European Community comments on
Codex Circular Letter CL 2008/33-AMR

Subject: Request for comments on the Proposed Draft Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance

The European Community and its Member States (ECMS) are very pleased to provide the following preliminary comments to CL 2008/33-AMR, in particular on its Appendix II.

The ECMS believe the electronic working group established at the second session of the TF AMR will find opportunities to streamline the text by deleting overlaps and increase readability. A number of questions of detail remain to be discussed and agreed, in particular those paragraphs which are now in brackets and sections that, due to time constraints, were not discussed at the second session of the TF AMR, The ECMS look forward to actively participate in the discussions of the electronic working group.

PART 1

The ECMS support the structure as proposed in Part 1 (ALINORM 09/32/42 Appendix II).

PART 2

The ECMS would like to express general support for Part 2 of the document. Although there might be minor issues remaining following compilation, such as details in Figure 1 and Table 1, with the other documents.

The ECMS note that Table 1 in part 2 and Annex 2 in part 3 (Exposure assessment) have many elements in common. As Table 1 is long and very detailed, it might be better placed as an annex (Annex 3 in that case). In any case, the ECMS consider that consistency between these two items should be ensured.

PART 3

The ECMS appreciate the possibility to streamline the presentation of the risk analysis process in the compiled document by putting preliminary risk management activities into context. Parts of the text need to be reconsidered to fit into the new structure, for example paragraph 18-21 where the establishment of risk management goals are discussed. This section seems to be a mix between establishment of true goals (such as reduction of amount animal related ESBLs in food or reduction of resistance levels in Salmonella) and other factors of relevance when selecting among different ways to reach these goals and whether to commission a risk assessment (such as potential impact on trade). Therefore, these paragraphs should either be removed or modified and possibly moved. As regards paragraph 19, the goal
of any risk managing is to adequately manage the risk (public health). The other factors must be considered when deciding how to manage the risk, but they are not part of the goal, they are part of the decision process.

The ECMS note that the TFAMR discussed that paragraph 15 (on provisional measures) was also reflected in part 4 (risk management) and that its location was to be discussed later. The paragraph was therefore bracketed. The contents of this paragraph relates to a situation when a risk assessment is not available but action is deemed necessary. The ECMS are therefore of the opinion that this paragraph should be located in the section on preliminary risk management activities.

**PART 4**

**IV- Identification of the available options**

In the list of risk management options the wording should clearly indicate that these are options, as opposed to recommendations. The text on how to evaluate and select among those options are presented elsewhere in the document and the text should not be prescriptive. As the options should be selected in the context of the risk analysis process, it should be acknowledged that the final selection and implementation of options should be done in accordance to conclusions drawn from the risk profile/risk assessment.

**A.2- Food animal production**

The ECMS would like to express support for the important list of sub-bullets under the last bullet point. Therefore, the square brackets should be removed.

**A.3- Food crop production**

As regards the text in the fourth paragraph "Prophylactic use on healthy crops should be discouraged. Preventative uses of antimicrobials on crops known to be “at risk” of developing disease (exposed to pathogens, unusual stress, trauma) are acceptable" the ECMS consider that "prophylactic use" and "preventative use" should be defined or a similar wording should be used for crops production as in food animal production. In addition, the text should be rephrased as it is too prescriptive.

**V- Evaluation of identified risk management options (RMO)**

As indicated during the Task Force, the ECMS consider that this section is very general, not specific for the management of AMR, or already covered in other section (e.g. principle 1). If there are not AMR specific issues to be taken into account, just a reference to evaluation within guidelines on microbiological risk management (CAC/GL 63-2007) could be made or the section could be merged with section VI. Preferably, the text should focus on not only what factors to consider when evaluating but also give advice on how to proceed when considering the alternatives.
VI- Selection of risk management (RM) options

A.1- Benefit-risk approach

The current text only refers to the potential risk for animal health, but benefit/risk analysis could also apply to evaluation of risk management options at post-harvest and food crop production with their economic impact.

Annex 2

The ECMS would like to add, as clearly expressed during the last Task Force meeting, that the Annex 2 is problematic as the “step wise approach” seems to be in contradiction with paragraph 5 (section IV) where it is stated that codes of practices are minimum requirements. Therefore, a step by step approach should not be suggested on measures belonging to these codes. In addition, the measures taken also depend on the possibility to implement and control them, the country situation, the public health impact, etc. As drafted it could imply that as many as possible of the options should be implemented independent on the risk analysis.

PART 5

Introduction

The text in the first paragraph should make reference not only to the use of antimicrobial agents in food-producing species but also include plant production. In addition, risk communication should be mentioned in the introduction and the language should be chosen so that the text covers both zoonotic bacteria and resistance determinant at all relevant places.

The second paragraph indicates at the end that “this guidance document presents a consolidated framework specific to AMR risk analysis”. It is suggested to introduce at the end “to be read in conjunction with the guidance mentioned below” otherwise is confusing when proceeding to the end of the introduction section and 7 more guidance are mentioned.

The text in the third paragraph which begins as “More specifically…” should be reconsidered when read together with the text under the heading Scope as there is likely to be overlaps between these two texts.

General principles

The ECMS note that animal health and welfare aspects are not mentioned in the principles although the ECMS believe this was agreed at the task force. The ECMS would therefore suggest that the following principle is added:

**Principle XX: Evaluation of pre-harvest AMR risk management options should include, whenever appropriate, aspects related to animal health and welfare.**

Risk communication

The ECMS generally support the content of the section on risk communication, but believe that during compilation of the document, the section may need to be condensed, removing unnecessary overlaps with other Codex texts while maintaining the general idea and those points that are specific for antimicrobial resistance.