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 - www.codexalimentarius.org

**Agenda Item 5** **CRD06**

**ORINGINAL LANGUAGE ONLY**

**JOINT FAO/WHO FOOD STANDARDS PROGRAMME**

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

**Seventh Session**

# Proposed Draft revision of the Code of practice to minimize and contain foodborne antimicrobial resistance (CXC 61-2005)

## Comments of International Feed Industry Federation (IFIF)

| Location | Current Text | Recommended Revision | Rationale |
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| **§1** | Antimicrobial resistance (AMR) poses an important, complex, and priority global public health challenge. Throughout the food chain, there is a need to address the risks associated with development, selection and dissemination of foodborne resistant microorganisms and resistance determinants. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in animal production (terrestrial and aquatic), plant/crop production ~~of food of plant origin,~~ food/feed processing, packaging, storage, transport, and wholesale and retail distribution should form a key part of multi-sectoral national action plans to address risks of foodborne AMR. | Antimicrobial resistance (AMR) poses an important, complex, and priority global public health challenge. **Along**~~Throughout~~ the food chain, there is a need to address the risks associated with development, selection and dissemination of foodborne **antimicrobial** resistant microorganisms and **antimicrobial** resistance determinants. Responsible and prudent use of antimicrobial agents in all sectors following a One Health Approach and strategies for best management practices in animal production (terrestrial and aquatic), plant/crop production ~~of food of plant origin,~~ food/feed processing, packaging, storage, transport, and wholesale and retail distribution should form a key part of multi-sectoral national action plans to address risks of foodborne AMR. | For consistency with the definitions |

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| **§2** | This Code of Practice addresses the responsible and prudent use of antimicrobial agents by participants in the food chain, including, but not limited to, the role of competent authorities, the pharmaceutical industry, veterinarians, and plant/crop health professionals, and food producers and processors. It provides guidance on measures and practices at primary production, and during processing, storage, transport, wholesale and retail distribution of food to prevent, minimize and contain foodborne antimicrobial resistance in the food supply. It also identifies knowledge gaps and provides guidance on communication strategies to consumers. | This Code of Practice addresses the responsible and prudent use of antimicrobial agents by participants in the food chain, including, but not limited to, the role of competent authorities, the pharmaceutical industry, veterinarians, and plant/crop health professionals, and food**/feed** producers and processors. It provides guidance on measures and practices at primary production, and during processing, storage, transport, wholesale and retail distribution of food to prevent, minimize and contain foodborne **AMR**~~antimicrobial resistance~~ in the food **chain**~~supply~~. It also identifies knowledge gaps and provides guidance on communication strategies to consumers. | For consistency with definitions and completeness |
| **§3** | In keeping with the Codex mandate this Code of Practice addresses antimicrobial use in the food chain. It is recognized that the use of antimicrobial agents in the food chain may result in exposure to antimicrobial resistant bacteria or their determinants in the food production environment. As part of a One Health strategy to minimize and contain antimicrobial resistance, only authorized products should be used and best practices in the food production sector should be followed to minimize the occurrence/persistence in the food production environment of antimicrobials and their metabolites from food production related activities, and to minimize the risks associated with the selection and dissemination of resistant microorganisms and resistance determinants in the food production environment. | . In keeping with the Codex mandate this Code of Practice addresses **the use of** antimicrobial **agents** ~~use~~ in the food chain **which**. ~~It is recognized that the use of antimicrobial agents in the food chain~~ may result in exposure to antimicrobial resistant bacteria or their determinants in the food production environment. As part of a One Health strategy to minimize and contain **AMR**~~antimicrobial resistance~~, only authorized antimicrobials should be used and best practices in the food production sector should be followed to minimize the occurrence/persistence in the food production environment of antimicrobials and their metabolites from food production related activities, and to minimize the risks associated with the selection and dissemination of **antimicrobial** resistant microorganisms and **antimicrobial** resistance determinants in the food production environment. | For better reading and for consistency with definitions |

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| **§4** | This Code of Practice is an integral part of risk analysis focusing on risk management options and should be read in conjunction with other Codex texts including the *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance* and the *Guidelines for risk analysis of foodborne antimicrobial resistance* (CXG 77-2011). In addition, the *Code of hygienic practice for fresh fruits and vegetables* (CXC 53-2003), ~~and~~ the *Code of practice on good animal feeding* (CXC 54-2004), and the *Guidelines for the design and implementation of national regulatory food safety assurance program associated with the use of veterinary drugs in food producing animals* (CXG 71-2009) are particularly relevant for use of agricultural chemicals on plants/crops, animal feed, and veterinary drugs, respectively. | This Code of Practice is an integral part of risk analysis focusing on risk management options and should be read in conjunction with other Codex texts including the *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance* and the *Guidelines for risk analysis of foodborne antimicrobial resistance* (CXG 77-2011). In addition, the *Code of hygienic practice for fresh fruits and vegetables* (CXC 53-2003), ~~and~~ the *Code of practice on good animal feeding* (CXC 54-2004), and the *Guidelines for the design and implementation of national regulatory food safety assurance program associated with the use of veterinary drugs in food producing animals* (CXG 71-2009) are particularly relevant for **the** use of ~~agricultural chemicals~~ **antimicrobial agents** on plants/crops, **in** animal feed, and **as** veterinary drugs, respectively. | The document focuses on antimicrobial agents. Therefore, the word ‘agricultural chemical is inappropriate’ |

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| **§6** | The *Principles and guidelines for the conduct of microbiological risk management* (CXG 63-2007) contains guidance for developing and implementing risk management measures. Setting priorities and identifying risk management measures should take into account the following:<br>• *WHO guidance on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach;*<br>• [*WHO list of critically important antimicrobials for human medicine, specifically the Annex with the complete list of antimicrobials for human use, categorized as critically important, highly important and important;*]<br>• Relevant chapters of the *OIE terrestrial and aquatic animal health codes* and the *List of antimicrobial agents of veterinary importance; and*<br>• *National/Regional lists of important antimicrobials for humans and animals where they exist.* | The *Principles and guidelines for the conduct of microbiological risk management* (CXG 63-2007) contains guidance for developing and implementing risk management measures. Setting priorities and identifying risk management measures should consider the following:<br>• **Relevant chapters of the Office International des Epizooties (*OIE) terrestrial and aquatic animal health codes* and the *List of antimicrobial agents of veterinary importance; and***<br>• ***Word Health Organisation (*WHO*)*** *guidance on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach;*<br>• [*WHO list of critically important antimicrobials for human medicine, specifically the Annex with the complete list of antimicrobials for human use, categorized as critically important, highly important and important;*]<br>• ~~Relevant chapters of the *OIE terrestrial and aquatic animal health codes* and the *List of antimicrobial agents of veterinary importance; and*~~<br>• *National/Regional lists of important antimicrobials for humans and animals where they exist.* | OIE is placed first as it is recognized by the World Trade Organisation.<br>As the acronyms OIE and WHO are used for the first time, the full name is introduced. |

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| **§8** | This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A progressive approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used inappropriately to generate barriers to trade. | This document is designed to provide a framework, for the development of measures to mitigate the risk of foodborne AMR that countries may implement, as part of their national strategy on AMR, in accordance with their capabilities, based on their national priorities and capacities, and within a reasonable period of time. A progressive approach may be utilized by some countries to properly implement applicable elements in this document proportionate to the foodborne AMR risk and should not be used ~~inappropriately~~ to generate barriers to trade. | There is no appropriate way to generate barrier to trade. |
| **§9** | 9 ~~7~~. This Code of Practice provides risk management guidance to address the risk to human health of the development and transmission of antimicrobial resistant microorganisms or resistance determinants through food. It provides risk-based guidance on relevant measures and practices along the food and feed chain to minimize and contain the development and spread of foodborne antimicrobial resistance, including guidance on the responsible and prudent use of antimicrobial agents in animal production (terrestrial and aquatic), plant/crop production, [~~food of plant origin~~] and ~~feed~~ and references other best management practices, as appropriate. Its objectives are to minimize the risk and adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain. | 9 ~~7~~. This Code of Practice provides risk management guidance to address the risk to human health of the development and transmission of antimicrobial resistant microorganisms or resistance determinants through food. It provides risk-based guidance on relevant measures and practices along the food and feed chain to minimize and contain the development and spread of foodborne **AMR**~~antimicrobial resistance~~, including guidance on the responsible and prudent use of antimicrobial agents in animal production (terrestrial and aquatic), plant/crop production, [~~food of plant origin~~] and ~~feed~~ and references other best management practices, as appropriate. Its objectives are to minimize the risk and adverse impact on human health from foodborne AMR resulting from the use of antimicrobial agents in the food chain. | Consistent use of acronyms |

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| **§11** | Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents, most of the recommendations in this Code of Practice will focus on antibacterials, [however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where scientific evidence supports foodborne AMR risk to human health.] | ~~Recognizing there are mechanisms of co-resistance or co-selection in a range of antimicrobial agents,~~ **~~m~~Most** of the recommendations in this Code of Practice will focus on antibacterials~~,~~ ~~[however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where scientific evidence supports foodborne AMR risk to human health.]~~ | This might create confusion. Hence, there is no need to explain why the document focuses on antibacterials. If recommendations are done on others, this should be indicated in the relevant paragraph. |
| **§12** | As there are existing Codex or internationally recognized guidelines, the following areas related to antimicrobial agents or AMR are outside the scope of this document: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants/crops and recombinant DNA microorganisms; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose; and certain food ingredients, which could potentially carry antimicrobial resistance determinants, such as probiotics. In addition, AMR from non-food animals, non-food plants/crops, or non-food routes are also outside the scope of this document. | As there are existing Codex or internationally recognized guidelines, the following areas related to antimicrobial agents or AMR are outside the scope of this document: residues of antimicrobial agents in food; AMR marker genes in recombinant-DNA plants/crops and recombinant DNA microorganisms; non-genetically modified microorganisms (for example, starter cultures) intentionally added to food with a technological purpose; and certain food ingredients, which could potentially carry antimicrobial resistance determinants, such as probiotics. ~~In addition, AMR from non-food animals, non-food plants/crops, or non-food routes are also outside the scope of this document.~~ | As the scope is clearly on the food chain, it is not necessary to include the last sentence. If this would be kept, the word 'non-food plants/crops', should be deleted anyway, as definition of plants/crops include use in food. |
| **Definitions** | | **Biosecurity: a group of measures taken on the farm and in feed/food production system to limit/avoid the introduction of pathogenic microorganism in the food production environment.** | As this word is used in the document, it is important to define it in the context of this document. |
| **Definitions** | **Food chain:** Production to consumption continuum including, primary production (food-producing animals, plants/crops), feed, harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption. | **Food chain:** Production to consumption continuum including, primary production (food-producing animals, plants/crops), feed, harvest/slaughter, packing, processing, storage, transport, and retail distribution to the point of consumption. | The word feed should not be added specifically, it is included in the primary production, similarly to other inputs, such as veterinary products, fertilisers… |

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| **Definitions** | **Food of plant origin**: All edible parts of plants/crops used as foods.] | ~~**Food of plant origin**: All edible parts of plants/crops used as foods.]~~ | The word is not used in the document and is replaced by plant/crop. |
| **Definitions** | **Marketing authorization:** Process of reviewing and assessing a dossier to support an antimicrobial agent to determine whether to permit its marketing (also called licensing, registration, approval, etc.), finalized by granting of a document also called marketing authorization (equivalent: product license). | **Marketing authorization process:** Process of reviewing and assessing a dossier ~~to~~ support**ing the use of** an antimicrobial agent to determine whether to~~ permit~~ **approve** its marketing (also called licensing, registration, approval, etc.).<br>**Marketing authorization: the result of the marketing authorization process, usually in the form of an official document** (equivalent: product license). | The word marketing authorization covers bot the process and the final document. it is proposed to split the definition in two parts for clarity and proper use in the document. |
| **Definitions** | **Therapeutic use:** Administration/Application of antimicrobial agents for the treatment, control/metaphylaxis or ~~and~~ prevention/prophylaxis of disease.] | | This definition shall be kept in the document. |
| **Principle** | **General principles to minimize and contain antimicrobial resistance** | **General principles to minimize and contain AMR~~antimicrobial resistance~~** | Consistent use of acronyms |
| **Principles** | | **General principle: It is everyone responsibility in the food chain to minimize and contain AMR** | It is important to emphasise that everyone should be involved in the activities. |
| **Principle** | ***Principles on AMR Risk Management (generally)*** | **Principles on AMR Risk Management ~~(generally)~~** | Word is not necessary |
| **Principle 4** | **Principle 4:** The *WHO list of critically important antimicrobials*, the *OIE list of antimicrobials of veterinary importance*, or national lists, where available, should be considered when setting priorities for risk assessment and risk management to minimize and contain antimicrobial resistance. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns. | **Principle 4: International guidance such as t**~~T~~he *WHO list of critically important antimicrobials*, the *OIE list of antimicrobials of veterinary importance*, or national lists~~, where available,~~ should be considered when setting priorities for risk assessment and risk management to minimize and contain **AMR**~~antimicrobial resistance~~. The lists should be regularly reviewed and updated as necessary when supported by scientific findings as new scientific data emerges on resistance patterns. | For better reading |

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| **Principle 15** | **Principle 15:** On a continuous and progressive 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 from a public health perspective | **Principle 15: Priority should be given to the most relevant elements from a public health perspective when ~~On~~developing** a continuous and progressive 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 from a public health perspective~~ | For better reading |
| **Principle** | ***Principle on preventing infections and reducing the need for antimicrobials*** | ***Principle on preventing infections and reducing the need for antimicrobial agents*** | For alignment with the definitions |
| **Principle 2** | **Principle 2:** Biosecurity, appropriate nutrition, vaccination, animal and plant/crop best management practices, and other alternative tools where appropriate, and that have been proven to be efficacious and safe, should be considered to reduce the need for use of antimicrobial agents. | **Principle 2:** Biosecurity, appropriate nutrition, vaccination, animal and plant/crop best management practices, and other alternative tools ~~where appropriate, and~~ that have been proven to be efficacious and safe, should be considered to reduce the need for use of antimicrobial agents. | |
| **Principle 13** | The decision to use antimicrobial agents should be based on sound clinical judgement, experience, and treatment efficacy. Where feasible and appropriate the results of bacterial cultures and integrated resistance surveillance and monitoring should also be considered | The decision to use antimicrobial agents should be based on sound clinical judgement, experience, and treatment efficacy. Where feasible and appropriate the results of **microorganism**~~bacterial~~ cultures and integrated resistance surveillance and monitoring should also be considered | |
| **Principle** | ***Principles on the responsible and prudent use of antimicrobials (generally)*** | ***Principles on the responsible and prudent use of antimicrobial agents*** ~~***(generally)***~~ | For alignment with definitions and not necessary. |
| **Principle 12** | **[Principle 12:** Medically important antimicrobials should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation.] | **[Principle 12:** Medically important antimicrobials should be administered, prescribed, or applied only by, or under the direction of, veterinarians, plant/crop health professionals, or other suitably trained persons authorized **or accepted** in accordance with national legislation.] | To consider differences between jurisdictions. |

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| **Principle 3** | **Principle 3:** Science-based species or sector-specific responsible and prudent antimicrobial use guidelines should be developed, implemented, and reviewed on a regular basis to maintain their effectiveness in minimizing the risk of foodborne antimicrobial resistance. Such guidelines could be included as a part of national action plans or stakeholder-led plans on antimicrobial resistance with development and dissemination shared among countries and organizations. | **Principle 3:** Science-based species or sector-specific responsible and prudent ~~antimicrobial~~ use **of antimicrobial agents** guidelines should be developed, implemented, and reviewed on a regular basis to maintain their effectiveness in minimizing the risk of foodborne **AMR**~~antimicrobial resistance~~. Such guidelines could be included as a part of national action plans or stakeholder-led plans on ~~antimicrobial resistance~~**AMR** with development and dissemination shared among countries and organizations. | Use of acronyms and alignment with definitions. |
| **Principle** | ***Principles on the use of antimicrobials in specific circumstances*** | ***Principles on the use of antimicrobial agents in specific circumstances*** | Alignment with definitions |
| **Principle 5** | **[Principle 5:** Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of antimicrobial agents that are considered medically important. Antimicrobial agents that are not considered medically important should not be used for growth promotion unless potential risks to human health have been evaluated through procedures consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CXG 77-2011 | **[Principle 5:** Responsible and prudent use of antimicrobial agents does not include the use for growth promotion of **medically important** antimicrobial~~ agents that are considered medically important.~~ Antimicrobial agents that are not considered medically important should not be used for growth promotion unless potential risks to human health have been evaluated through procedures consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance CXG 77-2011 | Alignment with the definition |
| **Principle 6** | **Principle 6:** Medically important antimicrobial agents should only be used for therapeutic purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease); or in certain circumstances for research and conservation. | **Principle 6:** Medically important antimicrobial**s** ~~agents~~ should only be **administered/applied**~~used~~ for therapeutic **uses**~~purposes (treatment, control/metaphylaxis or prevention/prophylaxis of disease)~~; or in certain circumstances for research and conservation. | Alignment with definitions |

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| **Principles 7 and 7bis** | **[Principle 7:** When used for prevention/prophylaxis of a specific disease risk, medically important antimicrobials should only be administered in well-defined circumstances, based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration. ~~Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.]~~<br><br>[**Principle 7bis:** When used for the control of disease/metaphylaxis, medically important antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose, and duration.] | **[Principle 7: Medically important antimicrobials should only be administered/applied to food producing animals**~~When used for prevention/prophylaxis of a specific disease risk, medically important antimicrobials should only be administered in well-defined circumstances,~~ based on epidemiological and clinical knowledge, and follow appropriate professional oversight, dose, and duration. **In addition, for prevention of a disease/metaphylaxis, professional judgement should be used when a specific disease risk has been identified. ,** ~~Medically important antimicrobial agents should only be used in well-defined circumstances for the prevention/prophylaxis of a specific disease risk and follow appropriate professional oversight, dose, and duration.]~~<br><br>[~~**Principle 7bis:** When used for the control of disease/metaphylaxis, medically important antimicrobial agents should only be used on the basis of epidemiological and clinical knowledge and a diagnosis of a specific disease and follow appropriate professional oversight, dose, and duration.~~] | Proposed combination of the two principles. |
| **Principle 7ter** | **Principle 7ter:** When used for plant/crop protection, medically important antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.] | **Principle 7ter:** When used for plant/crop protection, medically important antimicrobial agents should only be used to the extent necessary for a specific disease and follow appropriate professional oversight, dose, and duration.] | OK with principle 7ter, use of medically important antimicrobials to be in line with the definition |
| **Principle** | ***Principle on surveillance of antimicrobial resistance and use*** | ***Principle on surveillance of AMR~~antimicrobial resistance~~ and antimicrobial agents use*** | Alignment with definition and consistent use of acronym |

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| **Principle 10** | **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 resistance determinants are among the critical factors to consider when developing risk management measures and evaluating the effectiveness of implemented risk management measures. Use of antimicrobial agents in humans, food-producing animals, and plants/crops and transmission of pathogens and resistance genes between humans, food-producing animals, plants/crops, and the environment are additional factors to consider, through the foodborne AMR risk analysis process described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*. | **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 resistance determinants are among the critical factors to consider when developing risk management measures and evaluating the effectiveness of implemented risk management measures. Use of antimicrobial agents in humans, food-producing animals, and plants/crops and transmission of pathogens and **antimicrobial** resistance **determinants**~~genes~~ between humans, food-producing animals, plants/crops, and the environment are additional factors to consider, through the foodborne AMR risk analysis process described in the *Guidelines for risk analysis of foodborne antimicrobial resistance*. | Alignment with definitions |
| **§13** | 13 ~~10~~. The *OIE terrestrial and aquatic animal health codes* and the OIE list of antimicrobial agents of veterinary importance contain detailed information with respect to the control of veterinary medicines for use in food-producing animals and aquaculture | 13 ~~10~~. The *OIE terrestrial and aquatic animal health codes* and the OIE list of antimicrobial agents of veterinary importance contain detailed information with respect to the control of veterinary medicines for use in food-producing animals~~ and aquaculture~~ | Food producing animals also cover fish. It is not necessary to specifically mention aquaculture. |
| **§14** | 14 ~~11~~. For more information on the data requirements for authorization of antimicrobial agents for food-producing animals see relevant national guidelines or internationally harmonized guidelines, ~~such as the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines~~. | 14 ~~11~~. For more information on the data requirements for **marketing** authorization of antimicrobial agents for food-producing animals see relevant national guidelines or internationally harmonized guidelines, ~~such as the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) guidelines~~. | Based on the proposed definition above |

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| **§15** | 15 ~~12~~. The competent authorities, including the authority responsible for granting the marketing authorization for antimicrobials for use along the food chain, have a significant role in specifying the terms of the authorization and in providing appropriate information to the veterinarian and plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation and producers through product labelling and/or by other means, in support of the responsible and prudent use of antimicrobial agents along the food chain. It is the responsibility of competent authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications, as well as ensuring that antimicrobial agents used in the food chain are used in accordance with national legislation. | 15 ~~12~~. The competent authorities, including the authority responsible for ~~granting~~ the marketing authorization **process** ~~for antimicrobials for use along the food chain~~, have a significant role in specifying the terms of the **marketing** authorization and in providing appropriate information to the veterinarian and plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation and producers through product labelling and/or by other means, in support of the responsible and prudent use of antimicrobial agents along the food chain. It is the responsibility of competent authorities to develop up-to-date guidelines on data requirements **to be provided for the marketing authorization process**~~for evaluation of antimicrobial agent applications~~, as well as ensuring that antimicrobial agents used in the food chain are used in accordance with national legislation. | For alignment with definitions. |

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| **§16** | 16 ~~13~~. ~~It is the responsibility of competent authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications.~~ National governments in cooperation with animal, plant/crop, and public health professionals should adopt a One Health Approach to promote the responsible and prudent use of antimicrobial agents along the food chain as an element of a national strategy to minimize ~~for the~~ prevention ~~and~~ contain~~ment of~~ antimicrobial resistance. Good animal production (terrestrial and aquatic) and best management practices for plant/crop production, vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level contribute to reduce the prevalence of animal and plant/crop disease requiring antimicrobial administration and can be incorporated into national strategies to complement activities in human health. | 16 ~~13~~. ~~It is the responsibility of competent authorities to develop up-to-date guidelines on data requirements for evaluation of antimicrobial agent applications.~~ National governments in cooperation with **the relevant stakeholders**~~animal, plant/crop, and public health professionals~~ should adopt a One Health Approach to promote the responsible and prudent use of antimicrobial agents along the food chain as an element of a national strategy to minimize ~~for the~~ prevention and contain~~ment of~~ **AMR**~~antimicrobial resistance~~. Good animal production (terrestrial and aquatic) and best management practices for plant/crop production, vaccination and biosecurity policies and development of animal and plant/crop health programs at the farm level contribute to reduce the prevalence of animal and plant/crop disease requiring antimicrobial administration and can be incorporated into national strategies to complement activities in human health. | Also stakeholders active in the prevention of disease, e.g. through nutrition, should also be considered in the cooperation. |
| **§17** | [17 ~~13bis:~~. In order to promote responsible and prudent use of antimicrobial agents, it is important to encourage the ~~use~~ development, ~~and~~ availability, and use of validated, rapid, reliable diagnostic tools, where available, to support veterinarians and plant/crop health professionals in selecting the most appropriate antimicrobial to be administered/applied ~~prescribed for treatment~~.] | [17 ~~13bis:~~. In order to promote responsible and prudent use of antimicrobial agents, it is important to encourage the ~~use~~ development, ~~and~~ availability, and use of validated, rapid, reliable diagnostic tools, where available, to support veterinarians and plant/crop health professionals in selecting the most appropriate antimicrobial **agent** to be administered/applied ~~prescribed for treatment~~.] | To be in line with the definition. |
| **§19** | 19 ~~15~~. Competent authorities should ensure that quality controls are carried out in accordance with national or international guidance and in compliance with the provisions of good manufacturing practices, including with regard to ensuring quality and purity in manufacture, storage, and when mixed with feed, water, or other ingredients. | 19 ~~15~~. Competent authorities should ensure that quality controls are carried out in accordance with national or international guidance and in compliance with the provisions of good manufacturing practices, including with regard to ensuring quality and purity in manufacture, storage~~, and when mixed with feed, water, or other ingredients~~. | The quality of antimicrobial agents does not include its further use. |

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| **§20** | 20 ~~16~~. Assessment of efficacy is important to assure adequate response to the administration of antimicrobial agents. As part of the marketing authorization process, ~~it~~ the assessment should include the efficacy with optimal dosages and durations, supported by clinical trials, microbiological data (including antimicrobial susceptibility testing~~,) and~~ pharmacokinetic (PK) data, and ~~as well as~~ pharmacodynamic (PD) data. The ~~It may also include~~ assessment may also include evaluation of ~~through proper veterinary care, health program evaluation and~~ good pharmacovigilance practices. | 20 ~~16~~. Assessment of efficacy is important to assure adequate response to the administration of antimicrobial agents. As part of the marketing authorization process, ~~it~~ the assessment should include the efficacy with optimal dosages and durations, supported by clinical trials, microbiological data (including antimicrobial susceptibility testing~~,) and~~ pharmacokinetic ~~(PK)~~ data, and ~~as well as~~ pharmacodynamic ~~(PD)~~ data. **Data collected from pharmacovigilance (monitoring of an antimicrobial agent) can be considered as part its efficacy assessment**~~The It may also include assessment may also include evaluation of through proper veterinary care, health program evaluation and good pharmacovigilance practices.~~ | For consistency in the use of acronym and for better reading. |
| **§22** | 22 ~~19~~. In accordance with their national guidelines, ~~C~~competent authorities should consider foodborne AMR risk characterization ~~from~~ of ~~environmental~~ sources that contribute to the food production environment, such as pollution from pharmaceutical manufacture, reuse of waste water for irrigation, and use of manure, ~~and~~ other waste-based fertilizers and/or municipal wastes for soil fertilization. ~~the environmental aspects on foodborne AMR e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization.~~ When a foodborne AMR risk is determined through the *Guidelines for risk analysis of foodborne antimicrobial resistance* the need for monitoring and proportionate risk management measures ~~can~~ should be considered. | 22 ~~19~~. In accordance with their national guidelines, ~~C~~competent authorities should consider foodborne AMR risk characterization ~~from~~ of ~~environmental~~ sources that contribute to the food production environment, ~~such as pollution from pharmaceutical manufacture, reuse of waste water for irrigation, and use of manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization. the environmental aspects on foodborne AMR e.g. pollution from pharmaceutical manufacture, impacts of reusing waste water for irrigation, and using manure, and other waste-based fertilizers and/or municipal wastes for soil fertilization.~~ When a foodborne AMR risk is determined through the *Guidelines for risk analysis of foodborne antimicrobial resistance* the need for monitoring and proportionate risk management measures ~~can~~ should be considered. | The definition of food production environment is enough here. There is no need to specify the possible sources. It is the responsibility of the authorities to evaluate and prioritize the sources. |

| Location | Current Text | Recommended Revision | Rationale |
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| **§23** | 23. ~~20~~. Competent authorities should establish a Summary of Product Characteristics or similar document for each authorized antimicrobial veterinary medicinal product. The information in these documents ~~the summary of product characteristics~~ can be utilized in labelling and as a package insert. Such information may include:<br>• brand/chemical/drug name;<br>• drug description;<br>• dosage forms/strengths;<br>• contraindications; warnings;<br>• adverse reactions;<br>• drug interactions and uses in specific populations for each authorized antimicrobial veterinary medicinal product, when available. | 23. ~~20~~. Competent authorities should establish a Summary of Product Characteristics or similar document for each authorized antimicrobial **agent to be administered/applied to food producing animals**~~veterinary medicinal product~~. The information in these documents ~~the summary of product characteristics~~ can be utilized in labelling and as a package insert. Such information may include:<br>• brand/chemical/drug name;<br>• drug description;<br>• dosage forms/strengths;<br>• contraindications; warnings;<br>• adverse reactions;<br>• drug interactions and uses in specific populations **in accordance with the marketing authorisation** ~~for each authorized antimicrobial veterinary medicinal product, when available~~. | Only the use of antimicrobial agents for food producing animals is covered by the scope of the Code of Practice.<br>For better reading. |

| Location | Current Text | Recommended Revision | Rationale |
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| **§ 24** | Competent authorities should establish systems for the surveillance and monitoring of antimicrobial resistance and antimicrobial use following the *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance* as developed by Codex~~, taking into consideration relevant sections of *Guidelines for risk analysis of foodborne antimicrobial resistance*; *WHO guidelines on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach*; and *OIE terrestrial animal health code* Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals, the *OIE aquatic animal health code* Chapter 6.3 Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals and Chapter 6.4 Development and harmonization of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals and section 8 of chapter 6.9.3 on post-marketing antimicrobial surveillance~~. | 24 ~~21~~. Competent authorities should establish systems for the surveillance and monitoring of **AMRa**~~ntimicrobial resistance~~ and antimicrobial use following the *Guidelines on integrated monitoring and surveillance of foodborne antimicrobial resistance* as developed by Codex~~, taking into consideration relevant sections of *Guidelines for risk analysis of foodborne antimicrobial resistance*; *WHO guidelines on integrated surveillance of antimicrobial resistance in foodborne bacteria, application of a One Health Approach*; and *OIE terrestrial animal health code* Chapter 6.7 Harmonization of national antimicrobial resistance surveillance and monitoring programmes and Chapter 6.8 Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals, the *OIE aquatic animal health code* Chapter 6.3 Monitoring of the quantities and usage patterns of antimicrobial agents used in aquatic animals and Chapter 6.4 Development and harmonization of national antimicrobial resistance surveillance and monitoring programmes for aquatic animals and section 8 of chapter 6.9.3 on post-marketing antimicrobial surveillance~~. | Consistent use of acronyms |
| **§25** | Competent authorities should have in place a pharmacovigilance program for the monitoring and reporting of suspected adverse reactions to veterinary antimicrobial agents ~~drugs~~, including lack of the expected efficacy that could be related to antimicrobial resistance. The information collected through the pharmacovigilance program can contribute to a ~~should form part of the~~ comprehensive strategy to minimize antimicrobial resistance in food. | Competent authorities should have in place a pharmacovigilance program for the monitoring and reporting of suspected adverse reactions to veterinary **and plant/crop protection** antimicrobial agents ~~drugs~~, including lack of the expected efficacy that could be related to **AMR**~~antimicrobial resistance~~. The information collected through the pharmacovigilance program can contribute to a ~~should form part of the~~ comprehensive strategy to minimize **AMR**~~antimicrobial resistance~~ in food. | Consistent use of acronyms.<br>Inclusion of plant/crop protection products to be in line with paragraph 26. |

| Location | Current Text | Recommended Revision | Rationale |
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| **§26** | In cases, where the assessment of data collected from pharmacovigilance and from other post-authorization surveillance including, if available, targeted surveillance of antimicrobial resistance in veterinary or plant/crop pathogens, suggests that the conditions of use of the given ~~veterinary~~ antimicrobial agent marketing authorization ~~drug~~ should be reviewed, competent authorities shall endeavor to achieve this re-evaluation. | In cases, where the assessment of data collected from pharmacovigilance and from other post-authorization surveillance including, if available, targeted surveillance of **AMR**~~antimicrobial resistance~~ in veterinary or plant/crop pathogens, suggests that the conditions of use of the given ~~veterinary~~ antimicrobial agent **defined in the** marketing authorization ~~drug~~ should be reviewed, competent authorities shall endeavor to achieve this re-evaluation. | Consistent use of acronym and clarification |
| **§27** | Competent authorities, ~~to the extent possible,~~ should make sure approved antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation, including that ~~and~~ medically important antimicrobials are distributed to appropriately credentialed/registered veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation. | Competent authorities, ~~to the extent possible,~~ should make sure ~~approved~~ antimicrobial agents are distributed through appropriate distribution systems in accordance with national legislation, including that ~~and~~ medically important antimicrobials are distributed to appropriately credentialed/registered veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation. | The word approved is not necessary here as we relate to national legislation conditions. |
| **§28** | Competent authorities~~, to the extent possible,~~ should prevent illegal medicines and unapproved formulations from entering distribution systems | Competent authorities~~, to the extent possible,~~ should prevent illegal **antimicrobial agents**~~medicines~~ and unapproved formulations from entering distribution systems | To keep the recommendation within the scope of the Code of Practice. |
| **§31** | Advertising and promotion of antimicrobial agents should be done in a manner consistent with ~~prudent use guidelines and any other~~ specific regulatory recommendations for the product | Advertising and promotion of antimicrobial agents should be done in a manner consistent with ~~prudent use guidelines and any other~~ **the conditions set in the marketing authorisation** ~~specific regulatory recommendations for the product~~ | |
| **Training** | **Training on issues related to antimicrobial resistance and the responsible ~~of~~ user~~s~~ of antimicrobial agents** | **Training on issues related to AMR~~antimicrobial resistance~~ and the responsible ~~of~~ user~~s~~ of antimicrobial agents** | Consistent use of acronym |

| Location | Current Text | Recommended Revision | Rationale |
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| **§32** | Training should be supported, to the extent possible, by the competent authorities on issues related to antimicrobial resistance and the responsible use of antimicrobial agents. Training may take the form of communication and outreach and should be ~~involve~~ ~~the competent authorities,~~ ~~all the~~ relevant to veterinarians and plant/crop health professionals, manufacturers and marketing authorization holders, wholesale and retail distributors, food animal and plant/crop producers, and other participants along the food chain. Training and communication may broadly address other public health constituencies | Training should be supported, to the extent possible, by the competent authorities on issues related to **AMR**~~antimicrobial resistance~~ and the responsible use of antimicrobial agents. Training may take the form of communication and outreach and should be ~~involve~~ ~~the competent authorities,~~ ~~all the~~ relevant to veterinarians and plant/crop health professionals, manufacturers and marketing authorization holders, wholesale and retail distributors, food animal and plant/crop producers, and other participants along the food chain**, as appropriate**. Training and communication may broadly address other public health constituencies | Consistent use of the acronym.<br>The presence of the stakeholders depend on the type of training. |
| **§32**<br>**5th bullet** | information on appropriate storage conditions for antimicrobial agents before and during use and the safe disposal of unused and out of date antimicrobials | information on appropriate storage conditions for antimicrobial agents before and during use and the safe disposal of unused and out of date antimicrobial **agent**s | For consistency with definitions |
| **§32**<br>**7th bullet** | national action plans, if available, and international strategies to fight and control antimicrobial resistance | national action plans, if available, and international strategies to fight and control **AMR**~~antimicrobial resistance~~ | Consistent use of acronym |
| **§32**<br>**8th bullet** | good antimicrobial use practices, antimicrobial prescription writing and establishment of withdrawal period | good antimicrobial **agents** use practices, ~~antimicrobial~~ prescription writing and establishment of withdrawal period | Alignment with definition |
| **§32**<br>**9th bullet** | training in new methodologies for molecular analysis of resistance; understanding methods and results of susceptibility testing of antimicrobials and molecular analysis; | training in new methodologies for molecular analysis of **AMR**~~resistance~~; understanding methods and results of susceptibility testing **to**~~of~~ antimicrobial **agent**s and molecular analysis; | Alignment with definition and consistent use of acronym |
| **§33** | The relevant authorities ~~should~~ can encourage public and private research to | The relevant authorities ~~should~~ can encourage public and private research to **continue to study risks from foodborne AMR, such as** | Important to keep the focus on foodborne AMR as it is the scope of the Code of Practice |
| **§33**<br>**1st bullet** | improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of antimicrobial agents to optimize the ~~dosage~~ therapeutic regimens and their efficacy | improve the knowledge about the mechanisms of action, pharmacokinetics and pharmacodynamics of antimicrobial agents to optimize the ~~dosage~~ therapeutic **use**~~regimens~~ and their efficacy | Alignment with definition |

| Location | Current Text | Recommended Revision | Rationale |
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| **§33**<br>**3rd bullet** | develop practical models for applying the concept of risk analysis to assess the public health concern precipitated by the development of resistance | develop practical models for applying the concept of risk analysis to assess the public health concern precipitated by the development of **foodborne AMR**~~resistance~~ | Keep focus on the scope of the Code of Practice<br>Consistent use of acronym. |
| **§33**<br>**4th bullet** | further develop protocols to predict, during the authorization process, the impact of the proposed use of the antimicrobial agents on the rate and extent of resistance development and spread | further develop protocols to predict, during the authorization process, the impact of the proposed use of the antimicrobial agents on the rate and extent of **foodborne AMR**~~resistance~~ development and spread | Keep focus on the scope of the Code of Practice<br>Consistent use of acronym. |
| **§33**<br>**6th bullet** | assess the primary drivers leading to use of ~~medically important~~ antimicrobials at the farm, regional, and national levels, and the effectiveness of different interventions to change behavior and reduce the use of ~~medically important~~ antimicrobial agents in food production | assess the primary drivers leading to use of ~~medically important~~ antimicrobial **agent**s at the farm, regional, and national levels, and the effectiveness of different interventions to change behavior **related to the inappropriate** ~~and reduce the~~ use of ~~medically important~~ antimicrobial agents in food production | For better reading and alignment with definitions. |
| **§33**<br>**8th bullet (new)** | | **Supoprt the development of safe and effective solutions to keep the animals in good health, including, agree necessary, the creation of appropriate regulatory frameworks;** | It is important that research also work on preventive measures and that regulatory frameworks support the use of preventive measures, when necessary. |
| **§33**<br>**8th bullet (current)** | determine the potential transfer to fresh produce and other plants/crops of resistant microorganisms and resistance determinants from animal manures or other biological materials used as fertilizer or selected for during the use of production practices, and if there is subsequent transfer through food to consumers | determine the **risk of foodborne AMR** ~~potential~~ transfer to fresh produce and other plants/crops of resistant microorganisms and resistance determinants from animal manures or other biological materials used as fertilizer or selected for during the use of production practices, and if there is subsequent transfer through food to consumers | To be in line with the scope of the Code of Practice |

| Location | Current Text | Recommended Revision | Rationale |
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| **§34**<br>**9th and 10th bullets** | • improve knowledge on the role of the environment on the persistence of antimicrobial agents, and the emergence, transfer and persistence of antimicrobial resistance determinants and resistant microorganisms;<br>• ~~improve the knowledge and~~ on ~~the role of the environment on the emergence,~~ transfer ~~and persistence of antimicrobial agents, resistance determinants and AMR microorganisms~~;<br>• determine the potential transfer to animals and plants/crops ~~of~~ resistant microorganisms and resistance determinants due to agricultural chemical use. | • ~~improve knowledge on the role of the environment on the persistence of antimicrobial agents, and the emergence, transfer and persistence of antimicrobial resistance determinants and resistant microorganisms;~~<br>• ~~improve the knowledge and~~ on ~~the role of the environment on the emergence,~~ transfer ~~and persistence of antimicrobial agents, resistance determinants and AMR microorganisms~~;<br>• ~~determine the potential~~ transfer to animals ~~and~~ plants/crops ~~of resistant microorganisms and resistance determinants due to agricultural chemical use.~~ | Seems out of the scope of the Code of Practice |
| **§35** | The competent authorities should develop and ~~progress~~ implement effective procedures for the safe collection and destruction of unused, counterfeit, illegally marketed, or out-of-date antimicrobial agents~~, including proper disposal of containers and packaging materials~~. | The competent authorities should develop and ~~progress~~ implement effective procedures for the safe collection and ~~destruction~~ **disposal** of unused, counterfeit, illegally marketed, or out-of-date antimicrobial agents~~, including proper disposal of containers and packaging materials~~. | More appropriate, destruction is only one method of disposal. |
| **§36**<br>**1st bullet** | to supply all the information requested by the national competent authority in order to establish objectively the quality, safety and efficacy of antimicrobial agents | to supply all the information requested by the national competent authority in order to establish objectively the quality, safety and efficacy of **their** antimicrobial agents | The information provided shall be related to the product(s) of the marketing authorization holders. |
| **Title** | **Marketing and export of antimicrobial agents** | **Marketing~~ and export~~ of antimicrobial agents** | Export conditions are part of world trade agreements. |
| **§38** | Only antimicrobial agents meeting the quality standards of the importing country should be exported ~~from a country in which the products were produced~~ | ~~Only antimicrobial agents meeting the quality standards of the importing country should be exported from a country in which the products were produced~~ | This is part of world trade agreements |

| Location | Current Text | Recommended Revision | Rationale |
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| **§39** | The information necessary to evaluate the ~~amount~~ quantity (sales or volume) of antimicrobial agents marketed should be provided to the national competent authority and, when feasible, information on estimated of types of use (e.g. treatment, control, prevention), route of administration and target species | The information necessary to ~~evaluate~~**monitor** the ~~amount~~ quantity (sales or volume) of antimicrobial agents marketed should be provided**, when requested by** ~~to~~ the national competent authority ~~and, when feasible, information on estimated of types of use (e.g. treatment, control, prevention), route of administration and target species~~ | |
| **§40** | Package size and the concentration and composition of antimicrobial formulations should be adapted, as far as possible, to the approved indications of use in order to avoid improper dosing, overuse, and leftovers | Package size and the concentration and composition of antimicrobial **agents'** formulations should be adapted, as far as possible, to the approved indications of use in order to avoid improper dosing, overuse, and leftovers | Alignment with definitions |
| **§41** | It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 30-31~~25-27~~ on the Responsibilities of the Competent Authorities, Control of Advertising and to not advertise medically important antimicrobials to producers. | ~~It is the responsibility of the marketing authorization holders to only advertise antimicrobial agents in accordance with the provisions of paragraphs 30-3125-27 on the Responsibilities of the Competent Authorities, Control of Advertising and to not advertise medically important antimicrobials to producers.~~ | Redundancy with paragraph 31 and 32 |
| **§42** | Advertising should only be targeted to persons permitted to prescribe or supply antimicrobial agents. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should ~~be discouraged~~ not be used | ~~Advertising should only be targeted to persons permitted to prescribe or supply antimicrobial agents. Promotional campaigns involving economic or material benefits for prescribers or suppliers of antimicrobials should be discouraged~~ not be used | Redundancy with paragraph 31 and 32 |
| **§43** | It is the responsibility of the marketing authorization holders to support ~~participate in the~~ training on issues related to antimicrobial resistance and the responsible user~~s~~ of antimicrobial agents as ~~defined~~ described in paragraph 32 ~~28~~ | It is the responsibility of the marketing authorization holders to support ~~participate in the~~ training on issues related to **AMR**~~antimicrobial resistance~~ and the responsible user~~s~~ of antimicrobial agents as ~~defined~~ described in paragraph 32 ~~28~~ | Consistent use of acronyms |

| Location | Current Text | Recommended Revision | Rationale |
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| **§44** | It is the responsibility of the marketing authorization holders to supply ~~support the development of research~~ required data to register antimicrobial agents including data regarding ~~and appropriately assess~~ the safety and efficacy of products ~~as defined described in paragraph 29~~, as appropriate | It is the responsibility of the marketing authorization holders to supply ~~support the development of research~~ required data to register antimicrobial agents including data regarding ~~and appropriately assess~~ the safety and efficacy of **their** products ~~as defined described in paragraph 29~~, as appropriate | Marketing authorization holder can only supply data and information on their products. |
| **§45** | Research on the development of new antimicrobials, safe and effective alternatives to the use of antimicrobials, rapid diagnostics and vaccines are encouraged ~~should be performed~~. | Research on the development of new antimicrobials, safe and effective alternatives to the use of antimicrobial **agent**s, **safe and effective preventive strategies,** rapid diagnostics and vaccines are encouraged ~~should be performed~~. | It is important that research is also organized on preventive measures to reduce the use of antimicrobial agents. |
| **§46** | Wholesalers and retailers distributing medically important antimicrobial agents should only do so on the prescription of a veterinarian or order from a plant/crop health professional or other suitably trained person authorized in accordance with national legislation. All distributed products should be appropriately labelled | Wholesalers and retailers distributing medically important antimicrobial agents should only do so on the prescription of a veterinarian or order from a plant/crop health professional or other suitably trained person authorized in accordance with national legislation. All distributed **antimicrobial agents**~~products~~ should be appropriately labelled | To keep in the scope of the Code of Practice |
| **§47**<br>**2nd bullet** | name of receiving prescribing veterinarian or plant/crop health professional or other suitably trained and authorized person | name of **responsible** ~~receiving prescribing~~ veterinarian or plant/crop health professional or other suitably trained and authorized person | For clarification purpose |
| **§47**<br>**4th bullet** | name of medicinal product, formulation, strength and package size | name of medicinal product **containing the antimicrobial agent**, formulation, strength and package size | Keeping the scope of the Code of Practice |
| **§48** | Distributors should support training, as appropriate, on issues related to antimicrobial resistance and the responsible use of antimicrobial agents using information provided by the competent authorities, manufacturers and marketing authorization holders, veterinarians and plant/crop professionals and other relevant entities as described ~~defined~~ in paragraph 32 | Distributors should support training, as appropriate, on issues related to **AMR** ~~antimicrobial resistance~~ and the responsible use of antimicrobial agents using information provided by the competent authorities, manufacturers and marketing authorization holders, veterinarians and plant/crop professionals and other relevant entities as described ~~defined~~ in paragraph 32 | Consistent use of acronyms |

| Location | Current Text | Recommended Revision | Rationale |
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| **§50** | Professional or other organizations should be encouraged to develop species or sector-specific guidelines on the responsible and prudent use of antimicrobial agents. National action plans may include recommendations to develop species or sector-specific guidelines | Professional or other organizations should be encouraged to develop species or sector-specific guidelines **for**~~on~~ the responsible and prudent use of antimicrobial agents. National action plans may include recommendations to develop species or sector-specific guidelines | Editorial |
| **§51**<br>**1st and 2nd bullets** | • A prescription, ~~or~~ order for application, or similar document for medically important antimicrobial agents should indicate the dose, the dosage intervals, route and the duration of the administration, the withdrawal period, when appropriate, and the amount of antimicrobial agent to be delivered, depending on the dosage and the characteristics of the individual or population to be treated, in accordance with national legislation;<br>• The quantity of the antimicrobial provided to the end-user should, if feasible, be limited only for the administration concerned. Prescriptions or orders should also indicate the owner and the identification of the food-producing animals or plants/crops to which the antimicrobials are to be administered | • ~~A prescription, or order for application, or similar document for medically important antimicrobial agents should indicate the dose, the dosage intervals, route and the duration of the administration, the withdrawal period, when appropriate, and the amount of antimicrobial agent to be delivered, depending on the dosage and the characteristics of the individual or population to be treated, in accordance with national legislation;~~<br>• ~~The quantity of the antimicrobial provided to the end-user should, if feasible, be limited only for the administration concerned. Prescriptions or orders should also indicate the owner and the identification of the food-producing animals or plants/crops to which the antimicrobials are to be administered~~ | Part of the OIE documents and remit. |

| Location | Current Text | Recommended Revision | Rationale |
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| **§52** | . For food-producing animals, the appropriate use of ~~medically important~~ antimicrobial agents in practice is a clinical decision that should be based on the experience ~~and local expertise~~ of the prescribing veterinarian~~,~~ and epidemiological and clinical knowledge ~~the accurate diagnosis, based on adequate diagnostic procedures~~. ~~There will be occasions~~ When a group of food-producing animals~~,~~ ~~which~~ may have been exposed to pathogens, they may need to be treated without recourse to a~~n accurate~~ laboratory confirmed diagnosis based on ~~and~~ antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal welfare | . For food-producing animals, the appropriate use of ~~medically important~~**medically important** antimicrobial agents in practice is a clinical decision that should be based on the experience ~~and local expertise~~ of the prescribing veterinarian~~,~~ and epidemiological and clinical knowledge ~~the accurate diagnosis, based on adequate diagnostic procedures~~. ~~There will be occasions~~ When a group of food-producing animals~~,~~ ~~which~~ may have been exposed to pathogens, they may need to be treated without recourse to a~~n accurate~~ laboratory confirmed diagnosis based on ~~and~~ antimicrobial susceptibility testing to prevent the development and spread of clinical disease and for reasons of animal **husbandry**~~welfare~~ | No deletion for consistency with §53.<br><br>Better reading |
| **§54**<br><br>**3rd subbullet of 1st bullet** | the history of the production unit particularly in regard to the antimicrobial susceptibility profiles of the pathogens involved. Whenever possible, the antimicrobial susceptibility profiles should be established before the commencement of the administration. If this is not possible, it is desirable for samples to be taken before the start of the administration to allow, if necessary, for adjustment of therapy based on susceptibility testing. Should a first antimicrobial administration fail, or should the disease recur, the use of a second antimicrobial agent should ideally be based on the results of microbiological susceptibility tests derived from relevant samples | the history of the production unit particularly **with regards to**~~in regard to~~ the antimicrobial susceptibility profiles of the pathogens involved. Whenever possible, the antimicrobial susceptibility profiles should be established before the **start**~~commencement~~ of the administration. If this is not possible, it is desirable for samples to be taken before the start of the administration to allow, if necessary, for adjustment of therapy based on susceptibility testing. Should a first antimicrobial **agent** administration fail, or should the disease recur, the use of a second antimicrobial agent should ideally be based on the results of microbiological susceptibility tests derived from relevant **appropriately collected** samples | Alignment with definition, editorial<br><br>Ensure samples are properly collected |
| **§54**<br><br>**2nd bullet** | The need to minimize the adverse health effect from the development of antimicrobial resistance based on | The need to minimize the adverse health effect from the development of **AMR**~~antimicrobial resistance~~ based on | Consistent use of acronym |
| **§54**<br><br>**1st subbullet of 2nd bullet** | the choice of the activity spectrum of the antimicrobial agent. Narrow-spectrum antimicrobials should be selected whenever possible/appropriate | the choice of the activity spectrum of the antimicrobial agent. Narrow-spectrum antimicrobial **agent**s should be selected whenever possible/appropriate | Alignment with definition |

| Location | Current Text | Recommended Revision | Rationale |
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| **§54**<br>**6th subbullet of 2nd bullet** | the use of fixed combinations of antimicrobial agents (i.e. only combinations contained in authorized veterinary medicinal products) which are effective against the target pathogens; and | the use of fixed combinations of antimicrobial agents (i.e. only combinations **subject to a marketing authorisation**~~contained in authorized veterinary medicinal products~~) which are effective against the target pathogens; and | For clarification purpose |
| **§55** | For food-producing animals, the off-label use of a veterinary antimicrobial agent may be permitted in appropriate circumstances and should comply with the national legislation including the ~~appropriate and/or~~ use of approved or appropriate withdrawal periods ~~to be used~~. It is the veterinarian's responsibility to define the conditions of use including the therapeutic regimen, the route of administration, and the duration of the administration and the withdrawal period | For food-producing animals, the off-label use of a veterinary antimicrobial agent may be permitted in appropriate circumstances and should comply with the national legislation including the ~~appropriate and/or~~ use of approved or appropriate withdrawal periods ~~to be used~~. It is the veterinarian's responsibility to define the conditions of use including the **dose**~~therapeutic regimen~~, the route of administration, and the duration of the administration and the withdrawal period | For clarification purpose |
| **§56** | Human health risk related to foodborne antimicrobial resistance should be an important factor when considering the off-label use of veterinary antimicrobial agents in food-producing animals. | Human health risk related to foodborne **AMR**~~antimicrobial resistance~~ should be an important factor when considering the off-label use of veterinary antimicrobial agents in food-producing animals. | Consistent use of acronym |
| **§57** | Antimicrobials should not be used off-label for plants/crops | Antimicrobial **agent**s should not be used off-label for plants/crops | Alignment with definitions |
| **§58** | For food-producing animals and plants/crops, records on antimicrobial agent prescription or ~~administration~~ application should be kept in conformity with national legislation or best management practice guidelines<br><br>In particular, for investigation of antimicrobial resistance, veterinarians and plant/crop health professionals or suitably trained persons authorized in accordance with national legislation should | For food-producing animals and plants/crops, records on antimicrobial agent prescription or ~~administration~~ **administration/**application should be kept in **accordance**~~conformity~~ with national legislation or best management practice guidelines<br><br>In particular, for investigation of **AMR**~~antimicrobial resistance~~, veterinarians and plant/crop health professionals or suitably trained persons authorized in accordance with national legislation should | To keep consistency in the document<br><br>Consistent use of acronym |
| **§58**<br>**2nd bullet** | record the antimicrobial used, the dosage ~~regimen~~ and the duration; investigate adverse reactions to antimicrobial agents, including lack of expected efficacy, and report it, as appropriate, to the competent authorities (through a pharmacovigilance system, if available). | record the antimicrobial **agent** used, the dosage ~~regimen~~ and the duration; investigate adverse reactions to antimicrobial agents, including lack of expected efficacy, and report it, as appropriate, to the competent authorities (through a pharmacovigilance system, if available). | Alignment with definitions |

| Location | Current Text | Recommended Revision | Rationale |
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| **§60** | Professional or other organizations should ~~participate in~~ support the development and/or delivery of training on issues related to antimicrobial resistance and the responsible use~~rs~~ of antimicrobial agents as ~~defined~~ described in paragraph 32~~28~~ | Professional or other organizations should ~~participate in~~ support the development and/or delivery of training on issues related to **AMR**~~antimicrobial resistance~~ and the responsible use~~rs~~ of antimicrobial agents as ~~defined~~ described in paragraph 32~~28~~ | Consistent use of acronym |
| **Title** | **Responsibilities of food animal and plant/crop producers** | **Responsibilities of food-producing animal and plant/crop producers** | For consistency in the document |
| **§61** | Producers are responsible for implementing health programmes on their farms to prevent and manage disease outbreaks~~. They should call on the~~ with assistance of veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation. All participants involved in primary production of food have an important role to play in preventing disease and ~~to reduce~~ reducing the need to use antimicrobials ~~ensuring the responsible and prudent use of antimicrobial~~ agents to minimize risk of foodborne AMR | Producers are responsible for implementing health programmes on their farms to prevent and manage disease outbreaks~~. They should call on the~~ with assistance of veterinarians, plant/crop health professionals, or other suitably trained persons authorized in accordance with national legislation. All participants involved in **the** primary production of food have an important role to play in preventing disease and ~~to reduce~~ reducing the need to use antimicrobials **ensuring the responsible and prudent use of antimicrobia**~~l~~ agents to minimize risk of foodborne AMR | Editorial and need to keep the objective of the activity in the document. |
| **§62** | Producers of food animals and plants/crops have the following responsibilities | Producers of food-**producing** animals and plants/crops have the following responsibilities | For consistency in the document |
| **§62**<br>**3rd bullet** | to use antimicrobial agents in the species, for the uses and at the doses on the approved labels and in accordance with the prescription, product label instructions or the advice of a veterinarian, plant/crop health professional or other suitably trained person authorized in accordance with national legislation familiar with the food-producing animals or the plant/crop production site | to use antimicrobial agents in the species, for the uses and at the doses **indicated in the marketing authorisation**~~on the approved labels~~ and in accordance with the prescription, product label instructions or the advice of a veterinarian, plant/crop health professional or other suitably trained person authorized in accordance with national legislation familiar with the food-producing animals or the plant/crop production site | Alignment with definition and clarification |
| **§62**<br>**4th bullet** | to comply with the storage conditions of antimicrobial agents according to the approved product labelling | to comply with the storage conditions of antimicrobial agents according to **the marketing authorisation**~~the approved product labelling~~ | Alignment with definition and clarification |

| Location | Current Text | Recommended Revision | Rationale |
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| **§62**<br>**8th bullet** | to inform the veterinarian, plant/crop health professional, or other suitably trained person authorized in accordance with national legislation in charge of the production unit of recurrent disease problems or ~~failures of~~ suspected lack of efficacy of antimicrobial applications | to inform the veterinarian, plant/crop health professional, or other suitably trained person authorized in accordance with national legislation in charge of the production unit of recurrent disease problems or ~~failures of~~ suspected lack of efficacy of antimicrobial **agent administration/**applications | Alignment with definition and consistency within the text |
| **§62**<br>**4th subbullet of 11th bullet** | date of administration; species and number of animals or plants/crops | date of administration**/application**; species and number of animals or plants/crops | For consistency reason |
| **§62**<br>**8th subbullet of 11th bullet** | ~~daily dose and number of treatment days~~ | daily dose and number of treatment days | Should be kept |
| **§62**<br>**14th bullet** | To participate in training on issues related to antimicrobial resistance and the responsible use of antimicrobial agents as described in paragraph 32, as appropriate | To participate in training on issues related to **AMR**~~antimicrobial resistance~~ and the responsible use of antimicrobial agents as described in paragraph 32, as appropriate | Consistent use of acronym |
| **§62**<br>**15th bullet** | To assist the relevant authorities in surveillance programs related to antimicrobial use and antimicrobial resistance, as appropriate | To assist the relevant authorities in surveillance programs related to antimicrobial use and **AMR**~~antimicrobial resistance~~, as appropriate | Consistent use of acronym |

| Location | Current Text | Recommended Revision | Rationale |
|---|---|---|---|
| **§63** | The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimize infection during production. ~~and decrease exposure to antimicrobial agents.~~ Efforts should aim to improve health, thereby reducing the need for ~~antibiotics~~ antimicrobial agents. This can be achieved by, for example, improving hygiene, biosecurity,~~ and~~ health management on farms, improving animal and plant/crop genetics, and implementing national or international good animal production (terrestrial and aquatic), and plant/crop production practices | The responsible and prudent use of antimicrobial agents should be supported by continuous efforts in disease prevention to minimize infection during production. ~~and decrease exposure to antimicrobial agents.~~ Efforts should aim to improve health, thereby reducing the need for ~~antibiotics~~ antimicrobial agents. This can be achieved by, for example,<br>• **For food-producing animals, adequate nutrition** improving hygiene, biosecurity,~~ and~~ health management on farms **to reduce animal's exposure to foodborne pathogens and support animals resilience capabilities**, improving animal ~~and plant/crop~~ genetics, and implementing national or international good animal production (terrestrial and aquatic), ~~and plant/crop production practices~~<br>• **For plants/crops; improving plant/crop genetics and implementing national or international plant/crops good production practices** | For clarity |
| **§67** | Food business operators should provide training on good hygienic practices, including those for minimizing cross-contamination. The WHO Five Keys to Safer Food contains useful information for food handlers to minimize the transmission of foodborne illness, including ~~AMR~~ resistant infections | Food business operators should provide training on good hygienic practices, including those for minimizing cross-contamination. The WHO Five Keys to Safer Food contains useful information for food handlers to minimize the transmission of foodborne illness, including ~~AMR~~**antimicrobial** resistant infections | For consistency in the document |

| Location | Current Text | Recommended Revision | Rationale |
|---|---|---|---|
| **§68** | Government, food industry and other stakeholders along the food chain should inform and educate consumers on the risks of foodborne illness, including infections with resistant microorganisms and ways to minimize the risk of infection.<br><br>Some aspects to consider when communicating to consumers are:<br>• Identifying all the stakeholders and having a common message;<br>• Providing information that is clear, accessible, and targeted to a non-scientific audience;<br>• Considering local characteristics that affect how risks are perceived (e.g. religious belief, traditions).~~;~~<br><br>The *WHO Five Keys to Safer Food Manual* can be used as a tool to assist in awareness raising for consumers on how to minimize foodborne bacteria in their food | Government, food industry and other stakeholders along the food chain should inform and educate consumers on the risks of foodborne illness, including infections with **antimicrobial** resistant microorganisms and ways to minimize the risk of infection.<br><br>Some aspects to consider when communicating to consumers are:<br>• Identifying all the stakeholders and having a common message;<br>• Providing information that is clear, accessible, and targeted to a non-scientific audience;<br>• Considering local characteristics that affect how risks are perceived (e.g. religious belief, traditions).~~;~~<br><br>The *WHO Five Keys to Safer Food Manual* can be used as a tool to assist in awareness raising for consumers on how to minimize foodborne **microorganism**~~bacteria~~ in their food | For consistency in the document |

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