

Food and Agriculture Organization of the United Nations

Slowing down superbugs

Legislation and antimicrobial resistance (AMR)



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FOOD SAFETY TECHNICAL TOOLKIT FOR ASIA AND THE PACIFIC

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Abstract

Antimicrobial resistance (AMR) can be described as the quintessential One Health issue: it involves humans, animals and the environment. It is also a multisectoral food safety problem whose effects transcend borders. With such an interlinked context, legislation that has an impact on AMR is crucial to combat the issue, and to establish linkages among the various sectors and activities. As AMR is a holistic problem, the connections between AMR and its implications in the different areas of law need to be considered.

This document presents in detail the connection between food safety legislation and AMR. It discusses how the maximum residue limits of pesticides and antimicrobials can directly impact AMR. While some aspects of this connection are already established enough to take regulatory action, some others would need more consideration, for example, food additives with an impact on AMR. Analysis and strengthening of relevant regulatory systems are the primary concerns for food safety national authorities. Identifying existing regulatory mechanisms that can be utilized to introduce AMR-relevant considerations is also important. Through the lens of AMR, the legal framework will then need to be considered as a whole.

Keywords

antimicrobial resistance, AMR, food safety, food legislation, One Health, antimicrobials, MRL, maximum residue limits, Codex Alimentarius, Food and Agriculture Organization of the United Nations (FAO), Asia and the Pacific.



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Abbreviations and acronyms

AMR	antimicrobial resistance
ASEAN	Association of Southeast Asian Nations
FAO	Food and Agriculture Organization of the United Nations
MRLs	maximum residue limits
MRLVD	maximum limit for residues of veterinary drugs
OIE	World Organisation for Animal Health
SPS	Agreement on the Application of Sanitary and Phytosanitary Measures
WHO	World Health Organization
WTO	World Trade Organization



Introduction

Antimicrobial resistance (AMR) occurs when microorganisms (e.g. bacteria, fungi, viruses, and parasites), including those that cause infection and disease, acquire resistance to antimicrobial substances (e.g. antibiotics, antifungals, antivirals). While this phenomenon does occur naturally through microbial adaptation to their surrounding environment, inappropriate and excessive use of antimicrobials, particularly in human health and agriculture, exacerbate the problem.

At the interface of humans, animals and the environment, AMR has been described as the "quintessential One Health issue" (Robinson and Walzer, 2016) with clear links to human, animal and environmental health. Development and spread of AMR is also a food safety problem. We could be exposed to AMR through the resistant microorganisms that are present in our agricultural production systems and food chains. As more microorganisms become resistant to the drugs to which they were previously susceptible, some infections in humans, livestock and plants are becoming increasingly difficult or even impossible to treat.

With impacts that have the ability to transcend borders, AMR has become one of the most significant threats to human and animal health today. It has the potential to render current disease-treating medicines ineffective. Along the food production chain, antimicrobials have important uses from treatment of food-producing animals to essential food processing procedures. Left unchecked, the ramifications of the spread of AMR could reach well beyond health consequences and jeopardize the food safety, food security and economic well-being of people around the world.

Food safety and antimicrobial resistance relevant legislation

2.1. Background

In recent years, the issue of AMR has garnered increasing international attention and concern. The need to address the risks of AMR has prompted initiatives at the global, regional and national levels. Dealing with AMR requires a multisectoral One Health approach. The Tripartite organizations (the Food and Agriculture Organization of the United Nations, or FAO, the World Organisation for Animal Health or OIE, and the World Health Organization, or WHO) have been advocating for the need to tackle AMR in all sectors.

In 2015, the Tripartite organizations developed a Global Action Plan on AMR that invites countries to establish national action plans (NAPs) on AMR specific to the individual country's needs, but still heeding existing guidance and international standards. The Global Action Plan contains the following objectives:



Improve awareness and understanding of AMR through communication, education and training.



Strengthen the knowledge and evidence base through surveillance and research.



Reduce the incidence of infection through effective sanitation, hygiene and infection prevention measures.



Optimize the use of antimicrobial medicines in human and animal health.



Develop the economic case for sustainable investment that takes account of the needs of all countries and increases investment in new medicines, diagnostic tools, vaccines and other interventions (WHO, 2015).

In the food and agriculture sectors, the FAO Action Plan on AMR was developed to support the objectives of the Global Action Plan. The FAO plan focuses on four areas of action: improved awareness, surveillance and monitoring (evidence), governance, and good practices (FAO, 2016).¹ The Tripartite have been actively collaborating to support countries' efforts to tackle this issue through the development and implementation of their NAP.

¹ The initial FAO Action Plan on antimicrobial resistance was developed for the time frame of 2016–2020, and a new version of the plan is undergoing development and finalization at this time.

Box 1. The Association of Southeast Asian Nations' commitment to tackle antimicrobial resistance

Regions and sub-regions are also making efforts to tackle AMR. In 2017, leaders of the Association of Southeast Asian Nations (ASEAN) recognized the impending threats posed by AMR and the need for a One Health approach. They adopted the ASEAN Leaders' Declaration on antimicrobial resistance (AMR): Combating AMR through One Health Approach. In 2018, the ASEAN Plus Three Leaders' Statement on Cooperation Against Antimicrobial Resistance (AMR) placed further emphasis on the need for better regional collaboration, beyond the established networks. ASEAN Plus Three refers to the ten ASEAN members and the People's Republic of China, Japan and Republic of Korea.

To further the commitment demonstrated by the countries, technical guidance continues to be developed to aid countries in the region to implement their national action plans. For example, having identified the livestock sector as an area for priority action, in 2017 the ASEAN Sectoral Working Group for Livestock developed the ASEAN Guidelines for the Prudent Use of Antimicrobials in Livestock to address antimicrobial use in the food and agriculture sector (ASEAN, 2017).



2.2. What is antimicrobial resistance relevant legislation?

Legislation forms the backbone of the governance structure crucial to effectively combating AMR. Legislation has the role of enshrining the key regulatory controls within a sector into legally enforceable provisions. It establishes linkages among the various sectors and activities in different areas that have an impact on AMR, and facilitates coordinated implementation by the various competent authorities involved.

AMR-relevant legislation refers to laws that have an impact on AMR. The definition of AMR-relevant legislation is broad. It does not consist only of AMR-specific legal instruments. This is because legislative frameworks across many legal areas have potential impacts, direct or indirect, on AMR. These legal areas include human and animal health, veterinary medicinal products, pesticides management, environmental protection, food safety, and water or waste management. As with other One Health issues, the laws in these areas typically have not been developed to specifically address AMR, and so might not include overt references to AMR. In fact, it is not necessary to develop AMRspecific legislation in order to adequately address AMR issues. Without consideration of all the existing AMR-relevant legislation, the risk of introducing a new, separate piece of legislation only to address AMR would run the risk of legal fragmentation that may become the source of more confusion and uncertainty in an already complicated field.

Considering the legal landscape relevant to AMR, it is important to determine whether the laws include the necessary regulatory powers and appropriate mechanisms (prohibitions, licenses, permits) to effectively control and reduce AMR. Identifying the relevant regulatory areas and related legal issues is pertinent to assess and strengthen the capacity of a national legal framework to prevent and address AMR. However, identifying these key elements in the national legal framework is challenging. It requires an understanding of how legal provisions impact AMR across a diversity of legal areas.

In the food and agriculture sectors, the Development Law Service of the Legal Office of FAO has developed a methodology to support countries in identifying and analysing key legal areas, and key elements within the legal areas, that would have an impact on AMR (FAO, 2020a).² FAO developed the methodology based on existing international reference standards, including Codex Alimentarius standards, and good practices. AMR-relevant legislation is legislation that:



Determines how antimicrobials are regulated through their entire lifecycle, including antimicrobials as veterinary medicinal products, feed that contains antimicrobials, and antimicrobials as pesticides.







Minimizes the need for antimicrobials through better infection prevention and control, improving animal health and welfare, and environmental health.

The legal frameworks in these different areas contribute to a more comprehensive regulatory prevention and response to effectively address the threat of AMR.

² This guidance document has been launched for public review in 2020, at http://www.fao.org/antimicrobial-resistance/news-and-events/news/news-details/ en/c/1312103/ Countries have been engaging in initiatives to combat AMR across many legal areas. In fact, most countries have laws or regulations addressing some aspect of antimicrobial control. From authorization and registration, production, import and export to distribution, sale and consumption, the regulation of antimicrobials does not end at these stages. The entire lifecycle of the antimicrobial substance should be taken into consideration.

At the end stage of disposal, legislation should account for the potential effects of antimicrobial residues in food and the environment. Consideration needs to be given to contamination of the environment, soil and water resources with antimicrobials, AMR microorganisms or resistant genetic material. Preventing contamination is not only important for environmental protection, but also to protect communities from consuming contaminated food or water, or using agricultural inputs that have been contaminated with AMR microorganisms or antimicrobial residues.

AMR considerations could be integrated into existing regulatory mechanisms to prevent and control pollutant-emitting activities. Often, laws that contain relevant provisions governing these different stages of the lifecycle of antimicrobials might not be found in one single legal area. They can span laws on veterinary medicinal products, pesticides, food safety, waste, water quality, and the environment.

Legislation also plays a role in minimizing the need to use antimicrobials. It can help in the prevention, surveillance and control of pests and diseases. Appropriate legislation on plant health, animal health, pesticides, fisheries and aquaculture can serve as a basis to introduce regulatory mechanisms, such as licenses and permits. It can facilitate good production practices and biosecurity measures that would help to improve sanitary and phytosanitary status, reducing the need to use antimicrobials.

The traditional siloed approach of addressing specific AMR concerns in selected areas is no longer sufficient to combat AMR. Instead, AMR needs to be addressed across multiple relevant sectors. This calls for governments, regulators, and other stakeholders to take a multidisciplinary One Health approach to tackle AMR in their national legal frameworks.

2.3. The intersection between antimicrobial resistance and food safety

Food safety systems have a key role to play in addressing the risks of AMR. The development and spread of AMR could have devastating effects on the food supply and production chain, and could introduce AMR into the community. Effective management of AMR along the food chain from primary production to consumption would be crucial to curb the spread of AMR.

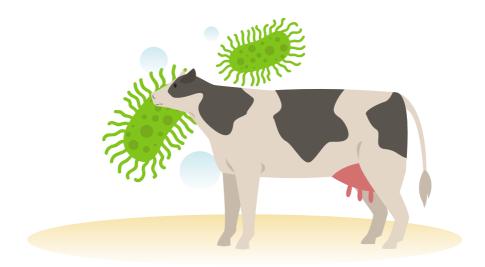
The broad food safety legal framework has an important role to play in the prevention and control of AMR. A very important element of food safety legislation is the setting of maximum residue limits of pesticides and veterinary medicinal products (antimicrobials), as they have a direct impact on AMR. Furthermore, the connection between AMR and food safety in legislation is not restricted to food safety laws. AMR-relevant legislation in other areas could also have an impact on food safety.

2.3.1. Food safety legislation

Legislation provides the basis for governments to control the safety and quality of food products and to prevent the transmission of foodborne diseases. This includes zoonoses that can be transmitted through food. Food safety can be regulated differently in different jurisdictions. Some countries regulate this through specific food safety legislation, while others regulate it through more general public health codes, or in specific legislation with a different scope, such as food and drugs legislation. Provisions related to food safety and quality could also be contained in other laws, such as consumer protection laws.

The food safety legislative framework covers the entire value chain of food products "from farm to fork." Based on international reference standards developed and adopted by the Codex Alimentarius Commission (Box 2: Codex Alimentarius), food safety legislation aims to maintain and protect the sanitary integrity of food as it moves through the supply chain. For the overall functioning of the food safety system, legislation should establish a national competent authority or authorities to coordinate food safety in all stages of the food production chain. Food safety spans human health and agriculture. There may be more than one national institution involved across different stages of the food chain. Legislation is important for clarifying the roles and responsibilities of the different institutions and can also be used to establish the legal mechanisms for institutional coordination.

In addition to horizontal coordination across government institutions, federal and decentralized countries face the additional challenge of ensuring clarity in the division of roles and responsibilities between the central government institutions and the decentralized level. Legislation that includes provisions that allow the authority to delegate some functions would be useful. It builds in flexibility and responsiveness for the competent authorities to effectively and efficiently carry out their work.



Box 2. Codex Alimentarius

There are key international reference texts related to food safety that offer guidance on various elements of AMR-relevant legislation in the area of food safety and guality. The World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (SPS) (Article 3; Annex A) recognizes the standards, guidelines and codes of practice approved by the Codex Alimentarius Commission (hereinafter "Codex Alimentarius") as international reference standards for food safety. Sanitary and phytosanitary regulatory measures influence the international trade in food and agriculture products and regulate the movement of pathogens associated with such trade. Under the SPS Agreement, WTO members that base their sanitary and phytosanitary measures on the standards set by the recognized organizations, including incorporating such measures in their national sanitary and phytosanitary legislation, do not have to further demonstrate that these measures are science-based and necessary to achieve their desired level of protection.

Codex Alimentarius standards are the international reference for food safety, spanning primary production to consumption, and for the purpose of ensuring the safety, quality and fairness of international food trade.

The Codex Alimentarius Commission has been developing texts addressing the issue of foodborne AMR since 2005 (Codex Alimentarius, 2005).³ In 2006, Codex established the first Task Force on antimicrobial resistance in recognition of the need for a multidisciplinary approach to develop science-based guidance in this area.

³ Revision of these texts is ongoing, as well as the development of a new guideline on AMR surveillance.

(Cont.)

Codex Alimentarius

In 2015, the Codex Alimentarius Commission compiled the Guidelines for Risk Analysis of Foodborne AMR (CAC/GL 77-2011) and the Code of Practice to Minimize and Contain AMR (CAC/RCP 61-2005) into one publication of Codex texts on foodborne AMR in support of the Global Action Plan (FAO and WHO, 2015). The Codex texts provide guidance on the responsibilities of each group of stakeholders along the food chain to contain and minimize AMR. from the regulatory authorities to producers. The Codex texts also contain guidance on the development and implementation of foodborne AMR risk analysis frameworks. The Codex Alimentarius Commission approves the reference maximum residue limits (MRLs) for veterinary drugs (Codex Alimentarius Commission, 2020a) and pesticides (Codex Alimentarius Commission, 2020b), which includes antimicrobial substances. In addition to specific texts on AMR, other Codex texts on food hygiene and animal feed are also relevant, as they contribute to reducing the development and spread of AMR in the food chain.

With the renewed attention on AMR and food safety, the Task Force on antimicrobial resistance was re-established in 2017 with the objective of developing science-based guidance on the management of foodborne AMR (Codex Alimentarius Commission, 2017). Currently, the Task Force is conducting a revision of the Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (CXC 61-2005), and is in the process of drafting the Guidelines on Integrated Monitoring and Surveillance of Foodborne Antimicrobial Resistance.

2.3.2. Where is the connection between antimicrobial resistance and food safety legislation?⁴

Food safety legislation plays a direct role in addressing AMR through preventing the contamination of food with antimicrobials and resistant microorganisms. Effective food safety systems must be enshrined in appropriate food safety legislation in order to address AMR. Food safety legislation contains key elements governing the overall functioning of the food safety system, as well as more specific elements to prevent the introduction of antimicrobials and their residues into the food chain. These include the MRL of pesticides and veterinary medicinal products, and the capacity of the food safety regulatory body to restrict or prohibit the use of other contaminants and substances in the food production chain. Robust food safety systems are essential for improving food safety. Reducing food safety risks also reduces the need for antimicrobials. Notably, the texts and standards developed by the Codex Alimentarius Commission are the international reference standards for formulating national food safety legislation.



⁴ Key elements of legislation mentioned in this section have been extracted from the Food Safety section of the Methodology to analyse AMR-Relevant Legislation in the Food and Agriculture Sector – Guidance Document for Regulators (FAO, 2020), which was developed based on the international reference standards and good practices.

2.3.3. Food safety institutional frameworks and antimicrobial resistance governance

Both food safety and AMR are cross-sectoral issues. Interministerial governing mechanisms are essential to facilitate the effective collaboration between actors. However, overall AMR governance may require the involvement of stakeholders beyond the food safety realm, and this should be reflected in the AMR governance framework.

In connection to AMR, the food safety authority should be legally mandated to:



Approve and enforce regulatory measures to prevent, identify and control food hazards, which include the food hazards of microbiological or AM contamination. This would include the mandate to prohibit or restrict the use of antimicrobials and other substances for food production.



Establish and conduct surveillance programs for the identification of food hazards, which include microbiological contamination.



Approve, monitor and control food safety and quality standards based on Codex standards, including AMR-related standards, such as MRL for pesticides and veterinary medicinal products.



Approve risk-based import requirements.



Designate and regulate reference, official and authorized laboratories for food safety purposes, including laboratories for residue monitoring.

Surveillance and monitoring in food safety systems are also crucial for detecting and responding to AMR risks in a timely manner, especially in facilitating information sharing among institutions. Legislation could establish the obligation for laboratories to share surveillance data with other reference, official and authorized laboratories or other entities undertaking AMR surveillance. Laws could provide the competent authority/authorities with the right to request that AMR-related information be given to those labs and entities.

To facilitate timely response to detected AMR risks in the food safety system, legislation should include provisions on food traceability and recall. It could include references to a rapid alert system that can declare a food outbreak/emergency, and to adopting risk-based food safety measures to contain the outbreak.

Additionally, food safety legislation can hold actors along the food production and supply chain accountable for food safety issues. Legislation could assign food operators with the primary responsibility for food safety, and establish regulatory mechanisms for food operators, such as registration, licenses or permits.

2.3.4. The role of maximum residue limits in combatting antimicrobial resistance

The use of antimicrobials in food-producing animals or crops could result in residues of antimicrobials in food products. Water and other drinks are also included in the Codex Alimentarius definition of food⁵ and should be subject to the same MRL as veterinary medicinal products and pesticides for food safety.

Legislation should establish monitoring and control of MRLs in food that are aligned with the international reference standards of Codex Alimentarius. Laws need to be clear regarding which authorities have the power and obligation to establish the MRLs of different substances. This is especially true when there could be more than one institution regulating antimicrobials used as veterinary medicinal products and antimicrobials used as pesticides. Subsequent to the establishment of MRLs, legislation should also provide the means for the authorities to create and implement monitoring and control systems, and contain appropriate mechanisms for enforcement. Which mechanisms would facilitate compliance and provide for effective enforcement should be taken into account at the inception of the legislation, in order to craft provisions that would be suitable and practical for the national context.



⁵ As discussed in the Codex Alimentarius Commission, 2018b p. 23, food means "any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance that has been used in the manufacture, preparation or treatment of 'food' but does not include cosmetics or tobacco or substances used only as drugs."

2.3.4.1. Limits for veterinary medicinal products

Residues of antimicrobials may be found in food-producing animals when the withdrawal periods of veterinary medicinal products have not been respected or following intensive treatments. The residues could be passed through the food chain when the animal products are consumed and could increase the risk of further development and spread of resistance. To address this risk to food safety, the Codex Alimentarius Commission recommends the maximum limit for residues of veterinary drugs (MRLVD) be legally permitted or recognized as acceptable in or on a food (definitions adopted by the Codex Alimentarius Commission - Codex Procedural Manual).⁶ The Codex Alimentarius Commission has determined standards denoting the acceptable MRLVD for food safety purposes. These MRLVD are defined as the maximum concentration of residue resulting from the use of a veterinary drug (expressed in mg/kg or μ g/ kg on a fresh weight basis) (Codex Alimentarius Commission, 2018a). Legislation should require the establishment of MRLs for approved/authorized veterinary medicinal products and provide for the monitoring and control of MRLVDs in food that are aligned with the international reference standards of Codex Alimentarius

⁶ Codex Alimentarius Glossary of Terms and Definitions (Residues of Veterinary Drugs in Food), MRLVD. These are based on the type and amount of residue considered to be without any toxicological hazard for human health as expressed by the Acceptable Daily Intake (ADI), or on the basis of a temporary ADI that utilizes an additional safety factor. It also takes into account other relevant public health risks as well as food technological aspects. When establishing an MRL, consideration is also given to residues that occur in food of plant origin and/or the environment. Furthermore, the MRL may be reduced to be consistent with good practices in the use of veterinary drugs and to the extent that practical analytical methods are available. CAC/MISC 5-1993, retrieved from http://www.codexalimentarius.org/download/standards/348/CXA_005e_u.pdf.

2.3.4.2. Limits for pesticides

Food could also contain residues of pesticides. The Codex Alimentarius Commission defines the MRL for pesticides as the "maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds" (Codex Alimentarius Commission, 2020c). MRLs are based on Good Agricultural Practice in the Use of Pesticides data. Food derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.⁷

⁷ According to the Codex Alimentarius (Pesticide Database Glossary), "Codex MRLs which are primarily intended to apply in international trade, are derived from estimations made by the JMPR [Joint FAO/WHO Meeting on Pesticide Residues] following: a) toxicological assessment of the pesticide and its residue; and b) review of residue data from supervised trials and supervised uses including those reflecting national food agricultural practices. Data from supervised trials conducted at the highest nationally recommended, authorized or registered uses are included in the review. In order to accommodate variations in national pest control requirements, Codex MRLs take into account the higher levels shown to arise in such supervised trials, which are considered to represent effective pest control practices. Consideration of the various dietary residue estimates and determinations both at the national and international level in comparison with the ADI should indicate that foods complying with Codex MRLs are safe for human consumption." Explanation retrieved from http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/glossary/en/.

Box 3. Food safety in Thailand – maximum residue limits

The main piece of legislation governing food safety in Thailand is the Food Act of B.E.2522 (1979). The competent authority under the Act is the Food and Drug Administration of Thailand. Under the Food Act, the Minister of Public Health has the authority to prescribe the quality or standard of food (section 6, Food Act).

The implementation of the Food Act led to a plethora of notifications issued by the Ministry of Public Health prescribing these standards. Of particular relevance to AMR, the Ministry issued the 2007 Notification of the Ministry of Public Health (No. 303) B.E. 2550, Veterinary Drugs Residues in Foods, prescribing the standards for MRLs of veterinary drugs in food, and the 2011 Notification of the Ministry of Public Health B.E. 2554, Food Containing Pesticide Residues, prescribing the standards for MRLs of pesticides in food.

2.3.4.3. Other areas of antimicrobial resistance relevant legislation that may impact food safety

Managing AMR along the food chain is not limited to food safety legislation. It also involves other areas of legislation that have an impact on food safety. In particular, animal production laws, inclusive of good production practices, are key to reducing food safety risks, including the development and spread of AMR. Measures that have the potential to reduce the need to use antimicrobials include prevention-focused measures in agricultural production that adopt good management practices such as biosecurity, vaccination and proper nutrition for terrestrial and aquatic animals, and Integrated Pest Management (IPM) for plant production (FAO, 2020b).

Conclusions

Some aspects of the connection between food safety and AMR are sufficiently established to take regulatory action, such as MRLs of antimicrobials in food. However, there are still areas that require better understanding to develop the necessary standards and to craft impactful regulatory interventions. For example, in the area of additives, food additives with antimicrobial effects could contribute to the spread of resistance when they are used in food production and/or disposed of in the environment. This can be the case for some disinfectants, fungicides and other substances approved as additives in food, or to ensure hygiene in food production.

As AMR is an area experiencing rapid scientific development, the focus from the legislative standpoint should be on analysing and strengthening the relevant regulatory systems. Attention should also be given to making sure that the regulatory measures are sufficient to achieve the desired level of public policy intervention, with due consideration to the challenges faced by the different actors in the chain. With this in mind, countries can already take action to ensure the capacity and mandate of the competent authorities are clear and capture the powers and responsibilities necessary to provide appropriate regulatory responses. They can identify existing regulatory mechanisms that can be utilized to introduce AMR-relevant considerations. And, they can review the legal framework as a whole to identify and address potential weaknesses to provide a comprehensive regulatory response to the threat of AMR.



Recommendations for food safety national authorities

Below is a set of practical recommendations that national food safety competent authorities might like to consider:

- 1. Analyse the national food safety regulatory system to identify whether it addresses the desired level of public policy intervention.
- 2. Understand whether the capacities and roles of the different competent authorities are clear and capture the powers and responsibilities necessary to provide appropriate regulatory responses.
- 3. Identify existing regulatory mechanisms that can be used to introduce AMR-relevant considerations.
- 4. Review the legal frameworks through the lens of AMR to identify and address potential weaknesses in providing a comprehensive regulatory response to AMR.
- 5. Check if the existing standards for various substances that have an impact on AMR are well addressed in the regulations.







5.1. FAO and Codex Alimentarius resources

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Legislations and antimicrobial resistance (AMR)

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