CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

Viale delle Terme di Caracalla, 00153 Rome, Italy - Tel: (+39) 06 57051 - E-mail: codex@fao.org - www.codexalimentarius.org

Agenda Item 6 **CRD 14**

Original Language Only

JOINT FAO/WHO FOOD STANDARDS PROGRAMME

***AD HOC* CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE**

Eighth Session
Virtual
GUIDELINES ON INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE
(For comments at Step 3)

(Prepared by the by Chair and co-chairs of the EWG (the Netherlands, Canada, Chile, China and New Zealand) based on the comments received in reply to CL 2021/59-AMR

The chair and co-chairs have proposed revised text in section 8.4 - 8.7 based on the comments received with the aim of facilitating the discussions at TFAMR8 and finding a consensus.

8. Components of integrated monitoring and surveillance program(s) for AMR

8.1. Sampling design (See CRD 13)

8.2. Sampling plan (See CRD 13)

8.3. Sample sources (See CRD 13)

8.4. Target microorganisms and resistance determinants

54. Selection of the target microorganisms and resistance determinants should be considered based on their relevance to food safety and public health.

55. Bacterial species may include:

- Foodborne pathogens such as *Salmonella*~~,~~, *Campylobacter* or other food borne pathogens depending on national or regional epidemiology and risks.

Co-chairs proposal:
The text indicates “or” as opposed to “and” and has “depending on” both of which provides flexibility. Suggest to maintain the original text. See also new paragraph 41bis.

- ~~Commensal~~ Indicator bacteria such as *Escherichia coli* and enterococci (e.g., *Enterococcus faecium* and *Enterococcus faecalis)*, which can contaminate food and harbor transferable resistance genes.

Co-chairs proposal:
For consistency with scope use “indicator” bacteria (Para 16).

56. Target microorganisms from aquatic animals and food of non-animal origin may ~~should~~ be determined based on available scientific evidence and/or relevance to public health.

Co-chairs proposal:
To change “and” to “and/or” and not include the proposed sentence “and is important when it come to contributing to new basic data on occurrence” for simplicity. The addition “where possible” proposed by a member country to add flexibility has not been added, as the terms “may” and “available” scientific evidence provides flexibility and is covered by the chapeau statement.

57. The selection of target microorganisms should consider the presence of high priority AMR genes or mobile genetic elements and horizontal gene transfer in a given bacterial population.

58. Monitoring and surveillance program(s) may begin with phenotypic susceptibility testing for AMR in representative foodborne pathogens and/or ~~commensal~~ indicator bacteria. Options for expansion may include a broader range of foodborne pathogens~~,~~ or ~~commensal~~ indicator bacteria, testing for genetic determinants of resistance, virulence and mobile genetic elements.

59. Whenever possible the characterization of bacterial isolates to the species-level and, as feasible, molecular analysis of particular isolates that may present a public health concern should be undertaken.

8.5. Laboratories

60. Laboratories participating in the monitoring and surveillance program(s) should consider:

a. Bacterial isolation, identification (to species and serotype level, where relevant), typing and antimicrobial susceptibility testing (AST) using standardized and validated methods performed by trained personnel.

Co-chairs proposal:
To incorporate "where relevant" for technical accuracy, as serotyping is not appropriate for all bacterial species. For example, *Campylobacter* is not serotyped.
The proposal to add "where possible" has not been incorporated as it is covered by the chapeau statement.

b. ~~Accreditation in accordance with national or international guidance or have a quality management system in lace.~~.
Laboratories should have quality assurance/management systems in place, or accreditation in accordance with national or international guidance.

Co-chairs proposal:
Bullet b: The first half of the sentence in bullet b. was moved to the beginning of the sentence to align with Principle 8.

c. ~~Whenever possible~~ Participating in external quality assurance/management system testing including proficiency testing in identification, typing and AST of the microorganisms included in the monitoring and surveillance program(s).

Co-chairs proposal:
Bullet c: "Whenever possible" deleted as it is covered by the chapeau sentence.

d. Being equipped with facilities and having procedures to maintain sample integrity including appropriate storage temperatures and ~~recording~~ records that track the time between sample reception and analysis and ensure traceability.

Co-chairs proposal:
Retain original text as agreed/discussed at PWG.
Incorporate editorial changes for accuracy and readability.

e. Storing isolates and reference strains using methods that ensure viability and absence of change in the characteristics and purity of the strain.

Co-chairs proposal:
The bullet has been retained. The chapeau sentence allows flexibility .

f. Access to a national reference laboratory or an international laboratory that can provide technical assistance if necessary and carry out molecular characterization ~~where feasible~~.

Co-chair proposal:
Retain original sentence as discussed during PWG in line with previous comments. Where feasible was deleted as it is covered by the chapeau sentence.

8.6. Antimicrobial susceptibility testing

8.6.1. Methods and interpretative criteria

61. Phenotypic s~~S~~usceptibility testing methods (minimum inhibitory concentration (MIC) methodologies or disk

diffusion) or genotypic methods that are standardized and validated by nationally or internationally recognized organizations should be used where available. Either phenotypic or genotypic methodologies may be ~~considered~~ used.

62. ~~Either phenotypic or genotypic methodologies may be considered for susceptibility testing; and the methods need to be standardized and validated by internationally recognized organizations.~~

Co-chair proposal: Merge 61+62 as the paragraphs fit together and changes were made for technical accuracy.

"nationally" was added since there are nationally recognized standards.

63. Quality control strains of bacteria should be included and used according to international standards where available to support validation of results and data harmonization.

Co-chairs proposal:
"Data harmonization" added as quality control/assurance serve multiple purposes centered on data validity and interlaboratory comparability.

64. Interpretation of results for MICs or disk diffusion~~,~~ should be undertaken consistently according to European Committee on Antimicrobial Susceptibility Testing (EUCAST) tables or the Clinical and Laboratory Standards Institute (CLSI) standards, and should include quantitative results (i.e., inhibition zone diameters including the disk content or MIC values). When neither tables nor standards are available, program-specific interpretive criteria or categories may be used.

Co-chairs proposal:
No changes were made to this paragraph as there was extensive discussion at the EWG and PWG (see paragraph 18 of the PWG report).
The suggestion to delete "consistently" was not included as the second sentence provides guidance when neither tables nor standards are available.

65. Categorization of the isolate and reporting of results may be undertaken based on the epidemiological cut off values (ECOFFs) which should be reported as wild-type, ~~or~~ non-wild type or by clinical breakpoint which should be reported according to the interpretative category. The use of ECOFFs as interpret~~at~~ive criteria will allow for optimum sensitivity for detection of acquired resistance, temporal analysis of trends and comparability between isolates from different origins. Clinical breakpoints may differ between animal species and countries or regions. The interpre~~ta~~tive criteria or category used should be included in the analysis and ~~reporting, interpretation and analysis~~ reporting of the data.

Co-chairs proposal:
Retain text as discussed at PWG. Some editorial amendments to improve the flow of the sentence.

66. Raw quantitative data should be maintained in order to allow comparability of results, for early recognition of emerging AMR or reduced susceptibility in order to maximize the ability to analyze and compare results across sample sources.

67. Quantitative results are ~~also~~ necessary for the analysis of resistance patterns over time and when retrospective data analysis is needed due to changes in clinical breakpoints or ECOFFs. Quantitative results are ~~also~~ necessary for quantitative microbiological risk assessment.

Co-chairs proposal:
Retain original text with editorial deletion of also.

8.6.2. The panel of antimicrobials for susceptibility testing

Co-chairs proposal:
Retain original title, as the content of this section includes other considerations about the panel that the selection of the antimicrobials.

68. The panel of antimicrobials for phenotypic susceptibility testing should be harmonized ~~across the~~ within national monitoring and surveillance program(s) as to ensure continuity and comparability of data. Attempts should be made to use the same antimicrobial class representatives across sample sources, geographic regions, and over time.

Co-chair proposal:
"Across the" has been modified by "within national", as suggested by one member country, to clarify that it's not

expected to harmonize a single global panel and better reflects the application.

69. The antimicrobials included in the panel should depend on the target bacteria, the clinical or epidemiological relevance of these antimicrobials and should allow for the tracking of isolates with particular patterns of resistance.

70. The antimicrobials included may take into account the classes and uses in the relevant animal and/or plant/crop production sectors, as well as their influence in the selection or co-selection of resistance. Antimicrobials that would give the best selection of cross-resistance profiling should be selected. Other antimicrobials which have the potential for co-selection of resistance due to gene linkage may also be included even if they are not used in animal and/or plant/crop production sectors.

71. Antimicrobials to be tested may be prioritized based on ~~those that have been ranked with~~ their higher priority ranking for human health, ~~based on~~ national context and/or other relevant ~~antimicrobials that have an~~ influence on the selection or co-selection of resistance.

Co-chair proposal:
Editorial amendment to improve readability.
Alternative sentence proposed by a member country has not been included, as the sentence is not saying that lower priority antimicrobials won't be tested. The sentence also includes "based on national context", which provides flexibility.

8.6.3. Concentration ranges of antimicrobials

72. The concentration ranges used should ensure that both ECOFFs and clinical breakpoints, when available, are included to allow for the comparability of results with human data. The concentration range of each antimicrobial agent should also cover the full range of allowable results for the quality control strain(s) used for each antimicrobial agent.

8.6.4. Molecular testing

73. Whenever possible, molecular testing should be conducted ~~used~~ for the ~~identification and~~ detection and characterization of resistance determinants and for epidemiological analysis according to country specific scenarios and resources.

Co-chairs proposal:
Some editorial changes for technical accuracy. The proposal to add "bacterial isolates" has not been included, as it is too prescriptive and limits use. For example, if a country wants to do metagenomics work, then the bacteria are not isolated in the traditional sense.

74. ~~Molecular characterization is a useful tool which may be used f~~For the rapid identification of resistance clusters and outbreak investigations~~.~~, molecular characterization may be used. Molecular characterization in conjunction with epidemiological information, ~~may~~ informs the determination of ~~epidemic~~ source and transmission chains, the detection of emergence and investigation of the spread of new resistant strains or resistance determinants, and source attribution by linking to molecular monitoring of pathogens or resistant microorganisms or resistance determinants across sectors.

Co-chairs proposal:
incorporate the edits as proposed by some member countries regarding "useful" and "which may be used" and delete "epidemic". Rationale: improves the readability and accuracy of the paragraph.

75. Sequence data generated and stored with appropriate metadata may be used for retrospective and prospective surveillance.

76. Molecular testing may be useful in addressing or confirming inconclusive phenotypic results and may be used for the early detection or detection of resistant microorganisms of high public health importance.

Co-chairs proposal:
Retain text as discussed in the PWG. Early detections was agreed after long discussion

77. Molecular methods may allow for the integration of resistance data with other relevant public health data (e.g., virulence determinants).

8.7. Collection and reporting of resistance data

78. The information collected and recorded may differ depending on the stage of sampling along the food chain, sampling design and the specific monitoring and surveillance objectives. To ensure consistency, sampling information

should be recorded at the isolate and sample level.

79. Information for each individual sample should include:

a. Reference to the general description of the sampling design and ~~randomization procedure~~ plan.

Co-chairs proposal:
To incorporate the proposed edits. The method of the sampling plan includes it and other information.

b. Specific information about the origin of the sample such as from what, where, how and when the sample was collected.

c. General information to identify the isolate, bacterial species, sero~~var~~type, other subtyping information as appropriate.

d. Specific information about the isolation of the bacteria and the AST (e.g., date of testing, method used, quantitative results). In the case of qualitative results, the interpretative criteria should be recorded.

80. Reporting of results from the monitoring and surveillance program(s) should be timely.

Co-chairs proposal:
Retain sentence as discussed during PWG. Examples of optimal time frame have not been added as suggested by a member country, not to be too prescriptive.

81. Antimicrobial susceptibility testing methods, sample sources, analytical methods and interpretive criteria should be clearly described, and differences transparently explained to show where data may not be directly comparable.