

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
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World Health
Organization

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Agenda Item 7

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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PROPOSED DRAFT GUIDANCE ON THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS

Comments at Step 3 in reply to CL 2019/71 -FH

Comments of Ecuador, European Union, Ghana, Nigeria, Senegal and Tanzania

Ecuador

Comentarios generales:

Ecuador agradece la propuesta realizada por el Grupo de trabajo por medios electrónicos y una vez revisado el ANTEPROYECTO DE ORIENTACIONES PARA LA GESTIÓN DE BROTES BIOLÓGICOS TRANSMITIDOS POR LOS ALIMENTOS, considera que el documento abarca los puntos básicos y necesarios para el establecimiento de un sistema de preparación y gestión de brotes biológicos transmitidos por los alimentos; así como también el país coincide en que las medidas de gestión de riesgos que se elijan, van a variar según la situación y el marco regulador de las autoridades competentes.

Con relación a la plantilla para la evaluación rápida de riesgos y la estructura gráfica de la red que figuran como anexos, estos instrumentos servirán de referencia y orientación cuando la situación lo amerite.

Por tanto, el país considera apoyar el documento y continuar en el trámite correspondiente.

European Union

The European Union and its MS (EUMS) would like to thank and congratulate Denmark as chair and Chile and the European Union as co-chairs for the development of this draft guidance.

The EUMS can support the conclusions made by the electronic working group and can, in general, support the Guidance.

The EUMS would like to make the following comments:

General comments:

The concept of rapid risk assessments is not satisfactorily described and needs to be more elaborated, in particular concerning the essential step of "formulating risk questions". Please see (and refer to) the WHO document "Rapid Risk Assessment of Acute Public Health Events" for better guidance to rapid risk assessments.

Specific comments:

- Paragraph 1, first sentence: The following amendment is proposed: "Foodborne illnesses encompass a wide spectrum of illnesses and are ~~a growing public health problem worldwide~~ **an important public health problem.**"

Rationale: "Growing public health problem" is not based on a shared notion applicable everywhere as it relies on data produced in a specific national context. It is therefore more appropriate to use the expression "important public health problem."

- Paragraph 1, last sentence: The following amendment is proposed: "The contamination.... and can result **from the presence of zoonotic hazards in animal production or** from environmental contamination, ..."

Rationale: animals, being sometimes carriers of zoonotic hazards, can also result in the contamination of food (e.g. poultry flocks infected with *Campylobacter*).

- Paragraph 2, first sentence: The following amendment is proposed: “Biological food-borne illness usually takes the form of gastrointestinal symptoms; however, such illnesses can also have neurological, gynecological, immunological and other symptoms, ~~including multi-organ failure.~~”

Rationale: underlining this type of syndrome (more than other illnesses) is not justified.

- Paragraph 3, first sentence: The following amendments are proposed: “**Large B**iological foodborne outbreaks ~~e.g. when the illness affects more people due to a common source,~~ can have significant socio-economic costs...”

Rationale: This conveys the same message but is easier to read

- Paragraph 5: The following amendments are proposed: “Such networks should use comparable methods and interpretations. ~~Cooperation and~~ **as well as** transparent exchange of information. **Full cooperation** through international networks is essential and should be a feature of any **national** network.”

Rationale: Current wording only links transparent exchange of information with international networks when it should be a feature of all networks

- Paragraph 7, fifth line: The following amendments are proposed: “(as e.g. Whole Genome Sequencing (WGS) and **Multilocus Sequence Typing (MLST)**)”.

Rationale: The use of WGS and MLST as examples will keep the document relevant into the future when other methods come into use

- Paragraph 7, last sentence: The following amendment is proposed: “The increase in the use of this methodology **is relevant and** will probably lead to the detection of more outbreaks in the future and the need for enhanced preparedness.”

Rationale: use of specified and reference methodology needs to be highlighted.

- Paragraph 10: The EUMS would appreciate clarification of the word “recovery” in this context.

- Paragraph 11, end of second sentence: The following amendments are proposed: “...as well as ~~recovery,~~ post outbreak **control** measures and “~~after action reviews~~” **outbreak management review** when an outbreak has been resolved.”

Rationale: It is not clear what is meant by ‘recovery’. ‘Outbreak measures’ is not a specific description and ‘after action review’ is not a well-known term internationally.

- Paragraph 13, first sentence: The following amendment is proposed: “A number of FAO/WHO documents describe in more details some.”

Rationale: editorial.

- Paragraph 23: The following amendment is proposed: ‘...(e.g. molecular testing such as ~~WGS~~ **whole genome sequencing**)..’

Rationale: Use of acronyms in definitions should be avoided to ensure maximum clarity.

- Paragraph 30: The following amendments are proposed: ‘In the following paragraphs, the composition and tasks of the networks ~~at any level~~ of competent authorities within a country are described. ~~These~~ **Competent authorities**, others than national/federal ones, are referred to as “local” ~~which and these~~ may contain sublevels that should all be involved.’

Rationale: Proposed rewording to improve the language and flow of the paragraph without changing the meaning.

- Paragraph 34, third bullet: The following amendment is proposed: ‘Supporting the local networks where needed ~~and maintain the communication channels;~~’

Rationale: Maintaining communication channels is already included in bullet 1 of the same paragraph.

- Paragraph 34, fourth bullet: The following amendment is proposed: ‘Assessing surveillance and monitoring data ~~information~~ received from the participating authorities/agencies;’

Rationale: The word ‘information’ is not necessary when using the word ‘data’

- Paragraph 35, first sentence: The following amendment is proposed: ‘The networks ~~and the structures~~ should be based on existing structures in the participating authorities and agencies’

Rationale: Best to focus on the networks having a structure which is the thrust of the paragraph. The concept of structure having a structure may be confusing.

- Paragraph 37, fifth bullet: Propose to replace “chapter e” by “Chapter E” or “Section E”.

Rationale: editorial.

- Paragraph 43, second bullet: The following amendment is proposed: ‘Access to relevant information on cases ~~for~~ of illnesses that do not require notification to human health authorities and an assessment of the usual level of illness’

Rationale: editorial.

- Paragraph 48, first sentence: The following change is proposed: “... but in recent years, other genetic based methods like WGS ...”

Rationale: Clarification purpose: MLVA is a genetic based method.

- Paragraph 53, last sentence: Propose to delete.

Rationale: repetition of preceding sentence.

- Paragraph 54, second bullet, last sentence: It is proposed to replace the last sentence by: “Examples are provided in Annex III of this Guidance and in Annex III of the WHO “Foodborne Disease Outbreaks: Guidelines for Investigations and Controls”.

Rationale: Editorial and clarity.

- Paragraph 57, first bullet: The following amendments are proposed: ‘Establish a **public** communication strategy ~~for among~~ the network members ~~and where appropriate~~, designate official spokespersons from the national network or the government ~~to the public and decide on which~~ **includes** the means of communication (websites, social media etc.) **that is appropriate to the size and nature of an outbreak**. Where it is possible, the jurisdiction of each of the competent authorities should be ~~taken into account~~ **accounted for** ~~to set the~~ **when setting** roles and responsibilities for **each organisation** ~~of each one~~ in the risk communication strategy.

Rationale: The level of public communication is dependent on the size and nature of the outbreak and ranges from discussions with only those people affected by public health officials involved in the outbreak team to full information to the general public through government spokespersons or official channels. The paragraph needs to capture this concept in any communication strategy developed.

- Paragraph 59, first sentence: The following amendment is proposed: ‘The investigation and control of biological foodborne outbreaks are multi-disciplinary tasks requiring skills in the areas of clinical medicine, epidemiology, ~~laboratory medicine~~ **clinical microbiology**, food microbiology.....’

Rationale: Laboratory medicine is not a known term. The term for laboratory work on microbiological infections in humans is called ‘clinical microbiology’.

- Paragraph 59, last two sentences (starting “When establishing ...”): propose to replace by: “**The management of a biological foodborne outbreak includes the establishment and confirmation, if possible, of the likely food source by epidemiological investigations of human cases, of food data (traceability of implicated food data) and laboratory analysis. Evidence from these three sources should be combined to find the likely source and should provide input for a (rapid) risk assessment, which serves as the basis for the communication. All investigations, including those to declare an outbreak over, actions and communication should be documented for post-break evaluation.**” .

Rationale: it seems opportune that these introductory sentences are more close to the headings of the Sections and cover all following Sections

- Paragraph 71, third sentence: The following amendments are proposed: ‘The recall should be carried out in the shortest time frame possible **by the food business operator** to avoid greater impact on public health and ~~the business~~ ~~the economy of food business operators~~.

Rationale: It should be clear that the FBO is responsible for the recall under Competent Authority scrutiny. Impacts on business is more than economic e.g. reputational.

- Paragraph 76: The following amendments are proposed: ‘For WGS for example, no standard “cut-off” values in terms of degree of differences between strains (e.g. single nucleotide polymorphisms (SNP’s)) are established **at present**. In general, the fewer the number of SNP differences **or allele differences in the case of MLST analysis**, the more likely the strains are originating from the same

source (e.g., the same facility). The actual number of SNP **or allele** differences among related outbreak strains will differ depending on a number of factors (e.g. species, length of outbreak, contamination route) and will require interpretation based on bioinformatics, epidemiological, and tracing analysis.'

Rationale: SNP differences and Cg/wgMLST are the most common analyses carried out in labs for strain comparison based on WGS. Therefore, the paragraph needs to account for both approaches and not just SNP analysis.

- Paragraph 82, second sentence: The following change is proposed: "Constant communication should be ensured between the risk assessors and the risk managers (~~outbreak investigators~~ from both human health and food safety authorities ~~and institutions~~) in order to: "

Rationale: organisation of risk management authorities depends on the national administrative structure and policy style. It is not appropriate to detail this organisation in the context of this Guidance.

- Paragraph 94, first sentence: The following amendment is proposed: 'The evaluation of preparedness systems can include "after action reviews" of major, serious or rare foodborne outbreaks.'

Rationale: 'after action review' is not a commonly used term globally and 'review' is sufficient to convey the meaning of the sentence.

Ghana

Para 12 bullet 1, 2 and 3: Conclusions of the EWG

Position for bullet 1: Ghana recommends to keep the text and refer to the templates in WHO "Foodborne Disease Outbreaks: Guidelines for investigation and Controls, as example and incorporate them as Annex in the guidelines.

Rationale: The existing template in WHO "Foodborne Disease Outbreaks: Guidelines for investigation and Controls sufficiently provides the relevant information but need to be consolidated in one document.

Position for bullet 2: Ghana supports the recommendation to elaborate an example of a template for asking a rapid risk assessment as an annex to the guideline. This will facilitate implementation of rapid risk assessment

Position for Bullet 3: Ghana supports the inclusion of the graphical structure of the network described in the text and placing it in an annex. This will enhance on the key elements to be considered when establishing networks at national and international levels.

Para 16: Definitions: the definition of Biological hazards i.e. "Biological hazards": agents including microorganisms that have the capacity to cause harmful effects in humans."

Position: Ghana would like to seek clarification whether "biological hazards" include metabolites of microorganism such as biotoxin.

Rationale: The definition provided seem to suggest that there may be other agents apart from microorganisms.

Para 49: Analytical Methods on Whole Genome Sequencing

Position: Ghana recommends para. 49 is deleted since the information provided is not relevant to the document.

Nigeria

Issue: Conclusions of the EWG, Para 12 bullet 1, 2 and 3

Position for bullet 1: Nigeria recommends to keep the text and refer to the templates in WHO "Foodborne Disease Outbreaks: Guidelines for investigation and Controls, as example and incorporate them as Annex in the guidelines.

Rationale: The existing template in WHO "Foodborne Disease Outbreaks" sufficiently provides the relevant information, but needed to be consolidated in one document.

Position for bullet 2: Nigeria supports the recommendation to elaborate an example of a template for asking a rapid risk assessment as an annex to the guideline. This will facilitate implementation of rapid risk assessment

Position for Bullet 3: Nigeria proposes the inclusion of the graphical structure of the network described in the text and placing it in an annex. This will enhance the key elements to be considered when establishing networks at national and international levels.

Senegal

Commentaire général : Le Sénégal recommande au niveau de la version française de changer partout le terme « Epidémies » en éclosion

Justification : le terme « Epidémie » renvoie à une situation de contagiosité alors que les maladies liées aux aliments ne sont pas forcément contagieuses

Question : Conclusions du groupe de travail électronique, paragraphe 12, points 1 et 2

Position : Le Sénégal recommande de conserver le texte et de se référer aux modèles figurant dans le document de l'OMS intitulé "Épidémies de maladies d'origine alimentaire: directives pour les enquêtes et les contrôles" et les incorporer en tant qu'annexe dans les directives.

Justification : Le modèle existant dans OMS "Épidémies de maladies d'origine alimentaire: directives pour les enquêtes et les contrôles" fournit suffisamment d'informations pertinentes, mais doit être regroupé dans un seul document.

Position : Le Sénégal appuie la recommandation tendant à élaborer un exemple de modèle pour demander une évaluation rapide des risques en annexe à la ligne directrice. Cela facilitera la mise en œuvre d'une évaluation rapide des risques

Pour la puce 3: Le Sénégal appuie l'inclusion de la structure graphique du réseau décrite dans le texte et son insertion dans une annexe. Cela renforcera les éléments clés à prendre en compte lors de la création de réseaux aux niveaux national et international.

Question : - définitions para. 16, définition des dangers biologiques, à savoir «risques biologiques»[cette définition correspond à celle des dangers biologiques et il faudrait remplacer « risques biologiques » par « dangers biologiques » : agents, y compris des micro-organismes, capables d'avoir des effets nocifs sur les humains. "

Position : Le Sénégal demande si les « dangers biologiques» incluent les métabolites d'autres microorganismes tels que les biotoxines.

Justification : La définition fournie semble suggérer qu'il peut exister d'autres agents que les micro-organismes.

Question : Méthodes d'analyse Para 49 sur le séquençage du génome entier

Position : Le Sénégal recommande de supprimer le par. 49 car les informations fournies ne sont pas pertinentes pour le document.

Tanzania

The members reviewed the proposed draft and commented as below:-

-Reference to existing WHO documents as examples accepted. Reference to existing WHO on food borne disease outbreaks that will give guidelines for investigation and controls.

-Accepted the inclusion of the graphical structure template as elaborated in the Annex

-Graphical structure of the network described in text is accepted.

-The United republic of Tanzania proposes countries to strengthen reporting mechanisms of food borne outbreaks through established INFOSAN contact points.