EUROPEAN UNION

Brussels
SANCO G2/MMK/lp (2012) 928254

Subject: **OIE – Next meeting of the Terrestrial and Aquatic Code Commissions, September 2012**

Dear Director General,

Please find here attached:

- comments of the European Union (EU) on Annexes XXXI and XXXIII of the report of the February 2012 meeting of the Terrestrial Animal Health Standards Commission, for consideration at its next meeting of September 2012; and

- additional comments of the EU on the report of the March 2012 meeting of the Aquatic Animal Health Standards Commission for consideration at its next meeting of September 2012.

I trust you will find this useful and I thank you for your continued cooperation.

Yours sincerely,

Dr Georgios Kyriakides Chief Veterinary Officer Cyprus	Dr Bernard Van Goethem Director Veterinary and International affairs DG Health and Consumers European Commission

Annexes: 4

Copy: All Directors / Chief Veterinary Officers of the EU 27 and Croatia, Iceland, Liechtenstein, Norway, Switzerland and Turkey.

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Annex XXXI

CHAPTER 6.10.

RISK ANALYSIS ~~ASSESSMENT~~ FOR ANTIMICROBIAL RESISTANCE ARISING FROM THE USE OF ANTIMICROBIAL AGENTS IN ANIMALS

EU comment
The EU thanks the OIE for its work and in general supports the proposed changes.
The reason to change the title from "assessment" to "analysis" is unclear. Chapter 6.10 almost exclusively addresses risk assessment activities while only cross-references are made to other chapters as regards of risk management and risk communication. For reasons of clarity, the EU proposes to limit Chapter 6.10 to risk assessment or, if the solution is chosen to have one chapter on Risk Analysis, to merge at least the Chapters 6.9 and 6.10, and even possibly together with Chapters 6.6, 6.7 and 6.8.
Furthermore, another structure of the current Chapter 6.10 should be considered. Indeed, there are a lot of common elements in Articles 6.10.1 to 6.10.3. These articles, focussing on risk assessment, could be structured as follows: "hazard identification", "hazard characterisation", "exposure assessment" and "risk characterisation" (based on Codex Alimentarius approach) or "hazard identification", "risk release assessment", "exposure assessment", "consequence assessment" and "risk estimate" (OIE approach).
In general, as outlined in the proposed new paragraph of the introduction in Article 6.10.1, other factors than the use of antimicrobial agents in animals can contribute to the risk related to antimicrobial resistance (AMR) for animals or public health, e.g. dissemination and spread of AMR in animal populations in the absence of use of antimicrobial agents. Indeed, the potential for a given resistant microorganism to cause harm in animals or humans will be no different if resistance has emerged as a result of the use of a specific antimicrobial agent in animals or if it has been disseminated and spread in the population in the absence of use. It is the presence of the resistant microorganism that is of concern, and irrespective of factors influencing the presence there is a need for guidance on how to assess the risk.
For example, enterobacteriaceae (*E. coli* and *Salmonella*) that are resistant to antimicrobial agents that are not used in livestock (carbapenems) have recently been detected in pigs and poultry in the EU (see Fischer *et al.* 2012 (attached) and opinions of the European Food Safety Authority at http://www.efsa.europa.eu/en/efsajournal/pub/2322.htm, http://www.efsa.europa.eu/en/efsajournal/pub/2741.htm and http://www.efsa.europa.eu/en/efsajournal/pub/2764.htm [especially section 4.3.4 on risk and protective factors]). In human medicine this type of AMR is considered a serious threat to public health. Enterobacteriaceae with carbapenemases could theoretically be amplified and spread in animal populations subsequent to the use of various antimicrobial agents (co-selection) and to poor biosecurity, clearly resulting in a need for the risk assessment to include such types of AMR.

However, since carbapenems are not used in food producing animals, that resistance type would not be covered by this chapter since it is not "*arising from the use of antimicrobial agents in animals*" (as stated in the title of the chapter and in the objective in point 2 of Article 6.10.1), nor has it "*emerged as the result of use of a specific antimicrobial agent in animals*" (as stated in the hazard definition in point 4 of Article 6.10.1).

Therefore, the EU suggests that a wording be considered by the OIE in the title, the objective and in the hazard definition that would not limit the scope of the chapter to the fraction of the hazard that AMR may constitute which can specifically be linked to the use of antimicrobial agents in the animal populations in question (e.g. by replacing "arising from" by "linked to" in the title and objective, and "emerges as a result of the use of a specific antimicrobial agent" by "linked to the use of antimicrobial agents" in the hazard identification and throughout the document).

Finally, the EU encourages close collaboration on common issues between OIE and Codex in areas such as AMR. A cross reference to the Codex Guidelines for risk analysis of foodborne antimicrobial resistance should be considered.

Specific comments are inserted in the text below for consideration by the TAHSC at its next meeting.

Article 6.10.1.

Recommendations for analysing the risks to animal and human ~~public~~ health from antimicrobial resistant micro-organisms of animal origin

1. Introduction

   Problems related to antimicrobial resistance are inherently linked to antimicrobial use in any environment, including human and non-human usages. However, the emergence of antimicrobial resistance can occur through factors other than use of antimicrobial agents.

EU comment

It is not clear what factors other than use of antimicrobials can contribute to emergence of antimicrobial resistance. Indeed, other factors can contribute to the dissemination and spread of resistance but seem less relevant to the "emergence".

It is therefore proposed to replace the sentence "However, the emergence of antimicrobial resistance can occur through factors other than use of antimicrobial agents" by "The dissemination and spread of AMR can be influenced by factors other than the use of antimicrobial agents".

   The use of antimicrobial agents for ~~therapy~~ therapeutic and non therapeutic purposes ~~, prophylaxis and growth promotion~~ in *animals* can reduce their efficacy in animal and human medicine, through the development of antimicrobial resistant strains of pathogenic micro-organisms. This *risk* may be represented by the loss of therapeutic efficacy of one or several antimicrobial agents ~~drugs~~ and includes the selection and dissemination of antimicrobial resistant micro-organisms ~~emergence of multi-resistant micro-organisms~~.

2. Objective

   The principal aim of *risk analysis*, for the purpose of this chapter, ~~for antimicrobial resistance in micro-organisms from *animals*~~ is to provide OIE Member Countries~~s~~ with a transparent, objective and scientifically defensible method of assessing and managing the human and animal health *risks* associated with the development of resistance arising from the use of antimicrobial agents in *animals*.

EU comment

In the paragraph above (and also in Art. 6.10.1 point 5 a), Art. 6.10.2 point 2. 1st and 2nd indent, and Art. 6.10.3 point 2. 1st and 2nd indent), the EU proposes to replace "arising from" by "linked to".

Furthermore, the following should be added at the end of the paragraph above:

"[…] and its dissemination and spread".

Indeed, as stated in the general EU comment above, the risks to human and animal health are linked to the presence of the AMR. The risks are therefore not limited to the development of resistance from the use of antimicrobial agents, but are also associated with the possible dissemination and spread of AMR in the population in the absence of use of antimicrobial agents. This should therefore also specifically be mentioned in the description of the objective of this chapter.

3. The risk analysis process

The principles of *risk analysis* are described in Chapter 2.1. ~~Section~~ of this *Terrestrial Code*. The components of risk analysis described in this chapter are *hazard identification*, *risk assessmsent*, *risk management* and *risk communication.*

~~A qualitative risk assessment should always be undertaken. Its outcome will determine whether progression to a quantitative risk assessment is feasible and/or necessary.~~

4. Hazard identification

Hazard identification is defined under the OIE *Terrestrial Code* Chapter 2.1.

For the purpose of this chapter, the *hazard* is the resistant micro-organism and/or resistance determinant that emerges as a result of the use of a specific antimicrobial agent in *animals*. This definition reflects the development of resistance in ~~a species of pathogenic~~ micro-organisms, as well as the development of a resistance determinant that may be passed from one species of micro-organisms~~-~~ to another. The conditions under which the *hazard* might produce adverse consequences include any scenarios through which humans or *animals* could become exposed to a pathogen which contains that resistance determinant, fall ill and then be treated with an antimicrobial agent that is no longer effective because of the resistance.

EU comment

In the first sentence above, the EU suggests to replace "emerges as a result of the use of a specific antimicrobial agent" by "linked to the use of antimicrobial agents" (for rationale, see general EU comment above).

Furthermore, it is proposed to modify the second sentence of the paragraph above as follows:

"This definition reflects the ~~development of resistance in a species of pathogenic micro-organisms, as well as the development of a resistance determinant that may be passed from one species of micro-organisms to another~~ potential for resistant microorganisms to cause adverse health effects, as well as the potential for horizontal transfer of genetic determinants between microorganisms".

Indeed, the hazard lies not in the resistance per se, but rather in the potential of the resistant micro-organism to cause adverse health effects.

Finally, for clarity reasons, it is proposed to modify the third sentence as follows:

"The conditions under which the *hazard* might produce adverse consequences include any scenarios through which humans or *animals* could become exposed to an antimicrobial resistant pathogen ~~which contains that resistance determinant,~~ fall ill and then be treated with an antimicrobial agent that is no longer effective ~~because of the resistance~~".

5. Risk assessment

The *assessment of the risk* to human and animal health from antimicrobial-resistant micro-organisms resulting from the use of antimicrobials in *animals* should examine:

a) the likelihood of emergence of resistant micro-organisms arising from the use of antimicrobial(s), or more particularly, dissemination ~~production~~ of the resistance determinants if transmission is possible between micro-organisms;

EU comment

In point a) above, the EU proposes to replace the words "resistance determinants if transmission is possible between micro-organisms" by "resistant clones and, if transmission is possible between micro-organisms, resistance determinants". Indeed, also resistant micro-organisms themselves should be considered.

b) consideration of all pathways and their importance, by which humans could be exposed to these resistant micro-organisms or resistance determinants, together with the ~~possible degree~~ likelihood of exposure;

EU comment

For better clarity and clearer understanding of the point, the EU proposes to modify point b) above as follows:

"b) consideration of all pathways and their importance, by which humans and animals could be exposed to these resistant micro-organisms or resistance determinants, together with the assessment of the relative importance of each of the pathways ~~likelihood of exposure~~".

c) the consequences of exposure in terms of *risks* to human and~~/or~~ animal health.

The general principle of risk assessment as defined in Chapter 2.1. of the *Terrestrial Code* applies equally to both qualitative and quantitative risk assessment. At a minimum, a qualitative risk assessment should always be undertaken.

EU comment

In the paragraph above, what is designated here a "qualitative risk assessment" is comparable to what is called a "risk profile" in the terminology used by Codex, WHO and FAO. The EU invites the OIE to consider referring to that term by adding "risk profile" in parenthesis after the words "qualitative risk assessment".

Article 6.10.2.

Analysis of risks to human health

1. Definition of the risk

The *infection* of humans with micro-organisms that have acquired resistance to a specific antimicrobial agent due to the used in *animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the human *infection*.

2. Hazard identification

- Micro-organisms that have acquired resistance, (including multiple resistance) arising from the use of an antimicrobial agent(s) in *animals*.

- Micro-organisms having obtained a resistance determinant(s) from other micro-organisms which have acquired resistance arising from the use of an antimicrobial agent(s) in *animals*.

The identification of the *hazard* must include consideration of the class or subclass of the antimicrobial agent(s). This definition should be read in conjunction with point 4) of Article 6.10.1.

EU comment

As regards classes or subclasses of antimicrobial agents, a reference to the WHO critically important antibiotics could be considered by the OIE (http://www.who.int/foodborne_disease/resistance/antimicrobials_human.pdf).

3. Release assessment

A release assessment describes the biological pathways necessary for the use of a specific antimicrobial agent in *animals* to lead to the release of resistant micro-organisms or resistance determinants into a particular environment, and estimating either qualitatively or quantitatively the probability of that complete process occurring. The release assessment describes the probability of the release of each of the potential *hazards* under each specified set of conditions with respect to amounts and timing, and how these might change as a result of various actions, events or measures.

EU comment

For reasons of clarity, the EU proposes to modify the first sentence of the paragraph above as follows:

"A release assessment describes the biological pathways necessary to lead to the release of resistant micro-organisms or resistance determinants into a particular environment due to ~~for~~ the use of a specific antimicrobial agent in animals ~~to lead to the release of resistant micro-organisms or resistance determinants into a particular environment~~. It also estimates~~, and estimating~~ either qualitatively or quantitatively, the probability of that complete process occurring".

The following factors should be considered in the release assessment:

- species of animal treated with the antimicrobial agent(s) in question;

EU comment

The EU proposes to amend the above indent to read as follows:

"- species and production type of animal treated […]".

Indeed, information on the production type is also necessary, as different classes of antimicrobials and different dosages and regimens are employed in different production types (e.g. veal calves or dairy cattle, broilers or laying hens).

- number of *animals* treated, sex, age and their geographical distribution ~~of those *animals*~~;

- prevalence of *infection* or *disease* for which the antimicrobial agent is indicated in the target animal population;
- data on trends in antimicrobial agent use and changes in farm production systems;
- potential extra-label or off-label use;
- ~~variation in~~ methods and routes of administration of the antimicrobial agent(s);
- dosage regimen including duration of use;
- ~~the~~ pharmacokinetics or pharmacodynamics~~/pharmacokinetics~~ of the antimicrobial agent(s);
- ~~micro-organisms developing resistance as a result of the antimicrobial(s) use~~ pathogens that are likely to acquire resistance in animal host;
- commensal bacteria which are able to transfer resistance to human pathogens;
- mechanisms and pathways of direct or indirect transfer of resistance;
- potential linkage of virulence attributes and resistance;
- cross-resistance ~~and/~~or co-resistance with other antimicrobial agents;
- data on occurrence of resistant micro-organisms through surveillance of *animals*, products of animal origin and animal waste products~~ for the existence of resistant micro-organisms~~.

EU comment

- Bullet point 2: The relevance of sex is not clear in this context. The EU would ask the OIE to explain the rationale or to delete the word "sex".

- Bullet point 5: The EU suggests replacing the word "potential" by "data on", as the assessment should be based on actual data not on potential use.

- Bullet point 9 and 10: The EU suggests adding the words "Prevalence of" in the beginning of the sentences.

4. Exposure assessment

An exposure assessment describes the biological pathways necessary for exposure of humans to the resistant micro-organisms or resistance determinants released from a given antimicrobial use in *animals*, and estimating the probability of the exposures occurring. The probability of exposure to the identified *hazards* is estimated for specified exposure conditions with respect to amounts, timing, frequency, duration of exposure, routes of exposure and the number, species and other characteristics of the human populations exposed.

The following factors should be considered in the exposure assessment:

EU comment

It is proposed to change the ordering of the bullet points below following a feed -> animals-> food -> human approach.

- human demographics and food consumption patterns, including traditions and cultural practices in respect to the preparation and storage of food;
- prevalence of resistant micro-organisms in food at the point of consumption;

EU comment

Since cross-contamination can occur e.g. during preparation of food in the household and data on prevalence in the household (after cooking) is mostly not available, data from previous stages should be considered. Furthermore, the term "point of consumption" should be further clarified, as it is often perceived as the household level only. Thus, the EU suggests amending the sentence above to read as follows:

"prevalence of resistant micro-organisms throughout the food chain and ~~in food~~ at the point of consumption (including retail, wholesale trade and catering levels)".

- microbial load in contaminated food at the point of consumption for quantitative risk assessment;

EU comment

Similarly as above, the EU suggests amending the sentence above to read as follows:

"microbial load in contaminated food throughout the food chain and at the point of consumption for quantitative risk assessment".

- environmental contamination with resistant micro-organisms;

EU comment

The EU suggests elaborating this point further, including reference to the risk of spread of resistant micro-organisms through faecal material of animals into the environment and to surface and drinking water for animals and humans.

Reference is made to the EFSA opinion on Campylobacter (http://www.efsa.europa.eu/en/efsajournal/pub/2105.htm) indicating that "Broiler meat may account for 20% to 30% of these, while 50% to 80% may be attributed to the chicken reservoir as a whole (broilers as well as laying hens)"

- prevalence of animal feed contaminated with resistant micro-organisms;

EU comment

For clarity reasons, the EU suggests amending the sentence above to read as follows:

"occurrence of resistant micro-organisms in animal feed".

- transfer ~~cycling~~ of resistant micro-organisms between humans, *animals* and the environment;

- ~~steps~~ measures taken for ~~of~~ microbial decontamination of food;

EU comment

The effect of decontamination will be reflected under the second bullet point (on prevalence of resistant micro-organisms in food). The EU therefore suggests deleting the bullet point above or to merge it with the second bullet point.

- ~~microbial load in contaminated food at the point of consumption;~~

- survival capacity and spread ~~redistribution~~ of resistant micro-organisms during the food production process (including slaughtering, processing, storage, transportation and retailing);

- disposal practices for waste products and the opportunity for human exposure to resistant micro-organisms or resistance determinants in those waste products;

- ~~point of consumption of food (professional catering, home cooking);~~

- variation in consumption and food-handling methods of exposed populations and subgroups of the population;

EU comment

The EU suggests deleting the point above as it is already covered by bullet point 1.

- capacity of resistant micro-organisms to become established in humans;

EU comment

For reasons of clarity, the EU suggests amending the sentence above to read as follows:

"capacity of resistant micro-organisms to colonize ~~become established in~~ humans ".

- human-to-human transmission of the micro-organisms under consideration;

- capacity of resistant micro-organisms to transfer resistance to human commensal micro-organisms and zoonotic agents;

- amount and type of antimicrobials used in response to human illness;

- pharmacokinetics (such as metabolism, bioavailability and, access to intestinal flora).

EU comment

The EU suggests a revision of these last bullet points as some of them seem to already be covered by previous bullet points.

5. Consequence assessment

A consequence assessment describes the relationship between specified exposures to resistant micro-organisms or resistance determinants and the consequences of those exposures. A causal process must exist by which exposures produce adverse health or environmental consequences, which may in turn lead to socio-economic consequences. The consequence assessment describes the potential consequences of a given exposure and estimates the probability of them occurring.

The following factors should be considered in the consequence assessment:

- microbial dose – host response relationships;

- variation in susceptibility of exposed populations or subgroups of the population;

- variation and frequency of human health effects resulting from loss of efficacy of antimicrobial agents and associated costs;

- potential linkage of virulence attributes and resistance;

- ~~changes in human medicinal practices resulting from reduced confidence in antimicrobials;~~

- changes in food consumption patterns due to loss of confidence in the safety of food products and any associated secondary *risks*;

EU comment

It is not clear what is meant by "secondary risk". The EU would therefore ask the OIE to explain.

- ~~associated costs;~~

- interference with first line/choice antimicrobial therapy in humans;

- importance of the antimicrobial agent in human medicine ~~perceived future usefulness of the antimicrobial (time reference)~~;

- prevalence of resistance in human bacterial pathogens under consideration.

6. Risk estimation

A *risk* estimation integrates the results from the release assessment, exposure assessment and consequence assessment to produce overall estimates of *risks* associated with the *hazards*. Thus, *risk* estimation takes into account the whole of the *risk* pathway from *hazard identification* to the unwanted consequences.

The following factors should be considered in the *risk* estimation:

- number of people falling ill and the proportion of that number affected with antimicrobial resistant ~~strains of~~ micro-organisms;

EU comment

In the above bullet point, it is proposed to replace the word "affected" by "infected", for reasons of clarity.

- adverse effects on vulnerable human sub-population (children, immuno-compromised persons, elderly, etc.);

- increased severity or duration of infectious *disease*;

- number of person~~/~~ or days of illness per year;

- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population);

- ~~importance~~ severity of the ~~pathology~~ infection caused by the target micro-organisms;

- existence or absence of alternative antimicrobial therapy;

- potential impact of switching to an alternative antimicrobial agent (e.g. alternatives with potential increased toxicity);

EU comment

The EU suggests adding the following bullet point:

"- potential impact and risk caused by the delay in administering an effective antimicrobial therapy on the outcome (e. g. probability of increased severity, duration, increased hospitalisation or disability rates, increased case-fatality rates)".

- occurrence ~~incidence~~ of antimicrobial resistance in target pathogens observed in humans;

- consequences of the overall ~~to allow weighted summation of different *risk*~~ impacts (e.g. illness and hospitalisation).

7. Risk management components ~~options and risk communication~~

EU comment

The added value of section 7 and section 8 is unclear since it is very general or already dealt with in detail in Chapter 6.9.

The OIE defines risk management as consisting of the steps described below. ~~Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.~~

a) Risk evaluation - the process of comparing the risk estimated in the risk assessment with the Member Country's appropriate level of protection.

b) Option evaluation.

A range of risk management options is available to minimise the emergence and spread of antimicrobial resistance and these include both regulatory and non-regulatory risk management options, such as the development of codes of practice concerning the use of antimicrobials in animal husbandry. Risk management decisions need to consider fully the implications of these different options for human health and animal health and welfare and also take into account economic considerations and any associated environmental issues. Effective control of certain bacterial diseases of animals will have the dual benefit of reducing the risks linked to antimicrobial resistance, in cases where the bacterial disease under consideration has also developed antimicrobial resistance.

c) Implementation

Risk managers should develop an implementation plan that describes how the decision will be implemented, by whom and when. National or regional authorities should ensure an appropriate regulatory framework and infrastructure.

d) Monitoring and review

Risk management options have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.

8. Risk communication

Communication with all interested parties be promoted at the earliest opportunity and integrated into all phasis of a risk analysis. This will provide all interested parties, including risk managers, with the better understanding of risk management approaches. Risk communication should be also well documented.

EU comment

In the paragraph above, please replace "phasis" by "phases" (typographical error).

Article 6.10.3.

Analysis of risks to animal health

1. Definition of the risk

The *infection* of *animals* with micro-organisms that have acquired resistance to ~~from the use of~~ a specific antimicrobial agent~~(s)~~ due to the use in *animals*, and resulting in the loss of benefit of antimicrobial therapy used to manage the animal *infection*.

2. Hazard identification

- m~~M~~icro-organisms that have acquired resistance, (including multiple resistance) arising from the use of an antimicrobial agent(s) in *animals*.

- m~~M~~icro-organisms having obtained a resistance determinant(s) from another micro-organisms which have acquired resistance arising from the use of an antimicrobial agent(s) in *animals*.

The *identification of the hazard* must include considerations of the class or subclass of the antimicrobial agent(s). This definition should be read in conjunction with point 4) of Article 6.10.1.

3. Release assessment

EU comment

There are some factors listed in the "release assessment" section of Article 6.10.2 ("analysis of risks to human health") which are not listed here and may be relevant for animal health as well, such as "*data on trends in antimicrobial agent use and changes in farm animal production systems*" and "*data on extra-label or off-label use*". The EU asks the OIE to consider listing these under Article 6.10.3 as well.

The following factors should be considered in the release assessment:

- animal species treated with the antimicrobial agent in question;

EU comment

The EU proposes to amend the above indent to read as follows:

"- animal species and production type treated […]".

Rationale: same as in comment above.

- number of *animals* treated, sex, age and their geographical distribution;

EU comment

Again, the relevance of sex is not clear in this context. Perhaps this would already be covered by the production type as suggested above.

- dosage regimen including ~~amounts used and~~ duration of ~~treatment~~ use;

- ~~variation in~~ methods and routes of administration of the antimicrobial agent(s);

- the pharmacokinetics or pharmacodynamics~~/ pharmacokinetics~~ of the antimicrobial agent(s);

- site and type of *infection;*

- development of resistant micro-organisms;

- mechanisms and pathways of resistance transfer;

- cross-resistance ~~and/~~or co-resistance with other antimicrobial agents;

- data on occurrence of resistant micro-organisms through surveillance of animals, products of animal origin and animal waste products ~~for the existence of resistant micro-organisms~~.

4. Exposure assessment

The following factors should be considered in the exposure assessment:

- prevalence and trends of resistant micro-organisms in clinically ill and clinically unaffected *animals*;
- prevalence of resistant micro-organisms in feed / the animal environment;

EU comment

The EU suggests replacing the sentence above by the following:

"occurrence of ~~*prevalence of*~~ resistant micro-organisms in feed and in ~~/~~ the animal environment;".

- animal-to-animal transmission of the resistant micro-organisms (animal husbandry methods, movement of *animals*);

EU comment

In the bullet point above, the EU suggests replacing the word "methods" by "practices".

- number ~~/~~ or percentage of *animals* treated;
- ~~dissemination of resistant micro-organisms from *animals* (animal husbandry methods, movement of *animals*);~~
- quantity and trends of antimicrobial agent(s) used in *animals*;
- ~~treatment regimens (dose, route of administration, duration);~~
- survival capacity ~~of resistant micro-organisms~~ and spread of resistant micro-organsims;
- exposure of *wild-life* to resistant micro-organisms;

EU comment

In the indent above, please replace "wild-life" by "wildlife" (typographical error).

- disposal practices for waste products and the opportunity for animal exposure to resistant micro-organisms or resistance determinants in those products;
- capacity of resistant micro-organisms to become established in *animals* ~~intestinal flora~~;
- exposure to resistance determinants from other sources such as water, effluent, waste pollution, etc.;
- ~~dose, route of administration and duration of treatment~~;
- pharmacokinetics, such as ~~(~~metabolism, bioavailability, access to intestinal flora~~)~~;
- transfer ~~cycling~~ of resistant micro-organisms between humans, animals and the environment.

5. Consequence assessment

The following factors should be considered in the consequence assessment:

- microbial dose – host response relationships;
- variation in disease susceptibility of exposed populations and subgroups of the populations;
- variation and frequency of animal health effects resulting from loss of efficacy of antimicrobial agents and associated costs;
- potential linkage of virulence attributes and resistance;
- ~~changes in practices resulting from reduced confidence in antimicrobials;~~
- ~~associated cost;~~
- ~~perceived future~~ importance~~usefulness~~ of the ~~drug~~ antimicrobial agent in animal health (see OIE list of antimicrobials of veterinary importance) ~~(time reference)~~.

6. Risk estimation

The following factors should be considered in the *risk* estimation:

- additional burden of disease due to antimicrobial resistant micro-organisms;

EU comment

In the bullet point above, the EU suggests adding the words "and cost of illness" after the words "additional burden of disease". Indeed, also the economic impact of AMR should be estimated.

- number of therapeutic failures due to antimicrobial resistant micro-organisms;
- increased severity and duration of infectious disease;
- *animal welfare;*
- ~~economic cost;~~
- deaths (total per year; probability per year or lifetime for a random member of the population or a member of a specific more exposed sub-population);
- existence or absence of alternative antimicrobial therapy;
- potential impact of switching to an alternative antimicrobial agent e.g. alternatives with potential increased toxicity;
- estimation of the economic impact and cost on animal health and production.
- ~~incidence of resistance observed in *animals.*~~

7. Risk management ~~options~~components ~~and risk communication~~

The relevant provisions contained in Article 6.9.7. do apply.

~~Risk management options and risk communication have to be continuously monitored and reviewed in order to ensure that the objectives are being achieved.~~

~~The relevant recommendations (Articles 2.1.5., 2.1.6. and 2.1.7.) in the *Terrestrial Code* apply.~~

~~A range of *risk management* options is available to minimize the emergence and spread of antimicrobial resistance and these include both regulatory and non-regulatory *risk management* options, such as the development of codes of practice concerning the use of antimicrobials in animal husbandry. *Risk management* decisions need to consider fully the implications of these different options for human health and animal health and *welfare* and also take into account economic considerations and any associated environmental issues. Effective control of certain bacterial *diseases* of *animals* will have the dual benefit of reducing the *risks* linked to antimicrobial resistance, in cases where the bacterial *disease* under consideration has also developed antimicrobial resistance. Appropriate communication with all stakeholders is essential throughout the *risk assessment* process.~~

8. Risk communication

The relevant provisions contained in Article 6.9.8. do apply.

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— Text deleted

Annex XXXIII

CHAPTER 8.4.

INFECTION WITH *ECHINOCOCCUS GRANULOSUS*

EU comment

The EU thanks the OIE for its work and for having taken into account previous EU comments. The EU supports the proposed changes and has further specific comments inserted in the text below for consideration by the TAHSC at its next meeting.

Article 8.4.1.

General provisions

Echinococcus granulosus is a cestode (tapeworm) found worldwide. The adult worms occur in the intestines of canids, and larval stages (hydatid cysts) in tissues of various organs of other mammalian hosts, including humans. Infection with the larval stage of the parasite in the intermediate host, referred to as 'cystic echinococcosis' or 'hydatidosis', is associated with significant economic losses in livestock production and causes a major disease burden in humans.

For the purpose of the *Terrestrial Code*, infection with *E. granulosus* is defined as a zoonotic parasitic infection of canids, ungulates, and macropod marsupials with *E. granulosus* (ovine, bovine, cervid, camelid and porcine strains).

EU comment

The EU would like to ask the OIE whether felids and carnivores other than canids or felids should be added to the above definition.

Transmission of *E. granulosus* to canids (definitive hosts) occurs through ingestion of hydatid-infected offal from a range of domestic and wild species of herbivores and omnivores (intermediate hosts).

Infection in intermediate hosts, as well as in humans, occurs by ingestion of parasite eggs from contaminated environments. In humans, infection may also occur following contact with infected canids or by consumption of food or water contaminated with *E. granulosus* eggs from canid faeces.

EU comment

In case the list of susceptible species should be amended to include further carnivores (see comment above), the words "canids" and "canid faeces" in the paragraph above (and throughout the text) should be replaced by "infected definitive hosts" and "infected definitive host faeces", respectively.

Preventing transmission can be achieved by targeting both the definitive and intermediate hosts. Infection in humans can be prevented by good food and personal hygiene, community health education and preventing infection of canids. Good communication and collaboration between the *Competent Authority* and the public health authority is an essential component in achieving success in the prevention and control of *E. granulosus* transmission.

EU comment

It is unclear what exactly is meant by "good food and personal hygiene". The wording should be revised. The OIE might also consider adding a reference to a relevant Codex standard.

This chapter provides recommendations for prevention of, control of, and surveillance for infection with *E. granulosus* in dogs and livestock.

Standards for diagnostic tests are described in the *Terrestrial Manual.*

[NOTE: The following terms 'owned dog', 'responsible dog ownership' and 'stray dog' used throughout this chapter are defined in Chapter 7.7. Once this chapter is adopted, this note will be deleted and these definitions will be moved to the glossary of the *Terrestrial Code*.]

Article 8.4.2.

Safe commodities

When authorising import or transit of the following *commodities*, *Veterinary Authorities* should not require any *E. granulosus* related conditions regardless of the status of the animal population of the *exporting country* or *zone*:

– skeletal muscle meat and skeletal muscle meat products;

EU comment

The EU would like to ask the OIE whether meat preparations would be covered by the above commodities. The EU is of the opinion that meat preparations made of skeletal muscle meat should be covered and included in the list. Perhaps a clear definition of the commodities would help avoid misunderstandings.

Moreover, the addition of fat derivatives to the list of safe commodities should be considered.

– casings;

– *milk* and *milk products*;

– hides and skins of livestock;

– embryos, oocytes and semen.

Article 8.4.3.

Prevention and control of infection with *Echinococcus granulosus*

In order to achieve success in the prevention and control of infection with *E. granulosus,* the *Competent Authority* should carry out community awareness programmes to inform people of the risk factors associated with transmission of *E. granulosus* and the importance of hydatidosis in animals and humans, the role of dogs (including stray dogs), the need to implement preventive and control measures, and the importance of responsible dog ownership.

1. Prevention of infection in dogs (owned and stray)

   The following measures should be undertaken:

   a) Dogs should not be fed offal from any animal species unless it has been treated in accordance with Article 8.4.6.

EU comment

The extent of this recommendation is unclear and seems unnecessarily wide. The EU would like to ask the OIE whether any offal in any country should be included and whether organs like e.g. liver that passed post mortem inspection as fit for human consumption would also be considered as offal. Perhaps a definition of offal would help to avoid misinterpretation in this connection.

Furthermore, it seems excessive to recommend the exclusion of raw offal from *any animal species*, as it is known that certain genotypes of *E. granulosus* only affect certain species (e.g. genotypes 8 and 10, which only affect cervids and are suggested by some experts as a different species, *E. canadensis*).

Therefore, the following alternative wording should be considered by the OIE:

"a) Dogs should not be fed offal from ~~any~~ animal species known to be or suspected of being infected in the country, unless the offal has been found free of the parasite in post mortem inspection or treated in accordance with article 8.4.6.".

b) Dogs should not have access to dead animals of any animal species, including *wildlife* species; all dead animals should be disposed of in accordance with provisions in Chapter 4.12.6.

EU comment

The recommendation above is unnecessarily wide as it would prevent hunting dogs from retrieving shot rabbits or game birds, since it states that dogs should not have access to dead animals.

Moreover, it is impractical as it would require specific disposal of all animals that die, including wild animals, whether or not their death is linked to an infectious disease. Indeed, Article 4.12.6 stipulates that the method of disposal of dead animals chosen be based on *inter alia* conditions required for the inactivation of the causative agent.

Therefore, the EU suggests rewording point 1 b) as follows:

"Dogs should ~~not have access to~~ be prevented from consuming dead animals of any animal species, including *wildlife* species; all dead animals where signs of a disease transmissible to animals or humans were identified should be disposed of in accordance with provisions in ~~Chapter~~ Article 4.12.6.".

c) The *Veterinary Authority* or other *Competent Authority* should ensure that *slaughterhouses/abattoirs* have implemented measures that prevent access of dogs to the premise, and to animal carcasses and waste containing offal.

d) When livestock cannot be slaughtered in a *slaughterhouse/abattoir,* and are home-slaughtered, dogs should be prevented from having access to offal, and not be fed offal unless it has been treated in accordance with Article 8.4.6.

2. Control of infection in dogs (owned and stray)

a) For control of stray dog populations, the *Competent Authority* should ensure compliance with relevant aspects of Chapter 7.7.

b) Dogs known to be infected or suspected of having access to raw offal, or in contact with livestock should be dewormed at least every 4-6 weeks with praziquantel (5 mg/kg) or another cestocidal product with comparable efficacy; where possible, faeces excreted up to 72 hours post treatment should be disposed of by incineration or burial.

EU comment

The EU suggests amending the end of the paragraph above as follows:

"Dogs known to be infected or suspected of having access to raw offal <u>from animal species known to be or suspected of being infected in the country</u>~~, or in contact with livestock~~ should be dewormed at least every 4-6 weeks with praziquantel (5 mg/kg) or another cestocidal product with comparable efficacy; ~~where possible,~~ faeces excreted up to 72 hours post treatment should be disposed of by incineration or<u>, if not possible, by</u> burial <u>after sprinkling with quicklime</u>".

Indeed, the recommended regular treatment of all dogs having access to raw offal seems excessive (see comment above). Moreover, there is no need to treat dogs just because of contact with livestock, as the infection does not spread through contact alone.

Finally, burial should be a last choice measure, when disposal of by incineration is not possible, and it is advisable to use quicklime before burial to prevent animals from digging up and getting in contact with faeces possibly containing *Echinococcus* eggs.

c) In areas of persistent transmission, the *Veterinary Authority* should identify the possible origins of the infection, and review and amend, as appropriate, the control programme.

EU comment

The EU suggests inserting the words "attempt to" before the word "identify" as it will not be possible in all cases to identify the origins of infection.

3. <u>Control of infection in livestock</u>

a) The *Veterinary Authority* should ensure that all slaughtered livestock are subjected to post-mortem meat inspection in accordance with Chapter 6.2., including inspection of offal for hydatid cysts.

b) When hydatid cysts are detected during post-mortem meat inspection:

i) offal containing hydatid cysts should be destroyed by incineration or burial, or rendered, or treated in accordance with Article 8.4.6.;

EU comment

The EU suggests amending point i) above as follows:

"[…] by incineration or<u>, if not possible, by</u> burial <u>after sprinkling with quicklime</u>, or rendered, or treated […]".

Indeed, burial should be a last choice measure, when disposal of by incineration or when rendering or the recommended treatment is not possible, and it is advisable to use quicklime before burial to prevent canids from digging up and eating hydatid cyst containing offal.

ii) an investigation should be carried out by the *Veterinary Services* to identify the possible origin of the infection, and review and amend, as appropriate, the control programme.

EU comment

Although cervid strains of *E. granulosus* are mentioned in the second paragraph of Article 8.4.1, there are no specific recommendations for the control and surveillance of infection in game. For example, offal from infected game should also be destroyed and

not fed to dogs. The EU therefore suggests including some recommendations on *E. granulosus* in cervids, both in Article 8.4.3. and 8.4.4.

Article 8.4.4.

Surveillance and monitoring for infection with *Echinococcus granulosus*

An *animal identification* and *traceability* system should be implemented in accordance with the provisions of Chapters 4.1. and 4.2.

1. Monitoring in dogs

   a) Monitoring for infection with *E. granulosus* in dogs should be undertaken as it is an essential component for assessing the current situation regarding transmission within different dog populations and for evaluating the success of control programmes.

   b) Appropriate monitoring strategies should be designed according to local conditions, in particular, where large populations of stray dogs and wild canids exist. Under these circumstances surveillance of environmental samples (faeces, soil) may provide a useful indicator of infection pressure.

   c) Where control programmes are conducted, regular monitoring for infection status should be undertaken. This can be achieved through testing of faeces from dogs, and canid faecal samples from the environment.

2. Surveillance in slaughterhouses/abattoirs

   a) The *Veterinary Services* should carry out systematic surveillance for hydatid cysts in livestock in *slaughterhouses/abattoirs*.

   b) Data collected should be used for the design or adaptation of control programmes.

Veterinary Authorities should use any information on cases of human hydatidosis, provided by the public health authorities, in initial design and any subsequent modification of surveillance and monitoring programmes.

EU comment

To avoid confusion, the EU suggests separating the paragraph above (related to cases of human hydatidosis) from Nr. 2 (related to surveillance in slaughterhouses) by inserting a new subtitle Nr. 3 before the paragraph above, as follows:

"3. Use of data on cases of human hydatidosis".

Furthermore, a second sentence should be added after "[…] surveillance and monitoring programmes" as follows:

"If possible, the data provided by the public health authorities should allow a differentiation at species level in order for cases of hydatidosis due to *E. granulosus* to be differentiated from alveolar echinococcosis due to *E. multilocularis*."

Article 8.4.5.

Recommendations for the importation of dogs and wild canids from an infected country

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animal* has been treated between 48 and 72 hours prior to shipment with praziquantel (5 mg/kg), or another cestocidal product with comparable efficacy against intestinal forms of *E. granulosus*.

EU comment

The EU is of the opinion that the animals should be treated between 24 and 48 hours before shipment. Indeed, this corresponds to the recommendation of the European Food Safety Authority in its opinion of 18 January 2007 (http://www.efsa.europa.eu/en/efsajournal/pub/441.htm), which states that "*The treatment should be administered between 24 and 48h prior to departure so that the probability of re-infection in the country of origin, and the probability of viable egg elimination in the importing country are reduced*".

Furthermore, it is important to avoid reinfection of the animal after treatment. Therefore, the following addition is suggested at the end of the sentence:

"[...] **forms of *E. granulosus*, and that adequate precautions have been taken to avoid reinfection of the *animal* between treatment and embarkation."**

Article 8.4.6.

Procedures for the inactivation of *Echinococcus granulosus* cysts in offal

For the inactivation of *E. granulosus* cysts present in offal, one of the following procedures should be used:

1. heat treatment to a core temperature of at least 80°C for 10 minutes or an equivalent time/temperature;

2. freezing to minus 20°C for at least 2 days.

EU comment

For clarity and consistency reasons, the EU proposes to replace Nr. 2 above by the following:

"2. freezing to a core temperature of minus 20°C or below for at least 2 days."

Annex XXXIII (contd)

CHAPTER X.X.

INFECTION WITH *ECHINOCOCCUS MULTILOCULARIS*

EU comment

The EU thanks the OIE for its work and for having taken into account previous EU comments. The EU supports the proposed changes and has further specific comments inserted in the text below for consideration by the TAHSC at its next meeting.

Article X.X.1.

General provisions

Echinococcus multilocularis is a cestode (tapeworm) which is widespread in some parts of the Northern Hemisphere, and it is maintained mainly in wild animal populations. The adult worms occur in the intestines of canids, particularly foxes, and larval stages (metacestode) in tissues of various organs of other mammalian hosts (commonly rodents), including humans. Infection with the larval stage of the parasite in the intermediate host, causes severe disease in humans (referred to as 'alveolar echinococcosis'), but does not cause discernible health impacts in livestock.

EU comment

Adult worms do occur in other species than canids (e.g. in felids), and canids can also serve as intermediate hosts. Therefore, in order to clarify the role of the different species and to avoid contradictions with the paragraphs below, the EU suggests amending the second sentence of the paragraph above as follows:

"The adult worms mainly occur in the intestines of canids, particularly foxes (definitive hosts), whereas~~and~~ larval stages (metacestode) occur in tissues of various organs of rodents and other mammalians including canids~~hosts~~ (intermediate hosts~~commonly rodents~~), as well as in~~including~~ humans (dead-end hosts)."

Furthermore, the third sentence should be amended as follows:

"Infection with the larval stage of the parasite ~~in the intermediate host,~~ may cause severe disease in humans (referred to as 'alveolar echinococcosis'), but may~~does~~ not cause discernible health impacts in other intermediate hosts~~livestock~~".

Indeed, severe disease usually is only seen in humans, several years or decades post infection, and sometimes in certain intermediate hosts like dogs. In other possible intermediate hosts, health impacts may not be seen because the animal might not live long enough to develop clinical signs. Moreover, it is not clear what species of livestock are being referred to in the proposed text and why. Indeed, *E. multilocularis* (as opposed to *E. granulosus*) would usually not affect livestock, and livestock does not seem to play an epidemiological role (e.g. pigs would be dead-end hosts, as stated below).

For the purpose of the *Terrestrial Code*, infection with *E. multilocularis* is defined as a zoonotic parasitic infection of domestic and wild canids, felids, rodents and pigs.

EU comment

To avoid confusion, the EU suggests moving the above sentence towards the end of the article, before the paragraph starting with "This chapter provides recommendations".

Transmission of *E. multilocularis* to canids (definitive hosts) occurs through ingestion of metacestode-infected viscera from a range of wild small mammalian species (intermediate hosts). Foxes and some other wild canids are the most important definitive hosts in maintaining the cycle at the wildlife-human interface through contaminating both rural and urban environments. Dogs may also act as important and efficient definitive host in both rural and urban environments, providing an important potential source for human infections. Even though the potential role of felids in transmission of infection to humans cannot be excluded, their epidemiological role is considered negligible. Pigs may become infected but the parasite remains infertile; therefore, they have no role in transmission of the parasite.

EU comment

The EU suggests amending the first sentence of the paragraph above as follows:

"[…] from a range of wild rodent and other small mammalian species […]".

Furthermore, the second sentence should be amended as follows:

"Foxes, racoon dogs and some other wild canids […]".

Finally, the last sentence should be amended as follows:

"Pigs, including wild boar, may become infected but […]".

Rationale: clarification of species affected.

Infection in intermediate hosts, as well as in humans, occurs by ingestion of parasite eggs from contaminated environments. In humans, infection may also occur following contact with infected definitive hosts or by consumption of food or water contaminated with *E. multilocularis* eggs from faeces.

EU comment

The EU suggests amending the second sentence of the paragraph above as follows:

"In humans, infection through egg ingestion may also occur […]".

Rationale: clarification of the mode of infection of humans.

Prevention of infection in humans is difficult, particularly in areas with a high infection pressure maintained by rural and urban foxes. The risk of infections can be reduced by good food and personal hygiene, community health education and preventing infection of dogs and cats. Good communication and collaboration between the *Competent Authority* and public health authorities is an important component in monitoring the extent of infection with *E. multilocularis* in human and animal populations.

EU comment

It is unclear what exactly is meant by "good food and personal hygiene". The wording should be revised or a reference added to a relevant Codex standard.

Moreover, as a reduction of the risk for human infection by food and personal hygiene has to our knowledge not actually been shown in a scientific study, the OIE should consider deleting that part of the sentence altogether or putting it in conditional form (i.e. "may be reduced").

Finally, the EU suggests adding baiting of foxes with cestocidal products as a possible risk reduction method in areas of high disease prevalence, as this will reduce the contamination of the environment and thus the risk of infection.

This chapter provides recommendations for prevention, control and monitoring of infection with *E. multilocularis* in dogs and cats, and monitoring in wild canids.

Standards for diagnostic tests are described in the *Terrestrial Manual*.

[NOTE: The following terms 'owned dog', 'responsible dog ownership' and 'stray dog' used throughout this chapter are defined in Chapter 7.7. Once this chapter is adopted, this note will be deleted and these definitions will be moved to the glossary of the *Terrestrial Code*.]

Article X.X.2.

Prevention and control of infection with *Echinococcus multilocularis* in dogs (owned and stray) and cats

In order to achieve success in the prevention and control of infection with *E. multilocularis,* the *Competent Authority* should carry out community awareness programmes to inform people of the risk factors associated with transmission of *E. multilocularis* and the importance of alveolar echinococcosis in animals and humans, the role of foxes and other wild canids, dogs (including stray dogs), and cats, the need to implement preventive and control measures, and the importance of responsible dog ownership and cat ownership.

Whenever the epidemiological situation makes a control programme necessary, the following measures should be undertaken:

1. Owned dogs and cats should not be allowed to roam freely unless treated according to point 3.

2. For control of stray dog populations, the *Competent Authority* should ensure compliance with relevant aspects of Chapter 7.7.

3. Dogs and cats known to be infected should immediately be treated with praziquantel (5 mg/kg) or another cestocidal product with a comparable efficacy; dogs suspected of having access to rodents or other small mammals should be treated at least every 21–26 days.

EU comment

The EU is of the opinion that cats should not be included in this article, as their epidemiological role is considered to be negligible, as stated in Article X.X.1 above.

Furthermore, the treatment interval for dogs should be 28 days, which corresponds to the prepatent period.

Finally, for the same reasons as in Chapter 8.4, faeces should be disposed of by incineration or, if not possible, by burial after sprinkling with quicklime. Therefore, the following should be added at the end of point 3 above:

"[…] at least every 21-26 days; faeces excreted up to 72 hours post treatment should be disposed of by incineration or, if not possible, burial after sprinkling with quicklime."

Article X.X.3.

Monitoring for infection with *Echinococcus multilocularis*

1. Monitoring in foxes and other wild canids

   a) Monitoring for infection with *E. multilocularis* in foxes and other wild canids should be undertaken as it is an essential component for assessing the current situation regarding prevalence of infection.

b) Appropriate monitoring strategies should be designed according to local conditions, in particular, where large populations of definitive hosts exist. Under these circumstances environmental sampling (faeces) may provide a useful indicator of infection pressure.

2. Surveillance in slaughterhouses/abattoirs

a) The *Veterinary Services* should consider carrying out targeted surveillance for larval lesions of *E. multilocularis* in livers of pigs raised in outdoor condition.

b) Data collected will provide useful additional information regarding prevalence of infection.

EU comment

The EU asks the OIE to clarify the need for the surveillance in slaughterhouses, if pigs as stated above do not play any role in the transmission of the parasite, by amending point 2 a) above as follows:

"a) Since pigs do not play an epidemiological role in the transmission to humans but may serve as indicators of the presence of the parasite in the environment, the Veterinary Services should consider carrying out targeted surveillance for larval lesions of *E. multilocularis* in livers of domestic pigs raised in outdoor condition, as well as in feral pigs and wild boar."

Indeed, as pigs raised in outdoor conditions should be targeted by this surveillance, it would be important to also include feral pigs and wild boar when these are presented to the Veterinary Services for post mortem inspection.

As a consequence, the title of point 2 should also be amended to read as follows:

"2. Targeted surveillance in pigs and wild boar".

Veterinary Authorities should use any information on cases of human infection, provided by public health authorities for estimation of parasite transmission.

EU comment

It is not clear whether mentioning cases of human infection after the paragraph on surveillance in slaughterhouses means that this infection in humans is solely related to pigs and to avoid confusion, the EU suggests separating the paragraph above (related to cases of human hydatidosis) from Nr. 2 (related to surveillance in slaughterhouses) by inserting a new subtitle Nr. 3 before the paragraph above, as follows:

"3. Use of data on cases of human hydatidosis".

Furthermore, a second sentence should be added after "[…] surveillance and monitoring programmes"as follows:

"If possible, the data provided by the public health authorities should allow a differentiation at species level in order for cases of hydatidosis due to *E. granulosus* to be differentiated from alveolar echinococcosis due to *E. multilocularis*."

Article X.X.4.

Recommendations for the importation of dogs, wild canids and cats from an infected country

Veterinary Authorities of *importing countries* should require the presentation of an *international veterinary certificate* attesting that the *animal* has been treated between 48 and 72 hours prior to shipment with praziquantel (5 mg/kg), or another cestocidal product with a comparable efficacy against intestinal forms of *E. multilocularis*.

EU comment

The EU is of the opinion that cats should not be included in this article, as their epidemiological role is considered to be negligible, as stated in Article X.X.1 above.

Furthermore, animals should be treated between 24 and 48 hours before shipment. Indeed, this corresponds to the recommendation of the European Food Safety Authority in its opinion of 18 January 2007 (http://www.efsa.europa.eu/en/efsajournal/pub/441.htm), which states that "*The treatment should be administered between 24 and 48h prior to departure so that the probability of re-infection in the country of origin, and the probability of viable egg elimination in the importing country are reduced*".

Furthermore, it is important to avoid reinfection of the animal after treatment. Therefore, the following addition is suggested at the end of the sentence:

"[…] forms of *E. multilocularis*, and that adequate precautions have been taken to avoid reinfection of the *animal* between treatment and embarkation."