

# 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](mailto:codex@fao.org) - [www.codexalimentarius.org](http://www.codexalimentarius.org)

Agenda Item 6

CRD 11

Original Language Only

## JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

Eighth Session

Virtual

#### PROPOSED DRAFT GUIDELINES ON INTEGRATED MONITORING AND SURVEILLANCE OF FOODBORNE ANTIMICROBIAL RESISTANCE

(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 9 based on the comments received with the aim of facilitating the discussions at TFAMR8 and finding a consensus.*

#### 9. Components of integrated monitoring and surveillance program(s) for AMU

*Co-Chair Comment: Suggestions to amend the title(s) may be discussed once the text of section 9 is agreed upon.*

81bis. (former paragraph 2). [For the purpose of these Guidelines “antimicrobial use” and its abbreviation “AMU” are used to refer to antimicrobials intended for use in animals or plants/crops, which may be obtained from data of antimicrobials sold and/or used in food-producing animals or plants/crops.](#)

81ter. [This section is intended to provide an enabling framework which countries can be utilized to establish monitoring and surveillance of AMU appropriate to their national situation, and which includes considerations of available resources. As such, monitoring and surveillance activities and the data collection may vary between countries.](#)

81quater. [For the monitoring and surveillance of AMU, including sources of sales/use data and the collection and reporting of AMU data in food-producing animals, the OIE’s Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.](#)

#### *Co chairs proposal:*

*Add the following paragraphs as suggested by some members.*

*New para 81bis. Paragraph 2 has been moved from the introduction section 9, with a footnote in Paragraph 3 drawing attention to Section 9 in order to try and obtain consensus from participants*

*New para 81ter. Added to provide flexibility to all the section, emphasizing that aspects related to national situation. A similar paragraph is also proposed to be used in Section 8. The basic content of the paragraph is used in other Codex documents.*

*New para 81quater. Added reference to OIE. Previous version of Section 9 had proposed this statement in two places of section 9. Suggest to add this statement earlier in Section 9.*

#### 9.1. Design of an integrated monitoring and surveillance program(s) for antimicrobial agents intended for use in food producing animals or plants/crops

82. Each country may decide to collect different types of data, sales and/or use, according to their monitoring and surveillance objectives. The antimicrobial sales data collection may evolve into the collection of use data. The competent authority should consider the limitations of each type of data. Some aspects of data collection or reporting need to be specified for sales versus other types of use data; this is reflected below.

82bis. [AMU data is important information to be considered during the interpretation of the results from the AMR monitoring and surveillance program\(s\), along with other relevant epidemiological data.](#)

**Co-chairs proposal**

Keep paragraph 82 as currently stated and add 82bis in line with proposal by one member country to provide further clarification:

*Rationale: Most proposals were editorial in nature or where to delete the paragraph entirely and replace it with reference to OIE. To maintain the guideline as a standalone document, the co-chairs feel it is important for this paragraph to remain and to add 82bis for clarification and to facilitate consensus.*

83. Sales data may be ~~a valuable indicator~~ used to monitor trends although ~~it sales data does do~~ not always reflect the ~~actual~~ real use, administration or application of antimicrobials.

**Co-chairs proposal**

Some amendments in paragraph 83 as suggested by members to improve the text.

*Rationale: the words "dosage, species/class" proposed by a member were not been added as they are covered in paragraph 86 points e, f & g. The co-chairs felt that "actual" may not be well understood and suggest to replace it with "real".*

84. The collection of antimicrobial use data from farms/producers ~~may be challenging but even when it is resource demanding, should be encouraged when possible, as it~~ provides valuable insight on the magnitude of use and species-specific information on how and why antimicrobials are ~~being used~~ administrated.

**Co-chairs proposal:**

The wording "may be challenging but" has been changed to "even when it is resource demanding should be encouraged when possible,".

*Rationale: the description of which is the challenge should provide better guidance ("challenge" is vague, whereas "resources" can imply either human or financial resources). Other editorial amendments for technical accuracy.*

85. The choice of units of measurement and indicators for AMU should be established depending on method and scope of the data collection and the monitoring and surveillance objectives.

**Co-chair proposal**

Indicators have been added.

*Rationale: The addition of "indicators" as both "units of measurement" and "indicators" should be chosen in advance. The suggestion to delete "method" was not incorporated to facilitate achieving consensus on previously discussed text.*

86. The following elements should be considered when deciding on the approach to collect sales and/or use data.

- a. Identification of the scope of the data to be captured (e.g., the antimicrobial agents, classes or sub-classes). The scope may also consider mechanisms of antimicrobial action, relevant resistance data and reporting requirements.
- ~~b. Identification of the most appropriate points of data collection and the stakeholders that can provide the data.~~
- c. Development of a protocol to collect qualitative (e.g., types of antimicrobials on farm) and quantitative information on the antimicrobials intended for use in food producing animals or plants/crops.
- d. Harmonisation of the nomenclature of antimicrobial agents ~~harmonized~~ with international standards where available.
- e. Identification, ~~where possible,~~ of the plant/crop type and species of food-producing animals for which the antimicrobials were intended to be used.
- f. Identification of the level of detail required to meet the surveillance requirements (e.g., production type, route of administration or reason for use).
- g. Information, ~~where possible,~~ on antimicrobial dose, dosing interval and duration.

- h. Technical units of measurement for reporting antimicrobial sales or use.

**Co-Chair proposal:**

Those changes which have been considered editorial or to improve clarity have been added to the body of the text above.

Bullet b: deleted as the text is in Para 40

Bullet c:

“antimicrobials intended for use” is language of the OIE. Flexible language. Put a footnote to refer to the OIE language as per their data collection tool.

Bullet d: editorial

Bullet e and g: The language use in the chapeau sentence is not binding.

Bullet g:

See OIE Chapter 6.9 – in line with OIE language

## 9.2. Sources of sales/use data

87. ~~Options for s~~ Sources of data may include:

- a) Sales data: may be collected from registration authorities, marketing authorization holders, wholesalers, veterinarians, retailers, pharmacies, feed mills, farm shops/agricultural suppliers, pharmaceutical associations, cooperatives or industry trade associations or any combination of these.
  - Import data: may be collected from the competent authorities ~~that are~~ in charge of registration of medicinal products, [the marketing authorization holder](#) or customs. Care must be taken to avoid double counting with sales data in the country and [take into account that some imported ~~these~~ antimicrobials may not be](#) intended for use within the country.
- b) Use data: may be collected from farm/plant health professional records, livestock/plant production company records or estimated from veterinary prescriptions or farm surveys.

88. Data on quantities of antimicrobials sold or used within a country may differ. Differences may include loss during transport ([package](#) damage), storage (due expiry date) and administration (whole package not administered), stock purchased and held for future use, and fluctuations in animal or plant/crop populations.

**Chair proposal:**

Editorial amendments for improvement of simplicity and accuracy of the text.

## 9.3. Collection and reporting of AMU

### Collection of data

~~89. The data collection should cover the following elements:~~

~~*The numerator*~~

90. ~~The numerator is the a~~Antimicrobial quantities representing the amount of antimicrobial agents sold or used [in food-producing animals and/or plants/crops](#). This is normally expressed as the weight in kilograms of the antimicrobials active ingredient which was sold or used ~~during~~ the monitoring and surveillance period. ~~In some cases t~~This may be based on estimates. [The calculation of the numerator should consider the quantities of antimicrobials which may be reported in different units of measurement according to monitoring and surveillance objectives and the types of data collected](#)

91. ~~To calculate the numerator data should include identification of the antimicrobial product, the number of packs quantity sold or used, the pack size and the strength per unit. To interpret and/or analyze the data, considerations for the numerator may include identification of the antimicrobial agent or product, the quantity of packages sold or used, and the strength per unit.~~

**Chair proposal:**

Editorial amendments for improvement of the text.

Paragraph 89: deleted for simplicity.

Text was addition to 90: “The calculation of the numerator should consider the quantities of antimicrobials which may be reported in different units of measurement according to monitoring and surveillance objectives and the types of data collected”.

The two sentences in Paragraph 90 were intended to capture: 1) what is the numerator and 2) what are considerations for calculation of the numerator. The language of Paragraph 90 was built on the concept of providing flexibility for countries implementing monitoring and surveillance of AMU.

The remaining sentence in Paragraph 91 was intended to reflect “additional” considerations for the numerator, using language that makes this sentence less prescriptive.

#### *The denominator*

92. The [denominator is the](#) total food producing animal population or plant/crop area or quantities harvested that may be exposed to the antimicrobials reported during the monitoring and surveillance period. The denominator provides the context for reporting and analyzing the sales and/or use data.

93. [Additional considerations for the denominator may include the c](#)Characteristics of the population of food producing animals or plants/crops treated with the relevant antimicrobial during the monitoring and surveillance period (e.g. [area or quantities harvested, number/percentage of farms included](#), species, type, number, body weight, age) ~~may also be considered~~.

~~94. For collection of data in food producing animals, the OIE’s Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.~~

#### Chair proposal:

Editorial amendments for improvement of the text and to provide added flexibility to countries when developing the denominator. The examples “area or quantities harvested, number/percentage of farms included” were deleted, as these were already covered in the beginning part of Para 92.

Para 94 delete as included in the new chapeau paragraph 81quater

#### **Reporting of data**

95. Multiple units of measurement [and indicators](#) for reporting of sales and/or use may be appropriate depending on the national situation and the monitoring and surveillance objectives.

~~96. For plants/crops, the information above is applicable and additional units of measurement may be established according to national priorities.~~

~~97. For reporting of data in food producing animals, the OIE’s Terrestrial Animal Health and Aquatic Animal Health Codes should be considered.~~

#### Chair proposal:

Delete para 96 and 97

96 is encompassed by 95; hence 96 is not needed and 97 is included in the new chapeau para 81quater.