

# PROJECT DOCUMENT

## Development of a Guidance Document for the Management of (Micro)biological Foodborne Crisis/Outbreaks

(Prepared by the European Union)

### 1 Purpose and Scope of the Guidance Document

The purpose of the new work is to provide guidance to competent authorities on the management of foodborne outbreaks/crisis. Such guidance intends to contribute to the limitation of the extent of such events by enhancing preparedness and an improved management. It is proposed to limit the scope to biological hazards but an extension to other hazards (chemical) might be considered at a later stage.

### 2 Relevance and Timeliness

Most Codex standards provide guidelines on general or sector-specific good hygiene practices, good manufacturing practices, etc. intended to prevent contamination and exposure of humans to hazards through the consumption of food. Unfortunately, exposure cannot always be prevented and sporadic cases or multiple cases linked to the same food source (outbreak, possibly crisis if very severe or extended) can occur. The proposed risk management guidance document therefore supplements the existing standards in cases where prevention was not fully effective.

### 3 Main aspects to be covered

The guidance will address recommendations on preparedness for outbreaks and on their management.

Preparedness will focus on recommendations to have a structured approach in place and maintained before an outbreak occurs. It will address the following aspects, but may not be limited to these:

- alert networks for public health and food safety,
- the use of molecular typing data of pathogens facilitating the detection of links between human cases and food,
- structures and tools to ensure exchange of information between public health and food safety authorities,
- the establishment of permanent management and crisis communication networks,
- traceability provisions,
- simulation exercises and trainings.

As regards outbreak/crisis management, recommendations will focus on the following aspects, but may not be limited to these:

- investigations in humans in order to identify the likely food source,
- (rapid) risk assessments,
- tracing back and forwards of the affected food,
- robustness of information (such as molecular typing analyses, environmental and epidemiological investigations),
- communication to consumers and trade partners.

## **4 Assessment against the Criteria for the establishment of work priorities**

### **4.1 Ensuring fair practices in food trade and taking into account the identified needs of developing countries**

Food-borne outbreaks/crises have a direct effect on public health (morbidity and sometime mortality). They are often accompanied by disproportionate reactions by consumers and trade partners, not only the affected batches. Guidelines on a structured approach for outbreak/crisis management and communication may limit these effects and result in a better preparation for such events in developing and developed countries.

### **4.2 Diversification of national legislation and apparent resultant or potential impediments to international trade**

Legislation on food safety focuses on prevention, monitoring and corrective actions (if required). In case of a foodborne outbreak or crisis, the lack of a coordinated approach, e.g. between public health and food safety authorities, and of a communication strategy might create confusion and uncertainties, causing impediments to domestic consumption and international trade. The introduction of a approach, agreed at global level, could reduce the impact on trade.

### **4.3 Scope of work and establishment of priorities between the various sections of the work**

See 4.7.

### **4.4 Work already undertaken by other international organisations in the field and/or suggested by the relevant international intergovernmental bodies**

Relevant is the "*FAO/WHO guide for application of risk analysis principles and procedures during food safety emergencies*"<sup>1</sup>. The FAO/WHO guide is generic. The new standard would provide a more integrated approach including links with data from investigations in humans towards the source and elaborating the tracing back and forward of affected consignments. Attention should also be drawn to some new tools (e.g. molecular testing), which contribute to the investigations and are specific for microbiological hazards.

The WHO "*Foodborne disease outbreaks: Guidelines for investigation and controls*"<sup>2</sup> focuses at investigations in humans cases and provides a summary of preliminary risk assessment data.

The "*FAO/WHO framework for developing national food safety emergency response plans*"<sup>3</sup> provides a generic basis for preparedness.

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<sup>1</sup> [http://apps.who.int/iris/bitstream/10665/44739/1/9789241502474\\_eng.pdf?ua=1](http://apps.who.int/iris/bitstream/10665/44739/1/9789241502474_eng.pdf?ua=1)

<sup>2</sup> [http://www.who.int/foodsafety/publications/foodborne\\_disease/outbreak\\_guidelines.pdf](http://www.who.int/foodsafety/publications/foodborne_disease/outbreak_guidelines.pdf)

<sup>3</sup> <http://www.fao.org/docrep/013/i1686e/i1686e00.pdf>

## **4.5 Amenability of the subject of the proposal to standardization**

Although food-borne outbreaks/crises are caused by a large range of hazards and circumstances might be different, a guidance document is needed providing a structured approach for the management of foodborne outbreaks/ crises in order to be well prepared, to limit the public health and trade impact and to act efficiently in a situation which requires immediate action.

## **4.6 Consideration of the global magnitude of the problem or issue**

Food-borne outbreaks/crises occur everywhere in the world. As examples, in 2015 over 4 300 (micro-)biological foodborne outbreaks were reported in the EU, involving more than 36 000 human cases, over 3 800 of which were hospitalised and 17 died, despite the presence of relatively high preventive food safety standards.

## **4.7 Criteria for the evaluation and prioritizing new Work by the Codex Committee on Food Hygiene**

### **4.7.1 Currency of information: Yes**

Collecting and sharing experiences in order to enhance preparedness all over the world may reduce the public health and trade impact of future outbreaks/crises.

In addition, more and more data become available from new molecular analytical methods (e.g. whole genome sequencing), facilitating the identification of clusters human cases and the food source. This information allows earlier detection of outbreaks, an improved management of such incidents and enables to, better narrow the identification of involved batches, and hence reduce the impact of actions taken.

There is a need to deal with these new and complex data in an appropriate risk management and risk communication framework.

### **4.7.2 Positive impact on public health – foodborne risk to public health: Yes, high rating (20)**

There are numerous descriptions of the public health impact of foodborne outbreaks. See also 4.6. In 2011, a single outbreak of STEC O104:H4 from sprouted seeds caused disease in at least 4 000 humans of which 55 died. Listeria in deli meat caused disease in 57 people, of which 24 died, in Canada in 2008. Better preparedness and management have a high potential to gain a positive impact on public health.

### **4.7.3 Impact on trade due to public health risk: Rating of 10**

The guidance is relevant for all food. Food outbreaks may result in reluctance of consumers to buy the specific culprit food or even other foods not directly associated with the outbreak. Consumers' confidence may further reduce by premature and inappropriate communication on the source of the outbreak. Restoring consumers' confidence is usually difficult and lengthy, putting food business operators in dire situations. During the 2011 STEC outbreak, farmers' losses in the fruit and vegetable sector were estimated at 812 Mio € in the first 2 weeks only. Export bans constituted an annual value of 600 Mio €. The lawsuit in Ontario was claiming damages of \$350 million for the 2008 Listeria outbreak.

## 5 Relevance to the Codex strategic objectives

### Strategic goal 1: Establish international food standards that address current and emerging food issues

(Micro-)biological outbreaks occur every day. Due to new analytical methods it is expected that the number of identified outbreaks will increase. This does not indicate an increased public health risk *per se*, as they were just not identified in the past, but it does enhance the need to manage outbreaks properly since they may have a significant economic impact (impact on consumption and on trade).

### Strategic goal 2: Ensure application of risk analysis principles in the development of Codex standards

The guidance document will not address a specific hazard or food commodities. It is intended to be relevant to all micro-biological hazards in all kinds of food causing an outbreak. The guidance document will include the three components of risk analysis in a distinct way: it will provide recommendations on preliminary risk management activities, including an initial, quick risk assessment within an outbreak situation, on what risk management measures should be in place to be well prepared and to limit the extent of an outbreak and on how communication should try to reassure consumers and trade partners on the safety of food produced.

### Strategic goal 3: facilitate the effective participation of all Codex Members

As outbreaks can occur anywhere in the world, the proposed guidance is of relevance for all members. In particular competent authorities of developing countries may benefit from this guidance since they may not have the resources to develop such guidance themselves. We therefore anticipate electronic working groups and physical, adjacent to CCFH meeting, when possible, and providing translation in the official languages of the Commission to the extent possible.

### Strategic goal 4: Implement effective and efficient work management systems and practices

During the development of the guidance, all working documents and electronic discussions will be distributed in a timely and transparent matter through the e-forum at <http://forum.codex-alimentarius.net/>. As the revision progresses, the latest versions of the texts will be translated to the official languages of the Commission ahead of the annual Committee meetings.

## 6 Information on the relation between the proposal and other existing Codex documents

The guidance will supplement the existing Codex standards that focus on the prevention of foodborne hazards and outbreaks. The proposed guidance provides recommendations in cases where prevention failed.

## 7 Identification of any requirement for and availability of expert scientific advice

Expert scientific advice is not needed as input to start this work since many different hazards and food commodities might be involved, for which risk assessments often already exist. The WHO "*Foodborne disease outbreaks: Guidelines for investigation and controls*" provide an overview of the epidemiology and methods of control and prevention of most important foodborne diseases.

## **8 Identification of any need for technical input in the standard from external bodies so that this can be planned for**

No additional need is identified at this stage.

## **9 The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at step 5, and the proposed date for adoption by the Commission.**

If the document is accepted for new work at CCFH 49 in 2017, conceivably it could go to Step 3 at CCFH50 in 2018. The 'guidance document' could go to Step 5 at CCFH51 (2019) and Step 8 at CCFH 52 (2020) with final adoption by CAC in 2021.