







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

Part II: Crisis management procedures

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

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#### Effectiveness /1

- According to the intervention logic developed in close cooperation with the EC, 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.

#### Effectiveness /2

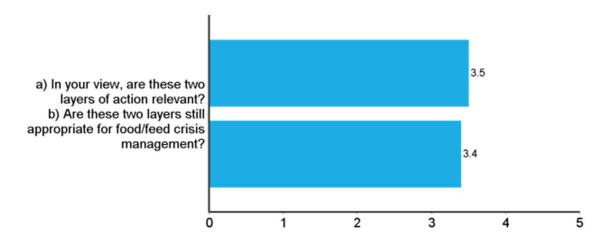
- Competent authorities and other relevant stakeholders that responded to our survey agree that existing crisis management arrangements at EU and MS levels have to a significant extent achieved consumer health protection, the efficient management of the incident and coordinated implementation of most effective measures to contain risk in past serious food/feed safety incidents.
- 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.
- Each aspect received a lower average rating at EU level than at MS level.

#### Effectiveness /3

- Evidence collected concerning case studies suggests that the effectiveness of crisis management arrangements differed considerably for different incidents.
- In the melamine crisis and glass fragments incident they were broadly considered to have been effective, while this was not the case during the E.coli outbreak.
- For this incident, the effectiveness was rated the lowest, and our case study confirmed that a limited disruption of the internal market and trade and upholding consumers' trust were not reached.
- Key factors that hindered their achievement included the difficulty to find the source of the outbreak and the lack of an effective strategy for communication to the public.

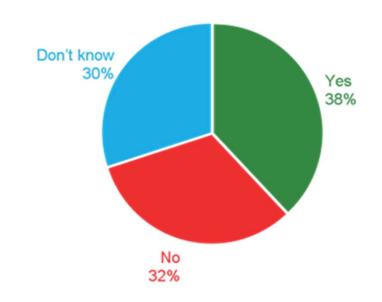
- A key question in the context of managing serious food/feed safety incidents is whether the EU legislative framework corresponds to the needs of food/feed crisis coordination.
- Current legislative framework (Commission Decision 2004/478/EC) provides two layers of action:
  - One layer of action related to potential serious risk, where a crisis unit is not set up but adequate provisions are made to ensure effective management;
  - Another layer of action implying the setting up of a crisis unit according to Article 56 of Regulation (EC) No 178/2002 (has not been used so far).

"In your view, are these two layers of action relevant? Are these two layers still appropriate for food/feed crisis management?"



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 largely relevant and still appropriate for food/feed crisis management.

"In your view, have the mechanisms foreseen in Sections 2.2 and 6 of Commission Decision 2004/478/EC (...) been sufficient for the management of past serious food/feed safety incidents?"



However, there are diverging assessments among respondents whether or not the first layer has been sufficient for the management of previous food/feed safety incidents.

- Case studies demonstrate that several dimensions of crisis and potential crisis management function effectively, e.g. information exchange on affected consignments and measures taken through the RASFF, coordination of measures and briefing on crisis situations through daily audioconferences led by EC, risk assessment and support to epidemiological investigations by EFSA, emergency measures taken by the EC.
- However, for 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 in the incident.

## Effectiveness and relevance: recommendations /1

- Results suggest that the effectiveness of crisis management differed considerably for different incidents, and that the current legal framework is less functional for addressing more complex crisis situations such as the E.coli outbreak. Commission Decision 2004/478/EC should therefore be reviewed and updated.
- This review could address:
  - 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 resources to be dedicated progressively.

## Effectiveness and relevance: recommendations /2

- Effective linking of food/feed safety and public health emergency procedures at EU level in case serious food/feed safety incidents affect public health;
- Replacing 'crisis unit' with a more neutral term, such as 'task force' to reduce possible public concerns in case additional resources have to be assigned to incident management under a step-wise escalation approach;
- The role of the network of crisis coordinators be reviewed.

## **Emergency measures and role of the European Commission /1**

- Central role of EC in the management of serious food/feed safety incidents, including through adopting emergency measures under Article 53 of Regulation (EC) No 178/2002. A large number of food/feed safety incidents have been contained and managed by the European Commission on this basis.
- Emergency measures used as instruments for the management the melamine crisis and the E.coli outbreak: these were considered to have been effective by interviewees as well as survey respondents.

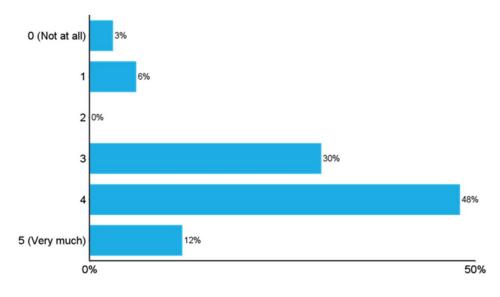
# **Emergency measures and role of the European Commission /2**

Excerpt of table presenting emergency measures adopted by the European Commission on basis of Article 53 of Regulation (EC) No 178/2002 (2002-2013)

Year adopted	Emergency measure	Legal instrument	Amended	In force
2002	2002/250/EC: Commission Decision of 27 March 2002 concerning the extension of the protective measures provided by Decision 2001/699/EC, with regard to the fishery and aquaculture products imported from Vietnam	Commission Decision		
2002	2002/247/EC: Commission Decision of 27 March 2002 suspending the placing on the market and import of jelly confectionery containing the food additive E 425 konjac	Commission Decision		
2002	2002/249/EC: Commission Decision of 27 March 2002 concerning certain protective measures with regard to certain fishery and aquaculture products intended for human consumption and imported from Myanmar	Commission Decision		
2002	2002/251/EC: Commission Decision of 27 March 2002 concerning certain protective measures with regard to poultry meat and certain fishery and aquaculture products intended for human consumption and imported from Thailand	Commission Decision	٧	٧
2002	2002/805/EC: Commission Decision of 15 October 2002 concerning certain protective measures with regard to certain products of animal origin for animal nutrition and imported from Ukraine	Commission Decision		٧
2002	2002/794/EC: Commission Decision of 11 October 2002 concerning certain protective measures with regard to poultry meat, poultry meat products and poultry meat preparations intended for human consumption and imported from Brazil	Commission Decision	٧	
2003	2003/477/EC: Commission Decision of 24 June 2003 amending Decision 2002/251/EC to revoke the protective measures with regard to the fishery and aquaculture products imported from Thailand	Commission Decision		
2003	2003/460/EC: Commission Decision of 20 June 2003 on emergency measures regarding hot chilli and hot chilli products	Commission Decision	٧	
2003	2003/493/EC: Commission Decision of 4 July 2003 imposing special conditions on the import of Brazil nuts in shell originating in or consigned from Brazil	Commission Decision		

### **Emergency measures**

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



9 in 10 respondents assessed emergency measures as effective for the management of serious food/feed safety incidents. A nearly as large majority assessed that they contributed to avoiding disparities between measures taken by MS and to ensuring a consistent approach in previous incidents

- Satisfaction with the EC's role of coordinator in past serious food/feed safety incidents was high for coordination with EFSA (3.7), coordination with international organisations and coordination with third countries (both 3.6).
- 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), while still positive.
- The role of the European Commission as coordinator was also 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.
- Coordination of communication to the public/relevant competent authorities seen as the weakest aspect, specifically in the E.coli outbreak.

- A significant number of complementary measures were taken by the EC, partly in response to the E.coli outbreak:
  - Cross-border crisis simulation exercise *Aristaeus*;
  - Working group to identify best practices for communication in times of crisis;
  - SOPs for rapid foodborne outbreak assessment;
  - Draft SOPs for crisis management;
  - FVO fact-finding missions;
  - BTSF;
  - Request to EFSA for technical support for the collection of molecular typing results of food borne pathogen.

"To what extent has the EC contributed to the coordination of national efforts (e.g. in outbreak investigations)?"



Among coordination activities that were examined, competent authorities tended to see the provision of training by the EC as contributing the most to the coordination of national efforts. The provision of guidance documents/SOPs and the sharing of technical information by the EC was also seen as contributing to the coordination 5 of national efforts.

#### Role of the EC: recommendations

- Implement measures/procedures to safeguard clear and effective communication during serious food/feed safety incidents, involving relevant EU and MS institutions.
- Continue and reinforce EU measures to improve crisis management procedures and preparedness and to test them on a regular basis during EU crisis simulation exercises, which should at least involve key contact points in MS, both for handling crisis management measures and communications.
- Continue FVO review of contingency plans/procedures at MS level, and conduct evaluations of crisis management procedures (with relevant MS) after a serious food/feed safety incident has been closed, to identify possible deficiencies and lessons learnt.

#### **Involvement of EU Member States /1**

- Member States are primarily responsible for assessing and countering risks deriving from food and feed.
- Article 13 of Regulation (EC) No 882/2004 requires Member States to draw up contingency plans. Most Member States that provided relevant information have adapted to meet this requirement, though in different ways:
  - Specific contingency plans for use in food/feed safety incidents;
  - General plan that can also be activated for a food/feed safety incident;
  - Sets of procedures to be used in food/feed safety incidents.

## Availability of contingency plans

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

#### **Involvement of EU Member States /2**

- A large majority of MS also report to have fulfilled the obligation of specifying the administrative authorities to be engaged in case of a serious food/feed safety incident, 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 that links to public health contingency planning are less frequent.
- The E.coli outbreak and crisis simulation exercises have led to reviews of crisis preparedness/crisis management arrangements in most MS that answered to our survey.

## **Involvement of EU MS:** recommendations /1

- It is recommended that MS review their contingency planning in regular intervals, specifically after a serious food/feed incident to improve arrangements in light of lessons learnt. Essential best practices include linking of food/feed safety and public health emergency procedures in case of food/feed safety incidents affecting public health.
- Changes in the designated contact points for crisis management should be communicated immediately to the EC to safeguard smooth coordination of measures.

## **Involvement of EU MS:** recommendations /2

- It is recommended that Member States organise crisis simulation exercises and trainings to complement EU level exercises. 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.

# Participation of Third Countries and International Organisations /1

- A key area of crisis management that relates to third countries is the use of 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 to seek ways to remedy the situation and normalise trade relations.
- Following the E.coli outbreak, the FVO carried out an audit in Egypt to trace back the source of the infection, evaluate the production /processing conditions and review emergency measures taken (Commission Implementing Decision 2011/402/EU).

# Participation of Third Countries and International Organisations /2

- 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 MS.
- Results also 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.
- Potential of RASFF for reaching beyond EU borders in crisis management: 107 countries with access to notifications via RASFF Window and increasingly close cooperation with INFOSAN.

# Third Countries/ International Organisations: recommendations /1

- Approaches for communication and cooperation of EU institutions with third countries or international organisations in a serious food/feed safety incident could be formalised, e.g. through dedicated SOPs or their inclusion in a revised version of Commission Decision 2004/478/EC.
- Recommended to strengthen international cooperation with third countries and international organisations to develop/refine contingency planning in third countries and increase capacities for crisis management in the area of food and feed through continued training programmes (such as BTSF).

# Third Countries/ International Organisations: recommendations /2

- The role of notification systems such as the RASFF as communication tools for the management of serious food/feed safety incidents could also be emphasised to this end.
- The EC could initiate and support a programme of voluntary reviews of contingency plans and procedures of third countries with significant potential for involvement in future serious food/feed safety incidents that could affect the EU, to provide benchmarking and allow for the dissemination of best practices.

### Efficiency /1

- In our survey, MS competent authorities assessed the balance of costs and benefits of crisis management at EU level as appropriate.
- The case studies 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 are considered to have been higher than the unavoidable minimum, e.g. in the E.coli outbreak. 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 have prevented or contained negative impacts remains unclear.

## Efficiency /2

#### Estimated costs of selected food/feed safety incidents (2002-2013)

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

## Efficiency /3

- Measures to improve the efficiency of crisis management arrangements relate 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 occurs.
- Suggestions made by MS 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 could be increased by refining the respective tasks and roles of existing mechanisms.

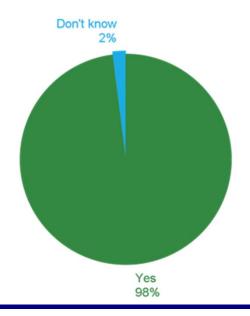
### Efficiency: recommendations

- 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 NCPs;
  - The Standing Committee on Plants, Animals, Food and Feed (PAFF).

This could be achieved 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.

## Added value of EU crisis management /1

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



- There is broad and unanimous consent that there is an added value resulting from the EC coordinating crisis management.
- All competent authorities (100%) who provided an answer viewed EC coordination of crisis management as providing an added value.

## Added value of EU crisis management /2

- 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.
- By strengthening its role as coordinator and improving its crisis management structure, the EC could increase the added value it brings to crisis management.