

29/11/2019

**Ad Hoc Codex Intergovernmental Task Force on Antimicrobial resistance
(7th Session)**

Pyeongchang, Republic of Korea, 9-13 December 2019

European Union comments on

Agenda Item 6:

**Proposed draft Guidelines on Integrated Monitoring and Surveillance of
Antimicrobial Resistance**

(CX/AMR 119/7/6)

*Mixed Competence
European Union Vote*

The European Union and its Member States (EUMS) would like to commend the Netherlands, Chile, China and New Zealand for leading the work on monitoring and surveillance of AMR. The EUMS would like make the following comments on the draft text.

General comments

The new draft text is well structured and has satisfactorily addressed many of the comments raised at TFAMR6.

The “Introduction and purpose” is rather long and could be split into two by moving paragraphs 6, 7, 10, 11 and 12 into a new section titled “Purpose” or “Use”. This would improve the flow and readability of the guidelines. There is also some duplication in the introductory section and the section on principles and, as the guidelines are quite comprehensive, repetitions should be avoided.

The terms “program” and “system” are used alternately. The EUMS suggest choosing only one with a preference to use the term “system”.

Specific comments

Paragraph 1

The 2nd sentence should be deleted.

Rationale: Taking into account the long lifespan of the Codex guidelines, it is preferable not to refer to any specific meetings.

Paragraph 2

This paragraphs gives definitions for monitoring and surveillance. They would better fit under the section “Definitions”.

Paragraph 5

Paragraph should be reworded as follows: **An integrated monitoring and surveillance system** ~~It~~ also contributes to the promotion and protection of public health by providing **data for the estimation of** burden of illness ~~information to risk managers about, how infections caused by resistant bacteria differ from infections caused by susceptible bacteria,~~ and **information on** the impact of interventions designed to limit the emergence, selection, and dissemination of foodborne AMR.

Rationale: For clarification. AMR/AMU surveillance can contribute to burden of illness studies, but they do not themselves provide information on the burden of illness or on how infections caused by resistant bacteria differ from infections caused by susceptible bacteria.

Paragraph 6

The last sentence should be deleted: ~~Such systems are a fundamental part of national strategies and plans to minimize foodborne AMR and are an important component of a national food safety system.~~

Rationale: This wording is repeated in principle 2 and is therefore not needed in the introduction.

Paragraph 9

Paragraph should be reworded as follows: New scientific knowledge should be incorporated into integrated monitoring and surveillance programs as it becomes available to improve ~~the design~~ of the systems and to enhance analysis and utility of existing information and data. Design and implementation of systems should ~~also~~ evolve **and adapt** as AMR policies and priorities change at the national and international level.

Rationale: Mainly editorial.

Paragraph 10

The 2nd sentence of the paragraph should be reworded as follows: A gradual approach to monitoring and surveillance should take into account broader capacity issues including the availability of information on AMU in humans, animals and crops, ~~human health care infrastructure,~~ **animal and** human clinical AMR data and reporting, availability of food consumption and agriculture production data, and crosssector laboratory proficiency and quality assurance.

Rationale: It is not clear what is meant by “human health care infrastructure” and whether it is relevant. Whereas AMR situation in clinical animal isolates is not within the scope of this document, emerging trends in clinical (non-zoonotic) isolates should also be considered in monitoring of foodborne pathogens and commensal bacteria to be able to assess the public health relevance.

Paragraph 13

The paragraph should read: These Guidelines cover the design and implementation of an integrated monitoring and surveillance system for foodborne AMR and AMU throughout the food chain, and the **food** production environment.

Rationale: To be in line with the definition

Paragraph 18

The paragraph should read: Implementation of these Guidelines will facilitate the generation and use of appropriate AMR and AMU data from ~~humans~~, animals, crops, food and the **food** production environment, **and the use of data on AMR and AMU in humans**, in order to conduct integrated analysis of all these data.

Rationale: According to paragraph 15, these guidelines do not cover monitoring and surveillance in humans. Hence, no human data will be generated by implementing these guidelines.

Paragraph 19, Principle 2

The principle should read: Monitoring and surveillance systems for AMR and AMU throughout the food chain are a fundamental part of national strategies and plans to minimize foodborne AMR and an important component of a national food safety ~~program~~ **system**.

Rationale: A “system” reflects better that national food safety requires multiple approaches and thus the term system is more appropriate. A program is much more focused on one specific objective within the system.

Paragraph 19, Principle 3:

The principle should read: A national monitoring and surveillance system should be tailored to the national situation and priorities and may be designed and implemented with the objective of progressive improvement as resources permit; ~~in order to facilitate reporting at the international level and to ensure that data is comparable international standards should be considered.~~

Rationale: The aspect of international comparability of the data is covered by principle 9.

Paragraph 19, Principle 5:

The principle should read: Risk analysis should be a guiding principle in the design, implementation and review of a national monitoring and surveillance systems for AMR **taking into account the ultimate goal of benefiting** ~~with best practice being informed by expected benefits to public health and in terms of preventing or minimizing the burden to human health.~~

Rationale: Benefits on public health or to prevent or minimize disease are not expected by monitoring alone.

Paragraph 19, principle 6:

The principle should read: Priority should be given to the most relevant ~~design~~ elements to be analyzed from a public health perspective...

Rationale: For readability and clarity.

Paragraph 19, Principle 10

The EUMS suggest deleting this principle

Rationale: Trade related aspects fall outside the scope of the guidelines.

Paragraph 20

The end of the paragraph should reads: "...in the food chain and their ~~relationship with~~ **potential to pose** risks to human health." would be more appropriate."

Rationale: Relationship is a mathematical term which reflects an interaction in both directions, but as regards AMR, only the risk for humans is of interest, but not the impact of humans on the occurrence of the hazards in the food chain.

Paragraph 22

The square brackets should be deleted from the term "initially" in the second sentence.

Rationale: The paragraph concerns the initial design of monitoring and surveillance programmes.

Paragraph 23

Hazard identification should include human microbiological pathogens and bacterial commensals (**indicator bacteria**) that may transmit AMR to humans.

Rationale: The scope covers indicator bacteria and this is to clarify that the bacterial commensals are used as indicator bacteria.

Paragraph 24

The paragraph should read: As countries improve their AMR systems over time, ~~an approach~~ ~~to~~ the development and implementation of monitoring and surveillance systems should lead to an increased use of generated data for risk assessment.

Rationale: For readability and clarity.

Paragraph 28

The third sentence should read: The level of engagement of stakeholders, including food industry, feed industry, pharmaceutical industry, veterinarians, **pharmacists**, animal, plant health and environment professionals, farmers, professional associations, civil society, consumer organizations, retail and others, will depend on the level of development of the monitoring and surveillance system and the degree of integration.

Rationale: It is important to specify also pharmacists amongst the relevant stakeholders.

Paragraph 29

This paragraph should be deleted.

Rationale: The paragraph repeats what is said in paragraph 28.

Section 7, Figure 1

The heading of the figure should be revised as follows: Progressive approach to the design and implementation of the integrated monitoring and surveillance system for foodborne **AMR and AMU**

Rationale: As the figure intends to reflect both, AMR and AMU, it should be mentioned in the heading.

In the middle part of the figure, in the box “AMR”, “general considerations” should be deleted and “methodology” added.

Rationale: General considerations are covered in the preliminary activities. Methodology is an important element which should be considered in the development of AMR monitoring and surveillance activities.

In the box “AMU”, “Expansion of collection should be deleted”. Instead, ‘targeted productions’ and ‘benchmarking approaches’ should be added.

Rationale: The expansion of data collection is true for AMR and AMU and already covered in the heading of the boxes. As regards AMU, similarly to AMR, some elements for further development might be mentioned. This should also include data collection appropriate for a benchmarking system for AMU.

Paragraph 37

The first sentence should read: Monitoring and surveillance priorities for microorganisms and resistance determinants, antimicrobials, ~~food commodities~~ and sample sources should be informed by national, regional and international data and knowledge where it exists

Rationale: Food commodity is an example of a sample source.

Paragraph 43

The first bullet should read: The highest priority microorganisms, panels of antimicrobials and ~~commodities~~ **sample sources** (see Section 8) to be targeted based on any existing national data and international recommendations.

Rationale: In section 8, a commodity is referred to as a food commodity and that would not capture all the relevant sample sources in this paragraph.

Paragraph 52

The 2nd sentence of the paragraph should read: For example, the program can expand to include a broader number of animal species, crop species and food commodities, and other sources such as feed, water, waste water, ~~reclaimed~~ **reused** water, sewage sludge, manure, surface water, etc.

Rationale: The term “reused water” is more widely used.

Paragraph 54

The 2nd sentence of the paragraph should be adjusted as follows: For example, surveillance of abattoirs according to slaughter volume, with stratification within animal species (e.g. broilers, layers,) and sample size sufficient to establish prevalence or to detect changes **with sufficient precision**.

Rationale: In the revised paragraph a new aspect on sample size was included, and two different objectives listed, the establishment of a prevalence or the detection of changes. It is necessary to mention that a sufficient number of samples is necessary to achieve these objectives.

Paragraph 54bis

A new paragraph 54bis should be inserted after paragraph 54 on data collection and reporting accompanied with bullet points 1 to 4 from paragraph 66 as these bullet points are related to AMR data only.

Paragraph 55

The program may be expanded by including a broader range of foodborne pathogens (e.g. ~~methicillin-resistant *Staphylococcus aureus* (MRSA)~~ ***Vibrio spp, Listeria monocytogenes***) and indicator bacteria (e.g. *Enterococcus* spp).

Rationale: The examples should be in line with section 8.5. MRSA is not the best example of a foodborne pathogen.

Paragraph 58

The first sentence should read: Antimicrobials to be tested should be prioritized based on antimicrobials that have been ranked **with higher priority** as ~~highest priority~~ for human health ...

Rationale: Limiting the prioritization only to antimicrobials ranked as highest priority for human health is too restrictive.

Paragraph 60

The paragraph should read: A basic source of data regarding antimicrobials intended for use in animals and crops is the collection of antimicrobial sales data from manufacturers and importer/exporter data. Sales data of antimicrobials may be collected in addition, from other

sources like **marketing authorisation holders**, wholesalers, retailers, pharmacies, **veterinarians**, feed mills or other agricultural associations. **Care should be taken to avoid double reporting.**

Rationale: Marketing authorisation holders are a valuable source of data on AMU. To ensure that double reporting is avoided.

Paragraph 60bis

A new paragraph should be introduced reading: Data relevant for the denominator can be collected from different sources, such as slaughter houses or by census of the animal populations.

Paragraph 62

The paragraph should be adjusted as follows: The AMU-program **should** ~~may~~ evolve to include collection of AMU data from end-user sources, such as collection of use data from veterinary prescriptions and farmers records with increasing national coverage of the data.

Rationale: The ultimate goal should be the collection of data on the use level, as this information is necessary to describe with sufficient precision which antimicrobials are used in the separate animal and crop populations. Furthermore, this data is necessary to establish a benchmarking system.

Title of section B

The title of section B should read: B. ~~Reporting~~ **Data collection plans**

Rationale: Section 7.2.3 is about reporting for both AMR and AMU, this section is about collection.

Paragraph 63

The introductory paragraph should read: The way of **collecting and** analyzing ~~and reporting~~ AMU data may vary depending on the type and source of the data collected, the level of detail of these data and the monitoring and surveillance objectives.

Rationale: This section should be about data collection.

The second bullet point should read as follows: Reporting of AMU data **should** ~~could~~ be expanded as follows:

Rationale: This adjustment is a necessary consequence of the adjustment of paragraph 62. Much more emphasis should be put on the collection of use data instead of sticking to sales data.

The first sub bullet under the second bullet point should read: Adjusted by the estimated animal population size and/or biomass and land area used for plants/crops, when this information is available

Rationale: Biomass is also an appropriate criterion.

Paragraph 64

The paragraph should read: The possibilities for integrated analysis and reporting of AMR and AMU data from various sectors may differ between countries.

Rationale: To clarify that integrated analysing and reporting includes data from various sectors.

Paragraph 65

The integrated analysis and reporting may start by including a sector-specific descriptive analysis and reporting of AMR data from the food chain and analysis and reporting of AMU data in terms of quantities of antimicrobials intended for use in animals and crops.

Rationale: To clarify.

Paragraph 70

The 4th bullet point should read: Identify risk management options, including informing interventions for disease prevention and control and to evaluate risk management interventions ~~to reduce risk~~.

Rationale: Reducing risk is not the purpose of evaluation of risk management interventions.

Paragraph 76

The fourth bullet point should read: Antimicrobials to be tested ~~and genes to be detected~~.

Rationale: This is covered by the 3rd bullet point.

Paragraph 78:

The paragraph should read: Additional sampling sources and stages in the food chain can be incorporated progressively according to priorities and resources as implementation advances- ~~E,~~ for example, detection of AMR in microorganisms isolated in zoonoses control programs. Information from samples taken for other purposes, such as in foodborne outbreaks investigations may also be used.

Rationale: There are no sampling programs for outbreak investigation.

Paragraph 82, Food producing animals

The second sentence of the second paragraph should read: Collection of samples from animals not immediately entering the food chain can provide population level information on animal health, **prevalence of (foodborne) zoonoses** and bacterial populations.

Rationale: Samples taken at herd level provide important information on the prevalence of zoonoses at this stage in the food chain.

The second sentence of the last paragraph should be either more elaborated or deleted.

Rationale: Currently, the information given is not useful. A sampling point is offered, but restrictions linked to specific animal species where this should be not considered appropriate is not explained.

Paragraph 82, Plants/crops

The second sentence of the second paragraph should read: Sampling soil ~~amendments~~ **enrichments** such as manure and sewage sludge should also be considered.

Rationale: Editorial.

Paragraph 83

The second sentence of the paragraph should be deleted.

Rationale: The sentence overlaps section 8.2, third bullet point.

Paragraph 84

The first sentence should read as follows: When designing a monitoring and surveillance program, representativeness of the data obtained is essential to ensure **high** quality information.

Rationale: This addition is considered necessary to strengthen the importance of an appropriate sampling plan.

Paragraph 85

The third paragraph of the first bullet point should read: Examples of sampling strategies (~~Simple Random Sampling, Stratified Sampling, Systematic Sampling, etc.~~) are provided in Codex documents on food hygiene and methods of analysis and sampling (e.g. *General Guidelines on Sampling* (CXG 50-2004)).

Rationale: This information does not give any added value.

The second sentence of the seventh bullet point should read: The incidence and seasonality of the microorganisms ~~or diseases~~ under study should be considered.

Rationale: In the AMR monitoring and surveillance program diseases are not under investigation, thus it is not useful to consider disease incidence or seasonality.

Paragraph 86

The second sentence should read: Bacterial species studied should include both foodborne pathogens and ~~indicator organisms or commensal bacteria~~ (**indicator bacteria**).

Rationale: To be in line with paragraph 23.

Paragraph 89

The paragraph should read: Target microorganisms for aquatic animals and food of non-animal origin should be determined based on available evidence and ~~risk~~ **relevance to public health. However, the following species should be included, as a minimum, in a surveillance and monitoring programme in aquatic animals: *Salmonella* spp., *Vibrio parahemolyticus*, *Listeria monocytogenes* and in food of non-animal origin: *Salmonella* spp., *Listeria monocytogenes***

Rationale: It is not possible to carry out a risk assessment before monitoring data are collected. The provision should be aligned with the corresponding OIE recommendation. Consideration of *Vibrio parahaemolyticus* should not be mandatory in food of non-animal origin.

Paragraph 99

The first sentence should read: The use of ECOFFs, as interpretive criteria will allow for optimum sensitivity for detection of acquired resistance and comparability between isolates from different ~~origins~~ **sample sources** (e.g. food, animal species).

Rationale: To be in line with the other paragraphs

Paragraph 113

The last two sentences of paragraph 113 could be deleted.

Rationale: No need to go into specifics of WGS.

Paragraph 114

Paragraph 114 could be deleted.*Rationale:* No need to go into specifics of WGS.

Paragraph 123

Add new sentence in the second bullet point reading: **Ways should be defined to exclude “double reporting”.**

Rationale: To avoid reporting sales between retailers.

The third bullet point should be split into two bullet points.

Rationale: Editorial.

Paragraph 124

Delete from the first bullet point (WHO) the details of the AGISAR guidance.

Rationale: Too detailed and may be change over time.

Delete the sub bullets (giving the options for the level of reporting) of the third paragraph of the second bullet point (OIE).

Rationale: Too detailed and may be change over time.

Paragraph 127

The paragraph should read: The minimum data collected to estimate the amount of antimicrobials **sold** should be **the number of packages sold per package-presentations weight in kilograms of active ingredient** of the antimicrobial(s) intended for use in food-producing animals per year. **The competent authority can then calculate these sales to the basic unit: kg active substance. For use data, other units may also be applicable, such as number of animals treated with relevant products** ~~It is possible to estimate total usage by collecting sales data, prescription data, manufacturing data, import and export data or some combinations of these.~~

Rationale: The competent authorities should have access to raw data to ensure the quality. The last sentence is repetitive.

Paragraph 129

The paragraph should read: Information on dosage regimens (dose, dosing interval and duration of the treatment) and route of administration are important elements to ~~include~~ **take into account** when assessing **analysing** antimicrobial usage in food-producing animals.

Rationale: To clarify.

Paragraph 131

The first sentence should read: Variables such as number of animals per farm/species/categories/production, weight of the animals in the population, ~~or differences in how animal species metabolize antimicrobials~~ are important for the interpretation and assessment of the amount of antimicrobials sold or used (numerator).

Rationale: This variable is not relevant in this context.

Paragraph 132

Delete the first bullet point.

Rationale: Too detailed and may be change over time.

Move the last bullet point to become the first bullet point.

Rationale: For a logical flow.

Paragraphs 137 and 142

Paragraph 137 should be adjusted to include information from paragraph 142 and read as follows: To ensure consistent collection and analysis of resistance data, sampling information should be recorded down to individual sample **and isolate** level and should be kept in a national digital database where possible **with each bacterial species and sample source reported to the database separately.**

Paragraph 142 should be deleted accordingly.

Rationale: These topics belong together and should not be dealt with in separate paragraphs.

Paragraph 147

The last sentence should read as follows: Appropriate statistical analysis such as univariate (logistic regression) and multivariate analysis should be used to ensure accuracy **proper interpretation of results.**

Rationale: Accuracy is a technical term which does not specify what is expected from the application of these methods. Thus a revised wording is suggested to express this more clearly.

Paragraph 149

The paragraph should read: Isolates obtained for AMR surveillance ~~should~~ **may** also include ~~representative~~ isolates from sporadic and outbreak foodborne disease cases.

Rationale: These isolates may not always be representative. Inclusion of isolates from sporadic and outbreak foodborne disease cases should be optional.

Paragraph 156

The first sentence should read: Risk communication processes should ~~allow~~ **support** the development of partnerships between the competent authorities and stakeholders.

Rationale: The wording should reflect a much more active approach to support the interaction among the parties involved.