

TECHNICAL REPORT

Annual report on EFSA's food and feed safety crisis preparedness and response 2011¹

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ABSTRACT

This report presents EFSA activities related to food and feed safety crisis preparedness and urgent responses. In 2011, one training exercise, in collaboration with the European Commission, Member States and the European Centre for Disease Prevention and Control was organised to raise awareness amongst EFSA response personnel of the principles of crisis response in the context of urgent risk assessment. In the same period, EFSA received one urgent request from the European Commission regarding an unusually large outbreak of Shiga-toxin producing *Escherichia coli* serotype O104:H4 in France and Germany. The response to the urgent request included careful consumer advice about risk mitigation and prevention and was delivered as public notices and EFSA statements online within statutory timeframes

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KEY WORDS

Food safety crisis, crisis preparedness, crisis response

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SUMMARY

The European Food Safety Authority (EFSA) has established procedures for responding to urgent requests for scientific advice, and carries out crisis preparedness training on a regular basis. During 2011 EFSA carried out one training exercise and issued, upon its own remit and at the request of the European Commission, several consumer advice statements and reports on the *E. coli* (STEC) O104:H4 epidemic in Germany and France.

In order to prepare for food and feed safety crises, EFSA has developed and implemented a multi-annual crisis preparedness training programme to improve EFSA crisis preparedness and to develop an effective coordination framework for internal and external cooperation with EFSA units and stakeholders.

The training event involved EFSA staff with the collaboration of participants from the European Commission, Member States and the European Centre for Disease Prevention and Control. The format of the day consisted of an exercise involving a developing situation that occurred as a result of a fictitious pathogenic bacterial strain that resulted from the acquisition of new virulence determinants from other unrelated bacteria, and that contaminated feed and food in the European Union.

The general aim of this training event was to raise awareness amongst EFSA response personnel of the principles of crisis response in cases of urgent risk assessment, and the activities required to support EFSA's response to a request for urgent advice. The specific aims of the exercise were to enable the EFSA to rehearse its information management, exchange procedures with MSs and log keeping.

Based on the feedback from the debriefing of participants and the contractor's evaluation, it was considered that the training event achieved its aim of raising awareness amongst EFSA response personnel and that participants had a good awareness of the EFSA procedures for responding to urgent advice needs and understood satisfactorily their role and that of other EFSA units as part of the response. The main recommendations made after the exercise with regards to future exercises were in the areas of information management and exchange, procedures, communications, and training.

The training exercise was found to be very relevant for EFSA preparedness, as a similar type of event, an outbreak due to a rare strain of food poisoning bacteria, was sadly mirrored by reality when an outbreak of shiga toxin-producing *E. coli* O104 in Germany and France resulted in almost 4.000 cases, including 800 cases of renal impairment and 53 deaths.

Through the training exercises, familiarity with the urgent response procedures enabled a rapid response on the half of EFSA to what proved to be one of the largest foodborne outbreaks in Europe in recent years. Having a Unit dedicated to providing organisational support during a crisis was critical. In the initial stage of the outbreak, EFSA rapidly produced two reports with supporting information, concerning the public health risk of STEC in fresh vegetables and, jointly with the European Centre for Disease Prevention and Control (ECDC), a report on STEC in humans, food and animals. A rapid risk assessment was also carried out jointly with ECDC. As the magnitude of the outbreak became evident, on the request of the German authorities and the European Commission, EFSA scientific staff with expertise in data collection, and epidemiological analysis including foodborne outbreaks, were dispatched to Germany to assist in the outbreak investigation.

Following the outbreaks in France, EFSA was asked by the European Commission to support the Member States and coordinate activities to trace the common source of contaminated produce implicated in the outbreaks to allow risk managers to make more informed mitigation and prevention management decisions.

A Task Force was set up by EFSA to provide immediate scientific assistance. EFSA scientists were joined on the Task Force by officials and experts from the European Commission, relevant EU Member States, the European Centre for Disease Prevention and Control (ECDC), the World Health Organisation (WHO) and Food and Agriculture Organisation (FAO).

EFSA's scientific output during the STEC outbreak included in total, six scientific reports and statements, with further follow-up activities instigated on the request of the Commission, following the end of the outbreak. .

This important pan-European outbreak also highlighted the importance of EFSA's risk communications mandate, and the need to coordinate communication between risk managers and risk assessors. This is reflected in the increased number of media enquiries and visitors to the Authority's website for the period end May to early July 2011.

In the light of the experience gained in 2011, the procedures for responding to urgent requests for advice are being further developed based on the on the internal evaluation of the crisis response to *E. coli*, captured in the annex of this report on lessons learnt.

Also during the same period, the Emerging Risks Unit carried out monitoring of a number of high profile chemical and biological issues considered of interest by EFSA to ensure timely preparation in the eventuality of EFSA being request to provide an urgent request.

TABLE OF CONTENTS

Abstract	1
Key words	1
Summary	2
Table of contents	4
List of Tables	4
Background as provided by EFSA	5
1. Introduction	7
1.1. EFSA procedure for responding to urgent advice needs.....	7
1.2. Crisis preparedness training exercises	7
1.3. Emergency response assessment.....	8
2. Results	9
2.1. EFSA emergency training exercise IV.....	9
2.2. EFSA responses to a request for urgent advice in 2011.....	9
Conclusions and recommendations	11
References	11
ANNEX. STEC O104:H4 outbreak: Lessons learnt - contribution from EFSA.....	12

LIST OF TABLES

Table 1: Core EFSA safety crisis preparedness activities	7
Table 2: Potential crises monitored in 2011	11

BACKGROUND AS PROVIDED BY EFSA

Regulation (EC) No 1781/2002, article 55 states that the European Commission shall draw up, in close cooperation with EFSA and the Member States (MSs), a general plan for crisis management in the field of the safety of food and feed. This plan will be activated when a situation arises which presents a risk to consumers, animal or plant health which cannot be controlled by the normal existing mechanisms.

EFSA wishes to be fully prepared for a crisis as defined above, as well as to be in a position to be proactive in addressing a situation before it is determined as being a crisis. EFSA therefore needs to be able to respond quickly and efficiently to provide scientific and technical support to inform risk managers and consumers in Europe on a "hot issue" and to communicate about its findings, if possible before it develops into a crisis.

Hence, EFSA has drawn up its in-house procedures, to complement the Commission Plan, for use within EFSA and to guide EFSA staff in case of an urgent request for scientific advice. The procedures are regularly updated in the light of experience gained during "crisis" responses and through exercising the plan, including those held with Member States (MSs) through EFSA's Advisory Forum. These activities are coordinated by the Emerging Risk (EMRISK) unit.

TERMS OF REFERENCE, INCLUDING RESPONSIBILITIES OF STAFF, WORKING GROUPS,

COLLABORATION BETWEEN UNITS/PANELS

1) EMRISK will prepare a report providing:

- A summary of EFSA's crisis preparedness activities
- An overview of EFSA responses to urgent requests for scientific advice .
- Recommendations for further crisis preparedness training activities
- Recommendations for further development of procedures for responding to urgent advice needs

The evaluation reports of the crisis preparedness activities will be annexed to this report.

2) EMIRISK, in consultation with the Advice Management Team and EMRISK's working group on crisis preparedness, and taking into account experience gained both from "crisis" exercises and training, and from responding to urgent requests will update the existing procedures for responding to urgent advice requests.

TIMELINE

The procedures for responding to urgent advice needs will be updated if and when needed, and published on EFSA's website.

A technical report on EFSA's crisis preparedness will be prepared annually and published on EFSA's website:

Publication date	Reporting year	Content	Annexes
Nov 2010	2009	Summary of crises handling of 2009; Summary of evaluation report on crisis exercises of 2009	Evaluation report of crisis exercises July and Nov 2009
May 2011	2010	Summary of crises handling 2010; Summary of evaluation report of internal exercise Dec 2010	Evaluation report of internal exercise Dec 2010
March 2012	2011	Summary of evaluation reports on handling of crises in 2011; Summary of evaluation report of crisis exercises 2011.	Evaluation report on external crisis exercise March 2011, Evaluation report on internal exercise fall 2011

EXPECTED DELIVERABLES

Updated procedures for responding to urgent advice needs.

An annual technical report on EFSA's preparedness for responding to food and feed.

This report replies to the deliverables for March 2012: and the annual report on EFSA's food and feed safety crisis preparedness and response activities in 2011.

1. Introduction

In EFSA, food and feed safety crisis preparedness is based on three areas, namely: the EFSA procedures for responding to urgent requests (EFSA, 2011), EFSA’s crisis preparedness training and simulation exercises and learning from responses to EFSA’s urgent scientific and technical assistance requests (Table 1).

Table 1: Core EFSA safety crisis preparedness activities

<i>Outputs</i>	<i>Key players</i>	<i>Activities</i>
EFSA procedure for responding to urgent advice needs	EMRISK , Advice Management Team ⁴	Update if and when needed
Crisis preparedness training and simulation exercises	EMRISK, Crisis preparedness working group and external contractor	To carry out one internal training exercise.
Learning from urgent scientific and technical assistance requests	Internal review team and/or external experts in relevant cases	Internal/external reports

1.1. EFSA procedure for responding to urgent advice needs

EFSA’s procedure for responding to urgent requests (also commonly referred to as “the Emergency Manual”) provides guidance on the practical arrangements necessary to ensure adequate responsiveness of EFSA to requests for urgent advice on food and feed safety.

The procedure provides criteria on the identification of urgent situations, introduces internal response levels, and explains how the urgent advice structures are activated, which steps must be followed, who the actors are, and also specifies the tasks to be conducted by them. The document also describes EFSA’s operational facilities and other arrangements relevant for dealing with requests for urgent advice.

The procedures are updated as necessary to reflect the experience gained from responding to urgent scientific and technical assistance requests and from crisis preparedness training exercises.

1.2. Crisis preparedness training exercises

EFSA operates a multi-annual crisis preparedness training programme to enable staff to achieve competence in the responses to food and feed safety crises. The programme encompasses different training formats such as workshops involving case studies, table-top exercises and command-post simulation exercises. The training events involve EFSA staff and stakeholders. The training activities were planned and organized in close collaboration with the EFSA working group on crisis preparedness and carried out with the an external contractor.

⁴ Technical Report of EFSA. EFSA Procedures for responding to urgent advice needs. EFSA-Q-2010-01235, issued on 24 January 2011.

1.3. Emergency response assessment

EFSA's procedure for responding to urgent advice needs foresees that each response for urgent scientific advice is reviewed. Particularly, the evaluation concentrates on the clear definition of roles, responsibilities and leadership of the urgent response team; procedures and overall management effectiveness; internal and external communication strategy adequacy, and the quality and usefulness of the advice given.

Feedback is also sought from EFSA staff as well as from EFSA stakeholders involved in the urgent response advice. The recommendations received during the assessment are eventually incorporated in future revisions of the urgent response procedures.

2. Results

2.1. EFSA emergency training exercise IV

The 4th EFSA crisis simulation exercise was held on the 16th of May 2011 involving the participation from a number of key partners including the European Commission, European Centre for Disease Prevention and Control, Advisory Forum and Focal Point members.

The main aims of the exercise were to enable the EFSA to rehearse its information management, exchange procedures and log keeping.

The scenario of the exercise involved a developing situation that occurred as a result of a fictitious new pathogenic *Salmonella* spp. strain contaminating feed and food in the European Union.

The review of the exercise concluded that overall⁵, it was felt that all those who participated in the exercise had a good awareness of the EFSA procedures for responding to urgent advice needs and as such understood their role and that of other EFSA units as part of the response.

As a result of the exercise, a number of issues were identified and recommendations for improvement have been made by the contractor in its post-exercise evaluation report in the areas of information management and exchange, procedures, communications, and training.

The main areas for future action identified in the exercise included the following:

- (i) the need to further develop the log management tool and the associated procedures in order to enhance EFSA's recording and auditing process,
- (ii) the need to strengthen the co-ordination of internal and external information exchange, and
- (iii) EFSA should seek to identify additional senior staff that can deputise in the absence of the Executive Director and the Head of Risk Assessment to ensure that the EFSA response structure is resilient.

To address these issues adequately EFSA is evaluating existing logging tools developed by other European agencies, and updating the urgent response procedures to include solutions for consolidating the information exchange and defining the deputising of the Executive Director.

2.2. EFSA responses to a request for urgent advice in 2011

Between May and July 2011, there was a large outbreak of Shiga-toxin producing *E. coli* (STEC) O104:H4 human infections in France and Germany, resulting in around three thousand reported cases bloody diarrhoea and a further 800 cases of haemolytic uraemic syndrome. Fifty-three people died as a result of infection with the outbreak organism⁶.

At the request of the European Commission and German authorities, EFSA was closely involved in the scientific work related to the *E. coli* O104:H4 epidemic and also providing advice to consumers to reduce the risk of getting ill from potentially contaminated foodstuffs.

⁵ <http://www.efsa.europa.eu/en/supporting/pub/192e.htm>

⁶ <http://www.bfr.bund.de/cm/349/ehc-outbreak-2011-updated-analysis-as-a-basis-for-recommended-measures.pdf>

In particular, and following the outbreaks in France, EFSA was asked by the European Commission to support the Member States and coordinate activities to carry out source investigation activities in order to allow risk managers to make more informed mitigation and prevention management decisions.

EFSA's scientific work during the STEC outbreak included the following reports and statements:

- Joint EFSA/ECDC public health advice on prevention of diarrhoeal illness with special focus on STEC, also called VTEC or EHEC⁷
- Joint EFSA/ECDC technical report with ECDC on the prevalence and incidence of STEC in humans, food and animals based on data supplied by EU Member States annually and data from this outbreak investigation⁸
- A fast track risk assessment on consumer exposure to STEC/VTEC through the consumption of raw vegetables and advice on options to mitigate the risks of possible food contamination and human infection⁹.
- Joint EFSA/ECDC rapid risk assessment of the HUS outbreak in France focusing on four key areas: food source identification, collaborative trace-back investigations (coordinated by the EFSA Task Force), awareness-raising amongst clinical practitioners and public health advice¹⁰
- The final report from the EFSA Task Force on 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 (5 July 2011)¹¹
- A scientific report from EFSA containing a comprehensive overview of what happened from a food safety perspective during the outbreaks of Shiga toxin-producing *E. coli* (STEC) O104:H4 2011 in Germany and France¹²

An internal report of EFSA evaluating the lessons learnt on the STEC O104:H4 outbreak is presented as an annex to this report.

In the light of the experience gained in 2011, the procedures for responding to urgent requests for advice are being further developed based on the on the internal evaluation of the crisis response to *E. coli*, and from those recommendations captured in the annex on lessons learnt.

In addition to official requests for advice, a number of other high profile issues were identified for which intensive monitoring was carried out in the eventuality that an urgent request might be received by EFSA. The issues monitored in 2011 are presented in the following Table 2.

⁷ Public health advice on prevention of diarrhoeal illness with special focus on Shiga toxin - producing *Escherichia coli* (STEC), also called verotoxin - producing *E. coli* (VTEC) or enterohaemorrhagic *E. coli* (EHEC). News Story. 3 June 2011

⁸ Joint EFSA/ECDC technical report: Shiga toxin/verotoxin-producing *Escherichia coli* in humans, food and animals in the EU/EEA, with special reference to the German outbreak strain STEC O104. Question number: EFSA-Q-2011-00779 Issued: 8 June 2011

⁹ EFSA issues advice to mitigate risks from possible exposure to STEC in vegetables. Press Release. 9 June 2011. <http://www.efsa.europa.eu/en/press/news/110609.htm>

¹⁰ EFSA/ECDC Joint rapid risk assessment. Cluster of haemolytic uremic syndrome (HUS) in Bordeaux, France. 29 June 2011. <http://www.efsa.europa.eu/en/scdocs/doc/rraefsaecdcstec0104.pdf>

¹¹ 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. Question number: EFSA-Q-2011-00817. Issued: 5 July 2011

¹² Scientific Opinion on the risk posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria in seeds and sprouted seeds. EFSA Journal 2011;9(11):2424 [101 pp.]. doi:10.2903/j.efsa.2011.2424

Table 2: Potential crises monitored in 2011

No	Incident	Monitoring period
1	Dioxins findings in feed fats from Schleswig-Holstein	04/01/ 2011 to 03/02/2011
2	Fukushima Daiichi nuclear accident	14/03/2011 to 28/06/2011

CONCLUSIONS AND RECOMMENDATIONS

EFSA has established a tried and tested experience and science-based procedure for providing assistance and preparing within days scientific statements and coordinating intra-European responses in the event of food-related emergencies.

Experience has shown these to be fit for purpose.

The procedures for responding to such requests are continually improved by carrying out a formal evaluation of the responses highlighting lessons learnt for EFSA.

Further modifications have been identified for improving crisis preparedness from the exercise and urgent response carried out in 2011. The recommendations made by the exercise observers and EFSA staff should be incorporated into the next update of the urgent response procedures.

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ANNEX. STEC O104:H4 outbreak: Lessons learnt - contribution from EFSA

During the outbreak of Shiga toxin-producing *E. coli* (STEC) O104:H4 in Germany and France in May-July 2011, EFSA was requested to provide urgent scientific support to the European Commission (EC) and Member States (MS). At the time, more than 3900 cases linked to this outbreak were reported to the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO), including 47 deaths, making it one of the largest foodborne outbreaks reported in Europe in decades. EFSA has compiled a summary of the outbreak and its investigation¹³.

Cases were first reported in Germany during the first week of May 2011. Due to the low number of cases, compared to the expected level of reporting of non-haemolytic uraemic syndrome (HUS) STEC infections, nothing out of the ordinary was observable at that point. During the second week of May, the number of cases started to increase (up to 50 cases per day), and included the first reporting of HUS cases. By the third week of May, over 50 cases of HUS, and over 150 non-HUS cases were being reported each day. The epidemic peaked around the 20-23 May¹⁴. On 24 June, France reported, a cluster of patients with bloody diarrhoea, after having participated in an event in the Commune of Bègles near Bordeaux on 8 June.

The procedures of the European Food Safety Authority (EFSA) for responding to urgent requests foresee a post crisis phase of review of the Authority's performance, analysis of its procedures and interactions with key partners, in order to draw lessons from the experience and further improve performance in future crises. This report aims to contribute to the post-crisis assessment coordinated by the European Commission according to the General Plan for Food/Feed Crisis Management (Decision 2004/478/EC). It aims at identifying both what went well and what could possibly be improved with a view to better preparedness for future crises.

Overview of EFSA's urgent response

Concerning the STEC O104:H4 outbreak, the urgent response of EFSA took place in three different phases.

The first phase (24 May to 9 June 2011) involved a response to a demand for background information on the internalisation of enteric pathogens in plant material. Due to the urgent nature of the work, a team started gathering and analysing data and drafting a report before the receipt of a draft mandate from the Commission on 1 June. The report¹⁵ was finalised and published on 9 June. In addition, and at EFSA's initiative, a report summarising available data on STEC and particularly STEC O104 serotype in humans, food, animals, previously reported in Europe was compiled jointly with the ECDC. It was also published on the 9 June¹⁶. During this phase, the crisis procedures within EFSA were not yet activated. Nevertheless, a group was assembled, including staff from the BIOHAZ and BIOMO units with organisational support from the EMRISK unit, effectively a *de facto* Operational Team, as described in EFSA's urgent response procedures¹⁷. Despite this quick turn around, by the time the EFSA report was published, the outbreak investigation had moved on from fresh produce in general to fresh sprouted seeds. Such a rapidly developing understanding of an outbreak is typical, and flexibility needs to be anticipated in the urgent response.

¹³ EFSA; Shiga toxin-producing *E. coli* O104:H4 2011 outbreaks in Europe: Taking stock. EFSA Journal 2011; 9(10):2390.

¹⁴ Robert Koch Institute. Technical Report on presentation and evaluation of previous epidemiological findings regarding the EHEC/HUS O104:H4 outbreak, May/ June 2011. 30 June 2011.

¹⁵ EFSA ; Urgent advice on the public health risk of Shiga-toxin producing *Escherichia coli* in fresh vegetables. EFSA Journal 2011; 9(6):2274.

¹⁶ Joint EFSA/ECDC technical report: Shiga toxin/verotoxin-producing *Escherichia coli* in humans, food and animals in the EU/EEA, with special reference to the German outbreak strain STEC O104

¹⁷ <http://www.efsa.europa.eu/en/supporting/pub/102e.htm>

The second phase involved the placement of EFSA staff with the German authorities from Sunday 5 June, following a request from the European Commission and the German Federal Ministry of Food, Agriculture and Consumer Protection. While this was the first time a request for placing staff with a MS in the context of a crisis has been made to EFSA, to be ready for such an eventuality, staff had already been identified the days prior. They were people with expertise requisite for addressing the specific case, fluency in the MS's language, and familiarity with the MS's authorities involved in the crisis resolution. This phase was closed on the 17 June, following completion of the tracing of the seeds/sprouts of 41 outbreak clusters in Germany.

The final phase started with the reporting of the separate cluster in France (24 June) and involved EFSA coordinating at EU level the trace back process between Member States, to find the common source of the outbreak¹⁸. The EFSA crisis procedures were rapidly activated for this third part of the response, and EFSA benefited from being able to rapidly activate the groups and mailing lists from the previous phases of the response. This phase ended with the publication of the report on the tracing of fenugreek seeds⁵ (5 July).

The response for all three phases lasted for 6 weeks, excluding the follow up reporting activities. During this time staff from 10 EFSA units (AFSCO, BIOHAZ, BIOMO, CHAN, EDIT, EMRISK, IT, PLH, PRAS, SAS) and also individuals seconded from other units were involved at different intensities.

1. Declaration of a “crisis” and the establishment of a crisis management function

One of the critical stages in any outbreak investigation is the initial identification that there is an ongoing outbreak, and then the communication of this to the relevant parties. German authorities signalled this outbreak to the EC and MS on 21 May. EFSA was alerted on 24 May by its Communication team to the on-going outbreak in Germany following which EFSA commenced preparation for receiving an urgent request from the Commission for support on this issue. The Commission organised its first audio-conference with MS and relevant European Institutions on 26 May. The outbreak was discussed at EFSA's Advisory Forum meeting on the same day.

The criteria by which an incident such as a foodborne outbreak is determined to require an EU level response are indicated in Regulation (EC) No 178/2002 Article 53. Article 55 of the above mentioned Regulation refers to the General Plan for Crisis Management, and Articles 56 and 57 make reference to the Crisis Unit, and the inclusion of EFSA therein.

Epidemiological investigations of food-borne outbreaks, including tracing back, are always risk management activities as laid down in Article 8 of Directive 2003/99/EC. In the *E. coli* outbreak, EFSA was specifically requested by the Commission to coordinate the trace back activity to identify the source of the infection. Therefore, the division of responsibilities between risk management and risk assessment was clear.

Lessons learnt

The declaration of an incident should be clearly communicated, and the role of coordination of the technical response should be clearly attributed, particularly if this implies different reporting routes than normally apply in peace time. Similarly, a clearly communicated decision should be made to declare an incident finished.

¹⁸ EFSA ; Tracing seeds, in particular fenugreek (*Trigonella foenum-graecum*) seeds, in relation to the Shiga-toxin producing *E. coli* (STEC) O104:H4 outbreaks in Germany and France.

Considering that this was the first time in the last 9 years that EFSA has been asked to assist in an outbreak investigation, it would be useful to identify the particular properties of this outbreak that necessitated urgent technical support from EFSA, in order to be prepared for similar future requests.

2. Data collection

The recent outbreak demonstrated the importance of networking during times of crisis. Through its crisis exercises, through its formal data collection networks with MS, as well as through the Advisory Forum and the Focal Points, EFSA has put in place a culture of networking with, and between, the Member States and with the Commission. The day-to-day interaction through these groups has established important partnerships and shared working practices that enable smooth collaboration, which proved to be very valuable in times of crisis.

The exchange with MS of data relevant to this outbreak has been developed over the years through formal processes related to zoonoses data, and more recently, for data on exposure to chemical contaminants and residues in food. The work of the Biological Monitoring (BIOMO) and Dietary and Chemical Monitoring (DCM) units in this area means that EFSA has both the tools and the experience to manage data from the MS, and the MS are used to, and have confidence in, sharing information on a routine basis, with EFSA.

The data gathered through the zoonoses monitoring enabled, in collaboration with ECDC, the rapid compilation of an overview of STEC in humans, food and animals in the EU, so providing useful background information¹⁹. The two institutions collaborated well on this during the outbreak and also ensured a regular and open exchange of information.

The RASFF was used to exchange data on the trace back exercise. This follows the principle of using existing tools in times of crisis. Data exchange was fairly rapid, and access by all MSs to all data was thus assured. However, a possible shortcoming was (in the early stages) not reporting negative results through this system and that RASFF was not created as a tool for tracing products (data collection and analysis). These tools were developed during the course of the incident to identify the source of the outbreak.

The time taken to carry out the trace forward/backward exercise from start to completion may lead to the conclusion that traceability for plant products is in need of consideration, when compared to the extensive progress made for tracing animals and animal products.

Lessons learnt

Networking is key to the successful exchange of information. The establishment of databases in peace time is critical. Data most commonly used in crisis response should be identified and where practical, gathered in advance or at least their access secured in peace time. For this, an inventory of tracing systems for primary products could be established to characterise the existing traceability systems.

Methods and tools for tracing for the purpose of identifying the source of an outbreak should be further developed and tested in crisis exercises, involving all key actors, including the EU Reference Laboratories.

Criteria for reporting alerts into the RASFF by MS could be further developed. The role of EFSA in providing further assistance on the analysis of data reported to the RASFF, particularly in time of emergency, could be explored.

¹⁹ ECDC and EFSA. Shiga toxin/verotoxin-producing *Escherichia coli* in humans, food and animals in the EU/EEA, with special reference to the German outbreak strain STEC O104. Stockholm: ECDC; 2011.

In order to gather wider experience and opinion on the handling of this outbreak, it is also proposed that EFSA's Task Force on Zoonoses data collection and ECDC's Food- and Waterborne Disease Network provide feedback on the lessons learnt, particularly from the point of view of data gathering, and revising the recommendations on STEC serotypes to be monitored. These issues were addressed at a joint meeting of these networks in October 2011.

The BIOMO unit has regularly reported data on occurrence of enteric pathogens in vegetables and fruits collected by Member States, and these pathogens are seldom found. Also in the data on food-borne outbreaks, vegetables and fruits are among the minor food vehicle groups known to be involved in the outbreaks. Further analyses of these aspects might be useful, particularly the adequacy of the current diagnostic methods.

3. Crisis preparedness and training needs

Within EFSA, crisis preparedness is coordinated by the Emerging Risks unit (EMRISK)^{20 21}, which provides organisational support during rapid response. EFSA has over the last seven years, held seven training exercises, both in-house and also jointly with Member States' competent organisations. Recent training in 2011 was specifically targeted to those units addressing biological risks, as, until then, no urgent request concerning this type of hazard had been received by EFSA, hence these units were felt to be potentially the least current with EFSA's procedures for addressing urgent requests²². The theme of the training was data exchange with MS, which proved to be critical for the traceback operation EFSA was called upon to coordinate.

The EMRISK unit has, as its principal task, the identification of emerging risks in the food and feed chain. The approach for carrying this out is under development, but since autumn 2010, an approach for identifying emerging risks has been trialled. In this regard it is noteworthy that one of the issues identified was fresh produce (fruit and vegetables) being a potential emerging vehicle for exposure to enteric pathogens.

Lessons learnt

EFSA's crisis preparedness training was crucial in being ready to ensure a rapid response. The establishment of a unit (EMRISK) dedicated to coordinating crisis preparedness and also for establishing a process for anticipating new risks in the food/feed chain has been vindicated. Should the type of assistance provided by EFSA be a model for future operation, EFSA's capacity to coordinate traceback exercises could be further strengthened through exercises with Member States.

Coordination of and cooperation at EU level between concerned EU organisations during outbreak reporting and investigation needs strengthening. It would be beneficial if the Commission, ECDC and EFSA organise workshops with MSs to provide training on food-borne outbreak investigations and their reporting, for example through the "Better Training for Safe Food" programme coordinated by the Commission.

²⁰ Annual report on EFSA's food and feed safety crisis preparedness and response 2009.

<http://www.efsa.europa.eu/en/supporting/pub/100e.htm>

²¹ Annual report on EFSA's food and feed safety crisis preparedness and response 2010.

<http://www.efsa.europa.eu/en/supporting/pub/168e.htm>

²² EFSA procedures for responding to urgent advice needs.

<http://www.efsa.europa.eu/en/supporting/pub/102e.htm>

4. Communication

On 27 May 2011, EFSA issued a first brief statement informing interested parties that it was monitoring the German outbreak. The Authority issued a further seven news stories in the following five weeks addressing public health advice, the results of its urgent scientific advice as well as the role of the European Task Force. Public health advice was issued jointly with ECDC to ensure the European agencies were aligned.

EFSA tried to align its communication efforts with other organisations and liaise with its Focal Point and Advisory Forum Communications Working Group MS networks. The Authority also briefed the Commission's Health & Security Committee's Communicator's Network on its on-going activities on an *ad hoc* basis. Recognising the variety in consumer advice that was being given in different MS, EFSA created a table with an overview of who was communicating what and since when. This proved a useful tool for both Risk Communicators and Risk Managers.

EFSA's investment in establishing strong links with MS, also from a communications perspective, proved important also during this outbreak. However, after discussions with the MS, there was a sense that some were better informed about ongoing events than others. This arose from the involvement of only those MS directly implicated in the tracing exercise in the EFSA Task Force.

EFSA recognises that when it communicates on a specific MS-related issue, the seriousness of the situation takes on new proportions and questions can be raised regarding the ramifications for other MS and the European Union. It is crucial therefore, that the Authority does not communicate too early on an MS-specific issue even if this could be perceived as a slow response.

Lessons learnt

This outbreak highlighted the importance of EFSA's risk communications mandate, and the need to coordinate communication between risk managers and risk assessors. This is reflected in the increased number of media enquiries and visitors to the Authority's website for the period end May to early July 2011.

In order to improve information exchange in future crises, EFSA will propose means of communicating in a crisis to MS, through the Advisory Forum Communications Working Group, to ensure that there is equal access to information.

EFSA will follow-up with its respective networks to determine how in the future, it can better systematically capture MS communications on consumer advice.

Conclusion

The outbreak response was discussed in the Advisory Forum meeting of 28-29 September and the contributions from the MS were taken into account in this document. EFSA also presented its suggestions at a meeting organised by the Commission on 18 November 2011. It is understood that the Commission's post-crisis assessment will identify a number of follow up actions which will contribute to the revision of EFSA's procedures, with a view to improving its response.