

CODEx ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of the
United Nations



World Health
Organization

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Agenda Item 4

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

AD HOC CODEX INTERGOVERNMENTAL TASK FORCE ON ANTIMICROBIAL RESISTANCE

Fifth Session

PROPOSED DRAFT REVISION OF THE CODE OF PRACTICE TO MINIMIZE AND CONTAIN ANTIMICROBIAL RESISTANCE (CAC/RCP 61-2005)

Comments of New Zealand

NEW ZEALAND

| SPECIFIC COMMENTS | |
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| Section/paragraph | Member/Observer/ rationale |
| [3. Where available, national and local guidelines to minimize and contain antimicrobial resistance should be taken into consideration. Best practices and guidelines on the responsible and prudent use of antimicrobials developed by governmental and professional organizations should also be considered.] | |
| [3. Where available, national-intnational and local guidelines to minimize and contain antimicrobial resistance should be taken into consideration. Best practices and guidelines on the responsible and prudent use of antimicrobials developed by governmental and professional organizations should also be considered.] | Should also reference international guidance as appropriate eg WHO, FAO |
| <p>4. [4.] This document provides additional guidance for [on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on] the responsible and prudent use of antimicrobials in [the] food [chain]-producing animals, and should be read in conjunction with the Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993. It's objectives are [part of a One Health approach] to minimize the potential adverse impact on public [and animal] health resulting from the use of antimicrobial agents in [the] food [chain]-producing animals, in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of veterinary antimicrobial [agents]drugs in veterinary medicine by maintaining their efficacy. This document defines the respective responsibilities of authorities and groups[relevant stakeholders] involved in the authorization, production, control, distribution and use of veterinary antimicrobials such as the national regulatory authorities, the veterinary pharmaceutical industry[manufacturers], veterinarians [and plant health professionals], [wholesale and retail] distributors[,] and [food] producers[, and consumers] of food-producing animals.</p> | |
| <p>4. [4.] This document provides additional guidance for [on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on] the responsible and prudent use of antimicrobials in [the] food [chain]-producing animals, and should be read in conjunction with the Recommended International Code of Practice for Control of the Use of Veterinary Drugs CAC/RCP 38-1993. It's objectives are [part of a One Health approach] to minimize the potential adverse impact on public [and animal] health resulting from the use of antimicrobial agents in [the] food [chain]-producing animals, in particular the development of antimicrobial resistance. It is also important to provide for the safe and effective use of veterinary antimicrobial [agents]drugs in veterinary medicine by maintaining their efficacy. This document defines the respective responsibilities of authorities and groups[relevant stakeholders] involved in the authorization, production, control, distribution and use of veterinary antimicrobials such as the national regulatory authorities, the veterinary pharmaceutical industry[manufacturers], veterinarians [and plant health professionals], [wholesale and retail] distributors[,] and [food]</p> | <p>While it refers to One Health, there is no explanation of the aspirational goal of supporting an intergrated approach to risk management of AMR across all relevant sectors. While it is fully recognised that Codex only has a mandate for the food chain, methodologies, analysis of information and reporting should be aligned across all sectors to the greatest extent practical.</p> |

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| producers[, and consumers] of food-producing animals. The code also recognises the contribution of other stakeholders who undertake voluntary activities to monitor and minimise AMR through the food chain. | |
| [7. This Code of Practice addresses the risk to human health associated with the presence in food and animal feed, and the transmission through food and animal feed, of antimicrobial resistant microorganisms or determinants. It provides [risk-based] guidance on relevant measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices in agriculture (crops) and animal husbandry and guidance on the responsible and prudent use of antimicrobial agents in agriculture (crops), animal husbandry, and aquaculture. Its objectives are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. All actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.] | |
| [7. This Code of Practice addresses the risk to human health associated with the presence in food and animal feed, and the transmission through food and animal feed, of antimicrobial resistant microorganisms or determinants. It provides [risk-based] guidance on relevant <u>and proportional</u> measures along the food chain to minimize the development and spread of foodborne antimicrobial resistance, including guidance on good practices in agriculture (crops) and animal husbandry and guidance on the responsible and prudent use of antimicrobial agents in agriculture (crops), animal husbandry, and aquaculture. Its objectives are to minimise the potential adverse impact on public health resulting from the use of antimicrobial agents. All actors involved in the authorisation, manufacture, sale and supply, prescription and use of antimicrobials in the food chain together with those involved in the handling, preparation, distribution and consumption of food have a role to play in optimizing the use of antimicrobials and limiting the spread of resistant microorganisms and determinants.] | It is essential that a risk based approach is applied to selection of relevant measures that results in the proportional application of such measures. |
| [Medically important antimicrobials: Antimicrobial agents important for therapeutic use in humans.] | |
| [Medically important antimicrobials: Antimicrobial agents important for therapeutic use in humans.] | Does this relate to WHO critically important list or to antimicrobials per se used on humans? The definition needs more clarity. |
| [Treatment of disease: Administration of antimicrobial agents to infected individuals or populations to resolve clinical signs, infection or illness.] | |
| [Treatment of disease: Administration of antimicrobial agents to infected individuals or populations to resolve clinical signs, infection or illness.] | Does this cover use on plants? |
| [Marketing Authorization: Process of reviewing and assessing a dossier to support a medicinal product to determine whether to permit its marketing (also called licensing, registration, approval, etc.), finalized by granting of a document also called marketing authorization (MA) (equivalent: product license).] | |
| [Marketing Authorization: Process of reviewing and assessing a dossier to support a medicinal product to determine whether to permit its marketing (also called licensing, registration, approval, etc.), finalized by granting of a document also called marketing authorization (MA) (equivalent: product license).] | Delete medicinal as this is not relevant to plants |
| [Principle 4: The WHO list of Critically Important Antimicrobials, the OIE List of Antimicrobials of Veterinary Importance, and national lists, where available, should be used to set priorities for risk assessment and risk management. The lists should be regularly updated.] | |
| [Principle 4: The WHO list of Critically Important Antimicrobials, the OIE List of Antimicrobials of Veterinary Importance, and national lists, where available, should be used to set priorities for risk assessment and risk management. The lists should be regularly updated.] | In recognising this principle, the CoP should provide guidance on how risk management decisions such as this are arrived at by the relevant competent authorities. |
| [Principle 10: Monitoring and surveillance of the use of antimicrobial agents and the incidence or prevalence, and in particular trends, of foodborne antimicrobial resistant microorganisms and determinants are among the critical factors to consider when evaluating and determining the effectiveness of implemented risk | |

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| management measures. Use of medically important antimicrobial drugs in humans and animals, and transmission of pathogens and resistance genes between humans, animals, and the environment are additional factors to consider.] | |
| [Principle 10: Monitoring and surveillance of the use of antimicrobial agents and the incidence or prevalence, and in particular trends, of foodborne antimicrobial resistant microorganisms and determinants are among the critical factors to consider when evaluating and determining the effectiveness of implemented risk management measures. Use of medically important antimicrobial drugs in humans humans, animals and animals on plants, and transmission of pathogens and resistance genes between humans, animals, <u>plants</u> and the environment are additional factors to consider.] | |
| [Principle 12: Medically important antimicrobials should be administered or applied only by veterinarians, plant health professionals or other suitably trained person authorized in accordance with national legislation.] | |
| [Principle 12: Medically important antimicrobials should be administered or applied only by veterinarians, plant health professionals or other suitably trained person authorized in accordance with national legislation.] | What is meant by plant health professionals? |
| [Principle 14: Administration of antimicrobial agents should be based on sound clinical judgement and where feasible on the results of integrated resistance surveillance and monitoring (bacterial cultures and antimicrobial susceptibility testing), as well as relevant experience.] | |
| [Principle 14: Administration of antimicrobial agents <u>in animals</u> should be based on sound clinical judgement and where feasible on the results of integrated resistance surveillance and monitoring (bacterial cultures and antimicrobial susceptibility testing), as well as relevant experience.] | Is not really applicable to plants |
| [Principle 15: The reduce, replace and rethink (RRR) strategy should be actively promoted within all sectors.] | |
| [Principle 15: The reduce, replace and rethink (RRR) strategy should be actively promoted within all sectors.] | Is this appropriate for a Codex document. |
| [Principle 16: On a continuous and stepwise implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements as from a public health perspective.] | |
| [Principle 16: On a continuous and stepwise implementation of risk management measures along the food chain to minimize the possible risks associated with foodborne AMR, priority should be given to the most relevant elements as from a public health perspective.] | The end statement relating to relevant elements is unclear on meaning. We believe priorities should be given to those measures that have the greatest proportional impact on minimising AMR transmission. |
| QUALITY CONTROL OF ANTIMICROBIAL AGENTS | |
| 17-[12. Regulatory authorities should ensure that quality controls are carried out in accordance with international guidance and in compliance with the provisions of good manufacturing practices., in particular: | |
| <ul style="list-style-type: none"> • to ensure that the quality and concentration (stability) of veterinary antimicrobial drugs in the marketed dosage form(s) is maintained and properly stored up to the expiry date, established under the recommended storage conditions. • to ensure the stability of veterinary antimicrobial drugs when they are mixed with feed or drinking water. • to ensure that all veterinary antimicrobial drugs are manufactured to the appropriate quality and purity. | |
| 17-[12. Regulatory authorities should ensure that quality controls are carried out in accordance with international guidance and in compliance with the provisions of good manufacturing practices., in particular: | In relation to GMP, then this is currently not a requirement for antibiotics used on plants. |
| [ASSESSMENT OF ENVIRONMENTAL IMPACT] | |
| | Is this considered within the scope of Codex |
| [20. Regulatory authorities should consider the environmental aspects of AMR (e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation and using manure for soil | |

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| fertilization, harmonized monitoring and establishment of maximum admissible levels, etc.] | |
| [20. Regulatory authorities should consider the environmental aspects of AMR (e.g. pollution from pharmaceutical-manufacture, impacts of reusing waste water for irrigation and using manure for soil fertilization, harmonized monitoring and establishment of maximum admissible levels, etc.) | |
| ESTABLISHMENT OF A SUMMARY OF PRODUCT CHARACTERISTICS FOR EACH VETERINARY ANTIMICROBIAL DRUG FOR FOOD-PRODUCING ANIMALS | |
| | What about food producing plants? |
| 38.[35. The relevant authorities should develop effective [and compulsory] procedures for the safe collection and destruction of unused or out-of-date veterinary antimicrobial drugs[agents]. | |
| 38. [35. The relevant authorities should develop effective [and compulsory] procedures for the safe collection and destruction of unused or out-of-date veterinary antimicrobial drugs[agents]. | We are not sure whether it is appropriate to have this as a compulsory requirement. |
| 44.[42.] Retailers distributing veterinary [medically important] antimicrobial[s] drugs should only do so on the prescription of a veterinarian, [plant health professional] or other suitably trained person authorized in accordance with national legislation and all products should be appropriately labelled. | |
| 44. [42.] Retailers distributing veterinary [medically important] antimicrobial[s] drugs should only do so on the prescription of a veterinarian, [plant health professional] or other suitably trained person authorized in accordance with national legislation and all products should be appropriately labelled. | New Zealand would seek clarification on how this would operate for plant health professionals |
| 50.[48.] Veterinary a[A]ntimicrobial drugs[agents] should only be used when necessary and in an appropriate manner: | |
| 50. [48.] Veterinary a[A]ntimicrobial drugs[agents] should only be used when necessary and in an appropriate manner: | This is not a good fit for the plant side of things. |
| 54.[51.] [For food-producing animals, the]The off-label use of a veterinary antimicrobial drug may be permitted in appropriate [(exceptional)] circumstances and should be in agreement with the national legislation in force including the administrative withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, and the duration of the treatment. Off-label use of [medically important] antimicrobial growth promoters should not be permitted. | |
| 54. [51.] [For food-producing animals, the]The off-label use of a veterinary antimicrobial drug may be permitted in appropriate [(exceptional)] circumstances and should be in agreement with the national legislation in force including the administrative withdrawal periods to be used. It is the veterinarian's responsibility to define the conditions of responsible use in such a case including the therapeutic regimen, the route of administration, and the duration of the treatment. Off-label use of [medically important] antimicrobial growth promoters should not be permitted. | Is the reference to administrative withdrawal periods meant to mean a legal requirement? |
| <ul style="list-style-type: none"> to not use out-of-date veterinary antimicrobial drugs[agents] and to dispose of all unused veterinary antimicrobial drugs[agents] in accordance with the provisions on the product labels [and national legislation]; | |
| to not use out-of-date veterinary antimicrobial drugs[agents] and to dispose of all unused veterinary antimicrobial drugs[agents] in accordance with the provisions on the product labels [and national legislation]; | This may cause issues for antibiotics used on plants |
| <ul style="list-style-type: none"> to keep adequate records of all veterinary antimicrobial drugs[agents] used, including the following: | |
| to keep adequate records of all veterinary antimicrobial drugs[agents] used, including the following: | Parts of this section are most so relevant to plants |
| [57. The responsible and prudent use of antimicrobials must be supported by continuous efforts in disease prevention to minimise infection during production and decrease the volume of antibiotics used. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, and implementing national or international good | |

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| animal husbandry, aquaculture, or agricultural practices. Disease prevention through the use of vaccines and other measures such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonisation of some bacterial pathogens) should be considered and applied wherever appropriate and available.] | |
| [57. The responsible and prudent use of antimicrobials must be supported by continuous efforts in disease prevention to minimise infection during production and decrease the volume of antibiotics used. Efforts should aim to improve health, thereby reducing the need for antibiotics. This can be achieved by improving hygiene, biosecurity and health management on farms, and implementing national or international good animal husbandry, aquaculture, or agricultural practices. Disease prevention through the use of vaccines and other measures such as probiotics (beneficial bacteria found in various foods), prebiotics (non-digestible foods that help probiotic bacteria grow and flourish) or competitive exclusion products (intestinal bacterial flora that limit the colonisation of some bacterial pathogens) should be considered and applied wherever appropriate and available.] | This section is very animal focused |
| [Responsibilities of Consumers] | |
| [Responsibilities of Consumers] | Is there any recommendations for handling plant based foods? |