Centre for Science and Environment

STRATEGIC AND OPERATIONAL GUIDANCE ON ANIMAL AND ENVIRONMENTAL ASPECTS

NATIONAL ACTION PLANS ON ANTIMICROBIAL RESISTANCE FOR DEVELOPING COUNTRIES

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CSE is a public-interest research and advocacy organization based in New Delhi. It researches into, lobbies for and communicates the urgency of development that is both sustainable and equitable. CSE has been working to highlight and address the animal and environmental aspects of antimicrobial resistance in India and at the international level through necessary change in policy, practice and systems.

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FOREWORD

Antimicrobial resistance has been globally recognized as an emerging threat to public health, linked with high disease and economic burden on people and nations as well as with food safety, nutrition security, livelihood and Sustainable Development Goals. It is a 'One Health' issue, which recognizes that health of humans, animals and environment are interconnected. It needs to be addressed through cross-sectoral coordination among multiple stakeholders.

The momentum to combat antimicrobial resistance has increased. Following the adoption of 'Global Action Plan on Antimicrobial Resistance' in 2015, the tripartite alliance among the World Health Organization, Food and Agriculture Organization of the United Nations and World Organization for Animal Health is supporting member states in the development of National Action Plans to be submitted by mid-2017. The issue has also received global political support at the United Nations General Assembly in September 2016.

Historically, some developed countries, particularly of the European Union, have addressed antimicrobial resistance through systematic policy and practice initiatives. The scenario is different in the developing world because of limited stakeholder awareness and resources as well as weak laws and inadequate implementation. In the global context, and more so in the case of the developing world, the human side of the problem received the most attention and the environment part has been neglected. Limited attention has been given to animal aspects.

The Centre for Science and Environment has been working to highlight and address the animal and environmental aspects of antimicrobial resistance in India and at the international level. Recognizing the challenges of the developing world, Centre for Science and Environment organized a two-day international workshop aimed at formulating guidance for National Action Plans on antimicrobial resistance for developing countries. Experts from the tripartite alliance and several developed and developing countries contributed to the drafting of strategic and operational guidance on animal and environmental aspects of the National Action Plan during the workshop, held in New Delhi in November 2016.

It became apparent that food animal production is potentially a significant contributor to the emergence and spread of antimicrobial resistance. Further, the environmental spread of antimicrobial resistance deserves greater attention both in global guidance and country-level action plans. There are best practices and learnings from developed countries, which developing countries should consider adopting.

The expert group collectively developed strategic and operational guidance on three key areas, i.e. responsible antibiotic use in food animals; surveillance of antibiotic use, residues and resistance; and environment management to contain antimicrobial resistance. The guidance reflects what should be a part of National Action Plans of developing countries to contain emergence and spread of antimicrobial resistance in animals and the environment.

We hope that the countries consider and incorporate this guidance in their National Action Plans based on country-level scenarios in view of current status, resources, feasibility and priority. We also hope that representatives of the tripartite alliance at the national, regional and global level as well as global civil society benefit from this report and that the outcome of this report is incorporated in subsequent global guidance and country-level campaigns to address one of the biggest public health challenges.

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INTRODUCTION

Antimicrobial resistance (AMR) arises when microorganisms survive exposure to a drug that would normally kill them or stop their growth. Antibiotic resistance (ABR) is resistance to antibiotics that occurs in bacteria. With antibiotics becoming increasingly ineffective against bacteria, AMR (ABR in particular) is being recognized as an emerging public-health threat. It can lead to greater spread of infectious diseases, difficulty in treating common infections, uncertainty in success of surgical procedures, longer hospital stays and more expensive treatments. It also poses risks to the ability to treat animal disease effectively with development of AMR in veterinary pathogens. Any kind of antibiotic use, whether in humans or animals, accelerates AMR. For this reason it is imperative that all use is appropriate and necessary, and that inappropriate use, including overuse, is reduced to the absolute minimum.

In intensive food-animal production settings, such as poultry, pig and fish farms as well as poultry and fish hatcheries, antibiotics are routinely used for reasons other than treating sickness, i.e. for non-therapeutic purposes such as growth promotion and disease prevention. Such uncontrolled use leads to greater transfer of antibiotic residues and resistant bacteria into humans through three key routes, i.e. food, direct contact and the environment. Additionally, AMR is expected to impact economies, leading to reduction in global Gross Domestic Products, increased poverty, decline in global livestock production as well as exports.[1] By 2050, AMR (including to drugs for treating malaria, tuberculosis and HIV) in humans could lead to 10 million deaths per year and cumulative lost outputs worth up to US $100 trillion across the world.[2, 3]

Concerted action to address the animal aspects of AMR has been achieved in developed countries such as Denmark, Sweden and Netherlands. Efforts to address AMR in the environment have also been initiated in developed countries. In developing countries (mainly low and middle income countries), limited action has been observed in case of both animal and environmental aspects. Developing countries present a different set of challenges which include inadequate policy framework, limited stakeholder awareness, ineffective implementation of laws, limited focus on infection prevention and control, dearth of technology and resources, and huge information gaps. In these countries, the problem of AMR is expected to be exacerbated in the future in view of the anticipated growing demand for protein from animal foods and intensification of food-animal farming practices.

Across the world, there has been an increase in the momentum to address the threat from rising AMR. In 2015, the World Health Organization (WHO) adopted the 'Global Action Plan (GAP) on Antimicrobial Resistance', which was developed in close collaboration with the Food and Agriculture Organization of the United Nations (FAO) and World Organization for Animal Health (OIE).[4] The GAP lays out several measures as per five strategic objectives and underscores the need to limit emergence and spread of AMR through limiting antibiotic use in humans, animals, agriculture and the environment sector. The GAP emphasizes the need for an effective 'One Health' approach through cross-sectoral coordination among multiple stakeholders. Recognizing the variability in national resources, the GAP calls for member states to develop and submit their respective National Action Plans (NAPs) by mid-2017. The WHO–FAO–OIE tripartite alliance is supporting the implementation of the GAP.[5] Additionally, the FAO released its 'Action Plan on Antimicrobial Resistance 2016–2020', and the OIE came up with its 'Strategy on Antimicrobial Resistance and the Prudent Use of Antimicrobials' in 2016.[6, 7] A high-level meeting on AMR was also held at United Nations General Assembly (UNGA) in September 2016 to garner strong political commitments. This was the fourth time in the history that a health issue had been addressed at the UNGA.

The international workshop, organized by the Centre for Science and Environment (CSE), was aimed at developing guidance for NAPs for developing countries with reference to limiting resistance from antibiotic use in food animals as well as environmental spread of AMR. The workshop brought together about fifty global, regional and national experts from governments, inter-governmental organizations and civil society collectively representing human, veterinary and environment sectors. Experts from developed countries such as Denmark, the Netherlands, Sweden and the UK as well as developing countries such as Bangladesh, India, Kenya, Philippines, South Africa, Sri Lanka, Thailand and Vietnam participated in the workshop. There was representation from the WHO, FAO, OIE and international organizations such as the International Livestock Research Institute, ReAct—Action on Antibiotic Resistance, Institute for Agriculture and Trade Policy, Third World Network and Médecins Sans Frontières (India).

Considering its relevance for developing countries, the workshop comprised deliberations on three key areas, i.e. responsible antibiotic use in food animals; surveillance of antibiotic use, residues and resistance; and environment management to contain AMR. It facilitated the exchange of views on best practices, challenges, learnings and ground realities. The expert group collectively developed strategic and operational guidance on animal and environmental aspects of NAPs for developing countries.

SUMMARY OF DELIBERATIONS

Antimicrobial resistance is a quintessential 'One Health' issue, encompassing humans, animals, agriculture and the environment.[8] A multi-sectoral approach is critically important to combat AMR at a national level and so is collaboration at the regional and international levels. It is important that all stakeholders—including policymakers, regulators, human and animal health practitioners, farmers, drug industry, scientific community, civil society and consumers—adequately recognize the problem and aggressively work towards the solution. AMR, particularly the animal and environment aspects of it, does not receive adequate attention in the developing world. Some developed countries of the European Union (EU) have made systematic efforts towards containing AMR over the last two to three decades. There are best practices and learnings, which developing countries should consider adopting based on their country-level scenario.

RESPONSIBLE ANTIBIOTIC USE IN FOOD ANIMALS

Antibiotics are used worldwide in the production of terrestrial and aquatic food animals, both for therapeutic and non-therapeutic purposes. While therapeutic use pertains to treatment of the sick, non-therapeutic use involves routine administration of antibiotics through feed and water, to a group of animals to prevent disease (prophylaxis) or to enhance feed efficiency and weight gain (growth promotion). Such non-therapeutic use is most often an alternative to good animal husbandry and biosecurity measures and aimed to cushion the ill effect of high stocking densities. Even antibiotics that are critically important for human health and considered as a last resort, such as colistin, are routinely used in animal production in some countries.

Antibiotic use in animals is known to have strong linkages with emergence and spread of antibiotic resistance. A large proportion of antibiotics produced are used in food animals. The global livestock consumption of antimicrobials is estimated to increase by 67 per cent between 2010 and 2030. Two thirds of this anticipated increase is expected due to growth in the number of food animals and remaining is due to increased intensification of farms in response to increasing demand of animal proteins. Collectively, in Brazil, Russia, India, China and South Africa, the livestock consumption of antimicrobials is estimated to increase by 99 per cent during the same period.[9]

In developing countries, indiscriminate use of antibiotics is also linked with no or weak regulations, inadequate implementation and limited stakeholder awareness. For example, over-the-counter (OTC) availability of antibiotics, online marketing of antibiotic containing feed and feed premixes, and limited control on quality of antibiotics, including those imported, contribute to the inappropriate use of antibiotics. Farmers have low technical know-how and are largely unaware of implications of antibiotic misuse and overuse. They are often misguided by representatives of manufacturers of antibiotics and antibiotic-containing products.[10] There is limited support through unbiased veterinary advisory services and lack of diagnostic capacity.[11] Programmes targeted at veterinarians and farmers to promote judicious antibiotic use are also not common.

A few recent initiatives such as the AMR pledge by veterinarians in the Philippines, restriction on colistin use by the South African Veterinary Council, and the Thailand Antimicrobial Resistance, Containment and Prevention programme have been taken up to increase responsibility of veterinarians and promote the judicious use of antibiotics. In India, an advisory

has been issued to limit the use of antibiotics for growth promotion in poultry; however it is not enforceable.[12]

The EU has prohibited use of antibiotic growth promoters (AGPs) since 2006. Concern over the use of antibiotics in food-animal production predated the EU's ban on antibiotic growth promoters and continues. For example, Sweden banned the use of AGPs in 1986, while Denmark had banned certain antibiotics for growth promotion by 1998.[13] There has thus been continued focus on ensuring animal health and concern for public health implications of antibiotic use in food-animal production. The initiatives taken by EU countries have been based on evidence and supported by relevant research and analysis of antimicrobial use and resistance trends.

In Denmark, antibiotics can be procured only through prescription and administered to animals only under veterinary supervision. Veterinarians have no economic incentives by selling medicines. Antibiotics are sold only from licenced pharmacies. Voluntary phasing out of third-and fourth-generation cephalosporins has been implemented by the industry and fluoroquinolones are only used as a last resort in production animals. Denmark was also the first country in the world to implement herd-level monitoring of antimicrobial consumption in production animals. Going further, the Netherlands has since 2011 banned the prophylactic use of antibiotics. All antibiotic use is prescription only and administered exclusively by veterinarians. Fluoroquinolones, third- and fourth-generation cephalosporins are allowed only after mandatory susceptibility testing. Antibiotic reduction targets are set at the national level. At the farm level, quantitative benchmark indicators through colour codes are used to control antibiotic use. Each farm is required to register all antibiotic use in a centralized database to ensure transparency. In Sweden, antibiotics are used exclusively to treat individual sick animals and not administered in groups for non-therapeutic use. The sale of antibiotics is also restricted and the law does not allow veterinarians to earn money by selling antibiotics. Sweden has guidelines for optimum use of antibiotics in food animals and has restricted the use of quinolones and new-generation cephalosporins.

In addition, there has been considerable and concerted effort in these countries towards awareness creation and changing attitude of farmers and veterinarians on the judicious use of antibiotics. Significant attention has been put on biosecurity and use of antimicrobial alternatives. For example, Sweden emphasizes on animal welfare, rearing healthy animals, good farm management and controlling or eradicating infectious diseases through appropriate sanitation, biosecurity and food hygiene. Alternative actions to treatment by antibiotics and selective dry-cow therapy are presented to the farmers. Similarly, in the Netherlands, the use of antibiotics has been replaced by improved biosecurity, vaccination and herd-health management.

Globally, necessary interventions are required across the value chain to contain AMR from animals. These include strengthening veterinary capacity, extending the reach and influence of veterinary advice through allied professional services and shifting animal husbandry practices to sustainable and cleaner models. Other critical interventions include adequate financial and technical support, innovation in development of alternatives such as vaccines, complementary technologies, such as point-of-care diagnostics, and stewardship practices. Similarly, importance of engaging consumers in demanding food-animal products raised without the routine use of antibiotics and promoting appropriate labelling of food from animals needs to be underlined. For example, investor and consumer pressure have led major restaurant companies in the US to limit antibiotics in their meat supply.

The promotion of sustainable diets through dietary guidelines and consumer awareness may also help reduce antibiotic consumption in food animals. Rising incomes are linked with more meat production and consumption. Intensification is also linked with industry consolidation and export potential. There is need for reassessment of trade and investment treaties in food animal sector.

SURVEILLANCE OF ANTIBIOTIC USE, RESIDUES AND RESISTANCE

Surveillance of antibiotic use and ABR across human and food-animal sectors is critical to the success of the NAP. Analysis of integrated surveillance data is a key to understand the existing scenario and aid in the formulation of future policy and guidance on practice to contain AMR.

In the developing world, a huge information gap exists for data on consumption of antibiotics in animals. However, this may also be true for antibiotic use in humans in many countries. There are hardly any national-level surveillance programmes on tracking the quantum and trends of antibiotic use in livestock and fishery sectors. Collecting such data is challenging but provides a valuable resource. In many countries, there are no initiatives to collect and collate antibiotic user, prescription, sales and production data. There is limited information in most cases. For example, import data on selected antibiotics is available in countries such as in Sri Lanka and Kenya. In South Africa, only few veterinary pharmaceutical companies are said to have agreed to divulge data related to antibiotic usage. On the other hand, there is no data on antibiotics sold to veterinary sector by the pharmaceutical industry in India. Recently, the OIE has taken up an initiative to collect quantitative data on the use of antimicrobial agents in animals to establish a global database.[14]

The food chain is a well-known potential route for spread of resistant bacteria or resistance genes. Antibiotic residues in food are further linked with selection for resistance in humans. Besides resistance, monitoring antibiotic residues in food from animal origin is also significant. A comprehensive antibiotic residue monitoring framework and programme is lacking in many developing countries. Residue standards do not cover all food categories and antibiotic use. For example, in India, there are no Maximum Residue Limits (MRLs) for chicken meat, eggs or milk. On the other hand, countries like South Africa have adopted standards set by the Codex Alimentarius.

Another area of critical concern is the limited surveillance of AMR in food animal sector, leading to inadequate data and understanding on resistance trends. Reasons include absence of a concrete surveillance framework for animals, inadequate infrastructure, dearth of qualified professionals and limited availability and sustainability of funds. For example, the South African National Veterinary Surveillance and Monitoring Programme for Resistance to Antimicrobial Drugs (SANVAD) was initiated in 2000 but discontinued after the completion of the grant in 2007. While most developing countries do not have any systematic national-level surveillance programmes, specific research groups or institutions do, however, carry out sporadic, and sentinel studies to analyze drug resistance trends. Further, these studies and programmes cater largely to the surveillance of AMR in humans and not animals. For example, in India, the national programme on AMR surveillance is focused on humans at this stage.

The situation is different in some developed countries that have systematic surveillance programmes in place. For example, the Danish Integrated Antimicrobial Resistance Monitoring and Research Programme (DANMAP), Monitoring of Antimicrobial Resistance and Antibiotic Usage in Animals in the Netherlands (MARAN), Swedish Veterinary Antibiotic Resistance Monitoring (SVARM) and the UK Veterinary Antimicrobial Resistance and Sales Surveillance (UK VARSS) are some key surveillance programmes, the results of which are published regularly and available in the public domain. In addition, Denmark, recognizing the importance of resistance genes in the emergence of AMR, is currently exploring possibilities of whole community sequencing for detection of all resistance genes.

Importantly, the monitoring of antibiotic sale and consumption is also linked to the above-mentioned programmes. Continuous monitoring has led to reduction and control of antibiotic use

over the years. For example, in the Netherlands, a decline is reported in total sale of antibiotics, and use of colistin, fluoroquinolones and third- and fourth-generation cephalosporins. VetSTAT (the Danish system for surveillance of veterinary use of drugs for production animals) collects consumption data of target species at the herd level. Veterinary practitioners, wholesalers and licenced pharmacists are required to report directly to the VetSTAT with the necessary data, which feeds into the DANMAP. The European Surveillance of Veterinary Antimicrobial Consumption (ESVAC) project under the European Medicines Agency also collects data based on reporting from wholesalers or holders of marketing authorizations. The data is useful for comparison between member states.

ENVIRONMENT MANAGEMENT TO CONTAIN ANTIMICROBIAL RESISTANCE

While AMR has been recognized as a 'One Health' issue,[8] the linkages to the environment are crucial to address but currently are given a low priority. The issue is complex and research gaps exist but there is sufficient evidence to focus on this aspect. Many developed countries have been addressing the environmental dimension of AMR spread, although even in these countries, the action on environmental aspects tends to be less aggressive than in the human and animal health sectors. On the other hand, despite greater need, the environment has not really been a priority in developing countries. Environmental laws and their compliance is a huge concern in these countries. The environment linkages of AMR exist with farms, factories and healthcare settings. These include waste from food-animal farms; slaughter houses; fish, meat and dairy processing units; pharmaceutical research and manufacturing units; healthcare and veterinary care settings as well as disposal of unused antibiotics.

Farm waste is potentially a significant source of AMR spread. Misuse and overuse of antibiotics in food-animal production leads to transfer of antibiotic residues, resistant bacteria and resistance genes into terrestrial and aquatic environment through farm-generated waste. Measures for reducing this, e.g. through storage

REVIEW OF NATIONAL ACTION PLANS ON AMR

A review of the National Action Plans of different countries (sourced from the WHO Library on NAPs, as on September 2016) with reference to the efforts to address environmental spread of AMR suggests that most countries underscore the importance of infection prevention and control, and biosecurity. However, specific measures to tackle waste from farms, as well as the pharmaceutical industry, healthcare and food-animal processing settings are not common. Further, the environmental dimension gets greater mention in the NAPs of developed countries, wherein most cases it is about the need for initiating or intensifying research, while in a few cases it is about moving ahead with environmental monitoring. For example, Canada, the US and the UK refer to the need for research-based data to understand the mechanism and routes of environmental dissemination of AMR. On the other hand, the NAPs of Switzerland, the Netherlands, Japan, Australia and Norway consider environmental monitoring. In particular, Switzerland emphasizes the need for monitoring antibiotics in farmyard manure, soil and water. The Netherlands stresses on monitoring manure and wastewater from health facilities, treatment plants and residential areas. Japan emphasizes on surveillance of resistant bacteria as well as residues in aquatic and terrestrial environment. Sweden talks about controlling pharmaceutical waste and dealing with discarded antibiotics in an environmentally sound way.[16]

or treatment of waste prior to spreading on land or discharging into water exist in some countries, but are not universal. In view of high prevalence of infectious diseases, limited biosecurity, insufficient hygiene and sanitation and increased use of antibiotics, AMR spread from farms into the environment is of critical concern in the developing world. For example, in parts of India, aquaculture farm waste is found to be released directly into canals, sewage drains or agricultural fields without treatment. Poultry litter is often used as manure in agriculture fields. Untreated manure poses greater risk of dissemination of AMR into the environment. The situation is likely to be similar in other developing countries.

Another priority area for action is the waste from pharmaceutical manufacturing plants. Data published from studies undertaken in India and China showed manufacturing effluent pollution leading to high concentration of antibiotic Active Pharmaceutical Ingredients (APIs) in the local environment.[15] This is a huge concern due to size of the export-oriented antibiotic industry in these parts of the world.

While there is a need for more research on environmental aspects of AMR, emerging evidence related to the transmission pathways of resistance determinants among humans, livestock, aquaculture and environment as well as impact of contributing factors is gradually being consolidated. Research has shown that farm waste added to soil can considerably change the abundance of the antibiotic resistance genes. Among developing countries, some studies from Thailand, Bangladesh and Vietnam have shown the environmental spread of AMR in samples such as poultry litter, pig manure, stagnant and drainage water from pig farms, wastewater, surface water, supply water, fresh vegetable produce and wildlife.

The tripartite alliance reflects on the importance of containing environmental spread of AMR. The issue however deserves much greater attention and articulation in terms of how countries are to move ahead specifically in view of growing evidence of environmental spread. Also, the nature and gravity of the problem calls for an active involvement of global environmental organizations.

STRATEGIC AND OPERATIONAL GUIDANCE

To develop the guidance, the expert group identified a set of thematic and intervention areas, and collectively finalized strategic and operational guidance in the form of activities across each of the three overarching areas. These are:

- Responsible antibiotic use in food animals
- Surveillance of antibiotic use, residues and resistance
- Environment management to contain antimicrobial resistance.

The guidance is intended to support animal and environment aspects of NAPs on AMR for developing countries. The countries are expected to consider this guidance and incorporate it in their respective NAPs based on the country-level scenarios in view of current status, resources, feasibility and priority. This should help in effective adoption and implementation of activities to successfully contain AMR in the near and the distant future. Additionally, it is expected that representatives of the WHO-FAO-OIE tripartite alliance at the national, regional and global level as well as global civil society benefit from this report and that the outcome is incorporated in subsequent global guidance and country-level campaigns.

The expert group also prioritized timelines along with the activities. The reference timeframe considered is as follows:

- Short-term **(S)** for an activity that should be completed within one year
- Medium-term **(M)** for an activity that should be completed between one and three years
- Long term **(L)** for an activity that should be completed between three and five years
- In case the activity needs to continue throughout, the timeframe is presented as **(S-M-L).**

RESPONSIBLE ANTIBIOTIC USE IN FOOD ANIMALS

		THEMATIC AREAS				
		Supply of antibiotics	Production systems			Consumers
			Reduce need for antibiotics	Veterinarians and veterinary services	Farms and farmers	

INTERVENTION AREAS	**Policy/laws/ regulations/ standards/ programmes**	• Assessment of existing laws and regulatory framework before formulation of new laws **(S)**
		• National policy and regulatory framework on responsible antibiotic use with focus on **(S)**:
		  ○ Approval and authorization of antibiotics for animals
		  ○ Standard treatment guidelines for treating animals
		  ○ Ban/phasing out of non-therapeutic use such as for disease prevention and growth promotion
		  ○ Restricting use of critically important antibiotics for humans
		  ○ Antibiotic use under supervision and prescription
		  ○ Mitigating livelihood impact on small-holder farmers
		• Regulations to restrict antibiotics in animal feed and premix, registration of feed and premix, prescription and use of only registered products **(S)**
		• Regulations for importation of feed, feed premix and antibiotics for animal use **(S)**
		• Labelling laws for feed, premix **(S)**
		• Labelling laws for antibiotics for specie-specific use **(S)**
		• Regulations to control online marketing or direct distribution of antibiotics, premix, antibiotic feed or any other products with antibiotics **(S)**
		• Laws to ensure licencing of manufacturers, distributors and sellers of antibiotics, feed, premix and other inputs **(S)**
		• Laws to ensure prescription sale, including penalty for unauthorized sale **(S)**
		• Plan to set reduction targets for antibiotic use by a certain date and with a review process **(S)**
			• Develop guidelines for biosecurity **(S)**
			  ○ Plan/programme for internal and external biosecurity
			  ○ Programme to support small-holder farmers to implement biosecurity
			• Programme to research, develop, promote access to alternatives such as vaccination, probiotics etc. **(M)**
			• Plan for research and development of appropriate animal breeds which are, for example, resilient to disease **(M)**
				• Law for licencing/registration of veterinarians and those involved in fisheries **(S)**
				• Law to delink antibiotic prescription and incentives **(S)**
				• Programme for accessible, affordable and quality diagnostic services to support judicious use of antibiotics **(M)**
				• Programme for targeted, livestock specific veterinary services to provide free or low cost advisory services to farmers **(M)**
					• Law for licencing and auditing of commercial farms and farmers (such as intensive/semi-intensive farms or all farms based on country-level scenario) **(M)**
					• Programme to incentivize/dis-incentivize farmers based on extent of antibiotic use **(M)**
						• Labelling law for food from animals produced with or without routine use of antibiotics **(S)**

	Implementation tools—Infrastructure/ capacity/ systems/ resources	• Establish authority for approving veterinary drugs and market authorization **(S)** • Develop systems to enable data collection of antibiotic production, sale and import **(M)** • Provide enforcement systems through stakeholder agencies including customs, infrastructure, human resource such as those required for auditing/inspecting companies providing inputs (e.g. feed), ensuring prescription sale etc. **(M)**	• Develop systems to ensure adoption and implementation of appropriate biosecurity measures at the farm level **(M)** • Systems to register antibiotic-free alternative products and their use **(S)** • Support for programmes on development and adoption of vaccines **(M)** • Investment and research in development of appropriate animal breeds with disease resilience **(L)**	• Set up statutory body for licencing veterinarians and those involved in fisheries **(S)** • Develop capacity and infrastructure to ensure veterinary diagnostic services **(M)** • Develop system to dis-incentivize antibiotic prescription by veterinarian **(S)**	• Set up licencing authority for farms and registration of farmers **(S)** • Formulate a system based on incentives and disincentives that can help control antibiotic use **(M)**	• Systems to ensure compliance of labelling laws **(S)**
	Advocacy/ awareness and education/ training/ curriculum	• Awareness and training of regulators, customs officials, distributors and sellers to ensure approved sale, documentation etc. **(S-M-L)**	• Awareness and training of farmers, registered practitioners, veterinarians and other stakeholders on need for biosecurity, judicious antibiotic use and importance of alternatives **(S-M-L)**	• Awareness, training and education of veterinarians **(S-M-L)** • Ensure AMR focus in curriculum and continuous professional education **(S-M-L)**	• Targeted education on AMR and responsible antibiotic use for farmers **(S-M-L)** • Farmer training in agro-ecological/ alternative farming practices, participatory farming approaches **(S-M-L)**	• Consumer awareness on antibiotics in food and AMR, labelling of food from animals raised with responsible use of antibiotics and role of sustainable diets **(S-M-L)** • Awareness and promotion of institutional procurement of food raised without routine antibiotic use (such as through a score card system used to incentivize/dis-incentivize food procurement or through quality assurance accreditation schemes) **(S-M-L)** • Inclusion of AMR in school curriculum **(S)**
	Record keeping/ database generation/ collation/ dissemination and research/ survey	• A national database of licenced antibiotic producers, importers, traders and retailers including defaulters available online **(S)** • An online national/regional/sub-regional database on antibiotic production, sale and national database on import of antibiotics **(M)** • Online dissemination of updated policy, regulation and data including list of approved and unapproved antibiotics **(S)** • Annual report of antibiotic sale correlated with consumption and resistance data **(M)**	• A national database, available online, for approved and unapproved vaccines and other alternatives **(M)** • A list/database/rating of farmers/producers successfully adopting biosecurity and using alternatives and not antibiotics **(M)**	• A national database, available online, of registered veterinarians, and those who prescribe more antibiotics and without testing **(M)** • An updated list of diagnostic services/ laboratories available **(S)**	• A national database, available online, of registered farms and farmers including those who are non-compliant or use more antibiotics **(M)**	• Publically available database of farmers/ producers raising food from animals without routine use of antibiotics **(M)** • Database of farmers/producers not in compliance to labelling laws **(M)**
	Review/ monitoring/ feedback	• Periodic review and mapping of antibiotic production, import, sale as per sectors with consumption and resistance data for continued advocacy, awareness, and future policy and practice **(S-M-L)** • Annual report on antibiotic sale **(S-M-L)**	• Periodic review of use and success of alternatives, with reference to antibiotic use and resistance data at the farm/ sub-regional/regional/national level, for continued advocacy, awareness, and future policy and practice **(S-M-L)**	• Periodic monitoring of records at veterinary practice levels, for continued advocacy, awareness, and future policy and practice **(S-M-L)**	• Periodic monitoring of records at farm levels, for continued advocacy, awareness, and future policy and practice **(S-M-L)**	• Periodic assessment of initiatives with antibiotic use data **(S-M-L)**

SURVEILLANCE OF ANTIBIOTIC USE, RESIDUES AND RESISTANCE

INTERVENTION AREAS	THEMATIC AREAS[17]			
	Antibiotic use in food animals	**Antibiotic resistance in animals and food from animals**	**Antibiotic residues in food from animals**	**Environmental surveillance of residues and resistance**
Policy/laws/ regulations/ standards/ programmes	• Assessment of existing laws before formulation of new laws **(S)** • Legal provision for obtaining farm-level antibiotic use data **(S)** • Regulation to ensure prescription audit of veterinarians/authorized practitioners **(M)**	• National AMR surveillance programme to monitor resistance in animals and food from animals across all sectors **(M)** • Law compelling farmers and food processors to provide samples for analysis and share their internal data on resistance **(S)** • Ambitious and achievable resistance reduction targets **(S-M-L)**	• National antibiotic residue monitoring policy/ programme for food from animals **(S)** • Standards for antibiotic residues in food from animals such as chicken, eggs, milk, fish **(S)**	• National AMR surveillance programme to monitor resistance in environment **(M)** • Regulation on antibiotic residues in effluent and waste from industries and farms **(S)** • Standards for waste discharge from farms, slaughter houses, animal food processing industry, pharmaceutical industry, veterinary care and healthcare settings **(S)**
Implementation tools— Infrastructure/ capacity/ systems/ resources	• Systems to enable collection and collation of farm-level antibiotic use data **(M)**: ○ Harmonized system for data collection and analysis ○ Ensure farmer's responsibility to provide data ○ Factor-in priority markets/sectors	• Commission an expert advisory group/steering committee to decide on key elements such as networking experts/labs, terms of reference, priorities, linkages and international collaboration. This should involve details on target species, sampling site, types and frequency of sampling, testing methods and reporting systems **(S)** • Identify, establish and strengthen national reference laboratories who decide upon standards, protocols, organisms, data management mechanisms **(M)**:[18] ○ Ensure quality and harmonization with national/ international data and establish linkages with resistant bacteria and resistance genes in humans and environment ○ Enable collaboration between labs to provide support, build access to WHO, FAO and OIE labs • Develop and strengthen lab infrastructure, professional capacity, standardization of sample collection and testing protocols and assure quality both internally and externally through External Quality Assurance Scheme. **(M)**—sector specific; **(L)**— integrated quality assurance • Ensure surveillance systems for harmonization across all sectors such as animals, humans and environment. Integrated surveillance could begin with a pilot initiative **(S-M-L)**	• Develop comprehensive residue monitoring framework which enables surveillance of approved and unapproved antibiotic use **(S)**[19] ○ Export oriented residue monitoring framework could be considered for adaptation based on domestic antibiotic use • Ensure availability of required funds, infrastructure and resources for quantitative data collection **(S)**	• Monitoring and surveillance framework including monitoring of antibiotic residues and AMR in indicator bacteria in environment, farms, factories, slaughter house, wet market, processing unit, health care facilities, veterinary care facilities (prioritization based on ground realities) **(M)** • Assess infrastructure needs, accordingly build/strengthen appropriate infrastructure and capacity **(M)** • Develop systems to adapt, standardize, compare data across countries **(M)**
Advocacy/ awareness and education/ training/ curriculum	• Awareness campaigns for farmers to self-regulate themselves and keep records **(S-M-L)** • Awareness campaigns for veterinarians/ authorized practitioners to prescribe antibiotics judiciously and keep records **(S-M-L)** • Training programme on documentation for farmers and veterinarians/authorized practitioners **(S)** • Training needs assessment of those conducting surveillance, development of training material and protocols for data collection and management followed by enabling environment to collect data **(S)** • Advocacy at community and institutional level based on antibiotic use data reports **(S-M-L)**	• Awareness campaigns on importance and need of resistance surveillance across stakeholders **(S-M-L)** • Training needs assessment for those conducting surveillance **(S)** • Development of training material and protocols for resistance data collection and management followed by enabling environment for resistance surveillance **(S)** • Capacity-building and training programmes including integrated programmes with the WHO, FAO, OIE collaborating centres **(M)** • Advocacy at community and institutional levels based on antibiotic resistance data reports **(S-M-L)**	• Awareness campaigns on importance and need of residue monitoring **(S-M-L)** • Training needs assessment for those conducting surveillance **(S)** • Development of training material and protocols for residue testing and data management followed by enabling environment for residue surveillance **(S)** • Capacity building and training programmes **(M)** • Advocacy at community and institutional level based on antibiotic residue data reports **(S-M-L)**	• Awareness campaigns on importance and need of environmental surveillance across stakeholders **(S-M-L)** • Training needs assessment for those conducting surveillance **(S)** • Development of training material, protocols and data management **(S)** • Capacity building and training programme (including at university level) **(M)** • Training of peer/participatory monitoring systems **(M)** • Advocacy at community and institutional levels based on environmental surveillance data reports **(S-M-L)**
Record keeping/ database generation/ collation/ dissemination and research/ survey	• Online systems for collating and analyzing prescription data and farmer use data. This should include antibiotic consumption in different food sectors, therapeutic and non-therapeutic use, with weight as a unit **(M)**[20] • Surveys at farm level for data collection across different sectors **(M)** • Setting up of data standards, ensuring the quality assurance of data **(S)** • Establishment of national repository, publishing of annual reports and public dissemination of data to ensure transparency **(M)**	• Data collection, collation and analysis at regional and sub-regional level from laboratories, food processors, imported food and those generated from surveys at farm-level **(S-M-L)** • Correlation with antibiotic use and residue data **(S-M-L)** • Development of an online integrated information system, publishing of annual reports and public dissemination of data to ensure transparency **(M)** • Develop early warning system **(S)**	• Data collection, collation and analysis at regional and sub-regional level from laboratories, food processors, imported food and those generated from surveys at farm-level **(S-M-L)** • Correlation with antibiotic use and resistance data **(S-M-L)** • Development of an online integrated information system, publishing of annual reports and public dissemination of data to ensure transparency **(M)**	• Data collection, collation and analysis at regional and sub-regional level **(S-M-L)** ○ Selection of sentinel sites to begin with • Correlation with animal antibiotic use and AMR data **(S-M-L)** • Development of an online integrated information system, publishing of annual reports and public dissemination of data to ensure transparency **(M)** • Develop early warning system **(S)**
Review/ monitoring/ feedback	• Periodic review and mapping of data on antibiotic use, resistance and residues as part of integrated surveillance for continued advocacy, awareness, and future policy and practice **(S-M-L)**	• Periodic review and mapping of data on antibiotic use, resistance and residue as part of integrated surveillance for continued advocacy, awareness, and future policy and practice **(S-M-L)**	• Periodic review and mapping of data on antibiotic use, resistance and residues as part of integrated surveillance for continued advocacy, awareness, and future policy and practice **(S-M-L)**	• Periodic review and mapping of data with antibiotic use and resistance in animal and human for continued advocacy, awareness, and future policy and practice **(S-M-L)**

ENVIRONMENT MANAGEMENT TO CONTAIN ANTIMICROBIAL RESISTANCE

		THEMATIC AREAS[21, 22]			
		Registration/licencing (based on environment risk assessment)	**Biosecurity/sanitation and hygiene/good manufacturing practices**	**Waste management**	**Research**
INTERVENTION AREAS	**Policy/laws/ regulations/ standards/ programmes**	• Policy on registration/licencing of farms, factories, slaughter houses, wet markets, processing units, feed manufacturers, healthcare facilities, veterinary care facilities **(S)** • Siting guidelines for farms, factories, slaughter houses, wet markets, processing units, feed manufacturers, health care facilities, veterinary care facilities **(S)** • Policy on environmental risk assessment for registration and renewal of antibiotics for humans and animals **(M)**	• Development of biosecurity/sanitation and hygiene guidelines for farms, slaughter houses, wet market, healthcare facilities, veterinary care facilities and good manufacturing practices (GMPs) for pharmaceutical inudustry and fish/meat/dairy processing units **(S)**[23]	• Standards for antibiotic residues and microbial quality in effluent and solid waste from pharmaceutical industry, sewage treatment plants, farms, veterinary care facilities, healthcare facilities, processing units, slaughter houses and feed manufacturers **(S)** • Policy on Extended Producers Responsibility for unused antibiotics **(S)**	• Assessment of situation/ knowledge on residues and AMR bacteria in effluents and wastes for policymaking and regulations **(S)** • Programme for developing and promoting innovation in environmental monitoring **(S)**
	Implementation tools— Infrastructure/ capacity/systems/ resources	• Regulatory system for enforcement of laws, ensuring compliance with adequate funding and capacity **(M)** ○ Small producers to be facilitated through required measures • Tool for environmental risk assessment for siting, registration and renewal of antibiotics **(S)**	• Regulatory system for enforcement of laws, ensuring compliance with adequate funding and capacity **(M)** • Adopt progressive pathways to improve management **(S-M-L)** • Develop incentives and disincentives for compliance including performance benchmarks and rating system (such as through pond and farm health cards) **(S)**	• Standard Operating Procedures (SOPs) on management of effluent and solid waste from pharmaceutical industry, sewage treatment plants, farms, veterinary care facilities, healthcare facilities, processing units, slaughter houses, wet market, feed manufacturers **(S)** • Regulatory system for enforcement of laws, ensuring compliance with adequate funding and capacity **(M)**	• Development and adoption of test protocols **(S)** • Research on waste treatment technology with respect to resistant bacteria, genes, pharmacologically active substances **(S-M-L)** • Research on transmissions pathways of AMR among different environmental compartments including human, animal and agriculture for prioritizing intervention **(S-M-L)** • Cost-benefit analysis to assess socio-economic implications of antibiotic use and its impact on the environment **(M)** • Documentation of best practices **(M)**
	Advocacy/ awareness and education/training/ curriculum	• Sensitize regulators, industry and farmers **(S)** ○ Inclusion of environmental management in antibiotics awareness week • Build capacity of regulators **(S)** • Development of customized material for awareness and training **(S)**	• Training on biosecurity/sanitation and hygiene/ GMPs **(S)** • Sector-specific manuals and guidelines on progressive management pathways (for e.g., from the FAO[24]) to improve environmental management **(M)** • Inclusion of biosecurity in farmer-field school curriculum **(S)**	• Stakeholder training on waste management guidelines and SOPs **(S)**	• Survey of existing knowledge, attitude and practice at ground level **(S)** • Stimulation of international collaboration on research related to AMR **(M)**
	Record keeping/ database generation/ collation/ dissemination and research/survey	• Public database of licenced farms, factories, human and veterinary healthcare settings **(S)**	• Database on biosecurity/sanitation and hygiene/ GMP compliance performance/rating system (depending on local circumstances decision on public disclosure can be made) **(M)**	• Online database on waste discharge quality, rating system, compliance/non-compliance through appropriate pollution monitoring **(M)**	• Centralized database on ongoing research/output **(S)** • Sharing data on an international platform (for e.g., Global Environment Monitoring System) **(S-M-L)**
	Review/monitoring/ feedback	• Comprehensive review framework for policy/ regulations and standards **(S-M-L)**	• Review of progressive pathways to improve biosecurity/sanitation and hygiene/GMPs **(S-M-L)** • Review of guidelines for their success and impact **(S-M-L)**	• Development of success/failure indicators/milestones as part of review framework **(M)** • Compliance status with review framework **(S-M-L)**	• Review of research agenda for future policy and practice **(S-M-L)**

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17. Surveillance is recommended across the One Health framework including human, food animal, food product and the environment

18. Refer to 'Integrated Surveillance of Antimicrobial Resistance', guidance from a WHO Advisory Group, AGISAR. The document should also consider including guidance on environmental surveillance

19. Maximum Residue Limits (MRLs) and Risk Management Recommendations (RMRs) for residue of veterinary drugs in foods issued by Codex could be referred, http://www.fao.org/fao-who-codexalimentarius/en/

20. Information available at OIE could also be referred, http://www.oie.int/en/

21. Farms referred to in this section mean livestock, horticulture, crops, orchards, apiculture, aquaculture

22. Details for environmental monitoring have been included in the Table: Surveillance of antibiotic use, residues and resistance

23. Related OIE and Codex documents could also be referred, http://www.oie.int/en/, http://www.fao.org/fao-who-codexalimentarius/en/

24. The FAO is currently in the process of developing a Progressive Management Pathway (PMP). The PMP is as a step-wise approach to assist countries assess their current situation in relation to understanding of/available data on AMR/AMU, their manufacture or import, production sectors (aquatic and terrestrial animals, crop agriculture), surveillance systems, vocational and professional education, and good manufacturing practices, http://www.fao.org/home/en/

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