Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria (PACCARB)

Overview of the Codex ad hoc Intergovernmental Task Force on Antimicrobial Resistance (TFAMR)

Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance

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Codex Alimentarius[1]

- Purpose
  - The Codex Alimentarius is a collection of internationally adopted food standards and **related texts** aimed at protecting consumers' health and ensuring fair practices in the food trade.
- Scope
  - Standards for all the principal foods, materials for further processing into foods to the extent necessary, including provisions in respect of food hygiene, food additives, residues of pesticides and veterinary drugs, contaminants, labelling and presentation, methods of analysis and sampling, and import and export inspection and certification.
- Nature of Codex Texts
  - Codex standards and related texts are not a substitute for, or alternative to national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply.
- Revision
  - The Codex Alimentarius Commission and its subsidiary bodies are committed to revision as necessary of Codex standards and related texts to ensure that they are consistent with and reflect current scientific knowledge and other relevant information.

[1]https://www.fao.org/fao-who-codexalimentarius/about-codex/en/

Codex Alimentarius – Commission, Committees and Task Forces

- Codex Alimentarius Commission (CAC)
- Codex Committees
  - Standing Cmtes
    - Executive
    - Commodity (4)

    General Subject (10)
    - Codex Committee on Residues of Veterinary Drugs in Food (CCRVDF)

    Regional Coordinating (6)
  - Task Forces (as needed, time-limited)
- Codex *ad hoc* Intergovernmental Task Force on Antimicrobial Resistance (TFAMR)
  - TFAMR *2007-2011*
  - TFAMR *2017-2021*

Codex Texts

- Codex standards and related texts are **voluntary** in nature. They need to be translated into national legislation or regulations in order to be enforceable.
- General Standards, Guidelines and Codes of Practice
  - These are the core Codex texts and apply to all products and product categories. These texts typically deal with hygienic practice, labelling, additives, inspection & certification, nutrition and residues of veterinary drugs and pesticides.
- Commodity standards
  - Codex commodity standards refer to a specific product although increasingly Codex now develops standards for food groups i.e. one general standard for fruit juices and nectars as opposed to one per fruit.

Codex Alimentarius Related Texts on Antimicrobial Resistance (AMR)

- CCRVDF
  - Code of Practice to Minimize and Contain Antimicrobial Resistance (2005)
- TFAMR
  - Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance (2011)
- TFAMR
  - Code of Practice to Minimize and Contain Antimicrobial Resistance (2021)
  - Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance (2021)

CAC40: Proposal for new work on the revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005)

- Purpose: broaden the scope to address the entire food chain, in line with the mandate of Codex
- Main aspects to be covered:
  - determine and address the gaps that exist in the Code and updates to language, references, or tools, that are necessary;
  - strategies that prevent or reduce the need to use antimicrobial agents;
  - inclusion of references to the lists of critically important antimicrobials;
  - respective responsibilities of all involved in the production of food along the food chain, from primary producers to end consumers, including those involved in the production, selling, distribution and application of antimicrobial agents and;
  - the use of antimicrobials as growth promoters.

Development of the Revision of the Code of Practice (COP)

- EWG prior to first meeting of the TFAMR5
- TFAMR5 – Plenary review and discussion
  - Conducted in-session WG to further develop request for scientific advice from OIE and FAO
  - EWG to further develop revisions to the COP at Step 2/3
- TFAMR6 – Plenary review and discussion at Step 2/3
  - Receipt of scientific advice
  - Conducted in-session WG to further develop revisions to the COP
  - Established EWG to further develop revisions to the COP at Step 2/3
- TFAMR7 – Plenary review and discussion at Step 2/3
  - Conducted in-session WG to further refine the COP
  - Recommended draft document for adoption at Step 5
  - Established EWG to review remaining text in square brackets (therapeutic use)
- CAC43 – Adopted at Step 5
  - Held EWG to review remaining text in square brackets (therapeutic use) – 2 rounds
  - Webinar on COP
  - Virtual WG to review comments at Step 6
- TFAMR8 – Plenary review and discussion at Step 7
  - Recommended for adoption at Step 8

Revised Code of Practice to Minimize and Contain Antimicrobial Resistance

- **Introduction**
  - AMR - an important, complex, and priority global public health challenge.
  - Introduces the concept of the “food chain” to expand the current COP which focuses on animal production.
  - Roles and responsibilities of all participants along the food chain to manage risks associated with the use of antimicrobial agents.
  - One Health Approach to minimize and contain AMR throughout the document.
  - Animal production – terrestrial and aquatic.
  - Primary production – as well as processing, storage, transport, and wholesale and retail distribution of food.
  - Key guidance in other texts including reference to the lists of critically important antimicrobial agents.
  - Implemented by countries to ensure it is in accordance with their capabilities, based on their national priorities and capacities, and is accomplished within a reasonable period of time – and in a way that is proportionate to the risk and avoids unjustified barriers to trade.

Revised Code of Practice to Minimize and Contain Antimicrobial Resistance

- **Scope**
  - Foodborne AMR, in line with the mandate of Codex.
  - Risk management guidance along the food chain addressing all the relevant participants and sectors.
  - Focus on antibacterials, however some recommendations may also be applicable to antiviral, antiparasitic, antiprotozoal, and antifungal agents, where there is scientific evidence of foodborne AMR risk to human health.
  - Recognized existing Codex or internationally recognized guidelines related to some antimicrobial agents or AMR and clearly stated which ones are outside the scope of the document.

Revised Code of Practice to Minimize and Contain Antimicrobial Resistance

- **Definitions**
  - Food chain
  - Food production environment
  - One Health Approach
  - Medically important antimicrobials
  - Pharmacovigilance
  - Plants/crops
  - Plant/crop health professional
  - Treatment of disease, control of disease/metaphylaxis, and prevention of disease/prophylaxis
  - Veterinary medical use[4,5]/phytosanitary use[6] (food-producing animals or plants/crops): Administration or application of antimicrobial agents for the treatment, control/metaphylaxis or prevention/prophylaxis of disease

[4]See also OIE Terrestrial Animal Health Code, specifically the chapter on Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals.

[5]Also recognized as therapeutic use in some jurisdictions/organizations.

[6]See also IPPC International Standard for Phytosanitary Measures, Glossary of Phytosanitary Terms.

Revised Code of Practice to Minimize and Contain Antimicrobial Resistance

- **General Principles**
  - Following the approach taken by the Task Force in the *Guidelines for Risk Analysis of Foodborne AMR* (CXG77-2011), General Principles were developed to highlight and underscore key high level concepts.
- *Principles on AMR Risk Management (generally)*
- **Principle 1:** A One Health Approach should be applied, wherever possible and applicable, when identifying, evaluating, selecting, and implementing foodborne AMR risk management options.
- **Principle 2:** Considering that this document is to provide risk management guidance to address foodborne AMR risks to human health, for animal health and plant health aspects, relevant OIE and IPPC standards should be considered.
- **Principle 3:** Foodborne AMR risk management measures should be implemented in a way that is proportionate to the risk and reviewed on a regular basis as described in the *Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance*. Risk managers should consider potential unintended consequences to humans, animal, and plant health of recommended risk management measures.
- **Principle 4:** The *WHO List of Critically Important Antimicrobials for Human Medicine*, the *OIE List of Antimicrobial Agents 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 5:** 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.

Revised Code of Practice to Minimize and Contain Antimicrobial Resistance

Principle on preventing infections and reducing the need for antimicrobials

- **Principle 6:** 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.

Principles on the responsible and prudent use of antimicrobials (generally)

- **Principle 7:** 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.
- **Principle 8:** Medically important antimicrobials should be prescribed, administered, 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 9:** Antimicrobial agents should be used as legally authorized and following all applicable label directions; except where specific legal exemptions apply.
- **Principle 10:** The choice of which antimicrobial agent to use should take into consideration relevant professional guidelines, where available, results of antimicrobial susceptibility testing of isolates from the production setting, where appropriate, and make adjustments to the antimicrobial agent selection based on clinical outcomes or when foodborne AMR risks become evident.
- **Principle 11:** 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.

Revised Code of Practice to Minimize and Contain Antimicrobial Resistance

Principles on the use of antimicrobials in specific circumstances

- **Principle 12:** 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*.
- **Principle 13:** Medically important antimicrobial agents should only be used for veterinary medical use/phytosanitary use (treatment, control/metaphylaxis or prevention/prophylaxis of disease).
- **Principle 14:** Medically important antimicrobials should only be administered or applied for prevention/prophylaxis where professional oversight has identified well-defined and exceptional circumstances, appropriate dose and duration, based on clinical and epidemiological knowledge, consistent with the label, and in line with national legislation. Countries could use additional risk management measures for medically important antimicrobials considered highest priority critically important as described in the *WHO List of Critically Important Antimicrobials for Human Medicine*, the *OIE List of Antimicrobial Agents of Veterinary Importance*, or national lists, where available, including restrictions proportionate to risk and supported by scientific evidence.
- **Principle 15:** 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.

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Principle on surveillance of antimicrobial resistance and use

- **Principle 16:** 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*.

Revised Code of Practice to Minimize and Contain Antimicrobial Resistance

- **Responsible and prudent use of antimicrobial agents**
- Largest section of the COP, contains risk management guidance for different participants along the food chain, namely:
  - Competent Authorities
  - Manufacturers and Marketing Authorization Holders
  - Wholesale and Retail Distributors
  - Veterinarians and Plant/Crop Health Professionals
  - Food animal and Plant/Crop Producers

Revised Code of Practice to Minimize and Contain Antimicrobial Resistance

- **Responsible and prudent use of antimicrobial agents (continued)**
  - Building on Principle 9 (restricting use to legally authorized antimicrobial agents), guidance to competent authorities provides advice on systems for evaluating antimicrobial agents and granting a marketing authorization.
  - “Food production environment” to address the environmental component of the One Health Approach in line with the mandate of Codex and address specific potential sources of contamination in the food production environment.
  - Role of pharmacovigilance systems to collect data on adverse reactions, including lack of efficacy that could be related to foodborne antimicrobial resistance, is addressed and guidance is provided on how these systems can be used in conjunction with monitoring and surveillance programs.

Revised Code of Practice to Minimize and Contain Antimicrobial Resistance

- **Responsible and prudent use of antimicrobial agents (continued)**
  - Expanded section on training on foodborne antimicrobial resistance and the responsible use of antimicrobial agents by identifying a range of potential educational and communication topics and highlighting the roles of different participants along the food chain.
  - Identification of knowledge gaps and areas of research where additional data and information are needed to minimize and contain AMR.
  - Substandard and counterfeit drugs, and illegally marketed antimicrobial agents.
  - Additional guidance for the section on advertising and promotion of antimicrobial agents.
  - Specific advice for both Veterinarians and Plant/Crop Health Professionals. This is especially important for the plant sector, where limited guidance may be available with respect to minimizing and containing AMR.

Revised Code of Practice to Minimize and Contain Antimicrobial Resistance

- **Practices during production, processing, storage, transport, retail and distribution of food**
  - New section for the COP.
  - Food should be produced and handled in such a way as to minimize the introduction, presence and growth of microorganisms, which apart from having the potential to cause spoilage and foodborne illnesses can also disseminate foodborne AMR.
  - References Hazard Analysis and Critical Control Points (HACCP) and the Codex *General Principles of Food Hygiene* (CXC 1-1969).

Revised Code of Practice to Minimize and Contain Antimicrobial Resistance

- **Consumer practices and communication to consumers**
  - New section for the COP.
  - Focus on how government, the food industry, and other stakeholders should inform and educate consumers on the risks of foodborne illness, including infection with resistant microorganisms.
  - References available tools and related information on risk communication.

Revised Code of Practice to Minimize and Contain Antimicrobial Resistance

- Adopted at CAC44 – final report pending
  - Revised Code of Practice to Minimize and Contain Antimicrobial Resistance
  - Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance
- Sincere gratitude for support and leadership by the Republic of Korea
- Next steps: approaches for outreach and implementation