CODEX ALIMENTARIUS COMMISSION



Food and Agriculture Organization of the United Nations



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JOINT FAO/WHO FOOD STANDARDS PROGRAMME CODEX COMMITTEE ON FOOD HYGIENE

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DRAFT GUIDANCE FOR THE MANAGEMENT OF BIOLOGICAL FOODBORNE OUTBREAKS

(Comments from Dominican Republic, New Zealand, Perú and Rwanda)

Dominican Republic

República Dominicana agradece la preparación del documento de trabajo a Dinamarca, Chile y la Unión Europea.

República Dominicana apoya que el "Proyecto de Orientaciones para la gestión de brotes biológicos transmitidos por los alimentos" contenido en el Apéndice I del documento CX/FH 22/52/5 Add.1 avance al trámite 8, para su adopción final en la 45^a.-Sesión de la Comisión del Codex Alimentarius.

New Zealand

New Zealand would like to thank Denmark, Chile and the European Union and the members of the electronic working group for preparing the draft guidance for the management of biological foodborne outbreaks. New Zealand would like to submit the following comments to assist with finalising agreement on this guidance document.

Para #	Current text	Proposed text	Justification
1	The contamination of food may occur at any stage in the process from primary production through to consumption and can result from the presence of zoonotic agents in animal production or from handlers, environmental contamination, via equipment, water, soil or air.	The contamination of food may occur at any stage in the process from primary production through to consumption the consumer and can result from the presence of zoonotic agents in animal production <u>and/</u> or <u>cross contamination and</u> <u>spread to other foods by</u> from handlers, environmental contamination, via equipment, water, soil or air.	The inference is that all infections are from zoonotic agents/animal production. This ignores other food groups and the cross- contamination events that occur. Note that there is a significant risk from human to food items (HepA, norovirus and Salmonella for example)
2	The symptoms can be mild with recovery within days or have severe consequences for the individuals due to long- term sequelae with serious health effects or even death	The symptoms can range from be mild to severe in the acute phase with recovery within days or weeks but also can have severe chronic consequences for the individuals due to long- term sequelae with serious health effects or even death	This statement ignores serious illness that occurs immediately such occurs with STEC infections where cases can develop HUS in the acute phase and then get long term chronic sequelae/conditions. This also has a significant long term health burden that needs to be factored in
3	Biological foodborne outbreaks can have significant socio-	Biological foodborne outbreaks can have significant effect on socio-economic costs , which	Delete from this statement "which may be exacerbated in populations comprised of

Specific Comments

	economic costs which may be exacerbated in populations comprised of vulnerable groups, related to hospitalisations and medical treatment, lost productivity and effects on tourism.	may be exacerbated in- populations comprised of- vulnerable groups, related to hospitalisations and medical treatment, lost productivity and effects lost productivity and income. on tourism. In particular , they are important for vulnerable sub- populations that have a higher risk of illness.	vulnerable groups" and add in a separate statement This does not fit here – as written it implies that this comment is related to socio-economic costs which is incorrect. Vulnerable populations are just that; vulnerable and include groups such as pregnant women, neonates, young children etc – illness in these may or may not have a socio-economic cost as implied. I think it is important to state that there are vulnerable sub- populations that have a higher risk of illness. The effect of foodborne illness is greater than just affecting tourism and should be expanded.
5	such networks should use comparable methods and interpretations to the extent possible, as well as transparent exchange of information	such networks should use comparable methods, common definitions and interpretations to the extent possible, as well as transparent exchange of information	There needs to be a common vocabulary/definitions in place as well as methods and interpretations to ensure there are no misunderstandings that could jeopardise the assessment/ analysis
6	Communication and datasharing between and among networks, food bussioness operators and internationally is fundamental for the management of foodborne outbreaks	Communication and data sharing between and among networks, food business operators nationally and internationally is fundamental for the management of foodborne outbreaks	Need to define what is meant by "internationally" as this is part of a list of entities ie networks and food business operators. Does not make sense as written. Can modify the statement to say "national and internationally" if that is the intent. Note spelling error correction in sentence
8	The increase in the use of these methods will likely lead to the detection of more outbreaks and the need for enhanced preparedness.	The increase in the use of these methods will likely lead to the detection of more clusters and the need for enhanced preparedness.	For consistency and accuracy within this point; the use of these methods will identify clusters of linked human cases which may then be defined as an outbreak as per the definitions used in this document
9	The decision to categorize an outbreak as an incident, an emergency or crisis is at the discretion of the competent authorities which should be	The decision to categorize an outbreak as an incident, an emergency or crisis is at the discretion of the competent authorities and should be consistent at both local and	Add "at both local and national levels" to improve understanding

	consistent at the local	national levels.	
	and national level.		
11	These guidelines also describe the role of competent authorities at the local, national and, where applicable, the regional level (e.g., groups of countries)	These guidelines also describe the role of competent authorities at the local, national and, where applicable, the international level (e.g., groups of countries)	Although considered regional for Europe, this would be better phrased at the international level and the EU used as the example as these should implementable at all levels.
22	Lot: A definite quantity of ingredients or a food that is intended to have uniform character and quality, within specified limits, is produced, packaged and labelled under the same conditions, and is assigned a unique reference identification by the food business operator. It may also be referred to as a "batch".	Lot: A definite quantity of ingredients or a food that is intended to have uniform character and quality, within specified limits, is produced, packaged and labelled under the same conditions, and is assigned a unique reference identification by the food business operator and separated by a recognised microbiological break. It may also be referred to as a "batch'. "	Add :A Lot would also be separated by a recognised microbiological break which would involve either CIP or end of production cleaning.
29	Traceability/Product Tracing: The ability to follow the movement of a food through specified stage(s) of production, processing and distribution, where "Tracing back" refers to following the path towards its origin/source and "Tracing forward" refers to following the path towards its final distribution/point of consumption.	Traceability/Product Tracing: The ability to follow the movement of a food through specified stage(s) of production, processing and distribution, where "Tracing back" refers to following the path towards its origin/source and "Tracing forward" refers to following the path towards its final distribution/point to the consumer.	Should be to the last point in the supply chain if considering this to be a distribution/point which is "to the consumer" via a store or food outlet. "Consumption" is not part of product tracing.
35, new bullet point	The role of the national network should include:	Coordinating any communications released to the media	Also include the coordination of any communications released to the media
41, 42 and 43	Foodborne outbreaks do not respect borders. What seems to be a national outbreak at the outset may in fact be or turn into a regional or global foodborne outbreak.	Foodborne outbreaks do not respect borders. What seems to be a national outbreak at the outset may in fact be or turn into an international foodborne outbreak.	Change to be consistent with the concept of an "International Alert Network" As per previous comment for paragraph 11. Replace "global" and
45	Information from surveillance and monitoring of, e.g. animals, feed, food and environment, including equipment of food	Information from surveillance and monitoring of, e.g. animals, feed, food and environment, including food contact surfaces equipment at food businesses,	"regional" to "International" Change to food contact surfaces which will capture not only equipment but any other surfaces which in a production facility might come in contact with food

	businesses,		products during manufacture or handling
47	Tools for comparing and presenting data, such as a phylogenetic tree, (a branching diagram or "tree" showing the evolutionary relationships of the physical or genetic characteristics of the laboratory data at hand).	Tools for comparing and presenting data, such as a phylogenetic tree, (a branching diagram or "tree" showing the evolutionary relationships of the physical or genetic characteristics of the foodborne pathogen isolates at hand).	Change to "food borne pathogen isolates" rather than lab data as this where the isolate analysis should provide relationship data for the investigation.
49	WGS typing makes it possible to determine when isolates are highly related, and thereby enhances the ability of identifying the source of an outbreak with a high degree of accuracy.	WGS typing makes it possible to determine when isolates are highly related, and thereby enhances the ability of identifying the source of an outbreak with a high degree of accuracy when used in conjunction with epidemiological data.	Can be used in conjunction with epidemiological data to identify a potential source. Need to add to this paragraph.
50, new bullet point		Use of existing genomic sequence data hubs containing foodborne pathogens and associated tools for analysis	Additional bullet point to be added. Much of this technology already exists and can be accessed through PulseNet and the like. Cost effective to utilise these platforms and also to consider role of One Health approaches.
55	Availability of (regional/national/local) data on consumption, consumer habits and serving sizes that is as up to date as possible	Availability of (international/national/local) data on consumption, consumer habits and serving sizes that is as up to date as possible	Ensure consistency with earlier canges
58	Consider a structure to allow for the communication to be handled locally, in case of small and local outbreaks.	Consider a structure to allow for the communication to be handled locally, in case of small and localised outbreaks.	Grammar
61	Evidence from these sources should be combined to find the likely source and can provide input for an outbreak analysis, which serves as the basis for the communication.	Evidence from these sources should be combined to identify a potential source and can provide input for an outbreak analysis, which serves as the basis for communication, particularly if a food product recall is required.	Alternative wording. Need to consider in the management that a food recall may be required, and this would be a priority if a source has been determined.
65	to identify a <mark>suspect</mark> <mark>vehicle</mark> .	to identify a <mark>potential</mark> source.	Wording correction
66	Other tools that can be used for hypothesis generation to determine the source of attribution	Other tools that can be used for hypothesis generation to determine the source	Wording correction

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67	This could be the situation if the hypothesis is not very strong or if further evidence is needed to inform and back up control measures.	This could be the situation if the hypothesis is not very strong or if further evidence is needed to inform and back up long-term control measures.	Additional wording
69	When taking a sample, information on the product should include at least product name, comprehensive product description (e.g. animal/fish species, kind of vegetable, fresh, processed, frozen, canned), lot identification, place and date of sampling, in order to allow further investigations including tracing.	When taking a sample, information on the product should include at least product name, comprehensive product description (e.g. animal/fish species, kind of vegetable, fresh, processed, frozen, canned), lot identification, place and date of sampling, required and actual storage conditions (refrigeration and type of packaging), in order to allow further investigations including tracing.	Additional wording. Need to consider whether or not the food products are being handled and stored under appropriate conditions as this will also inform analysis of the sample data.
70	If the epidemiological investigations do not identify a source, the competent authority could use other information to elaborate their investigation of the cause of an outbreak.	If the epidemiological investigations do not identify a source, the competent authority could use other information to <u>inform</u> their investigation of <u>a</u> <u>potential</u> cause of an outbreak.	Change of wording for clarity
70	Such information should however be used prudently e.g. to target investigations and not for communications on the outbreak source without additional supporting evidence.	Such information should however be used prudently e.g. to target investigations and not for communications on the outbreak source without additional supporting evidence.	In this case need supporting evidence not additional evidence
71	Tracing enables the investigators to see the full distribution of the food item e.g. going back from the lot that caused illness to the place/source of initial contamination and identify from that source on, the distribution of all products made with that lot.	Tracing enables the investigators to see the full distribution of the food item e.g. going back from the lot that caused illness to the place/source of initial contamination and identify from that source <u>any other food</u> <u>products made with that food</u> <u>item or ingredient.</u>	Provide clarification
73	This includes preventing the distribution of the contaminated food and removing any contaminated food already in the marketplace.	This includes preventing further distribution of the contaminated food and removing any contaminated food already in the marketplace.	Change in wording – it is possible that the food may already have been distributed
75	Management of outbreaks benefits from	Management of outbreaks benefits from the food control	The comparison should be between two isolates not

	the food control and veterinary and agricultural sectors being able to share and combine relevant laboratory surveillance and monitoring data among themselves and with the public health sector in order to identify a match between a clinical human isolate and a food source	and veterinary and agricultural sectors being able to share and combine relevant laboratory surveillance and monitoring data among themselves and with the public health sector in order to identify a match between a clinical human isolate and <u>an</u> isolate from a food	with the food per se
77	The level agreed upon may differ according to the typing method and the biological hazard	The level agreed upon may differ according to the typing method and the pathogen	The level of similarity is between isolates and is dependent on the pathogen being investigated – confusing to refer to this as biological hazard.
80	biological hazards that contaminate food, are not likely to be evenly distributed,	pathogens that contaminate food, are not likely to be evenly distributed,	Confusing to refer to this as biological hazard when the laboratory will be identifying a pathogen. Consider changing in other bullet points in this paragraph
82	For molecular testing, and in particular WGS, it might be very useful to search for isolates in food databases with similar molecular profiles as in a cluster of human cases.	For molecular testing, and in particular WGS, it might be useful to search for isolates in pathogen databases with similar molecular profiles as this may identify a cluster of human cases not previously linked epidemiologically.	Rewording for clarity
82	Collaboration between public health and food manufacturers on sharing molecular data from ingredients and specific foods, should be encouraged. This can help hypothesis generation and potentially lead to more quickly identifying the source of an outbreak.	Collaboration between public health and food manufacturers on sharing molecular data of pathogenic isolates from ingredients and specific foods, should be encouraged. This can help hypothesis generation and potentially lead to more quickly identifying the source of an outbreak.	Additional words – the molecular data that is being compared is the pathogenic isolate data not the ingredient
86	Therefore, it may be necessary to conduct risk communication even if the source of the outbreak is still unknown.	Therefore, it may be necessary to conduct risk communication even if the source of the outbreak is unknown.	Delete "still"
Annex II, Point 7	Is this process inadequate to avoid growth of <i>Listeria</i> <i>monocytogenes</i> ?	Is this process in adequate to avoid growth of <i>Listeria monocytogenes</i> ?	Grammatical error
Annex III, Outbreak	Are there any common foods identified as being	Are there any common foods (<mark>or</mark> ingredients) identified as being	There could situation where a common ingredient might

Information	consumed by the cases?	consumed by the cases?	be the agent for example: flour, ground nuts, or sprouted seeds.
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Perú

Comentario General: "Perú felicita al GTE por el trabajo realizado en este documento y agradece la oportunidad

de presentar observaciones a efectos de lograr su adopción en el trámite acelerado 8 en la 52.ª reunión del CCFH"

Comentario(s) Específico(s):

N°	Sección/N° Párrafo del documento	Dice	Debe decir	Categoría de comentario: "Editorial, Técnico, Sustancial, Traducción".	Sustento Técnico de cambio /Comentario Específico
1	69	La investigación sobre el terreno puede incluir el muestreo ambiental (por ejemplo, hisopos de un entorno de elaboración o muestras de suelo/agua en un establecimiento agropecuario) para proporcionar información adicional sobre la fuente del brote y la causa fundamental. El conocimiento de las técnicas de muestreo, en particular de las técnicas asépticas, y de la manipulación de las muestras para su transporte al laboratorio son esenciales para garantizar la integridad de las muestras que se toman para la verificación.	La investigación sobre el terreno puede incluir el muestreo ambiental (por ejemplo, hisopos de un entorno de elaboración o muestras de suelo/agua en un establecimiento agropecuario) para proporcionar información adicional sobre la fuente del brote y la causa fundamental. El conocimiento y la correcta aplicación de las técnicas de muestreo, en particular de las técnicas asépticas, y de la manipulación de las muestras para su transporte al laboratorio son esenciales para garantizar la integridad de las muestras que se toman para la verificación; así como, la confianza en los resultados	técnico	Se requiere precisar la "correcta aplicación", toda vez que implica que el personal que toma la muestra debe contar con experiencia y competencia para esta actividad, de tal manera que, se asegure la confianza en los resultados.
2	82	Se debería fomentar la colaboración entre la sanidad pública y los fabricantes de alimentos para compartir datos moleculares de	Se debería fomentar la colaboración entre la sanidad pública y los fabricantes de alimentos para compartir datos	técnico	Es limitado el acceso a pruebas moleculares, por parte de los OEA. En ese sentido, la forma de

ingredientes y alimentos específicos. Esto puede ayudar a la generación de hipótesis y potencialmente conducir a una identificación más rápida de la fuente de un brote.	moleculares y/o de trazabilidad de ingredientes y alimentos específicos. Esto puede ayudar a la generación de hipótesis y potencialmente conducir a una identificación más rápida de la fuente de un brote.	colaboración más práctica, es poner a disposición la información sobre rastreabilidad de los ingredientes y alimentos específicos; para que la Autoridad competente, proceda con generar la data molecular para cepas implicadas en

Rwanda

Section or Paragraph:

Recommendation: The Committee is invited to consider the revised proposed Guidelines in Appendix I to this document with the intent to progress it to Step 8 for final adoption by CAC45.

Comment/Proposed Changes :

Rwanda supports the revised draft Guidance for the Management of Biological Foodborne Outbreaks to progress it to Step 8 for final adoption by CAC45.