011.0702) was subsequently withdrawn from the system, as a laboratory analysis of a counter sample did not confirm the original findings. The ECCP pointed out that withdrawal of a notification is not uncommon, as in the process of confirmation a separate sample is analysed, for example, if the affected operator requests this. The confirmation process may take several days. The case study therefore highlights that there is a trade-off between the need for rapid transmission of information concerning an identified risk – which is key for any alert system –, and the need for time for a comprehensive confirmation process. In practice, these two processes occur in parallel, and are addressed with a procedure of withdrawing notifications, where the original findings are not confirmed through subsequent analyses.

Regarding the same indicator, survey respondents were asked to provide a rating regarding the extent to which risk is accurately evaluated in the RASFF, using a scale of 0 ("Not all accurately") to 5 ("Very accurately").

Overall, respondents who expressed an opinion tended to assess that the evaluation of risks in the RASFF is accurate, with an average rating of 3.1. This was particularly the case for the RASFF National Contact Points, with an average rating of 3.6, compared to 2.8 for other respondents. However, even if the average assessment of other respondents was close to the midpoint of 2.5, it should be noted that nearly two thirds (62%) of respondents other than NCPs still provided a positive answer to this survey question (i.e. a rating of 3 or more). Respondents who provided low ratings in their answers to this question suggested e.g. that additional support from the European Commission for risk assessment and harmonisation of classifications would be needed. Examples given by respondents related to cases in which notifications are transmitted on the basis of a non-compliance or exceedance of a Maximum Residue Limit (MRL).

Finally, survey respondents were asked whether they had suggestions for improving the risk-based approach of the RASFF. The majority of respondents (54%) had suggestions in this regard. Stakeholder groups other than RASFF National Contact Points were particularly likely to offer suggestions (i.e. 63%, compared to only 42% for NCPs). The main suggestions provided included the harmonisation of guidelines for evaluating risk, closer cooperation with industry, increased training for risk assessment, engaging EFSA to have a closer involvement in the RASFF, and verifying the risk more accurately before it is transmitted through the network.

All relevant survey questions therefore indicate that there is a split of opinion between RASFF National Contact Points and other stakeholders regarding whether the notifications exchanged through the RASFF are sufficiently risk-based and whether the risk is accurately evaluated in the RASFF, leading to suggestions that revolve around harmonising and improving the evaluation of risk before notifications are transmitted. While it is undisputed that the ECCP contributes to harmonisation of approaches for evaluation of the risk, there remain factors, however, that may contribute to differences in the evaluation of risk:

- As described in the most recent revision of the Standard Operating Procedures for the RASFF, the decision about "whether or not there is a risk involved in

non-compliant food/feed, and whether the risk is such as to require the notification to the RASFF is the responsibility of the members of the network."⁶³ Especially regarding emerging risks or identified risks that do not frequently occur, member countries may apply different criteria in taking this decision, for example because the national risk assessment bodies may reach different conclusions in their guidance provided, or the available evidence is inconclusive and an updated opinion of EFSA is not available.

- Guidance documents that may lead to a more harmonised evaluation of the risk across Member States are only available to a limited extent.

These findings are confirmed by the results of the ongoing evaluation of the General Food Law, which found that a series of differences across Member States have led to varying applications and implementations of the principle of risk analysis described in Article 6 of Regulation (EC) No 178/2002. Moreover, the evaluation notes that differences in risk analysis occur in areas where EU legislation is not (or only partly) harmonised, such as contaminants and food contact materials.⁶⁴

The Standard Operating Procedures for the RASFF contain some guidance to NCPs for evaluating risk within the RASFF. The SOPs provide indicative, non-exhaustive lists of past cases, divided into three categories:

- Past cases where members of the RASFF have considered that risk *did not require* a notification to the RASFF, e.g. food or feed products with live parasites of no public health concern and food products that are obviously contaminated with dead parasites;
- Past cases where they considered that the risk *did require* rapid action, e.g. live parasites that may represent a health hazard to the consumer in foods that are not meant to undergo a treatment before consumption sufficient to kill parasites;
- Past cases where members considered that the risk *possibly required* rapid action (in some cases following an ad hoc risk evaluation), e.g. food presenting a physical risk to human health, especially foreign bodies.

It is obvious that especially the third category requires consideration of the individual circumstances of the case, which in consequence may lead to a 'grey area' for risk evaluation, if RASFF members come to different conclusions under similar circumstances. One way to address potential 'grey areas' is to provide further specific guidance for risk evaluation, e.g. in the form of decision tools. For example, for cases in which food/feed products are found to contain pesticide residues above MRLs, a document has been developed in order to provide guidance to NCPs concerning which type of notification, if any, to submit under different scenarios.⁶⁵ By providing a table with different scenarios of pesticide residues and indicating how different cases should be notified (i.e. 'notification' or 'no notification') such a document may provide rapid and clear guidance to competent authorities deciding whether or not a notification should be transmitted to the RASFF.

In contrast, for other risk types – such as contaminants – no such guidance exists. Therefore, while pesticide residues exceeding an MRL but falling below the acute reference dose (ARfD)⁶⁶ are not considered to necessarily pose a risk to human health

⁶³ European Commission, Standard Operating Procedures of the Rapid Alert System for Food and Feed, n.d. p. 15.

⁶⁴ Food Chain Evaluation Consortium, Study on the Evaluation of Regulation (EC) No 178/2002 ("the General Food Law Regulation" – Draft final report. p. 80.

⁶⁵ European Commission Health and Consumer Protection Directorate-General, Draft Guidance Document on Notification Criteria for Pesticide Residue Findings to the Rapid Alert System for Food and Feed (RASFF), 2004. http://ec.europa.eu/food/plant/pesticides/guidance_documents/docs/rasff_pest_res_en.pdf.

⁶⁶ The following definition of the ARfD was adopted by the 2002 Joint Food and Agriculture Organization of the United Nations (FAO)/World Health Organization (WHO) Meeting on Pesticide Residues (JMPR): "The ARfD of a Food Chain Evaluation Consortium

and thus may not require a notification in the RASFF, products containing a contaminant in exceedance of the legal limit tend to be automatically notified as an alert, even if the limit is exceeded only slightly. The lack of detailed guidance or decision tools for several areas of risk may be at the source of divergences in the way that NCPs notify risks. Therefore, additional decision tools to assist NCPs in evaluating risk – planned to be developed in cooperation with EFSA – would contribute to improving the risk-based approach and the effectiveness of the RASFF.

9.5.2. *What is the role of EFSA within the RASFF? Is EFSA fulfilling its role in RASFF as laid down in the Regulation?*

According to Article 50(1) of Regulation (EC) No 178/2002, EFSA is a member of the RASFF and therefore it is required to designate a contact point, alongside National Contact Points and the European Commission Contact Point. The Emerging Risks Unit (EMRISK) within EFSA serves as this single contact point required by the legislation.⁶⁷

EFSA may also supplement notifications concerning serious direct or indirect risks to human health deriving from food or feed with any scientific or technical information that will facilitate rapid and appropriate risk management, according to Article 50(2) of the Regulation. EFSA's role is most relevant in the context of major and serious food/feed safety incidents. To understand the extent to which EFSA has fulfilled this role in such incidents in the past and to examine whether EFSA's current role is adequate to address the needs of Member States and the EC, in-depth interviews were conducted with NCPs and relevant EU-level organisations. The following key points summarise the results regarding EFSA's role in the three food safety incidents considered:⁶⁸

- *Melamine crisis (2008)*: In the 2008 melamine crisis, EFSA was asked by the Commission to consider the health effects of melamine exposure via the consumption of contaminated biscuits and confectionary. Interviewees considered that the statement issued by EFSA on 24 September 2008 accurately evaluated the risks related to the presence of melamine in infant milk and other milk products from China; moreover, the statement was considered helpful in managing that risk.
- *Glass fragments in instant coffee (2010)*: EFSA did not play a role in the glass fragments incident, as due to the type of incident no risk assessment was needed.
- *E.coli outbreak (2011)*: In the E.coli outbreak, EFSA produced a number of scientific reports and statements,⁶⁹ gave support and methodological advice to the Task Force in Germany including exchange of staff (a liaison officer), and coordinated the tracing back and tracing forward exercise. EFSA experts also worked alongside the national experts in the Working Groups that were

chemical is an estimate of the amount of a substance in food and/or drinking-water, normally expressed on a body-weight basis, that can be ingested in a period of 24 h or less, without appreciable health risk to the consumer, on the basis of all the known facts at the time of the evaluation". See WHO Core Assessment Group on Pesticide Residues 2015, Pesticide residues in food - Guidance document for WHO monographers and reviewers.

⁶⁷ European Food Safety Authority, Establishment and Maintenance of Routine Analysis of Data from the Rapid Alert System on Food and Feed, Vol. 8, Vol. 8, 2010.

⁶⁸ Please note that several aspects mentioned concern EFSA's role in crisis management, and not just in RASFF – however, as the role of EFSA is only specifically addressed in this evaluation question, we have also included relevant aspects of crisis management here.

⁶⁹ 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>, European Food Safety Authority (EFSA), Scientific Report of EFSA: Urgent Advice on the Public Health Risk of Shiga-Toxin Producing Escherichia Coli in Fresh Vegetables, Vol. 9, Vol. 9, 2011, European Food Safety Authority (EFSA), "Tracing Seeds, in Particular Fenugreek (Trigonella Foenum-Graecum) Seeds, in Relation to the Shiga Toxin-Producing E.coli (STEC) O104:H4 2011 Outbreaks in Germany and France", 2011, 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.

organised during the outbreak, and a European Task Force was led by EFSA in the later stages of the incident. Interviewees unanimously agreed that the role played by EFSA in the E.coli outbreak was important, and that it fulfilled its role as set out in Article 50 of Regulation (EC) No 178/2002.

Our case studies and interviews have therefore confirmed that EFSA has largely fulfilled its role as laid down in Article 50 of the Regulation in the context of the three serious food/feed safety incidents reviewed in depth. Beyond these case studies, EFSA also played a significant role in other incidents such as the Hepatitis A outbreak in 2013-2014, providing coordination of the European outbreak investigations between Member States and publishing scientific reports on the outbreak and its potential sources.

Although EFSA's role in the mentioned major incidents was significant, EFSA's input to supplement RASFF alert notifications that are not related to such incidents appears to be less prevalent. According to data provided by the EC, the RASFF ECCP has not requested EFSA to supplement notifications with scientific or technical information in the reference year 2013; moreover, EFSA has not provided such information on its own initiative. In many cases, such input is simply not needed: as indicated by the ECCP, when alerts relate to well-known risks (e.g. aflatoxins or pesticide residues) for which there are clear guidelines and/or precedents, the ECCP can rapidly and consistently consider the risk involved during the verification of the notification. It appears, however, that on some occasions more involvement of EFSA could be helpful, specifically when the risk involved is less well known.

However, a key challenge for any input by EFSA into RASFF is the difference in the timeframes within which the two organisations are working due to their different remits. While the RASFF is expected to verify an alert notification and to transmit it to its members in 24 hours, EFSA's scientific risk assessment procedures typically entail a more time-consuming process with the involvement of external expertise. A recent evaluation of EFSA has documented that in some food/feed safety incidents, its reaction has been exceptionally swift, e.g. in the melamine incident, EFSA responded to a request for urgent advice within 3 days; in an incident involving chlormequat in table grapes in 2010, EFSA provided a response within 2 days. On the whole, between 2007 and 2011, all urgent requests sent to EFSA received a response within 30 calendar days.⁷⁰ More regular input by EFSA into the RASFF would therefore likely need to involve an even quicker way of providing supplementary information. The abovementioned planned guidance on evaluating risk in the framework of RASFF to be developed jointly by EFSA and the EC is another way in which EFSA could contribute to the RASFF in the future.

9.5.3. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section, the answers to the evaluation questions concerning the risk-based operations of RASFF and the role of EFSA are as follows:



The extent to which notifications exchanged through the RASFF are considered to be sufficiently risk based varies among stakeholder groups, with two thirds of RASFF National Contact Points stating that this is the case, while an almost similar majority of other stakeholders – mainly food business operators and their organisations – disagree. Those that find notifications transmitted through the RASFF to be insufficiently based on risks pointed out, for example, that differences in notifications issued by Member States indicate there is no harmonised approach to risk among members of the network. Others pointed out that the risk-based approach of the RASFF is limited due to a lack of involvement of food business operators. However, 62% of those stakeholders provided a rating of 3 or higher when considering the extent to which risk is accurately evaluated in the RASFF. While the ECCP contributes to the harmonisation of approaches for evaluation of the

⁷⁰ Ernst & Young, External Evaluation of EFSA - Final Report, 2012.

risk, there remain factors that may potentially lead to differences in the evaluation of risk. These include that RASFF members have the responsibility for deciding whether or not there is a risk involved in non-compliant food/feed (and subsequently whether the risk is such as to require the notification to the RASFF), which may lead in some cases to a "grey area" for risk evaluation, if RASFF members come to different conclusions under similar circumstances. Also, detailed guidance documents that may lead to a more harmonised evaluation of the risk across Member States are only available to a limited extent, e.g. in the area of pesticides.



Alongside National Contact Points and the European Commission Contact Point, EFSA is a member of the RASFF, with the Emerging Risks Unit serving as single contact point. Results of this evaluation confirm that EFSA has largely fulfilled its role as laid down in Article 50 of the Regulation during the serious food/feed safety incidents considered in depth in this evaluation by providing risk assessments and methodological advice. However, for alerts that do not relate to a major incident, EFSA rarely supplements RASFF notifications concerning serious risks with scientific or technical information that will facilitate rapid and appropriate risk management. In many cases, such input is simply not needed: alerts often relate to well-known risks, and there are clear guidelines and/or precedents that allow a rapid and consistent consideration of the risk involved. It appears, however, that 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. However, a key challenge for any input by EFSA into RASFF are the differences in the timeframe within which the two organisations are working due to their different remits, which would need to be addressed when strengthening the involvement of EFSA in RASFF. A planned guidance on evaluating risk in the framework of the RASFF to be developed jointly by EFSA and the EC is another way in which EFSA could contribute to the RASFF in the future.

9.6. Involvement of EU Member States

9.6.1. *To what extent have the MS developed their legislation to meet the requirements of the Regulation?*

In our survey, National Contact Points were asked to indicate whether their country had adopted national legislation in order to implement the RASFF, or whether they were in the process of doing so. Half of the respondents to this question, i.e. 16 respondents from 15 different member countries indicated that national legislation implementing the RASFF had been adopted, while 15 respondents from 13 member countries stated that no national legislation had been adopted to implement the RASFF. One respondent stated that such national legislation is currently under development. In those countries that have adopted national legislation to implement the RASFF, its form differs; in some the RASFF has been implemented via acts or administrative regulations, in others, by using decrees.

The following table maps out the members of the RASFF according to whether or not they have implemented the RASFF through national legislation. It also provides for each country the staff numbers (measured in Full Time Equivalent Posts) involved in running the RASFF at the National Contact Point and the number of original notifications transmitted in the reference year, to explore whether or not national legislation implementing the RASFF has an effect on the running of the system. As the data in the table indicates, there is no clear link between having or not having national legislation and both indicators.

Similarly, there does not seem to be a link between the adoption of national legislation to implement RASFF, and the quality of notifications a member country submits, if the decision made by the ECCP to reject or transfer a notification is taken as a benchmark. In fact, the average number of rejected notifications for countries who have not adopted

national legislation in this field is slightly lower than for the group of countries who have adopted such legislation (6% compared to 10%).⁷¹

Table 4: Adoption of national legislation and involvement of countries in the RASFF

Country	National legislation to implement RASFF	Number of Full Time Equivalent Posts in RASFF NCP	Number of original notifications transmitted to the network in 2013	Number of rejected notifications in 2013 (as % of notifications submitted)
Italy	X	9.5	534	39 (7%)
Germany	✓	5.5	331	26 (7%)
United Kingdom	X	13	327	17 (5%)
Netherlands	:	:	264	5 (2%)
France	X	8.0	249	8 (3%)
Spain	✓/X	11.5	201	35 (15%)
Belgium	X	2.0	164	7 (4%)
Poland	✓	4.0	120	6 (5%)
Denmark	X	1.5	112	9 (7%)
Sweden	X	1.5	91	7 (7%)
Finland	✓	1.0	88	1 (1%)
Czech Republic	✓	3.0	70	4 (5%)
Greece	X	4.0	65	5 (7%)
Bulgaria	✓	3.0	54	4 (7%)
Austria	✓	3.0	46	1 (2%)
Norway	✓	1.5	45	3 (6%)
Cyprus	X	2.5	44	4 (8%)
Ireland	X	3.5	40	-
Portugal	Under development	1.0	40	8 (17%)
Switzerland	X	1.0	40	2 (5%)
Slovakia	✓	4.0	35	7 (17%)
Slovenia	✓	1.5	34	-
Estonia	X	2.0	32	3 (9%)
Lithuania	✓	2.0	28	9 (24%)
Latvia	✓	1.0	27	5 (16%)
Luxembourg	:	:	17	1 (6%)
Romania	✓	1.0	14	8 (36%)
Malta	X	:	12	4 (25%)
Croatia	✓	1.0	8	0 (0%)
Hungary	✓	2.5	3	2 (40%)
Iceland	:	:	1	-
Liechtenstein	:	0	0	0

Source: Civic Consulting based on survey data and data on rejected notifications provided by the EC for this evaluation. Notes: Combines data on FTE posts for food and feed contact points. ✓ indicates that a country has adopted national legislation to implement the RASFF, X indicates it has not. : signifies that no information was provided by the country in the survey. Spain has adopted national legislation to implement the RASFF in the area of feed, but not food. – indicates that information on the number of rejected notifications was not provided.

⁷¹ Excluding countries for which no data was available, whose national legislation was under development at the time of the survey, or which provided different answers for food and for feed.

9.6.2. *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?*

In light of the key obligations of RASFF member countries deriving from the legislation, National Contact Points were asked to provide a self-assessment of the extent to which their country had fulfilled the organisational aspects of their duties deriving from the implementing measures. Around half of the NCPs provided a rating of 5, while all other respondents providing an opinion provided a rating of 4 when asked whether their country has ensured the efficient functioning of the RASFF within its jurisdiction.⁷²

When asked in detail regarding other obligations and requirements related to organisational aspects, the overall results were consistently positive:

- Most RASFF National Contact Points confirmed that they had adapted to the requirements of the Regulation by designating one contact point for the RASFF. In two Member States separate contact points were created for food and for feed, and in a third Member State, a partial contact point for feed operates via the NCP. An additional Member State pointed out that two contact points share competences for the RASFF in that country;
- 90% of the RASFF National Contact Points stated that the Commission “always” had been informed about any changes regarding the designated RASFF contact point and of contact details while the remaining 10% stated they had provided the relevant information “most of the time”;
- Similar positive responses of fulfilment of duties by 90% or more respondents concerned: “ensuring an effective communication between the RASFF NCP and the Commission contact point” and “the availability of an on-duty officer reachable on a 24-hour/7-day-a-week basis” (both 100%). For the duty to “set up an effective communication network between the RASFF NCP and all relevant competent authorities in their country”, 96% of respondents confirmed that this had been fulfilled, and for the duty to define “the roles and responsibilities of the RASFF NCP and those of the relevant competent authorities in their country” 93% confirmed that this was the case;
- When asked whether their country had submitted notifications using the templates provided by the Commission contact point, 86% of NCPs who answered the question confirmed that this had been done “in all cases”. The remaining 13% of respondents indicated that templates were used “in most cases”.

Respondents were also then asked to assess the extent to which their country had fulfilled its obligations related to the submission of notifications. Overall, responses indicated that duties were fulfilled most of the time or always.⁷³ To validate these self-assessments, member countries were also asked to assess their peers’ fulfilment of obligations under the RASFF. National Contact Points were asked to evaluate whether all, most, some, or none of the other Member States fulfil their duties.

While several NCPs responded that they do not know to what extent other Member States fulfil their duties, all other respondents tended to have a positive view regarding other Member States fulfilling their duties.⁷⁴ In the same vein, the ECCP has confirmed that Member States are largely fulfilling the requirements deriving from the legislation. Also, the case studies and in-depth interviews did not provide evidence that would

⁷² NCPs were asked to indicate to what extent their country has ensured the efficient functioning of the RASFF within its jurisdiction on a scale from 0 “not at all” to 5 “very much”. Around half (52%) of the NCPs provided a rating of 5, while all other respondents providing an opinion (48%) provided a rating of 4, when asked whether their country has ensured the efficient functioning of RASFF within its jurisdiction.

⁷³ See Figure 39 in Annex 5.

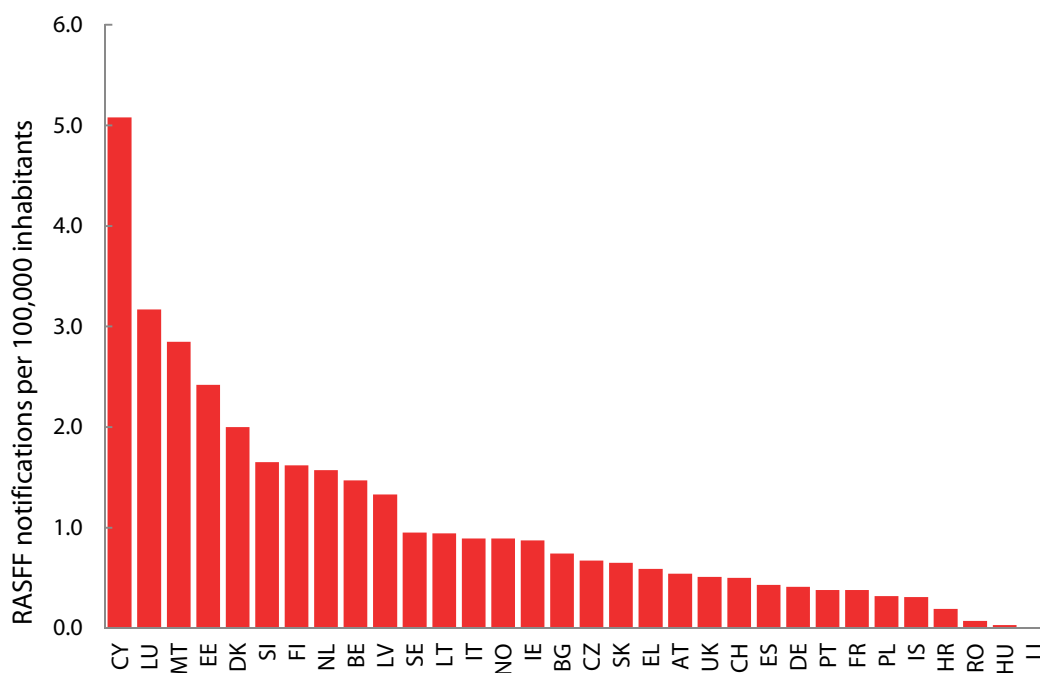
⁷⁴ See Figure 40 in Annex 5. Specifically, 41% of respondents stated that in their view “all” Member States fulfil their duties, 47% considered that “most” Member States do so, while 13% of NCPs did not know. Thus, the assessment by Member States of their peers is largely consistent with their self-assessment.

contradict this positive assessment of NCPs regarding their adaptation to the requirements set out by the Regulation and the fulfilment of their duties under the RASFF during past serious food/feed safety incidents.

9.6.3. *To what extent are the MS actively participating in the RASFF?*

An analysis of the data provided on the information flow in the RASFF reveals that for the reference year considered in the evaluation (2013), members of the network submitted a total of 3,137 original notifications. This represents an average of 95 notifications per member. Table 4 in the previous section provides the number of notifications per member of the RASFF. As shown in the table, the extent to which countries submit notifications varies significantly, ranging from none to over five hundred within one year. It is notable that the five top notifying countries account for more than half of the total number of original notifications. When the population size of countries is considered, notification numbers vary between none to just over 5 original notifications per 100,000 inhabitants (see figure below).

Figure 7: 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.

Similarly, when trade activity in terms of imports from third countries is considered, differences in the rate at which member countries submit notifications remain. Using the value of extra-EU imports in food, drinks and tobacco as an indicator, Member States submit between 0.11 and 3.68 notifications per €10 million of imports of those products (see Figure 4 in Annex).

Beyond differences in population size and trade activity, a number of factors may influence the number of notifications Member States transmit through the RASFF. These include:

- Particular national approaches concerning certain risks deriving from food and feed;
- Specific national legislation which causes some countries to carry out controls which are not required by EU legislation;

- Differences in enforcement of EU legislation or intensity of official controls; and
- Country-specific administrative structures and procedures, and the political organisation of a Member State, e.g. a federal versus a centralised structure.

In our survey, RASFF National Contact points were asked to rate their satisfaction with how actively other Member States participate in the network. Overall, respondents providing an opinion tended to be notably satisfied.⁷⁵ For the item that received the least positive rating ("The quality of follow-up notifications provided by other MS"), some explanations provided by National Contact Points included the following:

- "Some countries use their national language to notify, and translation can take up to 1 day to follow";
- "Information on follow-ups which concern [some] MS only are not interesting for other MS. Perhaps a different way of exchange of information could be developed."

In addition to the comments cited above, NCPs were asked whether they considered that the involvement of the Member States in the RASFF could be improved. Of the 22 RASFF National Contact Points who answered the question, a majority did not consider that an improvement is needed. Suggestions by those indicating that the involvement of Member States into the RASFF could be improved included providing information in notifications in English and adding explanations where necessary.

9.6.4. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section the answers to the evaluation questions concerning involvement of EU Member States are as follows:

- ▶ Approximately half of RASFF member countries have adopted national legislation to implement the RASFF. The others have implemented the RASFF without legislative changes. However, there does not appear to be a link between having or not having national legislation and the running of the system, when considering the staffing of the NCP the number of original notifications transmitted in the reference year, and the number of notifications rejected by the ECCP.
- ▶ RASFF member countries have largely adapted to meet the requirements of the Regulation and generally fulfil their duties under the RASFF as required by Regulation (EC) No 178/2002 and Commission Regulation (EU) No 16/2011, according to their peers and self-assessments, as well as the assessment of the EC Contact Point. The evidence collected in case studies of three serious food/feed safety incidents largely supports this assessment.
- ▶ The extent to which member countries submit notifications through the RASFF varies significantly, ranging from none to over five hundred original notifications in the reference year 2013. The five top notifying countries account for more than half of the total number of notifications. Even when population size and trade activity of the notifying country are considered, differences between countries in notification numbers remain.

⁷⁵ NCPs were asked to rate their satisfaction with how actively other MS submit original notifications, as well as their satisfaction with the rapidity and quality with which they submit follow up notifications on a scale from 0 to 5. The highest satisfaction was achieved in regard to "How actively other MS submit original notifications to the RASFF", followed by "The rapidity of follow-up notifications provided by other MS" (4.0) and "The quality of follow-up notifications provided by other MS" (3.8).

9.7. Participation of Third Countries/International Organisations

9.7.1. *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?*

Currently, 107 countries outside the EU/EFTA have access to RASFF notifications via RASFF Window, an IT tool developed for distributing notifications to third countries.⁷⁶ To further assess the accessibility of the RASFF to third countries and international organisations, selected third country RASFF contact points were asked to evaluate the extent to which the system is open to their participation. The average rating provided by the three responding third countries was 3.7, with none of them providing a negative rating.⁷⁷

International partners of the RASFF who participated in the survey were also asked to indicate the current purposes for which they use the RASFF, and to identify any obstacles, which, in their view, obstruct their participation in the system. Regarding the use of the RASFF by its international counterparts, respondents were asked to rate whether or not they used the system for the following purposes:

- To prevent affected consignments from being exported to the EU;
- To prevent affected consignments from being imported to the given third country;
- To remove any affected consignments from the market in the given third country;
- To improve compliance with EU rules of products to be exported, and
- To provide information to stakeholders and consumers.

All three third country contact points indicated that they use the RASFF for the first four purposes listed above. However, one of the three third countries indicated that their country does not use the RASFF to provide information to stakeholders and consumers (the other two did so). In an in-depth interview, one interviewee from a non-member country specified that RASFF notifications received by that country serve as an initial signal regarding the safety of a notified product; however, given that according to the interviewee, the approach of the RASFF tends to be hazard-based rather than risk-based, there is a need for third countries to perform their own risk assessment before undertaking one of these actions. Survey respondents were also asked to indicate whether any obstacles (such as language requirements, level of detail requested, confidentiality provisions, legal basis etc.) were preventing them from providing more information to the RASFF. Two out of the three third country contact points who responded to the survey did not consider that there were any obstacles preventing their organisation from providing more information to the RASFF, despite the fact that the official language of those countries was not English. One third country contact point commented that "agreements to protect confidential business information may be in place with some [RASFF] members, but not others".

The openness of the RASFF to international partners was further examined in case study/in-depth interviews with two selected third countries. The results from those interviews confirm that the RASFF is considered to be sufficiently open to non-member countries; moreover, the interviewees confirmed that their country has been informed without undue delay by the ECCP when notified products have originated from or were

⁷⁶ According to data provided by the EC, 89 countries have direct access through the IT tool, 6 third countries have access to RASFF Window through country desks at the European External Action Service, and 12 other countries receive information from RASFF Window through EC Delegations.

⁷⁷ i.e. a rating of 2 or less on a scale from 0 ("not at all") to 5 ("very much").

distributed to them (see above). However, one interviewee pointed out that in some cases, there are inconsistencies in the information provided by the RASFF, and occasionally, notifications are incomplete. As a result, the interviewee considered that a greater role of the EC in the verification process would be appreciated by international partners.

To further assess the scope for improvement, all respondents to our survey were asked whether they would have suggestions to improve the participation of Third Countries/International Organisations in the system. Of the one third of respondents that indicated they would have such suggestions, several suggested to include third countries in trainings or workings groups with the EC. Others suggested to:

- Grant third countries access to iRASFF;
- Develop a mentoring system between members of the RASFF and similar non-member countries; and to
- Promote the development of systems like the RASFF in third countries.

Additional ways in which the participation of third countries/international organisations into the RASFF could be improved were identified through case study/in-depth interviews. Suggestions included developing an international template for submitting information from third countries, e.g. for identifying the product, the risk, and for tracking information, in order to make communication more efficient. It was also noted that efforts are currently being made to allow the access of INFOSAN to the RASFF Window, which could improve the efficiency of managing incidents involving non-EU countries.

9.7.2. *To what extent is the reciprocity of information flow between the RASFF and the International Organisations appropriate?*

The INFOSAN, a joint programme of the WHO and FAO, is the main international partner system of the RASFF, and the most relevant cooperation of the RASFF with international organisations. National authorities of 181 Member States are part of the network.⁷⁸ The information flow between the RASFF and INFOSAN varies in terms of number of notifications and the impact achieved by them, depending on the year and incidents considered. The information flow is most relevant in times of large international food/feed safety incidents, such as the 2008 melamine crisis, in which INFOSAN was a key source of information for the RASFF and acted as intermediary between the EU and China. In order to assess reciprocity of the information flow, the number of notifications to and from INFOSAN was examined for the reference year 2013. According to the data provided by the European Commission, during this year the RASFF provided INFOSAN with 17 notifications and in return, received information resulting in two RASFF (News) notifications.

9.7.3. *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 the RASFF there?*

Indicators to answer these evaluation questions relate to the number of notifications from third countries and the percentage of RASFF National Contact Points indicating there is a need for more information from certain regions. For the reference year 2013, third countries were informed on 329 occasions about a product that had been distributed to their country which was subject to a RASFF notification.⁷⁹ Moreover, they were informed 2,231 times about RASFF notifications which concerned a product originating from their

⁷⁸ For more information, see http://www.who.int/foodsafety/areas_work/infosan/en/.

⁷⁹ European Commission, The Rapid Alert System for Food and Feed: 2013 Annual Report, 2013, p. 39-40.

country. The non-member countries informed most frequently about notifications concerning products originating from their country in 2013 were as follows:

- China (441 notifications);
- India (263 notifications);
- Turkey (234 notifications);
- Brazil (193 notifications); and
- United States (106 notifications).

Third countries provided follow up to the RASFF about the products originating from or distributed to them 335 times in 2013. According to the 2013 Annual Report, the following third countries provided follow-up to the RASFF most frequently in the reference year:

- Hong Kong (54 follow-up notifications);
- Brazil (51 follow-up notifications);
- Dominican Republic (35 follow-up notifications);
- Thailand (23 follow-up notifications); and
- Mozambique (18 follow-up notifications).

Moreover, in our survey, just over half of National Contact Points who provided an assessment indicated that they need to receive more information from third countries through the RASFF. Around a third considered that this was not the case.⁸⁰ Those NCPs who expressed a need to receive more information from third countries through the RASFF were also asked to specify which regions of the world they viewed as a priority (with the opportunity to select several options). The most frequently selected option was Asia, with more than 92% of those respondents that indicated a need for additional information viewing this as a priority region. This result is consistent with the data provided above, which identifies India and China as the two countries informed most frequently about notified products originating from them. Together, these two Asian trade partners account for nearly one third of instances in which a non-member country was informed about a product originating from it. While no explanations concerning the additional data needed are available from survey results, evidence from interviews suggests that more information is needed from third countries concerning measures taken or other follow up related to notified products originating from those countries.

Following Asia, survey respondents considered the Western Balkans (62%), North America (38%), North Africa (38%), the Middle East and Arabian Peninsula (31%) and Latin America and the Caribbean (31%) as priority regions from which they would need to receive more information. Oceania and Sub-Saharan Africa were only assessed as priority areas by a minority of respondents, i.e. 15% in each case. Additional priority regions mentioned by respondents were "Russia" and "Countries bordering the Mediterranean Sea".

9.7.4. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section the answers to the evaluation questions concerning participation of third countries and international organisations are as follows:

⁸⁰ 52% indicated that they need to receive more information from third countries through the RASFF, 32% considered that this was not the case, while 16% indicated that they did not know.

- ▶ The 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. A selection of third countries who participated in our survey mainly use information from the RASFF to prevent affected consignments from being exported to the EU, to prevent affected consignments from being imported or remove affected consignments from their market, and to improve compliance with EU rules of products to be exported.
- ▶ In spite of the partial integration of third countries into the RASFF, a majority of National Contact Points of RASFF member countries suggest that they need to receive more information from third countries through the RASFF, for instance on the measures taken or other follow up related to notified products originating from those countries. Among the regions of the world, Asia stands out as a priority region from which more information would be required, followed by the Western Balkans.
- ▶ The information flow between the RASFF and INFOSAN, its main international partner system, is most relevant in times of large international food/feed safety incidents, such as the 2008 melamine crisis, in which INFOSAN was a key source of information for the RASFF and acted as an intermediary between the EU and China. According to both the ECCP and INFOSAN the reciprocity of the information flow between the RASFF and the International Organisations is considered to be appropriate, and is helped by an alignment of procedures and membership of the RASFF and INFOSAN in recent years.

9.8. Efficiency

9.8.1. *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?*

When considering the efficiency of the RASFF, a key criterion is the balance of costs and benefits of the system. However, no comprehensive data on the costs of the RASFF is available. Therefore an estimate was calculated in the course of this evaluation, focusing on the costs of running the system during normal operation (i.e. in absence of a serious food/feed safety incident). Costs of the RASFF mainly accrue for the members of the network at the national level,⁸¹ EFSA, and the European Commission for managing the system. At EC level, costs relate to maintenance and development of IT tools as well as staff costs involved in managing the IT system and coordination at the ECCP. While the EC also incurs costs related to training staff from member countries and third countries on the use of the RASFF, in the reference year 2013 no such trainings were organised. The table below provides the estimated annual costs of running the RASFF according to the level of organisation.

⁸¹ Including the EFTA Surveillance Authority.

Table 5: Annual costs of running the RASFF at EU and member country level

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

Source: Civic Consulting. a) According to data provided by the EC, no BTSF (Better Training for Safer Food) trainings were conducted for the RASFF in the reference year. Costs calculated with data provided by National Contact Points and the European Commission. Staff costs accruing to member countries have been calculated on the basis of number of Full Time Equivalent (FTE) posts and training costs. FTEs at national level were monetised using hourly labour costs (including 25% overhead, in line with the Action Programme for Reducing Administrative Burdens) based on standardised Eurostat data (the four-yearly Labour Cost Survey and annual updates of labour cost statistics available at Eurostat code tec00014) and updated using data from the Labour Cost Index (available at Eurostat code lc_lci_r2_q) to ensure that data is comparable between countries. Staff costs at EU level were provided directly or monetised by calculating gross salaries and adding 25% for overhead. Missing data on FTE posts in three member countries were extrapolated based on the available data. Data provided in the table refers to the costs of running the RASFF at EU and national level. Costs at sub-national level, e.g. for official controls and reporting of risks to the NCP, are not considered.

According to the data provided by National Contact Points, on average member countries employ 2.4 FTE professional staff members and 1.0 FTE administrative or support staff to carry out the tasks of the RASFF National Contact Points (NCP).⁸² In total, 30 NCPs reported 97 FTE staff posts (not all NCPs employed support staff), although the number of FTEs differs between countries, and vary from 1 to 13. This figure does not include the staff of the EC's contact point, IT staff, nor staff at EFSA and the EFTA Surveillance Authority. Results of the financial analysis indicate that the RASFF costs approximately 5.9 million Euro at member country level. At the EU level, the costs involved in running

⁸² To safeguard that FTEs were calculated uniformly across countries, we provided the following explanation to NCPs: A fulltime equivalent (FTE) staff member is defined as fulltime 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).

and coordinating the system are estimated at 1,260,797 Euro (see table above), covering staff and IT (infrastructure, development and corrective maintenance) costs.⁸³

The costs of the RASFF, which amount to a total of 7,356,197 Euro, have to be compared to the benefits, which accrue to member countries and the EU as a result of their having a notification system for risks related to food and feed. Key benefits would relate to:

- *Rapid information of network members of risks identified*, allowing rapid action to be taken where appropriate. As mentioned before, in the reference year 2013 a total of 3,137 original notifications were transmitted (on average more than 8 per day), relating to a wide range of food safety concerns, including residues of veterinary medicinal products, food poisoning, the composition of dietetic foods and food supplements, pesticide residues, unsafe feed, and mycotoxins.
- *Comprehensive exchange of information on the follow-up to notified direct or indirect risks, and on measures to contain risk*, allowing for coordinated approaches to contain/eliminate the risk. In the reference year 2013 a total of 5,158 follow-up notifications were transmitted (on average 14 per day).
- *Information flow to third countries on risks detected to human health deriving from food and feed*, allowing third countries to take immediate measures to stop affected consignments, and mid- to long-term measures to improve food safety of exported goods. As discussed in Section 9.7, in 2013 information was transmitted to third countries 2,373 times about products originating from or distributed to their country (on average more than 6 times per day).

If original notifications, follow-up notifications and information transmitted to third countries are counted as separate information items, a total of 10,668 of such items were transmitted through the system in the reference year 2013, with a cost of roughly 690 Euro per item (if the total costs of the RASFF per year are divided by the number of information items). Considering that most notifications concern multiple countries, the cost per notified country is substantially lower. This amount appears to be reasonable, even though it cannot directly be compared to the resulting benefits. The reason for this is that the substantial information exchange through the system is not a benefit in itself, but rather contributes to benefits that accrue as result of measures taken on the basis of RASFF notifications. It can be expected that these measures have led to health benefits for consumers, as unsafe food and feed is removed from the market. Also, coordinated action across countries can contribute to minimising the impact of food safety incidents on consumption and markets, and likely contributes to improvements in the quality control of food and feed business operators, and related preventive measures. While it is plausible that these benefits have materialised and outweigh the costs of running the system, no data was available that would have allowed the benefits to be quantified in detail.

To explore the balance of costs and benefits of the RASFF in a member country perspective, RASFF National Contact Points were asked to indicate the extent to which costs incurred by their country for the RASFF had been appropriate when compared with the benefits of the RASFF. Those respondents providing an opinion found that the costs had been appropriate or even very much appropriate.⁸⁴ The main benefits identified by respondents related to the speed of information and communication exchange, the management of food/feed safety incidents, as well as the protection of consumer health and verification of product compliance that the RASFF enables. The benefits provided by the RASFF are further explored in the section on crisis management procedures, where the RASFF plays a key part in transmitting information for the management of food/feed safety incidents.

⁸³ According to data provided by the EC, no training costs related to the RASFF were incurred in 2013.

⁸⁴ On a scale of 0 to 5, the average rating provided by respondents was 4.3, with no respondents providing a negative rating (i.e. 2 or lower).

Another approach to explore efficiency is to consider the determinants of operational costs. As RASFF costs mainly consist of staff costs and IT costs, we consider both items separately. As mentioned above, the largest share of staff involved in the RASFF works in National Contact Points. To explore the efficiency of resource use at the NCP level, we considered the relationship between staffing and the number of notifications transmitted, which could be considered one possible indicator for NCP 'productivity'. An analysis of the relationship between the number of FTE posts employed across countries for handling tasks related to the RASFF, and the number of original notifications transmitted by the country in the reference year 2013 reveals that there is a positive, though not very strong correlation between the two variables, with the number of FTE posts explaining 60 percent of the variation in original notifications transmitted.⁸⁵

As a next step, we analysed whether the staffing of NCPs is largely determined by country requirements, as expressed in population size, or other factors. Unsurprisingly, the correlation is positive, with population size explaining 63 percent of the variation in the number of FTE posts in NCPs (see Figure 6 in Annex). From this analysis it can be concluded that 'productivity' of NCPs is partly determined by staffing levels, but that other factors also appear to play a role. Furthermore, while population size is an important factor in determining NCP staffing, significant differences in staffing exist between countries of similar sizes. This is likely to depend on further country-specific differences, such as the relevance of trade and the importance of food and feed business operators in the national economy, among others. Differences between countries in NCP staffing may also relate to resource availability and allocation decisions in the public administration.

The IT costs of the RASFF accrue mainly at central level, i.e. at the European Commission. They account for just under 10% of the overall costs. While these costs appear to be proportionate, interviews with the ECCP indicate that improvements in the efficiency of the IT systems currently in place are possible. The RASFF as it currently functions consists of two parallel IT platforms: a Microsoft Access Database which is the basis for RASFF Window, and the newer iRASFF online application. While RASFF Window allows access to all notifications for members of the network, or a subset thereof for authorised non-members such as third countries, the iRASFF application presents notable advantages such as allowing countries to be flagged for follow-up or for attention through the 'notify' function. On the other hand, the iRASFF does not contain the full data set of the RASFF, as border rejection notifications transmitted through TRACES are synchronised with RASFF Window, but not iRASFF. Moreover, the iRASFF does not currently allow notifications to be made available to third countries.⁸⁶ Given the technical advantages of the iRASFF and the linkage of RASFF Window to TRACES and to third countries, the two systems currently coexist. While the parallel existence of these two systems is not perceived as a major problem by the ECCP, and this situation could also be considered to create some resilience, the maintenance of two systems is likely to require additional effort, compared to a situation where all functions would be integrated into one system, and a direct linkage between TRACES and iRASFF was provided. A possible approach for improving efficiency of the RASFF IT platform in the future is therefore to centralise all notifications into iRASFF and upgrade its technical capacity to allow for the automatic integration of notifications from TRACES,⁸⁷ as well as to provide third countries with access to notifications which concern them via iRASFF.

To explore the potential for increasing efficiency of the RASFF, our survey asked respondents whether the balance of costs and benefits of the RASFF could be improved for their country. Only around 9% considered that the balance of costs and benefits of

⁸⁵ See Figure 5 in the Annex for a scatterplot of the two variables.

⁸⁶ European Commission, Standard Operating Procedures of the Rapid Alert System for Food and Feed, n.d. p. 36.

⁸⁷ Section 9.8.2 below discusses also the possibility of transferring all border rejection notifications to TRACES in the future.

the RASFF for their country could be improved (e.g. in the area of training).⁸⁸ The remaining respondents indicated that this was not the case, although 50% of respondents who answered the question responded that they did not know whether or not the balance of costs and benefits could be improved.

9.8.2. *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)?*

An additional aspect in evaluating the efficiency of the RASFF relates to the extent to which the system could function better by transferring certain tasks and functionalities to be handled through other systems or mechanisms. Among RASFF National Contact Points and respondents from other national authorities/agencies who answered our survey, there was complete consensus that the RASFF is the appropriate tool to handle RASFF alert notifications, RASFF border rejection notifications and RASFF follow-up notifications. For information notifications, news notifications, status updates on crisis management measures taken in countries during a serious food/feed safety incident and (draft) press releases for informing the EC/other countries on crisis management measures taken, a high percentage of respondents also agreed that they should be handled through the RASFF, though some disagreed.⁸⁹

The case studies/in-depth interviews broadly support these results. Neither in the melamine nor in the glass fragments case study were tasks identified that should have been handled through another system than the RASFF. In the case study on the E.coli outbreak, however, there were some diverging views regarding the “state of play” reports required by the Commission to summarise the situation in Member States, which were by some interviewees considered to be outside the scope of the RASFF. Others considered that given the urgency of the situation, all of the information transmitted through the RASFF during the E.coli crisis was useful.

However, survey results show that for two items – notifications of food fraud and notifications of non-compliant consignments that are not related to risk containment – around half of respondents considered that the RASFF was not the right tool (51% and 43%, respectively) and other systems/mechanisms should be used in the future, such as the Administrative Assistance and Cooperation (AAC) system. The divided opinions observed for the final two items may reflect the recent and ongoing developments related to the Food Fraud Network, and more broadly, the Administrative Assistance and Cooperation system.

As discussed in Section 9.3, Member States are required to provide each other with administrative assistance for the purpose of enforcing food/feed legislation, as provided in Regulation (EC) No 882/2004. Communication in the AAC is currently e-mail-based and an IT tool to assist competent authorities in fulfilling this obligation is under development. As food fraud constitutes a particular case of economically motivated non-compliance, the Food Fraud Network (FFN) was put in place by the EC in 2013 to allow information to be exchanged between liaison bodies of Member States. This may explain why, although the RASFF was used extensively in the 2013 horsemeat scandal, less than half of respondents consider that it is the right tool for this purpose in the future. A similarly high proportion of respondents consider that notifications related to non-compliant consignments that are not related to risk containment should in the future be handled through another existing system/mechanism. As with tasks relating to food

⁸⁸ 3 of the 32 respondents who answered the question provided this assessment, 13 considered that the balance of costs and benefits could not be improved, while the remaining 16 selected “don’t know”.

⁸⁹ 94% of respondents thought that RASFF information notifications should continue to be handled through RASFF, for RASFF news notifications 91% agreed with this, for status updates on crisis management measures taken in countries during a serious food/feed safety incident, 89% thought they should be transmitted through the RASFF and for draft press releases 71% agreed with this.

fraud, cases of non-compliance having a cross-border dimension in the meaning of Articles 34-38 of Regulation (EC) No 882/2004 which do not present a risk to human health, animal health, or the environment are not intended to be handled through the RASFF, but through the AAC. Moreover, the RASFF SOPs and ongoing discussions surrounding the AAC system provide for the possibility of transferring information notifications (i.e. cases involving a risk which does not require a rapid action in another member country) from the RASFF to the AAC in the future.

Although most respondents to our survey suggested that information notifications should continue to be handled through RASFF, a possible transfer of (some) information notifications to the AAC would reduce the quantity of information exchanged through the RASFF and allow it to focus on those cases in which rapid action is needed by its members in order to contain a risk. In this context it is notable that, according to the Working Instruction 5.2 of the RASFF, there are two situations in which information notifications may be transmitted.⁹⁰ In the first, 'information for attention' is transmitted when the distribution of a product presenting a serious risk is restricted to the notifying country, and possibly third countries. The second situation concerns cases in which a notified product does not present a serious risk, but is potentially present on the market of other member countries. In those instances, notifications are transmitted as 'information for follow up'. Given that in the latter case, notifications relate to non-compliance (e.g. the presence of an undeclared ingredient or migration of a substance from food contact material) and, by definition, require action in more than one Member State, it is conceivable that this category be transferred to the AAC system in the future.⁹¹ However, because risk in a food/feed product may evolve and complete information is not always available at the time that a notification is made, in this case an adequate link between the RASFF and AAC system would need to be foreseen in order to accommodate situations where an information notification must be upgraded to an alert, and vice-versa.

Another option for improving the efficiency of the RASFF through better management of the available resources was identified in discussions with the ECCP. Currently, the RASFF is a highly centralised system in which all notifications are verified by the ECCP, independent from the number of countries for which a notification is relevant. In case a follow-up involves only two countries, this information can be handled by the RASFF involving the centralised procedure, or alternatively through a bilateral e-mail exchange of the countries involved. Of course, the latter alternative implies that other network members have no access to the exchange of information, even if it later turns out that the issue under consideration is in fact relevant for more than the two countries. It could therefore be foreseen to change the centralised structure of the RASFF and to allow for bilateral exchange of network members through the system in specific situations. For these 'bilateral notifications' the ECCP could be relieved of its obligation to verify, while it would continue to have access to and oversight of the interaction between RASFF members. In other words, the ECCP would no longer be actively involved in these specific bilateral communication processes, thereby allowing resources to be dedicated to tasks requiring more urgent action (e.g. verification and transmission of alert notifications and their follow up).

Finally, a third option to transfer certain tasks of RASFF to other systems or mechanisms identified in the course of the evaluation is to move border rejection notifications fully to TRACES. As mentioned before, after a consignment is rejected at a border, border inspection posts (BIPs) submit a notification using TRACES, which is transferred to RASFF

⁹⁰ RASFF, Working Instruction 5.2 : Guidance for the Classification of a Notification, 2014.
http://ec.europa.eu/food/safety/rasff/implementing_regulation_guidance/docs/rasff_wi_5-2_en.pdf.

⁹¹ It should be noted that the AAC may also be relevant in the first of the two situations described. If a product originating from one country and distributed in only one (notifying) Member State outside of it is found to be non-compliant, the notification would not require rapid action by RASFF members, but would still be considered as a cross-border case for transmission through the AAC.

Window in parallel. Considering the existing chain of command between BIPs and TRACES, this task could, in the future, be handled by TRACES alone, thereby providing efficiency gains. However, in some cases, border rejection notifications refer to products that have already been placed on the market. In those cases, effective cooperation between BIPs and food safety authorities must be ensured in order to remove the products from the market. If border rejection notifications were to be transferred to TRACES, an appropriate chain of command between the respective authorities should be established. Moreover, it should also be noted that the preference of the surveyed NCPs was clearly to keep these notifications in the RASFF.

9.8.3. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section the answers to the evaluation questions concerning efficiency of the RASFF are as follows:

- ▶ Results of the financial analysis conducted in this evaluation indicate that the annual costs of RASFF amount to a total of 7.4 million Euro, of which approximately 5.9 million Euro are spent at member country level. At the EU level, the costs involved in running and coordinating the system are estimated at 1.3 million Euro, including IT and staff costs. These costs have to be compared to the benefits, which accrue to member countries and the EU as a result of their having a notification system for risks related to food and feed. Key benefits relate to rapid information of network members of risks identified; comprehensive exchange of information on the follow-up to notified direct or indirect risks, and on measures to contain risk; and information flow to third countries on risks detected to human health deriving from food and feed. If original notifications, follow-up notifications and information transmitted to third countries are counted as separate information items, a total of 10,668 of such items were transmitted through the system in the reference year 2013, with a cost of roughly 690 Euro per item (if the total costs of RASFF per year are divided by the number of information items). Considering that most notifications concern multiple countries, the cost per notified country are substantially lower. These costs appear to be reasonable, even though they cannot directly be compared to the resulting benefits, as the substantial information exchange through the system is not a benefit in itself, but rather contributes to benefits that accrue as result of measures taken on the basis of RASFF notifications.
- ▶ Considering the financial resources that are involved in running the system in a member country perspective, the 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. The 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 and verification of product compliance that the RASFF enables. Only a small minority (9%) of respondents considered that the balance of costs and benefits of the RASFF for their country could be improved.
- ▶ The evaluation has identified several options to further improve processes of the RASFF, or to transfer tasks currently handled by RASFF to other systems. These include: the centralisation of information from all RASFF notifications into a single IT system (iRASFF); the automatic transfer of border rejection notifications from TRACES into RASFF or handling border rejection notifications only through TRACES; a transfer of information notifications on non-compliances that are not related to risk containment to the Administrative Assistance and Cooperation (AAC) system to reduce the quantity of information exchanged through the RASFF; and a change in the centralised structure of the RASFF by allowing for bilateral exchange of network members through the system in specific situations.

9.9. Stakeholder information, transparency and confidentiality

9.9.1. *To what extent does the RASFF inform involved professional operators? To what extent can stakeholders [sufficiently] consult the information managed by the RASFF?*

Article 50(1) of Regulation (EC) No 178/2002 foresees the RASFF as a tool for communication between members of the network (i.e. "the Member States, the Commission and the Authority"). As such, professional operators and stakeholders were originally not involved in the RASFF. However, while in some cases, companies may directly contact the European Commission Contact Point to report on findings concerning food/feed, IT tools have been developed by the European Commission specifically to serve as an information channel between the RASFF and industry or consumer stakeholders.

As a result, professional operators and other stakeholders are able to consult RASFF notifications using the RASFF Portal, a publicly available internet platform (accessible at <https://webgate.ec.europa.eu/rasff-window/portal/>). The platform enables users to find notifications using a search function, allowing them to perform queries according to e.g. the notification reference number, subject of the notification, notifying country, notification classification (i.e. alert, border rejection, etc.), hazard category, date, and others. After entering the relevant search criteria, users obtain a list of notifications corresponding to the criteria. The following information is directly visible:

- Classification (alert, border rejection, etc.);
- Date of case;
- Last change;
- Reference;
- Country;
- Subject;
- Product Category; and
- Type (i.e. food, feed, food contact material).

Users have the option to select individual notifications in order to obtain more details, including on the hazard, action taken, distribution status, and the countries concerned by the product.⁹² However, the name of the company or brand producing or distributing the given product is not provided in the RASFF Portal, in line with the professional secrecy provisions foreseen in Regulation (EC) No 178/2002.⁹³

In our survey, respondents were asked to assess whether this information is sufficient for professional operators. On average, respondents provided a rating of 3.0, slightly above the midpoint of 2.5. In total, 37% of respondents to this question provided a negative rating (i.e. 2 or lower).⁹⁴ It should be noted, however, that there was divergence in opinion between the various stakeholder groups. RASFF National Contact Points who expressed an opinion provided an average rating of 3.8, while other stakeholder gave a much lower (and on average slightly below the mid-point) rating of 2.4. Among stakeholders that provided a relatively negative rating, the reasons evoked related

⁹² European Commission Directorate-General for Health and Consumers, RASFF Portal User Manual.

⁹³ Article 10 of the Regulation provides for public authorities to take appropriate steps to inform the general public of the nature of the risk, identifying to the fullest extent possible the food/feed or type of food/feed in which the risk is present and measures taken or about to be taken, depending on the nature, seriousness, and extent of the risk. See Section 3.2.6 for confidentiality provisions of the RASFF.

⁹⁴ On a scale of 0 to 5 ("not at all sufficient" to "very sufficient").

mostly to a lack of details and insufficient information contained in the notifications, such as names of exporters that have delivered unsafe food materials.

Regarding the information flow to stakeholders in general, more than half (61%) of respondents who provided an answer considered that stakeholders can sufficiently consult the information in the RASFF Portal.⁹⁵ RASFF NCPs were particularly likely to consider that stakeholders can sufficiently consult the information in the RASFF Portal, with three quarters of those who answered the question considering this to be the case, compared to 49% of respondents from other stakeholder groups. A majority of comments made by respondents from other stakeholder groups who considered that stakeholders cannot sufficiently consult the information in the RASFF Portal related to a lack of detailed information, e.g. on the identification of the product or follow up actions to a notified risk.

However, a majority of 54% of respondents who provided an answer considered that there was a need for the information flow to stakeholders and professional operators to be improved.⁹⁶ Again, there was a marked difference between stakeholder groups: only 29% of NCPs who answered the question saw such a need, compared to 73% of respondents from other stakeholder groups. Explanations provided by respondents who answered 'Yes' also centred around the need for more information to be provided (e.g. lot number, information on follow up action taken, whether a notification has been closed or remains open, picture, brand name, etc.) to professional operators.

In contrast to the Rapid alert system for dangerous non-food products (RAPEX), the publicly accessible tools of the RASFF do not currently provide such information, as described above. Therefore, although users are informed about the origin of a product, the notification type, the hazard category and substance, the action taken, the distribution status and the countries concerned, they are often not able to directly identify the products in order to avoid purchasing or consuming them (if such detail is not provided on the national websites, see below). An example for relatively vague information transmitted through the RASFF Portal would be a notification concerning an unauthorised substance in a "food supplement from the UK". This specification is insufficient for retailers, wholesalers and other food business operators who wish to quickly identify whether the relevant product concerns their supply chain, leading to a difficulty in assessing whether or not action should be undertaken on their side.

On the other hand, however, revealing the names of food/feed business operators to the general public may deter professional operators from cooperating with the RASFF. Considering that 411 out of the 3,130 original notifications – or over thirteen percent – that were made publicly available on the RASFF Portal in the reference year 2013 were notified following a company's own-checks, dissuading business operators from informing the RASFF of unsafe food/feed it has placed on the market may prove to be a significant hindrance to the protection of consumers' health. Moreover, according to one interviewee, the RASFF Portal is a useful tool for business operators to monitor notifications and to identify which countries potential threats to food safety originate from. This interviewee considered that the added value of including a producer or brand name is limited, in comparison to the country of origin, which provides a good indication of trends in the safety of food coming from third countries. Finally, due to the nature of products notified in the RASFF, it may not be appropriate to disclose the name of a company for which a specific lot or consignment has been found to contain a risk, given that in many cases the risk only concerns a specific lot, and other lots of the same food or feed product are not affected. This contrasts with the types of products notified in RAPEX, in which faulty production is likely to impact an entire product line. While there are therefore reasons for not disclosing the names of food/feed business operators, similar arguments cannot be made regarding other information, such as information on

⁹⁵ 27% indicated that this was not the case, while 13% selected "don't know".

⁹⁶ 39% indicated that they saw no need to improve the information flow and 7% selected "don't know".

follow up action taken, or information whether a notification has been closed or remains open.

9.9.2. *To what extent is the RASFF transparent and accessible to the general public?*

As mentioned above, the RASFF was originally intended for informing its members on risks deriving from food and feed. However, in 2014, the Commission launched an internet platform, the RASFF Consumers Portal (accessible at <https://webgate.ec.europa.eu/rasff-window/consumers/>), specifically for consumers. It provides information on food recall notices and public health warnings issued by food safety authorities and food business operators. In this application, notifications are removed after a four-week period. Thus the RASFF Consumers Portal allows interested consumers to stay informed about the most recent risks related to food/feed safety. It allows to search according to the user's country, and provides a link to the country's national consumer website, where applicable. As in the RASFF Portal, the name of the company or brand producing or distributing the given product is not provided, though it may be found in the recall notice or relevant publication attached to the notification, where available.

To explore this topic, survey respondents were asked to what extent the RASFF Portal fulfilled a number of criteria relating to its use by the general public. In regard to the accessibility of the RASFF to the general public, respondents provided an average rating of 3.6, while a slightly lower average rating of 3.3 was provided in regard to transparency to the general public. When asked whether the RASFF Portal addresses the needs of the general public for information on unsafe food, however, respondents provided an average rating of only 2.6. Almost half of respondents (46%) rated the RASFF negatively in this respect.⁹⁷ However, it should be noted that evidence from the ongoing Evaluation of the General Food Law indicates that while consumers consider that the level and type of information provided to the general public remains variable according to the Member State and case considered, it has considerably improved over time.⁹⁸ Moreover, the study finds that both consumer groups and MS competent authorities consider the RASFF Consumers' Portal as a positive step to improved transparency.

In our survey, respondents were asked whether they had suggestions as to how the transparency of the RASFF could be improved. The comments provided by the survey respondents who offered suggestions largely focused on the provision of additional information through the RASFF, such as the name of the product and business operator (similar to responses to other questions mentioned above).

The issue of transparency and accessibility to the general public of information transmitted through the RASFF Portal and Consumers' Portal is comparable to the discussion surrounding the information flow to professional operators above. While the RASFF Consumers' Portal may be transparent – considering the constraint of the confidentiality provisions provided in Article 52 of Regulation (EC) No 178/2002 – its use is somewhat limited for individual consumers. For instance, including a line about "Salmonella in sausages from Spain" provides limited guidance to consumers about the exact product that is affected. Indeed, such a notification may deter consumers from purchasing sausages altogether, for lack of details enabling an informed decision. The draft final report of the Evaluation of the General Food Law also notes that information is not always provided and not always precise enough to allow consumers to be sufficiently informed.⁹⁹ However, for some notifications, users may be offered the option to view "More info" via a national consumers' website, to which links are provided from the

⁹⁷ i.e. 2 or lower on a scale from 0 to 5, with 0 representing "not at all" and 5 "very much".

⁹⁸ Food Chain Evaluation Consortium, Study on the evaluation of Regulation (EC) No 178/2002 ("the General Food Law Regulation") – Draft final report, 2015. p.104.

⁹⁹ Food Chain Evaluation Consortium, Study on the evaluation of Regulation (EC) No 178/2002 ("the General Food Law Regulation") – Draft final report, 2015. p.104.

Consumer's Portal. Links are provided to national websites for 23 of the 32 member countries. On national websites, member countries may provide pictures of the product, as well as the brand, producer's name, and other information to allow consumers to identify the product concerned.

9.9.3. *To what extent is the classification used pertinent and clear?*

As discussed in Section 6.2.3, information notified through the RASFF is transmitted according to a specific classification of notifications. In our survey, respondents tended to consider that this classification is pertinent and clear to competent authorities, the main addressees of the system.¹⁰⁰ For food/feed operators, who have a limited access to notifications through the IT tools discussed above, the classification appears to be less clear, though the average rating remained above the midpoint of 2.5.¹⁰¹ However, in regard to the general public, respondents tended to assess that the classification of notifications used was unclear (an average rating of 2.1). More than half (59%) of respondents provided a rating of 2 or lower for this aspect.

Respondents were asked to explain if they considered the notifications not to be clear for those stakeholder groups. Although the assessment regarding the clarity of the classification for competent authorities was positive, one National Contact Point reported a difficulty in differentiating between an alert and information notifications when notifying. To a certain extent, the publication of the SOPs may serve to clarify and harmonise the classification of notifications for Member States. Regarding the clarity of the classification for food/feed business operators, which was rated lower than for competent authorities, one organisation of food/feed business operators noted that while the classification of notifications may be clear for business operators with dedicated staff for monitoring RASFF notifications, but less so for small and medium size companies.

Finally, the assessment provided by respondents was lowest regarding the clarity of the classification for the general public.¹⁰² This may be explained by a lack of clear information regarding the different types of notifications and their definitions on the main page of the Consumers' Portal. To find the definitions, users have to navigate to the main website of the RASFF.

9.9.4. *To what extent is the RASFF respecting the confidentiality requirements as set in the Regulation? To what extent does the RASFF achieve an adequate balance between confidentiality and information to consumers and stakeholders?*

In our survey, RASFF National Contact Points and other stakeholders involved in the RASFF were asked to assess whether the members of the RASFF sufficiently respect the confidentiality requirements of Article 52 of Regulation (EC) No 178/2002. Overall, most respondents to this question considered that the members of RASFF sufficiently respect the confidentiality requirements as set out in Regulation (EC) No 178/2002.¹⁰³ However, there was some divergence in opinion according to stakeholder groups, with 75% of NCP respondents to this question affirming that confidentiality requirements were respected, while only 54% of respondents from other stakeholder groups shared this view.

Survey respondents were also asked whether they had suggestions as to how the confidentiality of the RASFF could be improved. Those that had suggestions most

¹⁰⁰ This aspect received an average rating of 4.0 on a scale from 0 to 5, with the competent authorities themselves providing a rating of 4.3.

¹⁰¹ The average rating was 2.9 on a scale from 0 to 5.

¹⁰³ Close to two thirds (63%) considered that RASFF members sufficiently respect the confidentiality requirements, 10% indicated that this was not the case, while 27% did not know.

¹⁰² The average rating was 2.1 on a scale from 0 to 5.

frequently voiced concerns that the confidentiality requirements of the RASFF were not clearly defined, leading some Member States to interpret them differently than others. These comments provided were reflected in the case study/in-depths interviews conducted with stakeholders in affected countries, EU institutions and international stakeholders.

In regard to the 2011 E.coli outbreak, for example, it was noted by an EU level stakeholder involved in RASFF that the confidentiality requirements throughout the E.coli outbreak lacked clarity, i.e. it was not fully known to members of the RASFF which information (e.g. names of companies involved) could be disclosed to non-members. Finding out whether information could be disclosed was time-consuming in the context of urgency. Another interviewee considered it was clear which information was confidential, suggesting that the RASFF Portal could be used as a benchmark for judging whether a piece of information could be disclosed outside the network or not. The SOPs cite examples of information that may be covered by professional secrecy. These include:

- Information listed in Article 7(3) of Regulation (EC) No 882/2004 (preliminary investigation proceedings or current legal proceedings, personal data, documents covered by an exception regarding public access to European Parliament, Council, and Commission documents, and information protected by national and Union legislation concerning professional secrecy, confidentiality of deliberations, international relations, and national defence);
- Commercial documents such as client or recipient lists, inventories, bills and invoices, and reports of companies' own-checks;
- Documents that are part of the intellectual property of a company such as recipes, process charts, pictures of processing equipment, etc.;
- Other specifically identified information, duly justified as to why it is covered by professional secrecy.

Moreover, the SOPs instruct NCPs not to forward complete notifications to private persons or business operators, and in cases where this is done (i.e. because they are directly concerned by the notification), to ensure that commercial sensitive information, particularly prices, are removed.¹⁰⁴

Overall, most survey respondents who provided an assessment on this issue tended to consider that the RASFF achieves an adequate balance between confidentiality and information to consumers and stakeholders, although around a quarter of respondents disagreed.¹⁰⁵ RASFF National Contact Points were particularly likely to provide a positive assessment: this was the case for 78% of NCPs who answered the question, compared to only 43% of respondents from other stakeholder groups. While most of the respondents who considered that the RASFF did not achieve an adequate balance commented on the need for more information to be provided to stakeholders, some also evoked the importance of protecting professional secrecy, while others considered that the needs of consumers and stakeholders such as businesses were different.

On the one hand, food/feed business operators expect that their brand names and information which may be commercially sensitive remain protected under the RASFF according to Article 52(1) of Regulation (EC) No 178/2002. On the other hand, the provisions of Article 52 and the guidance provided in the SOPs allow for an exception of the confidentiality requirements, for cases in which "information must be made public, if circumstances so require, in order to protect human health". In those cases, the legislation suggests that more transparency is required. As an appropriate balance has to

¹⁰⁴ European Commission, Standard Operating Procedures of the Rapid Alert System for Food and Feed, n.d.

¹⁰⁵ Overall, 58% of respondents to this question provided a positive assessment; 26% disagreed and 15% selected "don't know".

be found between those requirements, it may be helpful for the SOPs to specify in which circumstances the need for transparency prevails over the requirement of confidentiality.

9.9.5. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section the answers to the evaluation questions concerning stakeholder information, transparency and confidentiality are as follows:

- ▶ There is no consensus regarding the extent to which the RASFF sufficiently informs professional operators and other stakeholders. While on average, 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. The main issue appears to be the lack of detail regarding products concerned by RASFF notifications, preventing some professional operators from being able to quickly assess whether or not action should be undertaken on their side. Suggestions for improving the information flow to professional operators and other stakeholders included providing more information on follow up action taken, and information whether a notification has been closed or remains open.
- ▶ As an extension to the RASFF designed to inform users beyond the members of the network, the RASFF Portal is considered to be accessible and transparent to the general public by NCPs and other stakeholders involved in the system. However, they are sceptical that the Portal addresses the needs of the general public for information on unsafe food, with almost half of respondents rating the system negatively in this respect.
- ▶ While RASFF members are considered by large majorities of NCPs and other stakeholder groups to sufficiently respect the confidentiality requirements as set in Article 52 of Regulation (EC) No 178/2002 our case studies indicate a certain lack of clarity of confidentiality requirements. Also, these requirements may be interpreted differently by different member countries, particularly regarding which type of information is covered by professional secrecy. Still, most NCPs consider that RASFF provides an adequate balance between confidentiality and information to consumers and stakeholders, a view which is shared by a majority of other stakeholders.

9.10. Added value

9.10.1. *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?*


To address this evaluation question, respondents were asked in our survey whether they 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 respondents indicated that they did not know, while only one respondent (a business organisation) considered that RASFF had no added value, though no explanation for this assessment was provided. Among the comments regarding the added value provided by the RASFF offered by respondents, key areas included the enabling of rapid communication and information exchange, the prevention of food/feed crisis and the protection of consumers through risk management, as well as the increased consumer trust in food/feed safety.

The near-consensus regarding the significant added value of the RASFF was largely reflected in the case study/in-depth interviews, although the added value of the RASFF

was considered to be more limited in food/feed safety incidents concerning mainly national cases or where a company's procedures allowed the detected risk to be contained efficiently through a recall.

9.10.2. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section, the answer to the evaluation question concerning added value resulting from RASFF is as follows:

 The evidence collected in this evaluation 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. There is a near consensus among NCPs and other stakeholders involved in the system that the RASFF has an added value compared to what could be achieved by Member States without it. 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.

10. ANSWERS TO THE EVALUATION QUESTIONS: CRISIS AND POTENTIAL CRISIS MANAGEMENT

10.1. Effectiveness

10.1.1. *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?*

According to the intervention logic for EU crisis management procedures developed in close cooperation with the European Commission (see Annex 9), the general objective of EU crisis management is the adequate management of serious food/feed safety incidents that cannot be contained by individual Member States. In the broad sense of the term, crisis management procedures¹⁰⁶ as established by Articles 53 to 57 of Regulation (EC) 178/2002 aim to achieve:

- Coordinated implementation of most effective measures to contain risk;
- Efficient management of serious food/feed incidents;
- Consumers' trust in food/feed safety;
- Consumer health protection; and
- Limited disruption of internal market and trade.

In assessing the effectiveness of crisis management arrangements, the degree to which the above impacts have been achieved was considered. In our survey, competent authorities in the field of food/feed crisis management and relevant stakeholders were asked to assess on a scale of 0 to 5 (with 0 indicating "achieved not at all well" and 5 "achieved very well") the extent to which existing crisis management arrangements have achieved each of these impacts, first concerning arrangements at the Member State, and then at the EU level.

Survey results shows that when respondents were asked about the effectiveness of existing crisis management arrangements in their own Member State, the specific impacts that were considered to have been achieved best were consumer health protection, followed by efficient management of serious food/feed incidents and coordinated implementation of most effective measures to contain the risk.¹⁰⁷ Lowest rated were consumers' trust in food/feed safety and limited disruption of internal market and trade, although both these aspects still received on average a clearly positive rating.¹⁰⁸ When broken down by respondent groups, Member State competent authorities rated the first three items in the same way, but assessed consumers' trust in food/feed safety and limited disruption of the internal market and trade slightly more positively than other respondents.¹⁰⁹

In regard to the situation at EU level, consumer health protection remained the most highly rated aspect, but with a lower overall average. Although the order was the same as that in regard to the Member States, each aspect received a lower average rating at

¹⁰⁶ Crisis and potential crisis management at EU level consists of the provisions outlined under Sections 2 and 3 of Chapter IV of the Regulation. Section 2 refers to emergency measures, whereas Section 3 outlines the procedures to be used for crisis management strictly speaking, i.e. the use of the general plan and establishment of the crisis unit.

¹⁰⁷ The average ratings for these items were 4.5, 4.1 and 3.9 respectively.

¹⁰⁸ i.e. above the midpoint of 2.5 on a scale from 0 to 5. The average ratings were 3.6 and 3.3 respectively.

¹⁰⁹ These items were rated as 3.8 and 3.6 respectively by Member States' competent authorities.

EU level.¹¹⁰ When broken down by respondent groups, Member State competent authorities again provided more positive assessments than other stakeholders.¹¹¹ The lower rating provided by survey respondents regarding the protection of consumers' trust in food/feed safety is broadly supported by other relevant evidence collected throughout the evaluation. Results from Eurobarometer surveys on food related risks reveal that a higher proportion of European consumers considered in 2010 that the food they eat may damage their health to be a likely risk than five years before (48% compared to 42%), suggesting that consumers trust in food/feed safety has not been fully upheld throughout at least a part of the reference period. By contrast, the perceived likelihood of other risks, including those caused by environmental pollution or serious illness, have remained relatively stable.¹¹² Clearly, consumers' trust in food/feed safety is influenced by a large number of factors in addition to effective crisis management, including a growing awareness of the general public regarding potential risks deriving from food/feed, as well as developments in food technology such as GMOs.

To further examine their assessment of crisis management arrangements applied to specific food/feed safety incidents, respondents were asked to evaluate the effectiveness of crisis management arrangements in their country and at EU level during the glass fragments in instant coffee incident, the melamine crisis, and the E.coli outbreak (if these incidents affected their country). When asked to assess the effectiveness of crisis management arrangements for the three incidents in their own Member State, those respondents who expressed an opinion tended to provide positive answers.¹¹³ In addition to the examples listed above, respondents also had the opportunity to refer to other serious food/feed incidents, and those who did often cited the dioxin in pork meat crisis in 2008. On average the respondents who did so provided a rating of 4.5 at Member State level.

Respondents were then asked to assess the effectiveness of crisis management arrangements at the EU level. Those respondents who expressed an opinion also tended to provide positive assessments of crisis management arrangements at EU level during the specified examples of serious food/feed safety incidents, although in all cases the average rating selected by respondents was lower than at Member State level.¹¹⁴ Explanatory comments made by those respondents who assessed the effectiveness of crisis management arrangements during the E.coli outbreak relatively negatively referred to the confusion regarding the source of the outbreak, resulting in individual actions at MS level, and poor collaboration between food and public health sector at EU level. Again, survey respondents had the opportunity to provide other examples of serious food/feed safety incidents and to rate the effectiveness of crisis management arrangements which were used in those cases. For the dioxin in pork meat crisis, mentioned repeatedly, the average rating was 3.3 at EU level.

¹¹⁰ The average rating for each item at EU level was 3.7 (consumer health protection), 3.4 (efficient management of serious food/feed incidents), 3.3 (coordinated implementation of most effective measures to contain the risk), 3.0 (consumers' trust in food/feed safety) and 3.0 (limited disruption of internal market and trade).

¹¹¹ Consumer health protection at EU level was rated at 4.1, efficient management of serious food/feed incidents and coordinated implementation of most effective measures to contain the risk each received ratings of 3.6, while limited disruption of internal market was ranked above consumers' trust in food/feed safety (3.5 and 3.4 respectively).

¹¹² European Commission, Special Eurobarometer 354 - Food-Related Risks, Brussels, Belgium, 2010.

¹¹³ In all three examples the average ratings provided by respondents were higher than 4 on a scale from 0 to 5, (with 0 indicating "not at all effective" and 5 "very effective"), namely 4.7 for glass fragments in instant coffee, 4.3 for the melamine crisis and 4.2 for the 2011 E.coli outbreak. It is also worth noting that when broken down by stakeholder group, Member State competent authorities provided higher ratings for the melamine crisis and for the E.coli outbreak (4.6 and 4.5 respectively) than other stakeholders, though slightly lower for the glass fragments case (4.6).

¹¹⁴ At EU level, average ratings were 4.2 for the melamine crisis, 4.0 for glass fragments in instant coffee and 3.0 for the 2011 E.coli outbreak (it should be noted, however, that for each of these examples a higher number of respondents provided an opinion regarding arrangements at EU level than at Member State level). When broken down by respondent groups, the results for Member State competent authorities are again slightly higher than the assessment of other stakeholders for each example. The melamine crisis was rated as 4.3, the glass fragments incident and E.coli outbreak were assessed as 4.2 and 3.3 respectively.

Table 2 in the Annex to this report provides more details for the three case studies of serious food/feed safety incidents. It presents an overview of the key crisis management measures employed and an assessment regarding whether each of the intended impacts were (or were not) achieved based on the evidence collected during the case studies, which is then compared to the above quoted survey results regarding the effectiveness of crisis management arrangements.

The evidence collected suggests that the effectiveness of crisis management arrangements during the evaluation period differed considerably for different incidents. The way in which the melamine crisis and glass fragments incident were handled are broadly considered to have been effective, while this was not the case during the E.coli outbreak, specifically regarding 'limited disruption of the internal market and trade' and 'upholding consumers' trust in food/feed safety'. Factors contributing to this include:

- *Difficulty in finding the source of the outbreak* – In the E.coli outbreak, the complex nature of the pathogen combined with the unexpected source of the outbreak (sprouts) led to a significant delay in identification of the source, which in turn caused confusion and panic among the public, increasing the political pressure and ultimately leading to a fall in consumers' trust in the safety of certain vegetables.¹¹⁵ This, in turn, caused a significant disruption of the internal market and trade;
- *Lack of an effective communication strategy* – In the E.coli outbreak, extensive media coverage of the events contributed to the alarm among the public and increased the pressure to quickly identify and contain the risk. There was an apparent lack of a coordinated and effective strategy for communication to the public, which could have allowed the effects of this pressure to be mitigated and ensured the transmission of coherent messages to consumers by the different authorities involved;¹¹⁶
- *Extent of cooperation between the public health and food safety authorities* – Several interviewees criticized the cooperation between public health and food safety authorities during the incident at Member State and EU level. According to them, better sharing of information and coordination between the two sides would have been helpful in managing the outbreak. One of the conclusions drawn from the E.coli incident by the European Commission related to the need for inter-sectoral crisis preparedness exercises including public health and food safety authorities.¹¹⁷

In light of these conclusions it is not surprising that more than half of the respondents to our survey provided suggestions for the improvement of the effective functioning of existing crisis management arrangements. Suggestions included improved communication and cooperation; improved training and more frequent crisis simulation exercises; and the harmonisation of processes, arrangements and criteria for crisis management arrangements.

¹¹⁵ European Centre for Disease Prevention and Control (ECDC), "Understanding the 2011 EHEC/STEC Outbreak in Germany", 2011.

¹¹⁶ In its recent overview report on emergency preparedness arrangements, the FVO also focused on better communication. It emphasises the need for spokespersons to have sufficient technical knowledge in order to answer questions clearly; conversely, experts providing communication to the public should be familiar with communication techniques. See European Commission Directorate-General for Health and Food Safety, Overview Report of a Series of Fact-Finding Missions Carried out in 2013 and 2014 in Order to Gather Information on Emergency Preparedness Arrangements, 2015. http://ec.europa.eu/food/fvo/overview_reports/details.cfm?rep_id=73.)

¹¹⁷ European Commission, Lessons Learned from the 2011 Outbreak of Shiga Toxin-Producing Escherichia Coli (STEC) O104:H4 in Sprouted Seeds, 2011.

10.1.2. *Identify tangible and measurable criteria to evaluate effectiveness of existing crisis management arrangements in the EU.*

Tangible and measurable criteria for evaluating the effectiveness of existing crisis management arrangements are crucial for an ex-post evaluation of a serious food/feed safety incident and for enabling conclusions regarding the functioning of crisis management arrangements. However, no widely accepted and applied criteria in this respect exist. For this evaluation, we therefore developed a set of specific evaluation indicators regarding effectiveness, focusing on the evaluation questions provided in the Terms of Reference of this evaluation, as presented in Annex 11 of this report. In parallel, we asked competent authorities of EU Member States in our survey whether they use relevant criteria to evaluate the effectiveness of existing crisis management arrangements. Results show that only 18% of competent authorities who provided an answer indicated that they use criteria to evaluate the effectiveness of existing crisis management arrangements in their country.¹¹⁸ However, most competent authorities (64%) recognised the utility of having such criteria in place. Among those competent authorities who confirmed that they use criteria to evaluate the effectiveness of crisis management arrangements, criteria mentioned include the minimisation of reputation damage, risk communication, and press/media reporting.

Based on the research conducted in the course of this evaluation, we suggest differentiating two groups of indicators to evaluate the effectiveness of crisis management arrangements: process related indicators and impact related indicators.

Process related indicators refer to the effectiveness of the processes applied in terms of time needed to detect the outbreak, to identify the source of the outbreak and to implement related measures until the incident is closed. They do not only refer to crisis management arrangements, but also depend on the effectiveness of surveillance and food control systems in place. Related indicators are:

- *The time between the occurrence and detection of the incident:* The longer the outbreak or contamination is ongoing before it is detected in the food chain, the higher the likelihood that the affected product is distributed across the food/feed chain and widely consumed. Short time periods may indicate effective surveillance and food control systems;¹¹⁹
- *The time between the detection of the outbreak and the identification of the source:* The more time needed for the identification of the source of the outbreak or contamination, the more widespread its effects are likely to be. Short time periods may indicate effective epidemiological research and tracing back exercises, as well as functioning traceability systems;
- *The time between the identification of the source and the closure of the incident:* The duration of this phase depends upon the measures that are put in place when the source of the risk is identified; the more effective they are, the shorter the time period until the closure of the incident.

Process related indicators therefore provide insights in the ability of the surveillance, food control and crisis management systems to respond quickly to an incident. While longer durations do not necessarily indicate ineffective systems (as an outbreak may be very difficult to detect, and the identification of the source can be very time consuming under atypical circumstances, as the E.coli outbreak has shown), short durations of time needed to detect the outbreak, to identify the source of the outbreak and to implement related measures until the incident is closed are likely an indication of effective systems and mechanisms in place.

¹¹⁸ 73% reported not using such criteria and 9% selected "don't know".

¹¹⁹ While surveillance and food control systems are not considered to be part of crisis management and are therefore not subject to this evaluation, this indicator is listed here to maintain a systemic perspective.

Impact related indicators refer to the negative effects of a food/feed safety incident. They include:

- *Number of patients/deaths* in a food/feed safety incident;
- *Economic losses* (borne by e.g. producers, hospitals, public authorities for managing the crisis);
- *Impact on trade* (as measured by comparing trade flows before and after incident);
- *Effect on consumer trust* (e.g. as measured by consumer surveys);¹²⁰
- *Number of stakeholder complaints*.

Impact related indicators may serve as a benchmark or guidance in view of minimising the impacts on consumers, producers, and other stakeholders. However, numerical values obtained from such indicators must be interpreted with great care. Indeed, in assessing the effectiveness of crisis management arrangements, caution is needed when linking crisis management measures taken and resulting effects of the food/feed safety incident. For instance, while the E.coli outbreak resulted in 55 deaths and thousands of patients, this figure cannot easily be compared with other incidents, in which less or no consumers were harmed, due to the very specific circumstances of the outbreak. At a hypothetical level, an incident with a similar E.coli strain and less people affected would not necessarily indicate that crisis management measures were more effective. It could be simply the case that the outbreak source was easier to identify. One could even imagine scenarios in which an outbreak with less affected consumers was still ineffectively handled, because if all procedures had been applied in an appropriate manner an even lower number of people would have been affected. In other words, it is hardly possible to compare the effectiveness of crisis management arrangement regarding specific outbreaks based on simple indicator values, be they impact or process related. The appropriate comparison would in all cases be the counterfactual of applying all necessary measures, i.e. could under the specific circumstances of the outbreak additional crisis management measures have shortened the duration of the incident and reduced its impact, or not? As the counterfactual is very difficult to establish, and by definition requires establishing the facts in detail, it may be favourable to adopt a systemic view of crisis management arrangements when considering their effectiveness. In this perspective, instead of solely considering *duration* and *impacts* of a food/feed safety incident, the emphasis is on an examination of *how* the incident was managed in practice by focusing on the contingency plans triggered, the processes used, the measures implemented and the roles played by the various actors, etc. Assessing the effectiveness of crisis management procedures using this approach requires a comparison of the measures, procedures and actions that were foreseen according to provisions in contingency plans and other legislation, with the measures and actions taken in practice. This assessment could be applied to crisis management procedures across all levels involved in handling a food/feed safety incident: Member States, EU institutions, and also at the level of the food business operator(s) involved in the incident. In a similar vein, the competent authority of one Member State reported that in this country, evaluations are carried out each time an incident leads to the activation of the national crisis structure. In such evaluations, the following aspects are examined:

- A summary of events including figures and numbers for future reference;
- The collaboration that occurred with the operators/industry involved;
- The collaboration with other authorities involved;
- The measures taken including the sampling and analysis performed;
- Strong points and weaknesses and items to improve; and

¹²⁰ See for example European Commission, Special Eurobarometer 354 - Food-Related Risks, Brussels, Belgium, 2010.

- Recommendations.

To obtain the most complete assessment of crisis management arrangements with respect to their effectiveness, numerical indicators and systemic evaluation criteria could therefore be applied in a complementary way. While the latter assess the extent to which the crisis management tools were appropriately employed, the former serve to provide an overview of key characteristics of the crisis. For example, an incident that was managed according to procedures outlined in the contingency plans which nonetheless took a long time to resolve and resulted in a significant number of patients and significant economic losses could serve to indicate areas in which crisis management arrangements or other key elements of the food/feed safety system need to be improved. Using this approach, the appropriate lessons can be drawn following an incident, allowing crisis management arrangements to be continuously revised and updated in view of improving their effectiveness.

10.1.3. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section, the answers to the evaluation questions concerning the effectiveness of existing crisis management arrangements are as follows:

- ▶ **Competent authorities and other stakeholders agree that existing crisis management arrangements have to a significant extent achieved (in order of average rating) consumer health protection, the efficient management of food/feed safety incidents and coordinated implementation of most effective measures to contain the risk in past serious food/feed safety incidents. According to respondents, consumers' trust in food/feed safety and limited disruption of internal market and trade were achieved to a lesser degree, although the average rating was still positive.**
- ▶ **Regarding the E.coli outbreak in 2011, the effectiveness of crisis management was rated the lowest, and our case study confirmed that a limited disruption of the internal market and trade and upholding consumers' trust in food/feed safety were not reached. Key factors that hindered their achievement in this incident included the difficulty to find the source of the outbreak and the lack of an effective strategy for communication to the public. Several interviewees emphasised that the incident also highlighted the need for improved cooperation between public health and food safety authorities at Member State and EU level, and related inter-sectoral crisis preparedness exercises. Competent authorities and other stakeholders provided suggestions for the improvement of the effective functioning of existing crisis management arrangements, including concerning harmonisation, improved communication and cooperation, improved training, and crisis simulation.**
- ▶ **Although four in five competent authorities report that they do not use criteria to evaluate the effectiveness of existing crisis management arrangements in their country, most also recognise the utility of having such criteria in place. The definition of harmonised EU criteria to evaluate the effectiveness of existing crisis management arrangements would therefore be welcomed by most competent authorities and other relevant stakeholders. A regular evaluation of the effectiveness of crisis management arrangements could combine: process related indicators, which focus on the time needed to detect the outbreak, to identify the source of the outbreak and to implement related measures until the incident is closed; impact related indicators, which focus on different dimensions of the impact of an incident such as the number of patients/deaths, economic losses, impact on trade, effect on consumer trust, etc.; and a systemic perspective of the response to the incident, under which is examined how an incident was managed in practice by focusing on the contingency plans triggered, the processes used, the measures implemented and the roles played by the various actors during the incident. Based on this framework, a dedicated evaluation report in the aftermath of a serious food/feed safety incident would draw conclusions regarding gaps and deficiencies identified, allowing crisis management arrangements to be continuously revised and updated in view of improving their effectiveness.**

10.2. Relevance

10.2.1. *To what extent does the legal framework correspond to the current needs for food/feed crisis coordination?*

As described in the background section of this report (Section 6.3), Regulation (EC) No 178/2002 foresees that when a relevant risk cannot be contained satisfactorily by the Commission or by the Member State(s) concerned, emergency measures (according to Articles 53 and 54) are complemented by a general plan for crisis management in the field of the safety of food and feed (Article 55) and a crisis unit (Articles 56 and 57). The general plan and the role of the crisis unit were elaborated in the Annex to Commission Decision 2004/478/EC. According to the Decision, the general plan provides two layers of actions: (1) one layer of action related to potential serious risk, 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.

Survey respondents who provided an assessment tended to consider that the two layers of actions introduced in the general plan for food/feed crisis management are relevant, providing an average rating of 3.55. This was particularly the case for competent authorities, who gave an average rating of 3.6. For all other respondents the figure was 3.5. Likewise, respondents tended to view these two layers as still appropriate for food/feed crisis management, with an average rating of 3.4.¹²¹ This was particularly the case for competent authorities (3.5), while the average rating of the other stakeholder groups was lower (3.1).

The relatively positive results regarding relevance and appropriateness of the mentioned two layers of action are notable, because so far a crisis unit according to Article 56 of Regulation (EC) No 178/2002 has never been set up, i.e. the second layer of action has not been used during serious food/feed safety incidents experienced during the last decade. While it still could be initiated in case this is required in the context of a large-scale emergency, several serious food/feed safety incidents have occurred in the meantime that in principle could have triggered setting up a crisis unit, most notably the E.coli outbreak in 2011.

Respondents to our survey were therefore also asked whether 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) have been sufficient for the management of past serious food/feed safety incidents. Overall, the answers provided were almost evenly split between "Yes", "No", and "Don't know".¹²² When broken down by stakeholder group, it can be seen that competent authorities who answered the question were more likely than other respondents to indicate that the mechanisms foreseen in Sections 2.2 and 6 of Commission Decision 2004/478/EC had been sufficient for the management of past serious food/feed safety incidents.¹²³ However, other stakeholders were more likely to indicate that they did not know whether the mechanisms had been sufficient, which is due to the likely lack of awareness that they may have regarding the crisis management arrangements used in the past.

¹²¹ Both questions provided a scale from 0 to 5 (with 0 representing "not at all" and 5 "very much").

¹²² Just over a third (38%) of respondents who answered the question considered that the mechanisms foreseen in Sections 2.2 and 6 of Commission Decision 2004/478/EC had been sufficient for the management of past serious food/feed safety incidents. A nearly similar number of respondents (32%) indicated that they had not been sufficient, while another third of respondents (30%) did not know.

¹²³ This was the case for 50% of responding authorities, compared to only 18% for other stakeholders. However, 53% of other stakeholders selected "don't know", compared to 15% for competent authorities).

Several of those respondents who considered the mechanisms to be insufficient referred in their comments to the E.coli outbreak, with some suggesting that a crisis unit should have been established. This view is largely supported by the results of the case study/in-depth interviews regarding this incident. Most interviewees (several representatives of competent authorities and other stakeholders that were directly involved in the management of the outbreak) considered that it would have been helpful to set up a crisis unit at the EU level in response to the E.coli outbreak, noting that this would have contributed to improving coordination and communication and ensuring effective management of the crisis.¹²⁴ Moreover, several interviewees emphasised that although this was not the case at the EU level, crisis units (or 'task forces') were established internally at the level of their respective Member State or organisation. Several interviewees were also of the opinion that the European Commission should have played a bigger role, particularly at the beginning of the crisis, and that the network of crisis coordinators should have been used (see also the evaluation questions that focus on the involvement of EU Member States, below).

Evidence collected in this evaluation thus indicates that while the two layers of action provided for in the general plan are often considered to be relevant and appropriate for crisis management, one of the layers of action (the crisis unit) has never been used, and there is strong disagreement on whether or not the other layer of action (the mechanisms foreseen in Sections 2.2 and 6 of Commission Decision 2004/478/EC) has been sufficient to ensure the management of previous food/feed safety incidents. When considering the results of this evaluation regarding the effectiveness of crisis management (see above, Section 10.1), the following picture emerges:

- On the one hand the experiences of the glass fragments incident, the melamine crisis, and also the E.coli outbreak demonstrate that several dimensions of crisis and potential crisis management at EU level function effectively, including information exchange on affected consignments and measures taken through the RASFF (see Section 9.1 above), coordination of measures and briefing on crisis situations through daily audioconferences led by the European Commission (see Section 10.1), risk assessment and support to epidemiological investigations by EFSA (see Section 0), and emergency measures taken by the European Commission (see Section 0 below), among others.
- On the other hand, during more complex crisis situations like the E.coli outbreak which involve large scale public attention it proved to be not feasible to implement a clear and coherent communication strategy across the affected Member States and EU institutions. Also, while a clearer crisis management structure (either a crisis unit according to Article 56 or a similar structure) within the European Commission would have been considered beneficial by key stakeholders involved in the incident, no such structure was implemented. One consideration why a crisis unit during the E.coli outbreak was not established was the need to formally declare a crisis for this purpose. This was considered to be not opportune as it might have increased the level of public concern. In consequence, standard procedures, including information exchange through RASFF and procedures for involving Member States in decision-making regarding relevant EC measures (mainly through the SCOFAH)¹²⁵ were complemented by ad-hoc crisis management arrangements to handle the incident at EU level.

¹²⁴ Only one EU-level stakeholder and one competent authority considered that setting up a crisis unit was not necessary in that food safety incident, and that the mechanisms foreseen in Sections 2.2 and 6 of Commission Decision 2004/478/EC were sufficient, although these should have been put in place at an earlier stage of the outbreak.

¹²⁵ In the meantime, the SCOFAH has been replaced by the Standing Committee on Plants, Animals, Food and Feed (PAFF).

In other words, while crisis management at EU level is assessed on average positively and has worked well in the context of limited crises, during more complex crisis situations such as the E.coli outbreak the provisions in the general plan foreseen for this type of situations appeared not to be the appropriate tool. This indicates a need to review the provisions regarding the general plan according to Commission Decision 2004/478/EC, and to develop more workable arrangements that can be applied during relevant incidents, possibly including a greater role of the EC in communication and general coordination of Member States, as well as providing a step-wise approach for escalating measures of crisis management and related criteria for escalation, also considered by competent authorities and other stakeholders to be among the most needed measures related to crisis management at EU level (see below).

To assess the need for specific measures related to improving crisis management at EU level, survey respondents were asked to consider several alternative options that were identified through exploratory research. Those respondents who expressed an opinion with respect to this question tended to see all the specified measures as necessary.¹²⁶ The measure assessed by respondents as the most necessary were regular crisis simulation exercises at EU level (average rating of 4.1), a greater role of the EC in the coordination of the communication of serious food/feed safety incidents to the public/relevant competent authorities (4.1), a greater role of the EC in the coordination of Member States' efforts (3.9) and a step-wise approach for escalating measures of crisis management and for related criteria for escalation (3.9). The lowest rated measures were an IT tool at EU level for communication between Member States (3.6) and a mechanism that would be activated at an earlier stage than the general plan (3.5), although it should be noted that respondents still tended to view these measures as necessary.

In addition to the measures specified in the figure, respondents also had the possibility to suggest other necessary measures. Respondents who did so provided the following comments: "Harmonisation of the plans between Member States", "Earlier management and greater role of EC in co-ordination. Stronger involvement of business operators across the chain, including rapid response of EFSA (avoid individual MS risk assessments that are often not aligned)", "Further coordination and appropriate communication in a timely manner" and "communication strategy trainings".

10.2.2. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section, the answers to the evaluation question concerning the relevance of existing crisis management arrangements are as follows:



The general plan according to Commission Decision 2004/478/EC provides for two layers of actions: (1) one layer of action related to potential serious risk, where a crisis unit is not set up but adequate provisions are made to ensure effective management; and (2) another layer of action implying the setting up of a crisis unit according to Article 56 of Regulation (EC) No 178/2002. Competent authorities in the field of food/feed crisis management (and to a lesser degree also other stakeholders) consider these two layers of action to be relevant and still appropriate for food/feed crisis management. This is in spite of the fact that a crisis unit has never been set up, i.e. the second layer of action has not been used during serious food/feed safety incidents experienced during the last decade. Regarding the first layer of action, there are diverging assessments among respondents whether or not it has been sufficient to ensure the management of previous food/feed safety incidents: Just over a third considered that the first layer of action had been sufficient for the management of past serious food/feed safety incidents, a nearly similar

¹²⁶ All specified measures received positive ratings on average i.e. above the midpoint of 2.5, with 0 representing "not at all needed" and 5 "very much needed".

number of respondents indicated that it had not been sufficient, while another third of respondents did not know.

- ▶ The case study regarding the E.coli outbreak in 2011 confirms that the first layer of action has been partly insufficient for the management of this incident. During the outbreak, a clearer crisis management structure within the European Commission would have been beneficial, according to key stakeholders involved, either a crisis unit according to Article 56 or a similar structure that could be activated without formally declaring a crisis. There is also a broad consensus that additional measures are needed for crisis management at EU level. The measures considered most necessary are regular crisis simulation exercises, a greater role of the EC in the coordination of Member States' efforts and specifically the coordination of the communication to the public/relevant competent authorities, as well as a step-wise approach for escalating measures of crisis management. The results of this evaluation therefore indicate a need to review the provisions regarding the general plan according to Commission Decision 2004/478/EC, and to develop more workable arrangements that can be applied during serious food/feed safety incidents.

10.3. Role of the European Commission

As has been described in the description of the legislative framework for crisis management (see Section 6.3.3), key provisions of Regulation (EC) No 178/2002 for managing serious food and feed safety incidents are on the one hand those relating to emergency measures for food and feed according to Articles 53 and 54, and on the other hand the provisions regarding a general plan for crisis management and a crisis unit in Articles 55 to 57. In practice, emergency measures have been more relevant for managing food and feed safety incidents at EU level, and are therefore discussed first.

10.3.1. *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?*

A large number of serious food/feed safety incidents have been contained and managed by the European Commission through the adoption of emergency measures on the basis of Article 53 of Regulation (EC) No 178/2002. In almost all cases, emergency measures were adopted directly by the EC; exceptionally, they have served to extend, amend, or abrogate interim protective measures adopted by a Member State on the basis of Article 54.¹²⁷

Table 3 in the Annex to this report provides an overview of the emergency measures adopted by the EC in response to chemical and microbiological risks that have affected the EU/EEA throughout the course of the evaluation period. The table also indicates whether the emergency measures have been amended at a later stage, and are still in force at the time of writing, or not.

¹²⁷ It should be noted that while the use of Article 54 by Member States is rare, it has been used sporadically in the course of the reference period. For instance, in 2009, France adopted emergency measures prohibiting the marketing of milk and milk products from herds affected by scrapie. In 2013, it adopted interim protective measures following an incident in which Sudan dye 1 was found in imported hot chilli products in France. In the first case, the EC suspended the national interim protective measures (see Commission Decision 2009/726/EC below), while in the second case, it extended the emergency measures to the remainder of the EU through the adoption of Commission Decision 2003/460/EC.

Emergency measures taken by the EC on the basis of Article 53 of Regulation (EC) No 178/2002 have been adopted as Commission Decisions or Commission Regulations prior to the entry into force of the Lisbon Treaty on 1 December 2009. Since this date, emergency measures are adopted as Commission Implementing Decisions or Commission Implementing Regulations.

Two main differences should be noted between Commission (Implementing) Decisions and (Implementing) Regulations. Firstly, while both are legally binding, a Regulation is directly applicable in the EU from the day of publication and automatically becomes part of the national legal order of Member States. In contrast, Decisions may require certain Member States to adopt measures of national law necessary to implement them. Secondly, Regulations are of general application, while Decisions have an addressee (i.e. a Member State or a natural or legal person).

As can be noted from Table 10, a majority of emergency measures were adopted as Decisions, particularly prior to 2007. This can be explained by the fact that in the past, Member States had in place a variety of control systems in the area of food and feed. As a result, emergency measures were adopted with different Decisions addressing Member States according to the systems of official controls existing in their country. While this allowed emergency measures to be implemented taking into account these specific systems, two key shortcomings were observed. On one hand, the need for some Member States to adopt measures of national law in order to implement the emergency measures resulted in a delay of one or two days before the latter could be applied. This led to Member States across the European Union adopting the measures at slightly diverging moments, affecting in some cases their *efficiency*. On the other hand, given that the Decisions adopted were addressed to Member States' governments, in specific cases food business operators argued that the provisions contained in those emergency measures did not apply to them, making the measures less *effective*.

After the harmonisation of control systems of Member States following the entry into force of Regulation (EC) No 882/2004 in 2006, emergency measures have been increasingly adopted as Regulations. This instrument addresses the two shortcomings described above; moreover, given the harmonisation of controls systems in Member States, there is no longer a need for the Commission to address countries separately when adopting emergency measures. Therefore, while Decisions may be used in the future to address one or several concerned Member States, e.g. when the product concerned is of Community origin, the use of Regulations is expected to allow a more effective and efficient management of (potential) crises resulting from food/feed of third country origin.

Table 3 in the Annex also shows that 25 of the 40 emergency measures adopted in the evaluation period have been repealed or have expired without being extended, suggesting that these measures are no longer needed because the risk is contained or otherwise no longer relevant. Those that are still in force indicate the continued relevance of the measures. However, it should be noted that some of the emergency measures still in place have been substantially amended. For instance, an initial ban of a product from a third country may be amended to impose special conditions on the import of those products, such as the requirement of a health certificate for consignments or reinforced controls at the border. Therefore, an emergency measure that is still in place but has been modified in such ways through an amendment could have been similarly effective as a measure that has been repealed.

Emergency measures were issued in two of the three case studies conducted in the framework of this evaluation. Key aspects of the relevant case studies include:

- *Melamine crisis (2008)*: In the melamine incident, three consecutive Commission Decisions established and specified emergency measures. The first Decision (Commission Decision 2008/757/EC) banned the import of composite products containing milk or milk products intended for the particular nutritional use of infants and young children and imposed the control of the

presence of melamine in all consignments originating in or consigned from China of composite products containing more than 15% of milk products, and in all consignments of such composite products whose amount of milk product content could not be established. It also introduced the obligation to control for the presence of melamine in products already placed on the market and to destroy products found to contain melamine in excess of 2,5 mg/kg product.¹²⁸ The second Decision (Commission Decision 2008/798/EC) refined the emergency measures of the previous one and introduced random checks prior to importing other feed and food products with a high protein content originating from China, encouraging Member States to increase their import controls.¹²⁹ The third and final Decision (Commission Decision 2008/921/EC) extended the existing emergency measures to ammonium bicarbonate and to feed and food containing soya and soya products.¹³⁰ Interviewees considered that the emergency measures taken at the EU level in response to the melamine incident were effective. Moreover, there were no known cases of humans affected by the melamine incident in the EU.¹³¹

- *E.coli outbreak (2011)*: In response to the E.coli outbreak, the Commission issued Commission Implementing Decision 2011/402/EU on emergency measures applicable to fenugreek seeds and certain seeds and beans imported from Egypt.¹³² This was considered to be effective by all interviewees, although the ban came at the end of the crisis once the source of the outbreak has been identified and it therefore mainly consolidated protective measures taken.¹³³

In both of the serious food safety incidents in which emergency measures were used, these were considered to have been effective; moreover, no disparities between measures taken by different Member States were noted. This is in spite of the fact that in the E.coli outbreak, France also adopted 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. These national instructions also provided 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 2011.¹³⁴ While initially the measures taken at the national level in France applied stricter provisions, the national instructions were not extended beyond October due to the effectiveness of the EU emergency measures, according to the account of an interviewee.

Beyond the case studies considered, another example of the effective use of emergency measures is the 2008 sunflower oil incident, in which sunflower oil originating from Ukraine was found to be contaminated with high levels of mineral oil. Interim protective measures were adopted by the Commission one month after the reception of the RASFF notification in which the contamination was revealed (see Commission Decision 2008/388/EC in the table above). Following an FVO inspection in September 2008, the

¹²⁸ European Commission, Commission Decision 2008/757/EC of 26 September 2008 Imposing Special Conditions Governing the Import of Products Containing Milk or Milk Products Originating in or Consigned from China, 2008.

¹²⁹ European Commission, Commission Decision 2008/798/EC Imposing Special Conditions Governing the Import of Products Containing Milk or Milk Products Originating in or Consigned from China, and Repealing Commission Decision 2008/757/EC, 2008.

¹³⁰ European Commission, Commission Decision 2008/921/EC of 9 December 2008 Amending Decision 2008/798/EC, 2008.

¹³¹ 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.

¹³² OJ L 179, 7.7.2011, p.10.

¹³³ Whereas the E.coli outbreak was considered to reach its peak on 22 May 2011, the emergency measure was issued on 6 July 2011, i.e. 45 days later. Nonetheless, the Commission Decision was implemented the day after EFSA published its report linking the outbreaks in Germany and France to a specific lot of fenugreek seeds imported from Egypt.

¹³⁴ 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.

results of import controls demonstrated the accuracy and reliability of the control and certification system put in place by the Ukrainian authorities and confirmed the correctness of mineral oil levels declared in the certificates. As a result, the measures were reviewed and Commission Regulation (EC) No 1151/2009 was adopted, replacing Decision 2008/433/EC.¹³⁵

On the other hand, other examples illustrate the continuing challenges faced by the EU in containing certain food safety risks. For example, guar gum and products containing the substance have been the subject of three emergency measures issued by the EC since 2008 (see table above). However, the most recent measures¹³⁶ continue to impose special conditions and random checks on the imports of guar gum and compound mixtures containing at least 20% guar gum originating in or consigned from India, indicating that there continue to be insufficient guarantees about the safety of those products.¹³⁷

Nonetheless, survey respondents who expressed an opinion on this issue mostly assessed emergency measures as having been moderately to very much effective for the management of past serious food/feed safety incidents. The average rating provided was 3.5, with competent authorities providing an average rating of 3.6, compared to 3.4 for other respondents. Less than 10% of respondents expressing an opinion (3 of 33) assessed the effectiveness of emergency measures negatively (rating of 2 or lower).¹³⁸ Moreover, they tended to assess that the mechanism of emergency measures provided by Articles 53 and 54 of Regulation (EC) No 178/2002 had contributed to avoiding disparities between measures taken by different Member States and to ensuring a consistent approach during past serious food/feed safety incidents. The average rating for this aspect provided by respondents was 3.45. Those respondents who provided a negative assessment did not provide any clear explanations for their rating.¹³⁹

10.3.2. *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?*

As mentioned above, in addition to emergency measures, Regulation (EC) No 178/2002 provides specific provisions for crisis management. Related obligations for the European Commission stem from Article 55, which requires that the EC draws up a general plan for crisis management in the field of the safety of food and feed, and from Article 56 which foresees for specific situations that a crisis unit is set up. With respect to Article 55, the EC has fulfilled its obligation in adopting Commission Decision 2004/478/EC, which specifies the types of situations involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54 (i.e. emergency measures). The general plan also specifies the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy. However, the general plan has so far not been formally triggered. Also, a crisis unit according to Article 56 has never been established (see previous section). Therefore, possible EC obligations under the Decision would mainly refer to practical preparatory steps that can be derived from the Decision before a crisis, such as the establishment of a network of crisis coordinators, training activities, and crisis simulation exercises. These have been implemented to varying degrees, as indicated in the relevant sections below. Furthermore, the role of the

¹³⁵ European Commission, The Rapid Alert System for Food and Feed: 2008 Annual Report, 2008.

¹³⁶ Commission Implementing Regulation (EU) 2015/175 of 5 February 2015 laying down special conditions applicable to the import of guar gum originating in or consigned from India due to contamination risks by pentachlorophenol and dioxins.

¹³⁷ https://www.food.gov.uk/business-industry/imports/banned_restricted/guargumindia

¹³⁸ On a scale of 0 to 5, with 0 representing “not at all” and 5 representing “very much”.

¹³⁹ When broken down by stakeholder group, the results show that competent authorities who expressed an opinion provided an average rating of 3.5, compared to 3.3 for other stakeholder groups.

European Commission as coordinator in past serious food/feed safety incidents can provide insights to which extent the European Commission played the role as coordinator in past serious food/feed safety incidents, and fulfilled related obligations. The specific aspects of this role that were scrutinised are:

- General coordination of national efforts;
- Coordination with EFSA;
- Coordination of communication to the public/relevant competent authorities;
- Coordination with international organisations; and
- Coordination with third countries.

According to survey results, satisfaction with the EC's role of coordinator in past serious food/feed safety incidents is on average quite high for three of the five items: The average rating provided by respondents was highest for coordination with EFSA (3.7), coordination with international organisations (3.6) and coordination with third countries (3.6).¹⁴⁰ In contrast, ratings were clearly lower concerning the EC's role in coordination of communication to the public/relevant competent authorities (2.9) and for general coordination of national efforts (2.8). When looking at the results in more detail, it is notable that this split is found both in the assessments of competent authorities as well as in the assessments provided by other stakeholders. The lower average is caused by about one third of respondents that did not consider the EC had a significant role regarding these two aspects, i.e. that provided an assessment of 2 or lower (in contrast, for the other three aspects only about 10% of respondents provided a similarly low rating). Finally, survey respondents were specifically asked to assess the EC's role of coordinator during the three examples of past serious food/feed safety incidents (and other examples, if relevant) that were subject to dedicated case studies. Respondents tended to rate the EC's role of coordinator highest regarding the melamine crisis (with an average rating of 3.6). For both other incidents (glass fragments in instant coffee and the 2011 E.coli outbreak) the average rating given by respondents was slightly lower (3.0).¹⁴¹

These survey results were partly reflected in the case study/in-depths interviews conducted with competent authorities in affected countries, EU and international stakeholders. These interviews and other evidence collected confirmed the role of the European Commission in each of the three incidents, which differed notably based on the specific situations involved in the three incidents. Key aspects of the case studies that are relevant for answering this evaluation question include:

- *Melamine crisis (2008)*: This incident concerned an international food safety incident that led to a large number of RASFF notifications and Commission actions including an extra-ordinary session of the SCOCAH, a request to EFSA for urgent scientific advice on the risks to human health due to the possible presence of melamine in composite products, and three Commission Decisions, which by their nature entailed coordination with Member States and international partners (for details regarding the three Decisions, see above). Interviewees generally agreed that the EC played the role of coordinator in the melamine incident, though some had difficulties in assessing the EC's contribution to coordination with EFSA, third countries, or to the general coordination of national efforts. Interviewees unanimously agreed that the European Commission contributed to the coordination with INFOSAN to a large

¹⁴⁰ Average ratings provided by Member State competent authorities and other stakeholders when asked to assess on a scale of 0 to 5 (with 0 indicating "not at all" and 5 "very well") the extent to which the EC has played the role of coordinator in past serious food/feed safety incidents affecting their Member State.

¹⁴¹ Again, respondents rated the extent to which the EC played the role of coordinator in the incidents on a scale of 0 (not at all) to 5 (very well).

extent; moreover, they considered that this cooperation was good and efficient.

- *Glass fragments in instant coffee (2010)*: Case study results indicate that – other than providing information through RASFF – the EC did not play a notable role, which is mainly due to the character of this incident (a voluntary recall by a large scale operator, Nestlé).
- *E.coli outbreak (2011)*: As this incident was the largest known STEC-associated outbreak worldwide, the importance of the outbreak and the extent of public concerns led to an EC involvement from the very onset of the crisis, although most actions were taken by the Member State that was mainly affected (Germany). For example, daily audio conferences started the day after an urgent inquiry sent by German authorities through the ECDC's Epidemic Intelligence Information Sharing System (EPIS), and three days after the outbreak was first notified through EWRS. As discussed before, at a later stage of the outbreak, the Commission played a coordinating role through the adoption of Commission Implementing Decision 2011/402/EU, which suspended the import of seeds and beans from Egypt and called on Member States to adopt measures for the withdrawal and destruction of fenugreek seeds imported from Egypt. While most interviewees expressed satisfaction with the EC's role in the coordination of national efforts throughout the E.coli outbreak, e.g. through the use of the mentioned conference calls and coordination of national reference laboratories across the EU, others indicated that the Commission should have played a bigger role, or emphasised that since the E.coli outbreak was mainly a national event, there was no need for more coordination of national efforts. Interviewees mainly agreed about the Commission's positive contribution to coordination with EFSA. In terms of coordination of communication to the public and relevant competent authorities, interviewees expressed dissatisfaction with the way this was handled throughout the E.coli outbreak. A majority of interviewees emphasised this as a point for improvement (see also above, Section 10.1).

10.3.3. *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? [EU level]*

The indicators for answering this evaluation question relate to the extent to which the EC has identified lessons learnt from past experiences and whether those lessons learnt, if any, were translated into improvements in their crisis preparedness and crisis management arrangements. The experiences examined relate to past serious food/feed safety incidents, as well as to crisis simulation exercises.

Several measures that aim at improving arrangements were introduced at EU level following the E.coli crisis, based on a EC review of the outbreak that identified lessons learnt and outlined possible actions to prevent future outbreaks.¹⁴² Suggested actions in the document referred to the need to strengthen coordination between health and food safety authorities, the elaboration of an EFSA and ECDC Standard Operational Procedure (SOP) for joint risk assessment in the event of outbreaks of infectious diseases, the necessity of carrying out inter-sectoral preparedness exercises on outbreak coordination and response, and the creation of a database for molecular typing. The document also emphasised the need to review existing processes established by Decision 2004/478/EC. Several measures were implemented at EU level since then, including:

¹⁴² European Commission. (2011). Lessons learned from the 2011 outbreak of Shiga toxin-producing *Escherichia coli* (STEC) O104:H4 in sprouted seeds.

- The cross-border crisis simulation exercise *Aristaeus*, which was commissioned by the EC and took place on 14-15 May 2013;¹⁴³
- A working group to identify best practices for communication in times of crisis was set up by the EFSA;¹⁴⁴
- EFSA has also conducted annual crisis training exercises since 2012, with a full crisis simulation exercise planned for this year (2015)¹⁴⁵;
- Standard Operating Procedures for rapid foodborne outbreak assessment were drafted in collaboration between ECDC, EFSA and the Commission;
- Draft Standard Operating Procedures have been developed by the Commission to codify the procedures and processes to be followed within DG SANTE to manage serious food/feed safety incidents;¹⁴⁶
- Five fact-finding missions were conducted by the FVO in 2013-2014 to identify best practices in emergency preparedness of Member States;¹⁴⁷
- Training courses on food-borne outbreaks investigations are provided in the framework of the BTSF (Better Training for Safer Food) programme, including for Member States (ongoing);¹⁴⁸
- The EC has requested EFSA to provide technical support for the collection of molecular typing results of food borne pathogens, which will help in establishing links between specific pathogen strains and specific food types and/or outbreaks (ongoing).¹⁴⁹

While it was out of the scope of this evaluation to establish the quality of specific individual measures for improving crisis management at EU level, the list above confirms that a significant number of complementary measures were taken by the European Commission during the evaluation period, partly in response to the E.coli outbreak. To address the Member State perspective of these measures, competent authorities were asked to assess the extent to which relevant experiences had improved crisis management arrangements at the EU level. Competent authorities who expressed an opinion tended to assess the experience gained from the EU-level *Aristaeus* exercise quite highly in terms of improving current crisis management arrangements at the EU level.¹⁵⁰ This positive assessment is consistent with the evaluation provided by participants of the *Aristaeus* exercise, of which an overwhelming majority agreed or strongly agreed that the exercise was well organised, that the scenario and injects generated good discussions, that the exercise generated important issues and lessons identified, and that the aim of the exercise ("to explore outbreak coordination and response to a food-borne incident involving public health and food safety authorities at the national and international level") was achieved.¹⁵¹ In our survey, *Experience gained from past serious food/feed safety incidents* received an average rating of 3.5, while

¹⁴³ Public Health England, "Exercise *Aristaeus* Draft Report", No. May, 2013.

¹⁴⁴ The Advisory Forum Working Group on Communications – EFSA.

¹⁴⁵ Instinctif Partners, External Scientific Report - EFSA's food and feed crisis preparedness training: 2014 Crisis Training Exercise, 2014.

¹⁴⁶ At the time of the research, the draft SOPs were confidential and had not yet been made available to Member State competent authorities.

¹⁴⁷ European Commission Directorate-General for Health and Food Safety, Overview Report of a Series of Fact-Finding Missions Carried out in 2013 and 2014 in Order to Gather Information on Emergency Preparedness Arrangements, 2015.

http://ec.europa.eu/food/fvo/overview_reports/details.cfm?rep_id=73.

¹⁴⁸ Ongoing, see <http://www.trainsaferfood.eu/Trainings/Foodborneoutbreaksinvestigation.aspx>.

¹⁴⁹ Since the end of 2014, EFSA has been piloting the collection of molecular typing data from food and animals together with European Union reference laboratories. The European Commission requested EFSA to provide technical support for the collection of molecular typing results of food and animal isolates of *Salmonella*, *Listeria monocytogenes*, and Shiga-toxin producing *E. coli*. ECDC is carrying out similar work for human isolates, see <http://www.efsa.europa.eu/en/topics/topic/moleculartyping.htm>.

¹⁵⁰ This item received an average rating of 3.8.

¹⁵¹ Public Health England, "Exercise *Aristaeus* Draft Report", No. May, 2013. 78 of 102 delegates who attended the exercise provided their feedback in a participant evaluation.

experience gained from other crisis simulation exercises in which the authority's Member State had taken part received an average rating of 3.0.

10.3.4. *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?*

During the evaluation period, the EC conducted a number of activities that contributed to the coordination of national efforts in outbreak investigations and to the development of best practices. These included the previously mentioned cross-border crisis simulation exercise *Aristaeus*, the development of Standard Operating Procedures for rapid foodborne outbreak assessment and management of serious food/feed safety incidents, the training courses for Member States on food-borne outbreaks investigations that are provided in the framework of the BTSF (Better Training for Safer Food) programme and fact-finding missions conducted by the FVO to identify best practices in emergency preparedness of Member States (see previous evaluation question for more details).

Reflecting on these activities, the first indicator for answering this evaluation question relates to the assessment of competent authorities in the field of food/feed safety regarding the extent to which these EC activities in fact contributed to the coordination of national efforts of Member States, for instance in outbreak investigations. The specific coordination activities that were examined are:

- The provision of trainings;
- The provision of guidance documents or Standard Operating Procedures (SOPs);
- Sharing of technical information; and
- The provision of infrastructure for coordination (e.g. audio conferences or meeting facilities).

Competent authorities who provided an opinion tended to see the provision of training by the EC as contributing the most to the coordination of national efforts.¹⁵² Also in regard to the provision of guidance documents/SOPs and the sharing of technical information they tended on average to see the EC as contributing to the coordination of national efforts.¹⁵³ However, in terms of providing infrastructure for coordination (e.g. audio conferences, meeting facilities) the rating provided by respondents was on average negative, with 42% of the 19 competent authorities responding to this question providing a rating of 1 or 0 (none indicated 2).¹⁵⁴ It is unclear what motivated the low rating, but it is possibly related to a certain ambiguity in the wording of the question, that could be interpreted as either referring to coordination in a country or between countries.¹⁵⁵ The result should therefore be interpreted with care. If respondents did indeed refer to the coordination of national efforts between countries, a low rating regarding technical infrastructure would be a relevant aspect to consider. In this context, it is notable that during the E.coli outbreak in 2011, the technical infrastructure used for coordination during the incident (audioconferencing) was criticised as being of insufficient quality (see below).

The evidence collected through case study/in-depth interviews confirms that the EC contributed to the coordination of national efforts during serious food/feed safety incidents, e.g. by providing technical information, but also through the provision of

¹⁵² This item received an average rating of 3.2, with 0 indicating "contributed not at all" and 5 "contributed very much".

¹⁵³ Both items received an average of 2.9.

¹⁵⁴ This item received an average rating of 2.2, below the midpoint of 2.5.

¹⁵⁵ A comment received by a competent authority indicated: "What kind of national efforts are intended? between the MS or only at the national level of a country?".

infrastructure such as audio conferencing. In more detail, the results of the case studies regarding this aspect are:

- *Melamine crisis (2008)*: At the request of the Commission, technical information was shared by EFSA in the form of a scientific statement assessing the risks for public health due to the presence of melamine in infant milk and other milk products in China. The worst-case scenario developed by EFSA allowed the EC to issue Commission Decision 2008/757/EC, which imposed special conditions governing the import of products containing milk or milk products originating from China and established several emergency measures.
- *Glass fragments in instant coffee (2010)*: As noted in previous evaluation questions, the glass fragments incident did not require the EC to coordinate national efforts beyond its role as manager of the RASFF.
- *E.coli outbreak (2011)*: From the early stages of the outbreak, the European Commission organised audio conferences with Member States' and EU-level authorities to discuss the progress of the investigation. However, according to competent authorities from one affected Member State, in several instances separate audio conferences about similar issues were held with representatives of the Commission and Member States responsible for public health and with those responsible for food safety, which was considered to be inefficient and to putting additional strain on officials that were heavily involved in crisis management. The same interviewee noted that the technical quality of audio conferences was sometimes problematic,¹⁵⁶ although this assessment was disputed by another interviewee from an EU institution.

To further examine the effect of EU efforts as perceived by Member States, competent authorities were asked to indicate whether or not their Member State had participated in the training activities and working groups organised by the EC, as well as the FVO missions or reports, and to assess to what extent these activities had contributed to the development of best practices in the management of serious food/feed safety incidents. On the whole, competent authorities who expressed an opinion tended to assess that the three specified activities had contributed to the development of best practices for the management of serious food/feed safety incidents. Most highly rated were working groups and FVO missions/reports, closely followed by training activities.¹⁵⁷

10.3.5. Answers to evaluation questions

Based on the evidence collected and the summary of findings presented in this section, the answers to the evaluation questions concerning the role of the European Commission in crisis management are as follows:



Food/feed safety incidents have typically been contained and managed by the European Commission through the adoption of emergency measures on the basis of Article 53 of Regulation (EC) No 178/2002. Emergency measures have also been used as instruments for the management of two of the three past serious food safety incidents scrutinised in depth, the melamine crisis and the E.coli outbreak. In both of these incidents, the emergency measures taken at the EU level were considered to have been effective. This assessment is confirmed by the results of the survey of competent authorities and stakeholders, with nine in ten respondents assessing emergency measures as having been moderately to very effective for the management of serious food/feed safety incidents. Similarly, a nearly as large majority of competent authorities and stakeholders assessed that the mechanisms provided by Articles 53 and 54 have contributed moderately to very

¹⁵⁶ According to this interviewee, multiple participants used speaker phones that amplified ambient noise and made conversations difficult to understand.

¹⁵⁷ These items received average ratings of 3.6, 3.6 and 3.5 respectively on a scale of 0 to 5, with 0 indicating "not at all" and 5 "very much".

much to avoiding disparities between measures taken by different Member States and to ensuring a consistent approach in previous serious food/feed safety incidents.

- ▶ Regulations, rather than Decisions, are considered to be often more effective and efficient for the adoption of emergency measures. While mainly Decisions were used prior to the harmonisation of official food and feed controls through Regulation (EC) No 882/2004 (which entered into force in 2006), the use of a Regulation allows emergency measures to be directly applicable in all Member States and to all stakeholders, including food business operators, where relevant.
- ▶ The EC has fulfilled its obligations deriving from Article 55 of Regulation (EC) No 178/2002 insofar that it has drawn up a general plan for crisis management through the issuing of Commission Decision 2004/478/EC. The elements to be included in the general plan as required by the Regulation have been taken into account. The EC has also played the role of coordinator in the management of past serious food/feed safety incidents. However, the extent to which this was the case and the satisfaction of competent authorities and other stakeholders with the EC's role varies depending on the specific coordination aspect and incident considered, as our case studies revealed. Areas in which the EC contributed significantly to the coordination of the national efforts in response to serious food/feed safety incidents include through its role as manager of the RASFF, the coordination/support provided during outbreaks, the provision of trainings courses for Member States on food-borne outbreaks investigations, and the provision of technical information.
- ▶ At EU level, the E.coli outbreak in 2011 was reviewed and several measures were implemented that address deficiencies identified in managing the crisis. These measures include the elaboration of SOPs, the organisation of a crisis simulation exercise, fact-finding missions by the FVO to identify best practices in emergency preparedness, and training courses on food-borne outbreaks investigations for Member States.

10.4. Involvement of the EU Member States

10.4.1. *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?*

There is no complete overview of how Member States have elaborated contingency plans in the field of food/feed as defined in Art. 13 of Regulation (EC) No 882/2004 available. Existing research includes a recent 2014 report by a working group of 17 Member States in the framework of the Heads of European Food Safety Agencies (HoA) that examines the management and communication protocols applied by those countries.¹⁵⁸ In parallel, the Food and Veterinary Office (FVO) conducted fact-finding missions in five Member States (Denmark, Netherlands, Slovenia, France and the Czech Republic) between June 2013 and March 2014 with the objective of gaining insight into the emergency preparedness of those countries. The missions examined issues such as monitoring and surveillance, contingency planning and existing channels of coordination and communication in those Member States.

According to the HoA report, the ways in which Member States have adapted to the requirement of the Regulation vary across countries; in particular, different types of documents (national crisis plan, protocols, Standard Operating Procedures, contingency plans, legislation) are used, and the territorial scope to which they apply may also vary. Moreover, in some Member States a general contingency plan/procedure is available, while others have designed specific plans in relation to food/feed safety incidents.

¹⁵⁸ "Sharing Protocols, Experiences and Knowledge on Management and Communication during Food Crisis", Heads of European Food Safety Agencies (HoA), 2014.

However, the HoA report finds that 15 out of the 17 Member States considered have some formal document for risk assessment, management, and communication to be used in a food or feed crisis. The FVO fact-finding missions have also observed that four of the five Member States studied had a dedicated procedure in place for dealing with food-borne outbreaks.¹⁵⁹

To obtain additional insights, in our survey competent authorities were asked to specify in more detail the type of contingency plan available in the field of food/feed in their country. Three different types of contingency plans were listed, and the question allowed for multiple answers, as a country may have several (complementary) contingency plans in place. Table 4 in the Annex provides a mapping of the contingency plans and procedures available in those Member States that participated in our survey. Most Member States that provided relevant information have adapted to meet the requirements of Article 13 of Regulation (EC) No 882/2004 on official food and feed controls. The ways in which they have adapted, however, vary from country to country. While some Member States have drawn up specific contingency plans for use in food/feed safety incidents, others have a general plan that can also be activated when serious risks related to food/feed arise, or sets of procedures to be used in emergencies in the field of food/feed. Moreover, these types of plans/procedures are not mutually exclusive: Member States may have some combination of plans/procedures available in their country. In several countries that provided information on this subject, contingency plans in the field of food/feed were under development at the time of research.

To further examine the content of the plans and procedures developed by Member States, competent authorities were asked in our survey to indicate whether their countries have fulfilled their obligations with regard to Regulation (EC) No 882/2004. Competent authorities were asked whether their contingency plans/procedures specified each of the following elements:

- Administrative authorities to be engaged in case the contingency plan is activated;
- Their powers and responsibilities; and
- The channels and procedures for sharing information between relevant parties managing the risk.

In addition to these elements which are required by the Regulation, competent authorities were asked to indicate whether their contingency plans/procedures specified the formal coordination mechanisms between authorities at different (territorial) levels, and whether or not they included linkages to public health contingency planning, which are considered to be essential in light of the experiences made during the E.coli outbreak in 2011. All respondents (100%) answered that the contingency plan or procedure to be used in case of emergencies in the field of food/feed in their Member State specifies the administrative authorities to be engaged. Other items specified in the contingency plans/procedures, according to most respondents, were formal coordination mechanisms between authorities at national, regional and local levels (95%), channels and procedures for sharing information between relevant parties (95%) and the powers and responsibilities of the administrative authorities (90%). However, less than two thirds (58%) of respondents indicated that linkages to public health contingency planning were specified by the contingency plan/procedures, while 11% did not know whether this was the case.

Finally, competent authorities were asked to indicate which other elements of crisis management are available in their Member State. The additional elements indicated are:

¹⁵⁹ European Commission Directorate-General for Health and Food Safety, Overview Report of a Series of Fact-Finding Missions Carried out in 2013 and 2014 in Order to Gather Information on Emergency Preparedness Arrangements, 2015. http://ec.europa.eu/food/fvo/overview_reports/details.cfm?rep_id=73.

- Regular meetings of competent authorities in the fields of food/feed safety and public health to exchange information on relevant incidents/risks;
- The systematic exchange of information with food/feed business operators;
- A communication strategy for serious food/feed safety incidents;
- A designated crisis coordinator and alternate; and
- Infrastructure for the management of serious food/feed safety incidents (e.g. audio conference tools, IT tools, call centre, etc.).

85% of competent authorities who provided an answer responded that a designated crisis coordinator and alternate were available. The same number indicated the existence of a national crisis management committee or unit. Other elements that were available included a communication strategy for serious food/feed safety incidents (80%), infrastructure for the management of serious food/feed safety incidents (76%) and regular meetings of competent authorities in the field of food/feed safety and public health to exchange information on relevant incidents/risks (71%). Less than two thirds (62%) indicated the existence of a systematic exchange of information with food/feed business operators.

Regarding all of the elements listed, a small but significant number of authorities indicated that the element was not yet available, but its introduction was planned. Gaps in coverage of specific elements of crisis management at the country level were also experienced regarding other aspects. For example, in some Member States the names and contact details of the designated crisis coordinator were outdated, making the functioning of the network in times of crisis questionable.¹⁶⁰

10.4.2. *To what extent are the MS actively managing crisis or dealing with incidents such as foodborne outbreaks?*

A key indicator in answering this evaluation question relates to the degree of satisfaction of competent authorities and other stakeholders regarding how actively Member States other than their own have managed past serious food/feed safety incidents. Survey results indicate that 79% of respondents who expressed an opinion were at least moderately satisfied¹⁶¹ with how actively other MS have managed serious food/feed safety incidents that have affected their country. The average rating of respondents was 3.3, though competent authorities provided an average rating of 3.4, compared to only 3.0 for other respondents. Explanations of respondents who were not satisfied with how actively other Member states had managed serious food/feed safety incidents included that too little information is shared by the Member State involved, and that Member States respond slowly to notifications or not at all.

Survey results that indicate deficiencies in some instances, but also a certain level of satisfaction with how actively other MS have managed serious food/feed safety incidents are supported by the findings of the case study/in-depth interviews conducted with the competent authorities in affected countries, EU and international stakeholders. The level of satisfaction with crisis management of other Member States regarding incidents that remained under control in an EU perspective (such as the melamine crisis in 2008 and the glass fragments in instant coffee incident in 2010) appears to be higher than in other cases, such as the E.coli outbreak in 2011, where crisis management was overall considered to be less effective (see above) and several interviewees emphasised deficiencies, such as insufficient cooperation between food safety and public health authorities and between the local and national levels in certain Member States.

¹⁶⁰ A meeting of an expert group on crisis management that took place in Brussels on 14 November 2014 decided to re-emphasise the requirement of Member States to nominate a crisis coordinator, and future meetings are envisaged.

¹⁶¹ i.e. these provided a rating of 3 or higher on a scale between 0 and 5, with 0 representing "not at all satisfied" and 5 "very much satisfied".

10.4.3. *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? [MS level]*

The indicators for answering this evaluation question relate to the extent to which Member States have identified lessons learnt from past experiences and whether those lessons learnt, if any, were translated into improvements in their crisis preparedness and crisis management arrangements. The experiences examined relate to past serious food/feed safety incidents (such as the E.coli outbreak 2011), as well as to crisis simulation exercises.

Potential improvements of crisis management arrangements at Member State level were subject to several detailed questions in our survey of competent authorities in the field of food/feed crisis management, which was completed by 23 competent authorities from 21 Member States, thereby providing a broad empirical basis for the evaluation.¹⁶² A key prerequisite for introducing any improvements is a thorough review of existing arrangements for managing serious food and feed safety incidents in light of experiences made. Conducting such reviews is also a requirement of Article 13 of Regulation (EC) No 882/2004 on official food and feed controls.¹⁶³ In our survey, the competent authorities were therefore asked to indicate whether systematic reviews of crisis preparedness/crisis management arrangements had been carried out in their Member States on the basis of past experiences, crisis simulation exercises, and reviews of the organisation of competent authorities.

Survey results indicate that of those competent authorities who provided an answer, indicated that a review of crisis preparedness/management arrangements on the basis of *lessons learnt from past serious food/feed safety incidents* had been carried out – according to 45% this took place regularly, while 30% indicated that it only occurred sometimes and 5% that it had only taken place once.

A review on the basis of *crisis simulation exercises* was reported from 50% of responding competent authorities: In 25% of cases did competent authorities respond that a review on this basis took place regularly, while 20% of responding authorities answered that it took place sometimes. According to a further 5%, a review on the basis of *crisis simulation exercises* had taken place once.

Finally, a *review of the organisation of competent authority/ies* was reported from 57% of respondents – however, only 10% indicated that this was a regular occurrence; according to 33% of the respondents, such a review was carried out sometimes, and in 14% of cases it had been conducted once. In two Member States, competent authorities indicated that reviews had never taken place on the basis of lessons learned, crisis simulation exercises, nor after a review of the organisation of competent authorities (Cyprus and Austria). In all other Member States, a review has taken place at least once on the basis of one of the three options. On the whole, regular reviews on the basis of lessons learnt from past food safety incidents were reported most frequently, with nearly half (9 out of 20) competent authorities confirming that this is the case in their Member State. Table 5 in the Annex to this report summarises the responses by Member State.

Competent authorities were also asked to indicate whether those reviews were translated into improvements of the crisis preparedness/crisis management arrangements available in their Member States. A majority of competent authorities who indicated that a review on the basis of *lessons learnt from past serious food/feed safety incidents* had taken place considered that this had led to improvements. While the figures were lower for

¹⁶² Competent authorities from Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Latvia, Netherlands, Poland, Portugal, Romania, Slovenia, Spain, Sweden, United Kingdom responded.

¹⁶³ Article 13(3) specifies that “Member States shall review these contingency plans as appropriate, particularly in the light of changes in the organisation of the competent authority and of experience, including experience gained from simulation exercises”.

crisis simulation exercises and review of organisation of the competent authority/ies, in both cases more than half of respondents indicated that reviews had led to improvements.¹⁶⁴

Finally, competent authorities were asked to rate more specifically the extent to which experiences gained from previous serious food/feed safety incidents, the *Aristaeus* simulation exercise, and other simulation exercises had improved crisis management arrangements in their Member State. Those competent authorities that expressed an opinion provided on average a positive assessment for *experience gained from past serious food/feed safety incidents* and for *experience gained from crisis simulation exercises* in which their country had participated.¹⁶⁵ In regard to *experience gained from the EU-level Aristaeus exercise* (the only simulation exercise at EU level so far), however, the average rating provided by the 17 competent authorities that had an opinion in this respect was lower.¹⁶⁶

10.4.4. Answers to evaluation questions

Based on the evidence collected and the summary of findings presented in this section, the answers to the evaluation questions concerning the involvement of EU Member States are as follows:

- ▶ Most Member States that provided relevant information have adapted to meet the requirements of Article 13 of Regulation (EC) No 882/2004 on official food and feed controls. The ways in which they have adapted, however, vary from country to country. While some Member States have drawn up specific contingency plans for use in food/feed safety incidents, others have a general plan that can also be activated when serious risks related to food/feed arise, or sets of procedures to be used in emergencies in the field of food/feed. Moreover, these types of plans/procedures are not mutually exclusive: Member States may have some combination of plans/procedures available in their country. In several countries that provided information on this subject, contingency plans in the field of food/feed were under development at the time of research.
- ▶ Similarly, a large majority of Member States report to have fulfilled the obligation of specifying the administrative authorities to be engaged in the case of a serious food/feed safety incident in their contingency plans/procedures, their powers and responsibilities, as well as determining channels and procedures for sharing information between relevant parties managing the risk. The results of the mapping indicate, however, that links to public health contingency planning are less frequent. Improving linkages between food/feed safety contingency planning and public health contingency planning are therefore potential areas for improvement in Member States.
- ▶ The E.coli outbreak and crisis simulation exercises have led to reviews of crisis preparedness/crisis management arrangements in most, though not all Member States that answered to our survey. Member States assessed that these experiences improved current crisis management arrangements to some extent.

¹⁶⁴ 88% of competent authorities who indicated that a review on the basis of lessons learnt from past serious food/feed safety incidents had taken place considered that this had led to improvements. For reviews on the basis of crisis simulation exercises and review of organisation of the competent authority/ies, 67% and 55% of competent authorities considered that the reviews had led to improvements respectively.

¹⁶⁵ For both of these items, competent authorities provided an average rating of 3.2 on a scale of 0 to 5, with 0 representing "not at all" and 5 "very much".

¹⁶⁶ For this item, the average rating was 2.4. 53% of competent authorities who answered the question provided an assessment of 2 or lower, i.e. they did not consider that experiences gained from the *Aristaeus* exercise improved crisis management arrangements in their country significantly.

10.5. Participation of Third Countries/International Organisations

10.5.1. *To what extent are the European crisis management mechanisms open to third countries' and international organisations' participation?*

The EU legislative framework for the management of food/feed crises does not include explicit mechanisms for communication and cooperation with third countries or international organisations in the event of a serious food/feed safety incident. While some provisions of the (so far never applied) General Plan relate e.g. to communication with non-EU countries and international organisations "to ensure that all relevant information is made available and shared" when a crisis unit is set up, such communication seems in practice to occur on an ad-hoc basis and using various structures, including missions of third countries to the EU, and existing information channels such as INFOSAN through its cooperation with the RASFF. A key area of crisis management that relates to third countries is the use of the above described emergency measures, which may serve to place restrictions on international trade with the EU. When trade with a third country is restricted, the EC may collaborate with the country in question to seek ways to remedy the situation and normalise trade relations. For instance, in the aftermath of the E.coli outbreak, the FVO carried out an audit in Egypt in order to trace back the source of the infection, evaluate the production and processing conditions, and review the emergency measures taken through the adoption of Commission Implementing Decision 2011/402/EU.¹⁶⁷

Indicators for answering this evaluation question in more detail mainly relate to the assessment by third countries and international organisations regarding the degree to which European crisis management mechanisms allow for their participation during serious food/feed safety incidents, and related obstacles. The assessment is based on a limited number of survey responses from third countries/international organisations, complemented by interviews with two third countries and the main relevant international partner (the WHO/INFOSAN).

Only one third country provided an assessment of the openness of the EU's crisis management mechanisms to non-EU countries in our survey, selecting a rating of 3 on a scale from 0 to 5. Survey respondents were also asked whether there had been any obstacles preventing them from providing more information to the EC during past serious food/feed safety incidents. Of the two international organisations/third countries who answered this question, one considered that there had been no obstacles to providing more information to the EC during past serious food/feed safety incidents. The other stakeholder disagreed, citing "confidentiality provisions of legal basis" as an obstacle.

The case study/in-depth interviews provided additional insight into the participation of international organisations and third countries in the crisis management arrangements of the European Union. These interviews confirm that crisis management mechanisms in the EU are open to the participation of its international partners. One interviewee noted that there is an increasing need for crisis management decisions to be consulted with counterparts at the international level to ensure they are coordinated and justifiable. Another interviewee affirmed that the EU has strong, long-standing bilateral agreements with the third country in question, which allows for effective communication to take place. Moreover, the interviewee considered that there have not been obstacles preventing the country from providing more information to the EC.

The three case studies conducted for this study provided additional evidence for answering this evaluation question, and confirmed that third countries and international

¹⁶⁷ European Commission Health and Consumers Directorate-General, Final Report of a Mission Carried out in Egypt from 21 to 25 August 2011 in Order to Trace Back the Source of Infection of the Recent E.coli O104:H4 Strain Outbreaks in the EU, n.d.

organisations were involved to some degree in the selected previous food/feed safety incidents:

- *Melamine crisis (2008)*: In the melamine case, third countries and international organisations were strongly involved in the incident. The international dimension of the incident resulted from the fact that contaminated products were exported from China to 47 countries worldwide.¹⁶⁸ Moreover, INFOSAN played an important coordinating role by acting as an intermediary between the EU and China. It was in daily contact with the Chinese investigators and maintained a global list of products and brands affected. However, it was not consulted regarding the crisis management measures taken in the EU. According to one interviewee, the melamine case provided an example of the need for international collaboration in sharing data and handling decisions related to crisis management.
- *Glass fragments in instant coffee (2010)*: As noted in previous evaluation questions, the glass fragments case did not necessitate the use of crisis management mechanisms at the EU level. However, several affected third countries were notified through the RASFF.
- *E.coli outbreak (2011)*: In the E.coli outbreak, the World Health Organisation (WHO) was involved in coordinating communication between the EU and Third Countries, and participated in a meeting organised by the EC in the early stages of the outbreak, in which it provided support and data on previous outbreaks in Third Countries.¹⁶⁹ Moreover, the Task Force which was set up in June 2011 included experts from the WHO.

10.5.2. *How well is the information flow between the other relevant partners, competent authorities and International Organisations (WHO, FAO, INFOSAN, UNIDO...)?*

In our survey, competent authorities were asked to rate their satisfaction of the information flow that has occurred between the EU and its international partners in past serious food/feed safety incidents that affected their country. Respondents who expressed an opinion tended to provide a positive assessment (an average rating of 3.7) both in regard to third countries and international organisations, with 0 indicating “not at all satisfied” and 5 “very much satisfied”.

Findings from the case study/in-depth interviews to a large degree reflect this assessment, especially in incidents with a clear international dimension. As noted in the previous evaluation question, the melamine crisis in 2008 provided an example of such a serious food safety incident, in which 47 countries were affected and INFOSAN played an important coordinating role. Interviewees expressed satisfaction with the information flow between international partners. However, the evidence collected also suggests that more information from third countries (e.g. regarding the measures put in place by them) would be welcomed by EU Member States. The information flow may be enhanced when INFOSAN gains fuller access to RASFF Window, an improvement which is currently under development. Interviewees also suggested developing an international template for submitting information to the RASFF from third countries, e.g. for identifying the product, the risk, and for tracking information, in order to make communication more efficient.


¹⁶⁸ 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>.

¹⁶⁹ Plachenstainer, Francesco, “Managing Food Safety Emergencies and Crises: A Multilevel Comparative Analysis of the US and EU Legal Frameworks”, 2013.

In a related survey question, respondents were asked to provide suggestions for improving the information flow between the EU and third countries/international organisations. Less than one fifth (18%) of respondents to this question provided suggestions, which included, for example improving interactions between RASFF and INFOSAN, establishing internationally agreed standards for response and identify emergency contacts, increasing the frequency of FVO visits to Third Countries in case of serious incidents, and using EU stakeholder organisations to improve communication with non-EU countries in parallel to official channels.

10.5.3. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section, the answers to the evaluation questions concerning the participation of third countries and international organisations are as follows:

 The EU's crisis management mechanisms appear to have allowed to some extent for the participation of third countries/international organisations in past serious food/feed safety incidents. Obstacles to providing more information to the EC during past serious food/feed safety incidents indicated by a responding third country related to confidentiality provisions in its legal basis. Overall, the information flow between the EU and third countries/international organisations is considered to be satisfactory, although more information from international partners would be welcomed by EU Member States.

10.6. Efficiency

10.6.1. *To what extent can the objectives of crisis management be achieved at a lower cost with synergies of the available resources?*

The criterion 'efficiency' considers in the context of this study the relationship between the inputs used and the outputs provided by EU crisis management. In particular, this evaluation question explores the extent to which the costs of crisis management can be lowered, while continuing to achieve the same objectives – above all the adequate management of serious food/feed safety incidents that cannot be contained by individual Member States. To consider the Member State perspective, competent authorities in the field of food/feed crisis management were asked to indicate the extent to which the balance of costs and benefits of crisis management at EU level has been appropriate. When asked whether the balance of costs and benefits of crisis management at EU level had been appropriate, those competent authorities that expressed an opinion (8 respondents) tended to provide a positive assessment. The average rating provided by the authorities was 3.5, with 0 representing “not at all appropriate” and 5 “very much appropriate”. A possible reason for the low response rate in this question is the lack of information that Member States dispose of regarding the costs involved in the management of serious food/feed safety incidents at EU level, as noted by one responding authority.

A higher number of competent authorities answered when asked whether they could provide suggestions for improving the balance of costs and benefits; however, only one fifth of competent authorities who answered the question (20 in total) indicated that they had such suggestions. These suggestions related to improving collaboration between the EC and Member States through the sharing of best practices, increasing common training and coaching of staff, and ensuring greater support from EFSA regarding emerging risks.

The case studies/in-depth interviews conducted with competent authorities in affected countries, EU and international stakeholders provided complementary insight on the

degree to which the objectives of crisis management at EU level could have been achieved at a lower cost in the E.coli outbreak. The main area identified by interviewees in which costs related to this incident could have been minimised is the harmonisation of communication towards the public and professional operators, and avoidance of communication errors such as the one committed by the regional authorities in Hamburg, which mistakenly identified Spanish cucumbers as source of the outbreak. While the implementation of a clearer and coordinated strategy for communication to the public might have contributed to avoiding this type of miscommunications, the extent to which an effective strategy would have reduced economic impacts of the crisis remains unclear. Interviewees emphasised that developing a common understanding of the risks involved in the incident was a way to safeguard better and correct communication, thereby minimising loss of consumer trust, as well as related economic impacts. Other ways in which costs of the incident could have been lowered, according to interviewees, included developing (better) tools for traceability and improving current IT tools for exchanging information.

Concerning the melamine crisis, no assessment of the costs of the incident is available. This was confirmed by the interviewees, which due to data limitations could not provide complementary information regarding whether or not the objectives of crisis management at EU level could have been achieved at a lower cost. Similarly, given that the glass fragments case was managed by Nestlé, most interviewees could not comment on the extent to which the incident could have been managed at a lower cost or with synergies of available resources.

While no comprehensive analysis of direct costs of crisis management and indirect costs and losses of the food/feed safety incidents scrutinised in the case studies could be identified, the literature research conducted for this evaluation provided some insight on the costs involved and economic impacts of selected incidents. Table 6 in the Annex to this report presents the estimated costs of five serious food/feed safety incidents which occurred within the reference period, distinguishing between direct and indirect costs, where this is possible. The limited data that could be identified for the case study incidents is also included.

While the estimated costs are necessarily incomplete (due to a lack of relevant data) and only consider a small selection of relevant incidents, it is notable that already the direct costs of major incidents can easily reach several tens of millions of Euro, with indirect costs reaching in some cases hundreds of millions of Euro. In the E.coli outbreak indirect costs were even estimated to reach significantly beyond a billion Euro. Compared to these costs and losses of major incidents, which include losses related to trade restrictions and the loss of consumer trust and the resulting economic impacts due to changes in consumption patterns, the costs of managing identified food/feed safety risks, contingency planning and emergency preparedness in non-crisis periods (including training) are likely to be relatively minor. As indicated before, even though the RASFF can be considered one of the most costly tools of the EU food safety framework, and its utility goes beyond crisis management, its overall annual costs of 7.4 million Euro are comparatively minor when compared to the costs of a major incident, which can be more efficiently handled because this tool is available.

In conclusion, measures to improve the efficiency of crisis management arrangements relate primarily to actions in view of preventing serious food/feed safety incidents from developing, and to ensure an outbreak is rapidly detected and the source identified where a crisis nonetheless occurs. As such, the balance of costs and benefits is likely to improve with development of the food/feed safety system, including enhanced cooperation with business operators, improved controls and enforcement of food/feed legislation, and state of the art technologies for detection of contaminants and pathogens, as well as appropriate contingency planning and emergency preparedness.

10.6.2. *To what extent certain tasks of crisis management e.g. the dissemination of risk related information or communication issues, should be handled through an alternative existing mechanism?*

As described in Section 6.3.3, the General Plan for food/feed crisis management provides for the establishment of a network of crisis coordinators for the purpose of cooperating between Member States on risk communication in the event of a serious food/feed safety incident. While this network has already been enacted at a formal level, other structures and tools at EU-level exist which may be suited for handling certain tasks of crisis management.

Alternative existing structures include the network of RASFF National Contact Points and the Standing Committee on Plants, Animals, Food and Feed (PAFF) as well as its relevant sections. Both the RASFF National Contact Points and the PAFF sections function on a regular basis and allow for coordination and information exchange between Member States, with the EC taking on a managerial role. Moreover, both structures play a crucial role at different stages of crisis management. While RASFF National Contact Points are involved on a continuous basis in transmitting key information between Member States throughout a food/feed safety incident (e.g. regarding the risk involved, measures taken by MS, and the distribution of the product concerned), Member State representatives of the PAFF meet regularly to consider legislative measures, including the adoption of emergency measures.

Given these functions and the continuous operation of both of these structures, the role of the RASFF National Contact Points and/or PAFF Committee meetings in crisis management could be further refined. The (never activated) General Plan already foresees that in the event of a crisis, "[t]he crisis unit will use the technical arrangements in place for the RASFF network to communicate or disseminate information, particularly requests for information to the Member State(s) and the information submitted by them", thereby acknowledging the utility of using the RASFF network in the management of serious food/feed safety incidents.

While the General Plan does not outline the way in which the network of crisis coordinators should communicate, in practice several tools are available to enable efficient exchange of information in a food/feed safety incident, including the RASFF itself and the CIRCABC platform,¹⁷⁰ which allows members to upload and share documents between each other. Additional complementary available tools for crisis management include e-mail, audio- and/or video- conference facilities.

10.6.3. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section, the answers to the evaluation question concerning the efficiency of crisis management are as follows:



Whether the objectives of EU crisis management – above all the adequate management of serious food/feed safety incidents that cannot be contained by individual Member States – can be achieved at a lower cost, depends on the food/feed safety incident in question. In some cases, the economic impacts of serious food safety incidents are considered to have been higher than the unavoidable minimum, with the most relevant example being the 2011 E.coli outbreak. In this incident a clearer and coordinated strategy for communication to the public might have

¹⁷⁰ CIRCABC (Communication and Information Resource Centre for Administrations, Businesses and Citizens) provides a web-based application that is used to create collaborative workspaces. It is divided into categories and interest groups, allowing people to manage content, users and communication features. See http://ec.europa.eu/isa/ready-to-use-solutions/circabc_en.htm

contributed to reduced economic impacts, although to which extent a joint EU/Member States' strategy could indeed have prevented or contained negative impacts remains unclear.

- ▶ Compared with the costs and losses of major incidents, which include losses related to trade restrictions and the loss of consumer trust and the resulting economic impacts due to changes in consumption patterns, the costs of managing identified food/feed safety risks, contingency planning and emergency preparedness in non-crisis periods (including training) are likely to be relatively minor. Suggestions made by Member States to improve the balance of costs and benefits of crisis management revolve around measures such as sharing of experiences and best practices, or receiving scientific support for risk assessment regarding 'lesser known dangers' to avoid disproportionate measures.
- ▶ At EU level, efficiency of existing crisis management arrangements could possibly be increased by refining the respective tasks and roles of existing mechanisms for coordination and communication during serious food/feed safety incidents, which include the network of crisis coordinators, the network of RASFF National Contact Points and the Standing Committee on Plants, Animals, Food and Feed (PAFF) as well as its relevant sections.

10.7. Added value resulting from EU coordination

10.7.1. *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?*

In our survey, respondents were asked to assess whether or not 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.

Respondents who answered the question almost unanimously (98%) indicated that there was 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. No respondents considered that this was not the case, with only one respondent indicating "don't know". The areas of additional value highlighted by survey respondents are mainly that the EC enables a coordinated and harmonised approach across Member States and this improves sharing of information and best practices.

The findings from the case study/in-depth interviews reflect the survey results described above. For the incidents scrutinised in-depth for this evaluation in which the European Commission was involved in crisis management measures, this was considered to have brought additional value compared to what could have been achieved by Member States acting alone. According to these interviews and other evidence collected, there is a need for more – rather than less – coordination of feed/food safety incidents and involvement of the European Commission. Key aspects of the case studies relevant for answering this evaluation question include:¹⁷¹

- *Melamine crisis (2008)*: Given that the contaminated product in the melamine crisis originated from a third country, the European Commission had a key role to play in issuing emergency measures preventing the products from entering the single market. Specific areas of added value included the harmonised

¹⁷¹ While RASFF was used, the glass fragments in instant coffee (2010) incident did not necessitate further crisis management at the EU level, as it was handled mainly by the company in question. The case study is therefore not relevant in the context of this evaluation question.

management of the food safety incident achieved by the application of emergency measures and rapid decision-making, the sharing of information, and the coordination which the EC provided.

- *E.coli outbreak (2011)*: From the onset of the outbreak, the European Commission was involved in its management, e.g. by providing information on traceability and sampling through the RASFF,¹⁷² coordinating Member States, providing technical and expert support through EFSA and the EU Reference Laboratory for Escherichia coli, and by issuing an emergency measure after the source of the outbreak was identified. Accordingly, areas of added value include the reference method provided by the EU-RL, the involvement of EFSA, the recall of fenugreek seeds and EU-wide ban on the import of seeds and beans from Egypt.

10.7.2. *Answers to evaluation questions*

Based on the evidence collected and the summary of findings presented in this section, the answers to the evaluation question concerning the added value of crisis management are as follows:

► There is broad and unanimous consensus that there is an added value resulting from the EC coordinating crisis management of the Member States concerning serious food/feed safety incidents compared with what could be achieved if there were no coordination at EU level. Key points of the additional value include the sharing of information and best practices, and enabling a coordinated and harmonised approach across Member States, particularly in global incidents such as the melamine crisis which require a strong regional coordination to communicate effectively with international partners. Moreover, by strengthening its role as coordinator and improving its crisis management structure, the EC could increase the added value it brings to crisis management.

¹⁷² See RASFF Alert 2011.0842 and follow up notifications (e.g. 2011.0842 add-13).

11. CONCLUSIONS AND RECOMMENDATIONS

This evaluation has applied five main criteria: effectiveness, relevance, coherence, efficiency and added value, which are separately discussed in this section. Several methodological tools have been employed to provide a clear evidence basis, including an in-depth literature review, two complementary surveys, in-depth interviews, three case studies of past serious food safety incidents (complemented by an analysis of data on the economic impacts of other selected food/feed safety incidents), a financial analysis of the RASFF, and an analysis of the information flow of the system. Results obtained have been triangulated to ensure a consistent analysis. This forms the basis of the answers to the evaluation questions, and the conclusions and recommendations presented below, first for the Rapid Alert System for Food and Feed, and then for crisis and potential crisis management.

11.1. The Rapid Alert System for Food and Feed

The overarching conclusion of the evaluation is that on the whole, the **RASFF has functioned effectively** throughout the evaluation period in light of its objectives. The system is strongly appreciated by its addressees (the RASFF National Contact Points in member countries) and a large quantity of actionable information is transmitted through the system, allowing Member States and international partner countries to react swiftly to risks detected in food and feed. However, while the system as a whole is considered to function well, there remains some scope for enhancing its role as a cornerstone of the EU system for food/feed safety. In particular, more guidance on different risks as well as increased support from EFSA in certain cases could contribute to improving the risk-based approach of the system.

Moreover, since its conception in 1979, the **RASFF remains highly relevant**. The increasingly globalised trade in food and feed, as well as the deepening of the European single market reinforce the need for an effective way of transmitting information on risks detected and measures taken by individual Member States. The objectives pursued by the RASFF are largely considered to correspond to these needs, with some potential additional objectives identified that could be taken on board in the future, such as using the RASFF as a tool for analysing trends in food/feed safety risks, and recognising its key role in crisis management. In addition, the RASFF is largely **coherent** with a number of other notification systems, both at EU level and with its main international partner system INFOSAN. Where overlaps do occur, certain measures have been planned or have already been taken in order to minimise duplications.

In terms of efficiency, **the costs of the RASFF appear to be reasonable**, although they cannot be directly compared with the benefits of the system. This is because the information exchange through the system is not a benefit in itself, but rather contributes to benefits that accrue as result of measures taken on the basis of RASFF notifications. However, comparing total costs to the quantity of information transmitted provides some insight on the efficiency of the RASFF: for the reference year 2013, the costs amounted to 690 Euro per information item transmitted to RASFF members. Considering that most notifications concern multiple countries, the cost per notified country is substantially lower. Nonetheless, there is some scope for improving its efficiency in the future, specifically by upgrading the iRASFF application, moving certain tasks to other notification systems, further improving linkages between the RASFF and relevant systems, and allowing for a degree of de-centralisation of the system in specific cases. Finally, there is nearly unanimous consensus that **the RASFF provides added value** compared to what could be achieved without it by Member States acting at the national level. This conclusion is also confirmed by the results relating to previous criteria, in particular those pointing to the high relevance and effectiveness of the system.

The sections below present key conclusions for each of the criteria summarised above, as well as recommendations for improving the functioning of the system in order to more fully deploy the benefits it provides to the food and feed safety system in the EU.

11.1.1. *Effectiveness*

11.1.1.1. *Functioning of RASFF and achievement of objectives*

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: the Regulation transformed the practices followed by its members into specific obligations to be fulfilled by both Member States and the European Commission Contact Point (ECCP), and the requirements contained in the Regulation provided additional impetus for members to create the structures essential for running the RASFF at the national level.

The Regulation also formalised the objectives of the system, which are provided in the intervention logic elaborated in the course of this evaluation (see Annex 8) as follows:

- I. Provide a tool for information exchange between members of the network on direct or indirect risks in relation to food or feed;
- II. Inform members of the network on the follow-up to notified direct or indirect risks;
- III. Exchange of information between members of the network on measures to contain risk;
- IV. Information of third countries on risks detected to human health deriving from food and feed.

Since the adoption of the Regulation, a sharp increase in the number of original notifications and follow-up notifications transmitted through the system can be noted. Prior to 1992, approximately 10 notifications were sent through the RASFF annually. In 2001, this figure had increased to 1,567 notifications.¹⁷³ By contrast, in 2002, i.e. after the adoption of Regulation (EC) No 178/2002, the number of notifications nearly doubled to over 3,000.¹⁷⁴ The number of notifications reached a peak of about 3,800 original notifications in 2011. Since then, the number has stabilised to just over 3,200 in 2013.

Not surprisingly, the rise in the number of original notifications was accompanied by a similar increase in transmission of follow-up notifications. Initially referred to as "additions" to alert or information notifications, in 1999 these amounted to a total of 338 notifications, increasing to 859 in 2001 and to 1,498 in 2002. The number of additions continued to increase following the adoption of Regulation (EC) No 178/2002 and in 2008, these notifications – now renamed as "follow up notifications" – reached 3,975. In the reference year 2013, the number of follow up notifications amounted to 5,158. Accompanying the increase in original and follow up notifications of the RASFF, over time the number of member countries has also gradually grown, from 9 countries in 1979 to 32 in 2013, as a result of the expansion of the EU.

The RASFF therefore achieves its core objectives related to information exchange between members well, as is reflected in the large numbers of original notifications (objective I) and follow-up notifications (objectives II and III) handled by the system listed above. The objective of RASFF to inform third countries on risks detected to human health deriving from food and feed (objective IV) has also been largely achieved during

¹⁷³ European Commission, RASFF: 30 Years of Keeping Consumers Safe, 2009.

¹⁷⁴ European Commission, "The Rapid Alert System for Food and Feed: Report for the Year 2002", 2002.

the evaluation period, with third countries having been informed 2,373 times about products originating from or distributed to their country in the reference year.

The statistics provided above refer to notifications which were verified by the European Commission Contact Point and subsequently transmitted to the network, indicating that they were of *sufficient quality* if the ECCP's verification standards are used as a benchmark. Additional data on original and follow up alert notifications for the reference year 2013 indicates that notifications tend to be *useful* to members of the network, who *react* to them in a large majority of cases: 92% of original alert notifications gave rise to at least one follow up notification. Moreover, a majority of original alert notifications led to the transmission of two or more follow up notifications; in some cases more than 30 follow ups related to a single original alert notification.

National Contact Points and other stakeholders involved in the RASFF have also provided a positive assessment regarding the achievement of the RASFF objectives. Moreover, 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.

11.1.1.2. Role of the European Commission

This evaluation concludes that the EC has largely fulfilled its duties deriving from the RASFF legal basis during the evaluation period concerning organisational aspects, and, most importantly, the verification and transmission of notifications. Alert notifications and their follow-up have to be transmitted by the EC to all members of the network within 24 hours after reception, upon verification. In the reference year 2013, about 19 in 20 original alert notifications and 7 in 8 follow-up notifications to alerts were transmitted by the ECCP to RASFF members on the same or the following day. Where delays occurred, notifications have typically been forwarded in advance to NCPs of countries concerned, pending translation. A large majority of RASFF National Contact Points confirm that the EC largely fulfils its duties concerning the transmission and verification of notifications. Its contribution to the coordination of the members of the RASFF and to the development of good and common notification practices is also viewed very positively by National Contact Points. The Working Groups of the RASFF National Contact Points have contributed to the better functioning of the RASFF, and the Standard Operating Procedures on the functioning of the network are considered to be helpful, clear and consistent with needs and expectations.

11.1.1.3. Involvement of EU Member States

Although the legislation assigns the role of coordinator to the European Commission, member countries have a crucial role to play in ensuring the effective functioning of the RASFF as members of the network and its primary beneficiaries. Some key obligations relating to the RASFF derive directly from the legislation, but the active participation of members depends on a range of other factors and varies significantly from country to country. According to their peers and self-assessment, as well as the assessment of the EC Contact Point, RASFF member countries largely fulfil their duties under the RASFF as required by Regulation (EC) No 178/2002 and Commission Regulation (EU) No 16/2011. These duties include the obligation to designate a contact point for the RASFF, ensure the availability of an on-duty officer reachable on a 24-hour/7-day-a-week basis, send alert notifications to the ECCP within 48 hours upon reception and other notifications without undue delay. The evidence collected in case studies of three serious food/feed safety incidents largely supports this assessment.

The extent to which member countries submit notifications through RASFF varies significantly, ranging from none to over five hundred original notifications in the reference year 2013. The five top notifying countries account for more than half of the total number of notifications. Even when population size and trade activity of the notifying country are considered, differences between countries in notification numbers remain (see Section 9.6.3 for a detailed analysis). To a certain degree, these differences

could be caused by particular national approaches concerning certain risks deriving from food and feed, differences in national legislation and enforcement of EU legislation, and country-specific administrative structures and procedures. However, it appears unlikely that these factors fully explain the significant differences in the level of activity demonstrated by member countries, as measured by the number of notifications submitted annually. Possible other explanations for particularly low notification rates include different notification standards, weak or infrequent official controls carried out in the area of food/feed, or insufficient information flow between the bodies implementing official controls and the RASFF National Contact Point. Future audits of the national food and feed safety systems carried out by the European Commission could further explore the reasons for differences in the level of activity in detail.

11.1.1.4. Risk-based operations of the RASFF and the role of EFSA

The effectiveness of RASFF depends on the degree to which its operations are risk-based, i.e. the extent to which the notifications transmitted through the system adequately reflect the risks to food and feed involved, as intended by its legal basis. According to Article 50 of Regulation (EC) No 178/2002, the RASFF is a system for the notification of a direct or indirect risk to human health deriving from food or feed. Taking into account Commission Regulation (EU) No 16/2011 laying down the implementing measures for the RASFF, which further elaborated on the notion, risk is defined 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.” The RASFF is thus intended for notifying cases where a serious risk is involved, as well as other cases where a risk of lesser gravity or urgency is identified. In addition, the legislation foresees that as a member of the network, the European Food Safety Authority may supplement notifications “with any scientific or technical information, which will facilitate rapid, appropriate risk management action by Member States.”

The extent to which notifications exchanged through the RASFF are considered to be *sufficiently risk based* varies widely among stakeholder groups, with two thirds of RASFF National Contact Points (65%) stating that this is the case, while an almost similar majority of other stakeholders (60%) disagree. Those that find notifications transmitted through the RASFF to be insufficiently based on risks pointed out, for example, that differences in notifications issued by Member States indicate there is no harmonised approach to risk among members of the network, and that the risk-based approach of the RASFF is limited due to a lack of involvement of food business operators. A second indicator to inform the answer to this evaluation question is the extent to which the risk is *accurately* evaluated in the RASFF. Survey respondents were asked to provide a rating regarding the extent to which risk is accurately evaluated in the RASFF, using a scale of 0 (“Not all accurately”) to 5 (“Very accurately”). Again, the RASFF National Contact Points were significantly more positive, with an average rating of 3.6, compared to 2.8 for other respondents (still above the midpoint of 2.5, i.e. on balance more positive than negative assessments were provided by other respondents). Respondents who provided low ratings in their answers to this question suggested e.g. that additional support from the European Commission for risk assessment and harmonisation of classifications would be needed. Examples given by respondents related to cases in which notifications are transmitted on the basis of a non-compliance or exceedance of a MRL.

In spite of the ambiguous assessment by stakeholders, it is undisputed that the ECCP contributes to the harmonisation of approaches for evaluation of the risk. In particular, data on the information flow for the reference year 2013 provides insight on the evaluation of risk at EC level: according to EC data, in this year a total of 230 notifications submitted by RASFF members were rejected by the ECCP. In addition, 8 alert notifications were downgraded to information notifications. While this data does not provide an indication regarding the quality of the risk assessment, it at least shows a considerable involvement of the ECCP as gatekeeper of the system, with a likely

influence on consistency of the ways risks are assessed. The number of rejected notifications in 2013 was higher than previously (94 rejected notifications in 2011 and 67 rejected notifications in 2012) due to a more systematic verification of notifications based on Commission Regulation (EU) No 16/2011 and the Standard Operating Procedures, which were already substantially developed. In 2014, the number of rejected notifications fell again to 111, suggesting that the more stringent verification procedure initiated in 2013 had a positive impact on the transmission of risk-based notifications by member countries.¹⁷⁵

In spite of the ECCP's contribution to the risk-based approach of the RASFF there remain, however, factors that contribute to differences in the evaluation of risk. These include that RASFF members have the responsibility for deciding whether or not there is a risk involved in non-compliant food/feed (and subsequently whether the risk is such as to require the notification to the RASFF), which may lead in some cases to a "grey area" for risk evaluation, if RASFF members come to different conclusions under similar circumstances. Also, detailed guidance documents that may lead to a more harmonised evaluation of the risk across Member States are only available to a limited extent, e.g. in the area of pesticides.

The European Food Safety Authority (EFSA), established by Regulation (EC) No 178/2002, has a key role to play in the risk-based approach of the RASFF. Alongside National Contact Points and the European Commission Contact Point, EFSA is a member of the RASFF. As noted above, EFSA may supplement notifications concerning serious direct or indirect risks to human health deriving from food or feed with any scientific or technical information that will facilitate rapid and appropriate risk management, according to Article 50(2) of the Regulation. EFSA's role is most relevant in the context of major and serious food/feed safety incidents, and results of this evaluation confirm that EFSA has largely fulfilled its role as laid down in Article 50 of the Regulation during the serious food/feed safety incidents considered in depth in this evaluation by providing risk assessments and methodological advice, e.g. during the melamine crisis and the E.coli outbreak. However, for alerts that do not relate to a major incident, EFSA rarely supplements RASFF notifications concerning serious risks with scientific or technical information that will facilitate rapid and appropriate risk management. In many cases, such input is simply not needed: alerts often relate to well-known risks, and there are clear guidelines and/or precedents that allow a rapid and consistent consideration of the risk involved. It appears, however, that 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. However, a key challenge for any input by EFSA into RASFF are the differences in the timeframe within which the two organisations are working due to their different remits, which would need to be addressed when strengthening the involvement of EFSA in RASFF. A planned guidance on evaluating risk in the framework of RASFF to be developed jointly by EFSA and the EC is another way in which EFSA could contribute to the RASFF in the future.

11.1.1.5. Participation of Third Countries/International Organisations

Beyond the use of the RASFF by its members, the system is also intended for informing third countries when food or feed originating from or distributed to them has been found to present a risk to human health, animal health, or the environment. The 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. A selection of third countries who participated in our survey mainly use information from the RASFF to prevent affected consignments from being exported to the EU, to prevent affected consignments from being imported or remove affected consignments from their market, and to improve compliance with EU rules of products to be exported.

¹⁷⁵ European Commission, RASFF Preliminary Annual Report 2014, 2014.

For the reference year 2013, third countries were informed on 329 occasions about a product that had been distributed to them. Moreover, they were informed 2,231 times about RASFF notifications which concerned a product originating from their country. The non-member countries informed most frequently about notifications concerning products originating from their country in 2013 were as follows:

- China (441 notifications);
- India (263 notifications);
- Turkey (234 notifications);
- Brazil (193 notifications); and
- United States (106 notifications).


In spite of the partial integration of third countries into the RASFF, a majority of National Contact Points of RASFF member countries suggest that they need to receive more information from third countries through the RASFF. Among the regions of the world, Asia stands out as a priority region from which more information would be required, followed by the Western Balkans. Moreover, 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. In particular, the ECCP is not always informed about the follow up to such notifications, or the measures taken by the relevant country. While some countries regularly provide such information, others provide it with a significant delay, or not at all.

The information flow between the RASFF and INFOSAN, its main international partner system, is most relevant in times of large international food/feed safety incidents, such as the 2008 melamine crisis, in which INFOSAN was a key source of information for the RASFF and acted as intermediary between the EU and China. According to both the ECCP and INFOSAN the reciprocity of the information flow between RASFF and the International Organisations is considered to be appropriate, and is helped by an alignment of procedures and membership of RASFF and INFOSAN in recent years. To further improve collaboration, it could be beneficial to put in place a link between the RASFF and INFOSAN. Efforts are already underway to provide the latter with access to RASFF Window.

11.1.1.6. Recommendations

The results of this evaluation lead to the following recommendations to improve the effectiveness of the RASFF:

- ▶ **Ensuring that all Member States notify risks.** The European Commission should explore the reasons for differences in the level of notification activity in the RASFF during audits of the official control systems for food and feed in relevant Member States.
- ▶ **Improving the risk-based operation of RASFF.** The contribution of EFSA to the RASFF provided for by Article 50(3) of Regulation (EC) No 178/2002 could be better implemented by enabling the ECCP to obtain rapid (e.g. within 48 hours) feedback from EFSA when a risk is not well known or cannot be easily assessed using existing guidelines or precedents. Rapid feedback provided by EFSA could be based on in-house expertise and have the form of an initial review of available risk information by an EFSA scientist. While the role of EFSA is not to provide scientific assistance to the RASFF on a daily basis, its readiness to occasionally supplement notifications with scientific or technical information – particularly on less well-known risks – would likely serve to improve the risk-based operation of the RASFF. Further guidance to assist NCPs with evaluation of risks, similar to the document currently available concerning pesticide residues, should be developed jointly by the EFSA and the ECCP, as is already planned. These should provide clear guidance for NCPs and the ECCP to correctly identify the risk involved and classify alerts accordingly, e.g. for notifications related to contaminants found in food/feed.

 **Improving participation of Third Countries/International Organisations.** The EC should continue to emphasise the importance of providing follow up to RASFF notifications in bilateral meetings with third countries that concern food and feed safety. In its audits of third countries, *the FVO could identify which follow up actions or measures were taken by competent authorities in response to relevant RASFF notifications related to significant food/feed safety incidents, and identify reasons for limited follow up provided to the ECCP.* Also, increased cooperation between the RASFF and INFOSAN should be considered; if possible, this could be done by establishing an (IT) link between the two systems. This, however, would require modifying the current legal framework.

11.1.2. *Relevance*

11.1.2.1. *Relevance and information flow to Member States' National Contact Points*

The rapid growth of trade in food and feed and the increasing complexity of supply chains reinforce the need for a mechanism to rapidly exchange information on risks related to food and feed. Accordingly, 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 of National Contact Points and other stakeholders involved in the RASFF.

Moreover, in the future, the RASFF 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. A problem in this respect, however, is that currently not all data that could be necessary for this purpose is consistently collected and reported (such as the amount of affected food/feed). Also, in some cases multiple original notifications concern the same incident, which may make it difficult to retrieve data on an incident basis.

The RASFF also plays a critical, yet implicit role as a tool for crisis management. In previous serious food/feed safety incidents such as the 2011 E.coli outbreak or the 2008 dioxin in pork meat crisis, the transmission of regular updates containing results of analyses or measures taken across Member States through the RASFF was essential in keeping Member States informed on the development of the incident. Suggestions in regard to additional potential objectives of RASFF identified in the course of the evaluation 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 causing alerts and related measures taken.

11.1.2.2. *Relevance and information flow to consumers and stakeholder organisations*

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 objective of the RASFF. In practice, however, some information from the system is provided to the public through IT tools that have been developed by the European Commission for this purpose.

Professional operators and other stakeholders are able to consult RASFF notifications using the RASFF Portal, a publicly available internet platform. The platform enables users to find notifications using a search function, allowing them to perform queries in order to obtain information e.g. about the hazard identified in a food/feed product, the countries concerned by it, and the classification (i.e. alert, border rejection, information). However, the name of the company producing or distributing the given product, and its brand name are not provided in the RASFF Portal. Developed more recently, the RASFF Consumers' Portal provides information on food recall notices and public health warnings issued by food safety authorities and food business operators. In this application, notifications are removed after a four-week period. Thus the RASFF Consumers' Portal allows interested consumers to stay informed about the most recent risks related to food/feed safety. It allows to search according to the user's country, and provides a link

to the country's national consumer website, where applicable. As in the RASFF Portal, the name of the company or brand producing or distributing the given product is not provided. It is to be noted, however, that websites of national food safety authorities may provide additional information, potentially leading to differences in the information of consumers in different Member States.¹⁷⁶

There is 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. The main issue appears to be the lack of detail regarding products concerned by RASFF notifications, e.g. the name of the product, brand, producer or distributor. 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.

Although the RASFF Portal is considered to be accessible and transparent to the general public by NCPs and other stakeholders involved in the system, they are sceptical that the Portal addresses the needs of the general public for information on unsafe food, with almost half of respondents rating the system negatively in this respect. Moreover, 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. This may be explained by a lack of clear information regarding the different types of notifications and their definitions on the main page of the Consumers' Portal. To find the definitions, users have to navigate to the main website of the RASFF. Additional evidence indicates that even for businesses, the distinction between alert and information notifications is not unambiguous, and some operators may perceive any notification in the RASFF as an alert.

Although the transparency and accessibility of the RASFF to stakeholders and to the general public is desirable for the protection of consumers from risks related to food and feed, the effective functioning of the system also relies on the high level of confidentiality it can guarantee to business operators and to its member countries. While RASFF members are considered by a large majority of NCPs and other stakeholder groups to sufficiently respect the confidentiality requirements as set in Article 52 of Regulation (EC) No 178/2002, our case studies indicate a certain lack of clarity of confidentiality requirements. For example, in the 2011 E.coli outbreak it was not fully known to members of the RASFF which information (e.g. names of companies involved) could be disclosed to non-members. Finding out whether information could be disclosed was time-consuming in the context of urgency.

Also, confidentiality requirements may be interpreted differently by different member countries, particularly regarding which type of information is covered by professional secrecy. On the one hand, food/feed business operators expect that their brand names and information which may be commercially sensitive remain protected under the RASFF according to Article 52(1) of Regulation (EC) No 178/2002. On the other hand, the provisions of Article 52 and the guidance provided in the SOPs allow for an exception of the confidentiality requirements, for cases in which "information must be made public, if circumstances so require, in order to protect human health". In those cases, the legislation suggests that more transparency is required. As an appropriate balance has to be found between these requirements, it may be helpful for the SOPs to specify in which circumstances the need for transparency prevails over the requirement of confidentiality.

¹⁷⁶ For example, national websites in some Member States provide photos of the recalled product.

11.1.2.3. Recommendations

The results of this evaluation lead to the following recommendations to improve the relevance of the RASFF:

- ▶ ***Adapting the RASFF to enable improved data collection on notified risks.*** The 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 notified risks, affected food and feed products/materials, and measures taken. It is therefore recommended to further develop the RASFF as a cornerstone of the EU food and feed safety system and to collect additional data on notified risks. For example, currently a large number of notifications regarding a specific risk does not allow one to conclude that the risk is more relevant in terms of affected food and feed than other risks. A higher number of notifications could simply be caused by smaller lot sizes. If RASFF members provided the amount of affected food/feed consistently in notifications, distortions due to the number of notifications regarding a specific risk could be avoided. Also, if the sales channel were consistently provided regarding notified food and feed products that have reached the final consumer, it would be possible to identify trends by sales channel, and to take measures if an increasing number of notifications relate to one specific sales channel (such as e-commerce). It is therefore recommended to convene a working group of NCPs and independent food safety experts to discuss the scope of data collection through the RASFF. Moreover, this working group could also consider whether it would be useful to structure notifications according to the incident or source to which they relate. For example, assigning a unique identifier to notifications relating to the same food/feed safety incident or stemming from a common source would allow users to more easily identify relations between notifications and to have a better understanding of individual incidents and their development.
- ▶ ***Recognising the role of the RASFF in crisis management.*** Given the effectiveness of the RASFF as a platform for information exchange between member countries during previous serious food/feed safety incidents, its role in crisis management is central and should be recognised. Relevant practices should be reviewed and formalised. This includes, for example, the transmission of daily updates on serious food/feed safety incidents by the ECCP, or the compilation of a short incident report at the closure of the incident, to summarise key facts such as the amount of food/feed affected, the impact in terms of consumer safety, the measures taken and their results.
- ▶ ***Improving the information flow to stakeholders.*** To improve the information flow to professional operators, consumers and other stakeholders, the RASFF Portal and Consumers' Portal could provide additional details on the products involved in a notification. In particular, provision of information about the status of a notification could be considered, i.e. more details concerning which actions have been taken and whether or not the risk remains relevant, e.g. whether or not a recall has been completed. Moreover, an explicit legend containing the definition of notification types (alert, border rejection, information, and original versus follow-up) and accompanying examples could be clearly displayed on the main webpages of the RASFF Portal and Consumers' Portal. In addition, 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. While the RASFF Consumers' Portal foresees links to national websites of Member States informing citizens about recalls and food/feed safety issues, some MS have yet to develop their own webpages. Alternatively, the RASFF Consumers' Portal could provide this information for specific notifications that are directly relevant in a consumer perspective, such as recalls. The current reliance on national websites for this purpose may lead to different levels of information regarding a recall provided to consumers living in different Member States, even if the food product is available in all countries.
- ▶ ***Clarifying confidentiality provisions.*** The SOPs should 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, and where additional details concerning a notified product can be divulged outside the network. 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, and harmonise the interpretation of which type of information is subject to professional secrecy.

11.1.3. *Coherence*

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.¹⁷⁷

However, the multi-dimensional and oftentimes cross-border character of risks deriving from food and feed imply that the RASFF does not function in isolation, but as a component of a wider structure which includes European and international notification systems relating to public health, official controls, product safety, and early warning regarding specific risks such as radiological contaminations. The table on the following page presents other relevant notification systems at EU and international level, indicating the potential complementarities or duplications which may arise in interactions with the RASFF. All listed systems are potentially complementary to the RASFF. Also, some instances of potential duplications have been noted. They are partly unavoidable, e.g. in cases a risk relates to a product containing both a food and a non-food component (and is therefore notified through RASFF and RAPEX), or a radiological or nuclear accident affecting food/feed safety, as had been the case in the aftermath of the Fukushima accident (where Member States were required to report the results of their controls through both the RASFF and ECURIE). 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), which will integrate the various systems used for official controls, could further attenuate potential duplications through further facilitating data exchange between systems (although this will depend on the details of its implementation).

¹⁷⁷ It should be noted that the development of the AAC system may modify the scope of the RASFF in the future, as also acknowledged in the RASFF Standard Operating Procedures. European Commission, Standard Operating Procedures of the Rapid Alert System for Food and Feed, n.d. p.15.

Table 6: Potential complementarities and duplications between the RASFF and other EU and international notification systems

System	Potential complementarity to RASFF	Potential duplication with RASFF
EWRS – Early Warning and Response System	Exchange of information regarding the public health effects of a suspected foodborne outbreak.	No potential duplications between the RASFF and EWRS expected.
TRACES – TRAd e Control and Expert System	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	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 Radiological Information Exchange	Provision of complementary information in case a radiological or nuclear accident leads to a contamination of the food/feed chain.	In case of a radiological or nuclear accident that affects food/ feed safety, both systems may be used to report on measures taken and radioactivity levels measured.
EPIS – Epidemic Intelligence Information System	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	Complementary information exchange regarding a (potential) multi-sectoral crisis.	No potential duplications between the RASFF and ARGUS expected.
AAC – Administrative Assistance and Cooperation System	Where a non-compliance does not involve a risk which requires a notification to be transmitted to the RASFF, the systems are used separately and are considered to be complementary in scope.	The AAC and RASFF may be used simultaneously in cases where a non-compliance also poses a risk, 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 – Information Management System for Official Control	IMSOC will integrate various systems used for official controls, including the RASFF. The complementarity between 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	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.

Source: Civic Consulting. For additional sources and notes, refer to Table 1 in Annex 5.

▶ While RASFF is generally not considered to duplicate other relevant EU and international notification systems, some instances of potential duplications have been noted. Therefore, it is important to explicitly define in these instances (e.g. when food fraud involves a risk to human health) the scope of the relevant systems (in this case the RASFF and the AAC) and to communicate them clearly to members of the network. More specifically, it is recommended to provide guidance and training to RASFF National Contact Points once the scope of each system has been clarified in SOPs/guidance documents, in order to avoid misunderstandings and minimise potential duplications. Complementary suggestions to reduce areas of potential overlap between systems are provided in the following section on efficiency of RASFF.

11.1.4. *Efficiency*

To assess the extent to which the RASFF could achieve its objectives at a lower cost, as a first step an estimate of the annual costs of RASFF was calculated. Costs of the RASFF mainly accrue for the members of the network at the national level,¹⁷⁸ EFSA, and the European Commission for managing the system. At EC level, costs relate to maintenance and development of IT tools as well as staff costs involved in managing the IT system and coordination at the ECCP. The table on the following page indicates the estimated annual costs of running the RASFF according to the level of organisation.

Results of the financial analysis indicate that the annual costs of RASFF amount to a total of 7.4 million Euro, of which approximately 5.9 million Euro are spent at member country level. At the EU level, the costs involved in running and coordinating the system are estimated at 1.3 million Euro, including IT and staff costs. These costs have to be compared to the benefits, which accrue to member countries and the EU due to having a notification system for risks related to food and feed. Key benefits relate to rapid information of network members of risks identified; comprehensive exchange of information on the follow-up to notified direct or indirect risks, and on measures to contain risk; and information flow to third countries on risks detected to human health deriving from food and feed. If original notifications, follow-up notifications and information transmitted to third countries are counted as separate information items, a total of 10,668 of such items were transmitted through the system in the reference year 2013, with a cost of roughly 690 Euro per item (if the total costs of RASFF per year are divided by the number of information items). Considering that most notifications concern multiple countries, the cost per notified country are substantially lower. These costs appear to be reasonable, even though they cannot directly be compared to the resulting benefits, as the substantial information exchange through the system is not a benefit in itself, but rather contributes to benefits that accrue as result of measures taken on basis of RASFF notifications.

¹⁷⁸ Including the EFTA Surveillance Authority.

Table 7: Annual costs of running the RASFF at EU and member country level

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

Source: Civic Consulting. Notes: See table in Section 9.8.

Considering the financial resources that are involved in running the system in a member country perspective, the 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. The 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 and verification of product compliance that the RASFF enables. Only a small minority of respondents (9%) considered that the balance of costs and benefits of the RASFF for their country could be improved.

Given the significant increase in the number of notifications in recent years, the question arises whether the current centralised structure of the RASFF, in which the ECCP is the gatekeeper for all notifications, is sufficiently future proof. Currently, notifications that are only relevant for a very small number of Member States (or even only two Member States) have to pass the same verification and transmission procedure as notifications that are highly relevant for all or most Member States. Because of the administrative procedures involved in submitting notifications, Member States therefore in some cases prefer to communicate bilaterally by email, which is more efficient, but also means that information that could in principle at some point be relevant for other members (e.g. if an incident becomes more important as more consignments are affected than originally thought to be the case) is no longer in the system. It therefore could be considered to decentralise the RASFF to some extent by allowing bilateral information flow amongst members. While these bilateral information flows would be not verified by the ECCP, the related notifications would be captured in the RASFF database and could be used to inform other Member States or serve as data for monitoring purposes, where relevant.

An additional aspect in evaluating the efficiency of the RASFF relates to the extent to which the system could function better by streamlining its operation or by transferring certain tasks and functionalities to be handled through other systems or mechanisms. This evaluation has identified several options to achieve such efficiency gains: the centralisation of information from all RASFF notifications into a single IT system (iRASFF); the automatic transfer of border rejection notifications from TRACES into RASFF or handling border rejection notifications only through TRACES; a transfer of information notifications on non-compliances that are not related to risk containment to the Administrative Assistance and Cooperation (AAC) system to reduce the quantity of information exchanged through the RASFF; and a change in the centralised structure of the RASFF by allowing for bilateral exchange of network members through the system in specific situations (see above).

11.1.4.1. Recommendations

The results of this evaluation lead to the following recommendations to improve the efficiency of the RASFF:

- ▶ **Decentralising RASFF for specific information exchanges between members.** 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, including a degree of decentralisation of the system by allowing Member States to communicate directly through the RASFF under certain specific conditions. For instance, if a member of the network requires specific information from another member, bilateral communication could occur without requiring explicit verification by the ECCP. Future developments in this direction would require amending the current legislative framework and adapting the architecture of the iRASFF system accordingly.
- ▶ **Running RASFF as a single IT system.** Upgrading the iRASFF application to centralise information from all RASFF notifications into a single IT system and thereby replacing RASFF Window would increase the efficiency of the operation, as two parallel database systems would no longer have to be maintained by the ECCP for RASFF.
- ▶ **Improving linkages between information systems and further reducing overlaps.** Border rejection notifications are currently provided in both TRACES and RASFF Windows. In the future, the handling of border rejection notifications through TRACES alone could be considered. Alternatively, a direct IT link between TRACES and iRASFF could allow for the automatic transfer of notifications between the two systems, including from any future versions of TRACES, to reduce the effort for transferring border rejection notifications from TRACES to RASFF. In the future, the transmission of information on non-compliances which are not directly related to risk containment through the AAC system, to reduce the quantity of information exchanged through the RASFF, could also be considered. In this case, a direct link between the AAC and the RASFF should also be envisaged.

11.1.5. Added value of the RASFF

The evidence collected in this evaluation 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. There is a near consensus among NCPs and other stakeholders involved in the system that the RASFF has an added value compared to what could be achieved by Member States without it. 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.

11.2. Crisis and potential crisis management

While emergency measures adopted at EU level are broadly considered to have been effective and **successful in ensuring a consistent response** to past food/feed safety incidents by Member States, results of the evaluation suggest that the overall **effectiveness of crisis management has differed** in the reference period, depending on the food/feed safety incident and the objectives considered. In particular, while consumer health protection, the efficient management of the incident and coordinated implementation of most effective measures to contain the risk in past serious food/feed safety incidents are mostly considered to have been achieved, **crisis management arrangements were less effective** for protecting consumers' trust in food/feed safety and ensuring a limited disruption of internal market and trade, especially in the 2011 E.coli outbreak. The evidence also suggests that the EC **has played the role of coordinator** in the management of past incidents, although the extent to which this was the case and the satisfaction of competent authorities and other stakeholders with the EC's role vary, depending on the specific coordination aspect and incident considered.

Commission Decision 2004/478/EC provides for **two layers of action** related to crisis management at EU level: one layer of action related to potential serious risk, where a crisis unit is not set up but adequate provisions are made to ensure effective management, and another layer of action implying the setting up of a crisis unit according to Article 56 of Regulation (EC) No 178/2002. Both layers are considered by competent authorities and other stakeholders responding to our survey to be (in principle) relevant and still appropriate for food/feed crisis management. However, the second layer of action was never used, i.e. **a crisis unit has never been set up**, in spite of the fact that major food/feed safety incidents with significant impacts on consumer health occurred during the evaluation period. Regarding the first layer of action, the evaluation concludes that it has **not always been sufficient** for the management of previous food/feed safety incidents; moreover, during more complex crisis situations like the E.coli outbreak, a clearer crisis management structure within the European Commission would have been considered beneficial by key stakeholders involved. Finally, there is strong support by competent authorities and other stakeholders for **additional measures** to be taken for crisis management at EU level. As a result, one of the key outcomes of this evaluation is that there is a **need to review Commission Decision 2004/478/EC** in order to adapt it more closely to the current needs.

Mirroring the results of the evaluation concerning the effectiveness of crisis management, **the efficiency of EU crisis management has varied** depending on the case studied. While overall, costs of crisis management are considered to be appropriate, in some cases, the economic impact of a food/feed safety incident may have been higher than the unavoidable minimum. The evaluation concludes that a way to safeguard an improved balance of costs and benefits of crisis management is to focus on actions related to contingency planning and emergency preparedness, including training and simulation exercises. While the EC made **significant efforts** following the E.coli outbreak – including a cross-border simulation exercise, drafting of SOPs, training courses and conducting fact-finding missions on emergency preparedness planning in Member States – the evaluation identifies additional suggestions for improving the balance of costs and benefits at EU and Member State levels. These include a regular review of **contingency plans**, especially following serious food/feed incidents, and **organising crisis simulation exercises and trainings**. Finally, it is recommended to implement measures/procedures at all levels to **safeguard clear and effective communication** during future incidents.

Finally, as for the RASFF, there is **unanimous agreement that there is an added value** in the crisis management and coordination by the EC compared with what could be achieved by Member States acting individually. The sections below present the key results of the evaluation and provide recommendations, where relevant, that serve to enhance this added value.

11.2.1. *Effectiveness*

11.2.1.1. *Achievement of objectives*

According to the intervention logic for EU crisis management procedures developed in cooperation with the European Commission, the general objective of EU crisis management is the adequate management of serious food/feed safety incidents that cannot be contained by individual Member States. Specifically, crisis management procedures aim to achieve:

- Coordinated implementation of most effective measures to contain risk;
- Efficient management of serious food/feed incidents;
- Consumers trust in food/feed safety;
- Consumer health protection; and
- Limited disruption of internal market and trade.

Competent authorities in the field of food/feed crisis management and other relevant stakeholders that responded to our survey agree that existing crisis management arrangements at EU and Member State levels have to a significant extent achieved (in order of average rating) consumer health protection, the efficient management of the incident and coordinated implementation of most effective measures to contain the risk in past serious food/feed safety incidents. According to respondents, consumers' trust in food/feed safety and limited disruption of internal market and trade were achieved to a lesser degree, although the average rating was still positive. It is notable that the ranking provided by survey respondents was the same concerning EU crisis management procedures compared to those at Member State level in terms of which aspects received the highest ratings. However, each aspect received a lower average rating at EU level, i.e. was considered to have been achieved to a lower degree at EU level than at Member State level.

Moreover, the evidence collected concerning three serious food/feed safety incidents in the course of this evaluation suggests that the effectiveness of crisis management arrangements differed considerably for different incidents. The way in which the melamine crisis of 2008 and an incident involving glass fragments in instant coffee in 2010 were handled are broadly considered to have been effective, while this was not the case during the E.coli outbreak of 2011. For this incident, the effectiveness of crisis management was rated the lowest, and our case study confirmed that a limited disruption of the internal market and trade and upholding consumers' trust in food/feed safety were not reached. Key factors that hindered their achievement in this incident included the difficulty to find the source of the outbreak and the lack of an effective strategy for communication to the public.

Regulation (EC) 178/2002 attributes the primary responsibility for identifying and countering risk to Member States, in line with the principle of subsidiarity governing EU action. However, where a risk cannot be contained by Member States acting alone, there is a key role for the European Commission to play. As such, the following subsections discuss respectively the involvement of EU Member States and the role of the European Commission (including through emergency measures) and how these actors contribute to the effectiveness of European crisis management arrangements. The final subsection explores in which way Third Countries and International Organisations participate in crisis management.

11.2.1.2. *Involvement of EU Member States*

As part of their responsibility to counter risks arising from food/feed, Article 13 of Regulation (EC) No 882/2004 requires Member States to draw up contingency plans setting out measures to be implemented in serious food/feed safety incidents. Existing research indicates that the ways in which Member States have adapted to the

requirement of the Regulation vary across countries; in particular, different types of plans are used, and the territorial scope to which they apply may also vary. To obtain additional insights, in the course of this evaluation the types of contingency plans or procedures available in Member States were mapped. The results are presented in Table 4 of Annex 6. Most Member States that provided relevant information have adapted to meet the requirements of Article 13 of Regulation (EC) No 882/2004 on official food and feed controls. The ways in which they have adapted, however, vary from country to country. While some Member States have drawn up specific contingency plans for use in food/feed safety incidents, others have a general plan that can also be activated when serious risks related to food/feed arise, or sets of procedures to be used in emergencies in the field of food/feed. Moreover, these types of plans/procedures are not mutually exclusive: Member States may have some combination of plans/procedures available in their country. In several countries that provided information on this subject, contingency plans in the field of food/feed were under development at the time of research.

Similarly, a large majority of Member States report to have fulfilled the obligation of specifying the administrative authorities to be engaged in the case of a serious food/feed safety incident in their contingency plans/procedures, their powers and responsibilities, as well as determining channels and procedures for sharing information between relevant parties managing the risk. The results of the mapping indicate, however, that links to public health contingency planning are less frequent. Gaps in coverage of specific elements of crisis management at the country level were also experienced regarding other aspects. For example, in some Member States the names and contact details of the designated crisis coordinator were outdated, making the functioning of the network in times of crisis questionable.¹⁷⁹

11.2.1.3. Emergency measures and role of the European Commission

A key element of crisis management procedures in the EU relates to the possibility of adopting emergency measures in response to food or feed originating in the European Union or imported from a third country that is likely to constitute a serious risk to human health, animal health, or the environment. If the product is of European Union origin and if the risk cannot be contained satisfactorily by measures taken by the Member States concerned, the Commission, by way of Article 53 of Regulation (EC) No 178/2002, may suspend the placing on the market of the food/feed in question, lay down special conditions for the food/feed in questions, or apply any other appropriate interim measure. For products imported into the EU, the Commission may suspend the imports, lay down special conditions for the product in question, or adopt any other appropriate interim measure.

A large number of food/feed safety incidents have been contained and managed by the European Commission on this basis, as shown in Table 3 presented in the Annex. Of the 40 emergency measures adopted in the evaluation period, 25 have been repealed or have expired without being extended, suggesting that these measures are no longer needed because the risk is contained or otherwise no longer relevant. Those that are still in force indicate the continued relevance of the measures. However, some of the emergency measures still in place have been substantially amended. For instance, an initial ban of a product from a third country may be amended to impose special conditions on the import of those products, such as the requirement of a health certificate for consignments or reinforced controls at the border. Therefore, an emergency measure that is still in place but has been modified in such ways through an amendment could have been similarly effective as a measure that has been repealed. In almost all cases, these measures were adopted directly by the EC; exceptionally, emergency measures have served to extend, amend, or abrogate interim protective

¹⁷⁹ A meeting of an expert group on crisis management that took place in Brussels on 14 November 2014 decided to re-emphasise the requirement of Member States to nominate a crisis coordinator, and future meetings are envisaged.

measures adopted by a Member State on the basis of Article 54 of Regulation (EC) No 178/2002.

Emergency measures have also been used as instruments for the management of two of the three past serious food safety incidents scrutinised in depth in this evaluation, the melamine crisis and the E.coli outbreak. In both incidents, the measures are considered to have been effective, although in the E.coli outbreak it was adopted towards the end of the crisis once the source of the outbreak had been identified and it therefore mainly consolidated protective measures taken. This largely positive assessment concerning the effectiveness of emergency measures is confirmed by the results of the survey of competent authorities and stakeholders, with nine in ten respondents assessing emergency measures as having been effective for the management of serious food/feed safety incidents. Similarly, a nearly as large majority of competent authorities and stakeholders assessed that the mechanisms provided by Articles 53 and 54 have contributed to avoiding disparities between measures taken by different Member States and to ensuring a consistent approach in previous serious food/feed safety incidents.

In addition to emergency measures, Regulation (EC) No 178/2002 provides specific provisions for crisis management. Related obligations for the European Commission stem from Article 55, which requires that the EC draws up a general plan for crisis management in the field of the safety of food and feed, and from Article 56 which foresees for specific situations that a crisis unit is set up. With respect to Article 55, the EC has fulfilled its obligation in adopting Commission Decision 2004/478/EC, which specifies the types of situation involving direct or indirect risks to human health deriving from food and feed which are not likely to be prevented, eliminated or reduced to an acceptable level by provisions in place or cannot adequately be managed solely by way of the application of Articles 53 and 54 (i.e. emergency measures). The general plan also specifies the practical procedures necessary to manage a crisis, including the principles of transparency to be applied and a communication strategy. However, the general plan has so far not been formally triggered. Also, a crisis unit according to Article 56 has never been established. Therefore, possible EC obligations under the Decision would mainly refer to practical preparatory steps that can be derived from the Decision before a crisis, such as the establishment of a network of crisis coordinators, training activities, and crisis simulation exercises. These have been implemented to varying degrees, as indicated below. Furthermore, the role of the European Commission as coordinator in past serious food/feed safety incidents can provide insights to which extent the European Commission played the role as coordinator in past serious food/feed safety incidents, and fulfilled related obligations.

Competent authorities in the field of food/feed crisis management and relevant stakeholders were asked in our survey to assess the extent to which the EC has played the role of coordinator in past serious food/feed safety incidents affecting their Member State. Satisfaction with the EC's role of coordinator in past serious food/feed safety incidents was highest for coordination with EFSA, coordination with international organisations and coordination with third countries. In contrast, ratings were clearly lower concerning the EC's role in coordination of communication to the public/relevant competent authorities and for general coordination of national efforts, while still positive. Furthermore, the role of the European Commission as coordinator was scrutinised in our case studies of three serious food/feed safety incidents. Based on the evidence collected, this evaluation concludes that the EC has played the role of coordinator in the management of past serious food/feed safety incidents. However, the extent to which this was the case and the satisfaction of competent authorities and other stakeholders with the EC's role varies depending on the specific coordination aspect and incident considered, with coordination of communication to the public/relevant competent authorities seen as weakest aspect, specifically in the E.coli outbreak.

The evaluation also considered the extent to which the EC has identified lessons learnt from past experiences and whether those lessons learnt, if any, were translated into improvements in their crisis preparedness and crisis management arrangements. Several

measures that aim at improving arrangements were introduced at EU level following the E.coli outbreak, based on an EC review of the outbreak that identified lessons learnt and outlined possible actions to prevent future outbreaks. Suggested actions in the document referred to the need to strengthen coordination between health and food safety authorities, the elaboration of an EFSA and ECDC Standard Operational Procedure (SOP) for joint risk assessment in the event of food borne diseases, the necessity of carrying out inter-sectoral preparedness exercises on outbreak coordination and response, and the creation of a database for molecular typing. The document also emphasised the need to review existing processes established by Decision 2004/478/EC (a conclusion confirmed by this evaluation, see section on relevance below). Several measures were implemented at EU level since then, including:

- The cross-border crisis simulation exercise *Aristaeus*, which was commissioned by the EC and took place on 14-15 May 2013;
- A working group to identify best practices for communication in times of crisis was set up by the EFSA;¹⁸⁰
- EFSA has also conducted annual crisis training exercises since 2012, with a full crisis simulation exercise planned for this year (2015);¹⁸¹
- Standard Operating Procedures for rapid foodborne outbreak assessment were drafted in collaboration between ECDC, EFSA and the Commission;
- Draft Standard Operating Procedures have been developed by the Commission to codify the procedures and processes to be followed within DG SANTE to manage serious food/feed safety incidents;
- Five fact-finding missions were conducted by the FVO in 2013-2014 to identify best practices in emergency preparedness of Member States;¹⁸²
- Training courses on food-borne outbreaks investigations are provided in the framework of the BTSF (Better Training for Safer Food) programme, including for Member States (ongoing);¹⁸³
- The EC has requested EFSA to provide technical support for the collection of molecular typing results of food borne pathogens, which will help in establishing links between specific pathogen strains and specific food types and/or outbreaks (ongoing).

The list above confirms that a significant number of complementary measures were taken by the European Commission during the evaluation period, partly in response to the E.coli outbreak. Several of the measures contributed to the coordination of national efforts in outbreak investigations and to the development of best practices. Competent authorities who provided an assessment in our survey tended to see the provision of training by the EC as contributing the most to the coordination of national efforts. Also in regard to the provision of guidance documents/SOPs and the sharing of technical information they tended on average to see the EC as contributing to the coordination of national efforts, while providing infrastructure for coordination was not considered a relevant contribution.

¹⁸⁰ The Advisory Forum Working Group on Communications – EFSA.

¹⁸¹ Instinctif Partners, External Scientific Report - EFSA's food and feed crisis preparedness training: 2014 Crisis Training Exercise, 2014.

¹⁸² European Commission Directorate-General for Health and Food Safety, Overview Report of a Series of Fact-Finding Missions Carried out in 2013 and 2014 in Order to Gather Information on Emergency Preparedness Arrangements, 2015.

http://ec.europa.eu/food/fvo/overview_reports/details.cfm?rep_id=73.

¹⁸³ Ongoing, see <http://www.trainsaferfood.eu/Trainings/Foodborneoutbreaksinvestigation.aspx>.

11.2.1.4. *Participation of Third Countries/International Organisations*

The EU legislative framework for the management of food/feed crises does not include explicit mechanisms for communication and cooperation with third countries or international organisations in the event of a serious food/feed safety incident. While some provisions of the (so far never applied) General Plan relate e.g. to communication with non-EU countries and international organisations "to ensure that all relevant information is made available and shared" when a crisis unit is set up, such communication seems in practice to occur on an ad-hoc basis and using various structures, including missions of third countries to the EU, and existing information channels such as INFOSAN through its cooperation with the RASFF (see Section 9.7 of this report). A key area of crisis management that relates to third countries is the use of the above described emergency measures, which may serve to place restrictions on international trade with the EU. When trade with a third country is restricted, the EC may collaborate with the country in question to seek ways to remedy the situation and normalise trade relations. For instance, in the aftermath of the E.coli outbreak, the FVO carried out an audit in Egypt in order to trace back the source of the infection, evaluate the production and processing conditions, and review the emergency measures taken through the adoption of Commission Implementing Decision 2011/402/EU.

The results of this evaluation indicate that the EU's crisis management mechanisms appear to have allowed to some extent for the participation of third countries/international organisations in past serious food/feed safety incidents. Overall, the information flow between the EU and third countries/international organisations is considered to be satisfactory, although more information from international partners would be welcomed by EU Member States. With 107 countries having access to RASFF notifications via RASFF Window, and increasingly close cooperation with INFOSAN, the potential of the RASFF as tool for the management of serious food/feed safety incidents could be fully deployed by utilising its current outreach beyond the borders of the EU.

11.2.1.5. *Recommendations*

The results of this evaluation lead to the following recommendations to improve the effectiveness of crisis and potential crisis management:

- ▶ **Regular review of contingency planning and crisis management procedures.** It is recommended that the FVO continues its review of contingency plans/procedures for serious food/feed safety incidents at Member State level, and that the European Commission (with the involvement of affected Member States) conducts dedicated evaluations of crisis management procedures after a serious food/feed safety incident has been closed, to identify possible deficiencies of arrangements or measures taken, and lessons learnt (as has been the case after the E.coli outbreak). It is also recommended that Member States themselves review their contingency planning for serious food/feed safety incidents in regular intervals, and specifically after a serious food/feed incident in their country has been closed. While approaches for contingency planning at Member State level currently differ significantly, FVO reports on contingency planning and reports of Member States working groups, including of the Heads of European Food Safety Agencies, could provide a basis for harmonisation of approaches and identification of best practices. Essential best practices identified include effective linking of food/feed safety and public health emergency procedures in case serious food/feed safety incidents affect public health.
- ▶ **Ensuring clear and effective communication during serious food/feed safety incidents.** While the EC has played the role of coordinator in the management of past serious food/feed safety incidents, the extent to which this was the case and the satisfaction of competent authorities and other stakeholders with the EC's role varies depending on the specific coordination aspect and incident considered. Coordination of communication to the public/relevant competent authorities was seen as weakest aspect. It is therefore recommended to implement measures/procedures at local, regional, national and union level to safeguard clear and effective communication during serious food/feed safety incidents.

- ▶ *Reconsidering the role of the network of crisis coordinators.* Decision 2004/478/EC foresees a separate network of crisis coordinators nominated by Member States (in addition to the relevant regulatory committee), which is currently not fully functional. If this separate mechanism is to be maintained, Member States should ensure that changes in the designated contact points for crisis management are communicated immediately to the European Commission to safeguard smooth coordination of measures concerning serious food/feed safety incidents.
- ▶ *Conducting crisis simulation exercises.* A significant number of measures were taken by the European Commission during the evaluation period to improve crisis preparedness and crisis management arrangements, partly in response to the E.coli outbreak. It is recommended to continue and reinforce EU measures to improve crisis management procedures and crisis preparedness as well as to test them on a regular basis during EU crisis simulation exercises, which should at least involve key contact points in Member States, both for handling crisis management measures and communications. It is also recommended that Member States organise complementary crisis simulation exercises and training courses. These should take place on a regular basis and include, where possible, multiple sectors (such as health, food safety), different levels of government (such as national and regional) and neighbouring countries, where feasible.
- ▶ *Improving cooperation with third countries and international organisations.* It is recommended to strengthen cooperation with third countries and international organisations to develop/refine contingency planning for serious food/feed safety incidents in third countries and increase capacities for crisis management in the area of food and feed through continued training programmes (such as the Better Training for Safer Food programme). The EC could initiate and support a programme of voluntary reviews of contingency plans and procedures of relevant third countries, to provide benchmarking and allow for the dissemination of best practices. Criteria for benchmarking could preferably be developed in cooperation with international partners such as INFOSAN and take into account ongoing work to strengthen regional food safety programmes, also considering best practices in EU countries and experiences of major trading partners. These reviews could be conducted by a suitable international partner or through other mechanisms.¹⁸⁴

11.2.2. *Relevance*

A key question in the context of managing serious food/feed safety incidents is whether the EU legislative framework corresponds to the needs of food/feed crisis coordination. As described in the background section of this report (Section 6.3), Regulation (EC) No 178/2002 foresees that a general plan shall be drawn up by the Commission, specifying the types of situation involving direct or indirect risks to human health deriving from food and feed is not likely to be prevented, eliminated, or reduced to an acceptable level by provisions in place, or cannot be adequately managed through emergency measures (by application of Articles 53 and 54).

The general plan presented in Commission Decision 2004/478/EC provides for two layers of actions: (1) one layer of action related to potential serious risk, 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 according to Article 56 of Regulation (EC) No 178/2002. Competent authorities in the field of food/feed crisis management (and to a lesser degree also other stakeholders) consider these two layers of action to be relevant and still appropriate for food/feed crisis management. This is in spite of the fact that a crisis unit has never been set up, i.e. the second layer of action has not been used during serious food/feed safety incidents experienced during the last

¹⁸⁴ An example for a review and benchmarking programme (in the area of animal health) is the evaluation of performance of Veterinary Services by the World Organisation for Animal Health (the OIE PVS evaluations). The OIE PVS Pathway is a global programme for improvement of a country's Veterinary Services' compliance with OIE standards. While the OIE PVS Tool is broader in scope, it contains criteria relating to emergency response. For more details see <http://www.oie.int/support-to-oie-members/pvs-evaluations/>

decade. Regarding the first layer of action, there are diverging assessments among respondents whether or not it has been sufficient for the management of previous food/feed safety incidents: Just over a third considered that the first layer of action had been sufficient for the management of past serious food/feed safety incidents, a nearly similar number of respondents indicated that it had not been sufficient, while another third of respondents did not know.

When considering the results of this evaluation regarding the relevance of crisis management, the following picture emerges:

- On the one hand the experiences of the glass fragments incident, the melamine crisis, and also the E.coli outbreak demonstrate that several dimensions of crisis and potential crisis management at EU level function effectively, including information exchange on affected consignments and measures taken through the RASFF, coordination of measures and briefing on crisis situations through daily audioconferences led by the European Commission, risk assessment and support to epidemiological investigations by EFSA, and emergency measures taken by the European Commission, among others.
- On the other hand, during more complex crisis situations like the E.coli outbreak which involve large scale public attention it proved to be not feasible to implement a clear and coherent communication strategy across the affected Member States and EU institutions. Also, while a clearer crisis management structure (either a crisis unit according to Article 56 or a similar structure) within the European Commission would have been considered beneficial by key stakeholders involved in the incident, no such structure was implemented. In consequence, standard procedures, including information exchange through the RASFF and procedures for involving Member States in decision-making regarding relevant EC measures (mainly through the SCOFCAH)¹⁸⁵ were complemented by ad-hoc crisis management arrangements to handle the incident at EU level.

In other words, while crisis management at EU level is assessed positively and has worked well in the context of limited crises, during more complex crisis situations such as the E.coli outbreak the provisions in the general plan foreseen for this type of situations appeared not to be the appropriate tool. This indicates a need to review the provisions regarding the general plan according to Commission Decision 2004/478/EC, and to develop more workable arrangements that can be applied during relevant incidents.

Moreover, there is also a broad consensus that additional measures are needed for crisis management at EU level. The measures considered most necessary are regular crisis simulation exercises, a greater role of the EC in the coordination of Member States' efforts and specifically the coordination of the communication to the public/relevant competent authorities, as well as a step-wise approach for escalating measures of crisis management.

11.2.2.1. Recommendations

The results of this evaluation lead to the following recommendations to improve the relevance of crisis and potential crisis management:

¹⁸⁵ In the meantime, the SCOFCAH has been replaced by the Standing Committee on Plants, Animals, Food and Feed (PAFF).

► **Updating Commission Decision 2004/478/EC.** Results of this evaluation suggest that the current legal framework is less functional for addressing more complex crisis situations such as the E.coli outbreak in 2011. Commission Decision 2004/478/EC should therefore be reviewed and updated. Issues that this review could address include: a) the extent to which the existing workflow at DG SANTE could be gradually reinforced when serious food/feed safety incidents have to be managed, preferably through a step-wise escalation which allows additional (staff and technical) resources to be dedicated progressively as an incident develops; b) the effective linking of food/feed safety and public health emergency procedures at EU level in case serious food/feed safety incidents, mainly foodborne diseases, affect public health; c) the use of the term 'crisis unit' – a more neutral term such as 'task force' could reduce possible public concerns in case additional resources have to be assigned to incident management under a step-wise escalation approach; d) the role of the network of crisis coordinators (see above). It is recommended that the revised Decision (and, if applicable, related SOPs) should be short, unambiguous and build to the extent possible on procedures that have proven to work well during previous crisis, and on best practices used in crisis management at Member State level.

11.2.3. Efficiency

The criterion 'efficiency' considers in the context of this study the relationship between the inputs used and the outputs provided by EU crisis management. In particular, this evaluation explored the extent to which the costs of crisis management can be lowered, while continuing to achieve the same objectives – above all the adequate management of serious food/feed safety incidents that cannot be contained by individual Member States.

In our survey, Member States' competent authorities in the field of food/feed crisis management assessed the balance of costs and benefits of crisis management at EU level as appropriate. The three case studies of serious food/feed safety incidents concluded that it depends on the incident, whether the objectives of EU crisis management can be achieved at a lower cost. In some cases, the economic impacts of serious food safety incidents are considered to have been higher than the unavoidable minimum, with the most relevant example being the 2011 E.coli outbreak. Concerning this incident it was suggested that a clearer and coordinated strategy for communication to the public might have contributed to reduced economic impacts, although the extent to which a joint EU/Member States' strategy could indeed have prevented or contained negative impacts remains unclear.

The analysis of several major food/feed safety incidents also concluded that the costs of contingency planning and emergency preparedness (including training) as well as of managing identified food/feed safety risks in non-crisis periods are likely to be relatively minor, when compared to the costs and losses of major incidents, which include losses related to trade restrictions and the loss of consumer trust and the resulting economic impacts for food business operators due to changes in consumption patterns caused by the crisis (see Table 6 in Annex 6). Measures to improve the efficiency of crisis management arrangements therefore relate primarily to actions in view of preventing serious food/feed safety incidents from developing, and to ensure an outbreak is rapidly detected and the source identified where a crisis nonetheless occurs. As such, the balance of costs and benefits is likely to improve with development of the food/feed safety system, including enhanced cooperation with business operators, improved controls and enforcement of food/feed legislation, state of the art technologies for detection of contaminants and pathogens, as well as appropriate contingency planning and emergency preparedness.


Suggestions made by Member States to improve the balance of costs and benefits of crisis management revolve around measures such as sharing of experiences and best practices, or receiving scientific support for risk assessment regarding 'lesser known

dangers' to avoid disproportionate measures (see also recommendation in Section 11.1.1 on the RASFF regarding the role of EFSA).

At EU level, efficiency of existing crisis management arrangements could possibly be increased by refining the respective tasks and roles of existing mechanisms for coordination and communication during serious food/feed safety incidents, which includes the network of crisis coordinators, the network of RASFF National Contact Points and the Standing Committee on Plants, Animals, Food and Feed (PAFF) as well as its relevant sections.

11.2.3.1. Recommendations

The results of this evaluation lead to the following recommendations to improve the efficiency of crisis and potential crisis management:

 ***Refining tasks and roles of existing crisis management mechanisms.*** It is recommended to refine the respective tasks and roles of existing mechanisms for coordination and communication related to crisis management at EU level, which includes the network of crisis coordinators, the network of RASFF National Contact Points and the Standing Committee on Plants, Animals, Food and Feed (PAFF), either through dedicated SOPs or the clarification of their respective roles during serious food/feed safety incidents in a revised version of Commission Decision 2004/478/EC (see above).

11.2.4. Added value resulting from EU coordination of crisis management

There is broad and unanimous consensus that there is an added value resulting from the EC coordinating crisis management of the Member States concerning serious food/feed safety incidents compared to what could be achieved if there was no coordination at EU level. Key points of the additional value include the sharing of information and best practices, and enabling a coordinated and harmonised approach across Member States, particularly in global incidents such as the melamine crisis which require a strong regional coordination to communicate effectively with international partners. Moreover, by strengthening its role as coordinator and improving its crisis management structure, the EC could increase the added value it brings to crisis management.

