

**European Union comments**  
**CODEX COMMITTEE ON FOOD HYGIENE**  
**Fiftieth Session**  
**Panama City, Panama**  
**12-16 November 2018**

**Agenda Item 8: Proposed draft guidance for the management of  
(micro)biological foodborne crisis/outbreaks (CX/FH 18/50/8)**

*Mixed Competence*  
*European Union Vote*

The European Union and its Member States (EUMS) would like to thank and congratulate Denmark, the EU and Chile as chair and co-chairs of the EWG for the development of the first version of a draft guidance for the management of (micro)biological foodborne crisis/outbreaks.

The EUMS very much appreciate the work done and consider that the drafts has an added value in guiding competent authorities in being prepared for and manage biological foodborne outbreaks. A number of comments, mainly for editorial/consistency/clarity purposes, are provided below and need to be considered to further improve the draft.

### **Recommendations of the eWG**

The EUMS agree to continue this work. The EUMS in particular support the interdisciplinary approach and international cooperation in crisis preparedness that is given due prominence in the document.

As regards the scope and the terms used:

- a. and c.

The EUMS welcome a debate on the terminology "foodborne outbreak", "foodborne illness outbreak", "food safety emergency", "food safety event" and "food safety incident". The EUMS has no fixed position on this terminology and are willing to consider all options. However, the following remarks should be taken into account:

- Clear differentiation should be made between "outbreaks", which always include the detection of human cases, and broader wording (emergency, event, incident, crisis), which may include emergencies/events/incidents without detected human cases but where the detection of a serious

biological hazard in food, already largely distributed to consumers may indicate a substantial risk to a large group of consumers.

- Since the wording/definition "foodborne outbreak" already includes the detection of human illness cases, the wording "foodborne illness outbreaks" does not seem relevant.
  - In the EU experience, in the case of biological hazards, foodborne emergencies/events/incident are always accompanied by human cases, and therefore "foodborne outbreak" is considered as the most relevant term within the context of this guidance document.
  - Additionally, the use of "emergency/event/incident" to cover also "linked cases" without detected human cases, might open the scope too widely, covering any case where a biological hazard is detected in food.
- b.  
The EUMS believe that all biological hazards should be covered by the scope of this guidance; however specific emphasis should be given to microbiological hazards as microbiological hazards are most frequently the source of foodborne outbreaks.
  - d.  
The definition of "rapid risk assessment" in the WHO guidance "Strengthening surveillance of and response to foodborne diseases" should be used if considered appropriate within this draft (preferred option). If not appropriate within this draft, the wording "rapid outbreak assessment" should be used and defined to differentiate from the WHO wording. Only one term should be used in any case.

## Other general comments

### References

The EUMS suggest consulting the Codex secretariat on the way references to existing Codex Alimentarius and FAO/WHO documents are made (references in superscript). Spelling out these documents in the relevant sections might be more appropriate.

## Specific comments

- Paragraph 3: It might be considered to move this paragraph to the beginning and the following revision of the second sentence is proposed: "Foodborne ~~illness~~ outbreaks **contain several human cases of illness and** can have ..."  
**Rationale:** See general comment + to make a better link to the first sentence.
- Paragraphs 7 and 8: Pending on the outcome of the discussion on the terminology (see first general comment) these paragraphs need to be redrafted. The EUMS support that these paragraphs should explain that only one term is used throughout the draft but different wordings might be used at the discretion of competent authorities depending on a number of factors such as the extent and severity of human cases, perception by consumers and trade implications.  
**Rationale:** Editorial, for clarification and simplification.

- Paragraph 9: it is proposed to amend the first sentence as follows: "This document ~~collects~~ **provides** guidance ..."  
**Rationale:** Editorial.
- Paragraph 12: it is proposed to amend the first sentence at the end: "Codex Alimentarius ~~guidelines~~ **Codes of Hygienic Practice**."  
**Rationale:** Differentiation from guidelines referred to in second sentence. The EUMS consider that it is relevant to refer to these codes since they are the most relevant tools to prevent outbreaks.
- Paragraph 15: it is proposed to amend as follows: "of the current guidelines, ~~providing~~ **to provide** more detailed..."  
**Rationale:** editorial (not clear if "providing" refers to "guideline" or "documents").
- Paragraph 17:
  - see first general comment. The following definitions of a foodborne outbreak is proposed:  
"A **foodborne outbreak is**
    - **an incident of two or more human cases of the same disease and/or infection, or a situation in which the observed number of cases exceeds the expected number, and**
    - **where the cases are linked or probably linked to the same food source.**"**Rationale:** the observation of an increase of human cases should be considered as an outbreak. In addition there must at least be a probable link with a food source to call the outbreak "foodborne".
    - The definition of "monitoring" in CAC/GL 69-2008 could be considered instead of the proposed one.  
**Rationale:** consistency of terminology with other guidelines.
- Paragraph 19: it is proposed to replace the last sentence as follows: "The network should ~~take into account e.g.~~ **build on existing networks for** surveillance and monitoring **foodborne biological hazards in** ~~programmes for~~ humans and food **and** laboratory networks ~~and conditions for food production and distribution~~.  
**Rationale:** editorial; the last part is proposed for insertion in paragraph 21 (see below).
- Paragraph 21: it is proposed to add the following sentence after "daily routines": **"Participants should also have a good knowledge of the conditions for food production and distribution."**  
**Rationale:** moved from paragraph 19.
- Paragraph 22: it is proposed to replace "surgeon" by "local health authority"

**Rationale:** editorial.

- Paragraph 25 last bullet: it is proposed to amend as follows: "There is a ~~practice~~ **facility** in place..."

**Rationale:** It may not always be necessary to use an external group of experts.

- Paragraph 29: it is proposed to amend the second sentence as follows "However data from surveillance and monitoring of animals, feed, food and the environment, including equipment of food businesses ~~may also indicate an enhanced risk and are of value/assistance~~ **are essential** to help identify the source of a food safety [emergency/incident/event]".

**Rationale:** while to essential role of surveillance and monitoring of animals, feed, food and the environment is recognised, the detection of hazards in them without human cases should not be identified as a foodborne outbreak.

- Paragraph 31,
  - End of introductory part: It is proposed to replace "and may include" by "and it is recommended that they include where possible"
  - second bullet: it is proposed to amend as follows "The use of **preferably harmonised and** standardized laboratory methods to allow comparability..."

**Rationale:** Methods should not only be standardized but also harmonised to the extent possible.

- Paragraphs 32 and 33:
  - It is proposed to limit paragraph 32 to molecular testing in general (e.g. first paragraph only). Paragraph 33 should cover specifically WGS and could be: "**An increasing use of very specific whole genome sequencing as molecular typing is encouraged and expected to become more and more important in the next few years.** The use of WGS for surveillance .... (continue with the rest of the second paragraph of paragraph 32).
  - ~~Whole genome sequencing methods~~ (WGS) **methods** are more costly than other typing methods which can be an obstacle for their implementation. Furthermore the cost per analysis will be higher if the total number of tests is low. **Collaboration between countries to carry out WGS is therefore strongly encouraged.**"
  - A definition of "metadata" should be considered.

**Rationale:** Recommendations on the use of molecular methods in general should be included separately as not everybody may have access to WGS. Considering the increasing importance of WGS, but the difficulties some countries may have to use it, it should be treated separately and collaboration encouraged.
  - A definition of "metadata" should be considered.
  - It is proposed to replace (2x) "molecular testing" by "molecular typing".

- It is proposed to amend the end of the 4<sup>th</sup> bullet of paragraph 32 as follows: "... the samples thus only ~~allowing few metadata to follow the sequences~~ **providing a small amount of metadata with the published sequence.**"
- Headings below paragraph 42 and 46  
It is proposed to replace "side" by "approach" or delete the word  
**Rationale:** editorial
- Paragraph 47: the wording "food source or a location" is not clear. Does it refer to food sourced at a specific place?  
**Rationale:** Clarification needed.
- Paragraph 49:
  - It might be useful to define or describe "tracing backwards" and "tracing forwards".  
**Rationale:** Clarity of understanding
  - The last sentence should be amended as follows: "The information gathered should be compared with the epidemiological information ~~of the outbreak~~ **on the human cases** to see if cases are consistent with product distribution.  
**Rationale:** clarity.
  - It is proposed to add an additional sentence after "... and product data are available": " **For data to be useful, it should be gathered in a standard way using templates and business names and product descriptions curated to ensure that links are not lost due to abbreviation or spelling mistakes.**"
- Paragraph 53, second sentence: the EUMS propose the following amendment: "The ~~decided~~ **agreed** level may ..."  
*Rational:* editorial
- Paragraph 55: the EUMS propose to delete this paragraph  
**Rationale:** Repetition (addressed in paragraph 58).
- Paragraph 58: It is proposed to redraft this paragraph as follows: "Robust epidemiological evidence may be conclusive of the food safety incident even without positive laboratory results. **Efforts by sampling and analysis should be made to allow** laboratory results ~~can~~ **to** support the ~~epidemiology~~ **epidemiological evidence.** ~~but they will only be conclusive if the result is~~ Analytical evidence **should** be supported by ~~at least~~ some epidemiological information such as that obtained from the patients. **Since molecular testing and in particular WGS is becoming more and more specific, it might be very useful to search for isolates in food data bases with similar molecular profiles as in a cluster of human cases. If very similar profiles are found, targeted epidemiological investigations to identify the source should be carried out to confirm or exclude a possible link.**"

**Rationale:** It is proposed to elaborate the guidance in this paragraph based on experiences gained.

- Paragraph 59:
  - The paragraph should be redrafted since there seems to be some contradiction between the first sentence (a risk assessment should be carried out) and the second sentence (a risk assessment or outbreak assessment can be helpful).
  - The Committee may consider the usefulness for a model/template of a rapid risk/outbreak assessment.

**Rationale:** Urgent action is needed. Therefore, a ready-to-use template may facilitate quick action by competent authorities.

- Paragraph 61: in section e. Risk communication, a reference to the Principles and guidelines for the exchange of information in food safety emergency situations (CXG 19-1995) should be included.
- Paragraph 62: The following redrafting is proposed: "At the beginning of an incident, during the period when information is being gathered **and the source is not known yet**, there may be ~~be confusion~~ **uncertainty for the public and media interest may be difficult to handle. In such situations, it is extremely important to strictly follow the recommendations in this section on risk communication. Any premature announcement which might have to be recalled when not confirmed, may create a lot of confusion, fear and more uncertainty of consumers and trade partners.** ~~Ideally, risk communication will provide stakeholders outside the formalized network structure with the information they need to make informed decisions.~~

**Rationale:** It is proposed to expand this paragraph providing more guidance. A revision of the last sentence seems more appropriate in paragraph 63.

- Paragraph 63:
  - The nomination of an official communicator could be addressed in paragraph 41 on preparedness.  
**Rationale:** can be considered as part of preparedness.
  - It is proposed to add the following bullet point: "**Inform before the communication all relevant partners in order to allow them to be prepared for such communication and to provide to the extent possible the same message. Relevant partners include affected food business operators, affected competent authorities within the country (regional-central level, other regions where the affected food was distributed), affected competent authorities in other countries.**"

**Rationale:** It is important to coordinate communication with all affected partners.

- The need for one central website where people can find information about the outbreak should be included.
- Fifth bullet: the following amendment is proposed: "... an explanation of the cause, **where known**, and what is being done ..."

**Rationale:** the cause may not be known (yet).