

SAFE FOOD IN ACP A PROGRAMME FUNDED BY THE EU

HANDBOOK



TOPIC 12 Official Controls

13

GENERAL PRINCIPLES OF NATIONAL SURVEILLANCE AND OFFICIAL CONTROL PROGRAMMES IN ANIMAL PRODUCTION



The handbooks are tools designed for civil servants in charge of restructuring the food safety system, and for all operators involved in drawing up the food safety policy and organising official controls (qualified civil servants, heads of laboratories, heads of departments in official organisations, those in charge of official controls, trainers, technicians, researchers, experts or company executives). They aim to provide an overview of the main points of a specific subject. All of the topics addressed by EDES during the training sessions are covered in separate handbooks.



EDES is a European cooperation programme managed by COLEACP. COLEACP is an international network promoting sustainable horticultural trade. It is funded by the European Union and was implemented at the request of the ACP (African, Caribbean and Pacific) Group of States. EDES aims to promote food safety in African, Caribbean and Pacific countries. EDES operates in all sectors in response to a request filed at national level by any public or private stakeholder involved in the food safety process.



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1. Introduction



(Source: hellopro.fr)

The general aim of food supervision is to ensure that food is free of biological and chemical contamination. A framework for food safety systems have been developed by international agreements and implemented by many states and regional bodies around the world. These systems have introduced surveillance and official control programmes in animal and plant production which can be directed at biological or chemical hazards that affect animal and plant health or public health. Historically, biological hazards of concern have been agents that cause disease in animals with consequences for food production, human and animal health international trade in animals and their products and national economies. For some zoonotic agents (e.g. Brucellosis, bovine Tuberculosis) that cause disease in both animals and humans there is an overlap between animal health and public

health controls. Changing patterns of food-borne disease have increased awareness of zoonotic agents that cause disease in humans but are carried asymptomatically and do, in same cases, not cause clinical disease in animals (e.g. Salmonella, Campylobacter). The control of such agents may require specific interventions in animal production.

Exposure of animals to chemicals, either intentionally (e.g. veterinary medicines) or unintentionally (e.g. pesticides, environmental contaminants) can result in contamination of foods derived from animals and pose a threat to human health through their consumption.

Control measures for animal and in particular zoonotic diseases and for chemical contaminants in foods of animal origin require interventions at the level of primary production – on the farm. For food of animal origin, particularly meat, the term 'pre-harvest' is often used to describe the on-farm part of the production chain until slaughter.

Surveillance in animal production is a critical tool to detect new threats, to inform decision making across the animal disease control system and to measure the success of the system and to promote trade by providing evidence of disease freedom.

2. Control programme priorities

The starting point for the development of national official control programmes in animal production is to establish high-level strategy. Policy decisions must take account of a wide range of factors that have bearing on animal production in each country, including:

- · Public health
- Food safety
- Food security
- Economic factors including international trade
- Social factors (e.g. ethical factors linked to food production including animal welfare)
- Environmental factors
- Sustainability

Decision-making on national animal health strategy is an **important responsibility**. On one hand it deals with the protection of the health of the human population, and on the other hand with the protection and utilization of the whole animal population and its products in the country. The aim of the strategy is to **achieve the best possible results with available resources, or, to achieve its goals with the minimum possible inputs**.

There are several different types of animal health strategy, all relating to the specific problems of individual countries. The strategy should first provide general coverage for all animal health service activities and then complement this coverage with specific solutions for selected problems.

An example is the goals set by the EU Animal Health Strategy¹

Goal 1

To ensure a **high level of public health and food safety** by minimising the incidence of biological and chemical risks to humans.

Goal 2

To promote animal health by preventing/reducing the incidence of animal diseases, and in this way to support farming and the rural economy.

Goal 3

To improve **economic growth/cohesion/competitiveness** assuring free circulation of goods and proportionate animal movements.

Goal 4

To promote **farming practices** and **animal welfare** which prevent animal health related threats and minimise **environmental impacts** in support of the EU Sustainable Development Strategy.

Animal health services priorities risk based must be determined in each country, as there is no country in the world where conditions exist for solving all problems. Prioritising problems helps to define effective strategy and programmes.

Identification of priorities also facilitates the concentration of limited resources on the most important animal health problems. The order of priority should be the result of cross-evaluation of biological, economical, sanitary, social and environmental priorities, corrected by feasibility studies and the availability of resources. The availability of effective tools with which specific goals may be achieved under local conditions, as well as the availability of funds, labour and material resources, must be taken into consideration.

1 http://ec.europa.eu/food/animal/diseases/strategy/docs/animal_health_strategy_en.pdf

It has proved useful first to list the problems according to their rank of importance/risk. Those problems for which no practical or effective solutions or no diagnostic, control, treatment or eradication methods have been found should be moved to a lower rank of priority or postponed for the future. The same procedure should be applied if the necessary resources and other basic conditions are lacking. The pragmatic establishment of priorities should remain limited to a realistic achievable number.

Disease control programmes are often established with the aim of eventual eradication of the infectious agents at a country, zone or compartment level. While this approach is desirable, the needs of stakeholders may require a broader range of outcomes. For some diseases, eradication may not be economically or practically feasible and options for sustained mitigation of disease impacts may be needed.

The justification for the disease control programme should include a summary of the current knowledge about the epidemiological situation within the country detailing:

- 1. Description of the disease situation
- 2. Description of disease impacts (public health, food safety, food security and socioeconomic) and how these are distributed among stakeholders
- 3. Identification and engagement of stakeholders

The example below from the EU Animal Health Strategy illustrates the process of prioritisation.

Categorisation of animal-related threats

Profiling and categorisation of biological and chemical risks will provide the basis for decisions on where the responsibility for action lies.

Identified threats to animal health must be assessed to determine:

- their relevance to the four high level goals of the EU strategy;
- the "acceptable level of risk" for the Community;
- the relative priority for action to reduce the risk.

For serious threats to human health and the rural economy, we must strive to reduce the risk to a negligible level. But zero risk cannot be achieved. So even when dealing with high priority threats where a negligible level of risk is sought, we must analyse the cost-benefit and cost-effectiveness of possible interventions to ensure best use of limited resources, both in terms of EU funding and cost to producers. This is critical to our food supply and key to the sustainability of the environment and the rural economies of member states.

Where a potentially serious threat to health is identified, but there is scientific uncertainty about its likelihood of occurring, proportionate provisional measures should be taken to ensure a high level of health protection pending further scientific information clarifying the extent of the risk (the precautionary principle).

Profiling and categorisation of risks is an important and difficult process, which has already begun at EU level. Decisions must be based on sound science and appropriate risk assessment. But science alone will not provide all the answers. The Commission will therefore engage representatives of all interested parties in the risk management process to gain the widest possible agreement and shared responsibility for the judgements made and to deliver agreed objectives.

[EU Animal Health Strategy]

3. Animal disease control strategy

The desired endpoint of a disease control programme should be defined from the outset. Although eradication has traditionally been the goal for many disease control programmes it may not always be achievable within a reasonable timeframe or at an acceptable cost. The epidemiology of the disease along with the availability of technical tools as well as social and economic considerations dictate if eradication is achievable or if control at a certain prevalence level is adequate. For some diseases, or in certain situations, the emphasis of a programme should be on reducing the health and economic impact of the disease. Some of the factors to consider are listed below.

Biological factors

- Species affected
- Density of susceptible species
- Wildlife reservoir
- · Vector transmission
- Transmissibility
- Current extent of disease
- · Survival in the environment

Availability of technical tools

- Diagnostic tests
- Vaccines
- Treatment
- · Effectiveness of isolation/quarantine
- Disinfection

Socioeconomic factors

- · Cost and benefits of intervention
- Ease of implementation
- Stakeholder engagement
- Political will

3.1. Economic evaluation of disease control measures

Benefit/cost analysis should be treated as only one part of effective animal health planning and management. Simple comparisons of benefits and costs may be made with available data to obtain some idea of priorities in disease control. Comprehensive economic and social analysis capabilities need to be developed in each country, and evaluation should cover problems of depressed animal productivity and subclinical disease, as well as specific infectious diseases. Other forms of economic analysis, such as cost-effectiveness, cost utility and consumer and producer surplus analysis, should also be considered.

Benefits need to be separated in to:

- · the avoidance of direct observable losses
- · benefits not obtained, in the form of unrealised potentials for the improvement of animal productivity

- · direct benefits, such as gains in agricultural production, exports and import substitution
- · unquantifiable benefits, including improved human health, welfare and prosperity

An evaluation of an animal health programme requires a logical procedure that should comprise:

- rough estimates of the extent and impact of each problem under consideration, using existing data for preliminary assessment of priorities
- population and herd/flock structure data, together with existing evidence of specific disease incidence/ prevalence and production losses and, where necessary, the conduct of statistically designed cross-sectional or case-control studies to fill gaps in the information required
- conceptual or diagrammatic models to illustrate the epidemiological characteristics and impact of the problem under consideration
- biological models in mathematical form to estimate risks and extent of problems with and without control and to quantify and value the direct impact on animal production. Indirect benefits should also be incorporated
- systematic quantification for each type of production unit herd, flock or population grouping of estimated gains in production achievable and control costs for each control or production scheme undertaken or proposed, using static or dynamic models to show cumulative results wherever feasible
- the conduct of a partial budget analysis to ascertain the ratio of benefits to costs for individual farmers, which will influence their willingness to undertake and share the costs of health-control activities
- the conduct of benefit/cost analysis so as to be able to compare, from the animal industry's and nation's
 points of view, returns to costs from health-control activity, having made appropriate price adjustments for
 such issues as import substitution, exports, subsidies and opportunity costs of resources. Within these
 evaluations, thorough sensitivity analyses should be undertaken to reveal the effect of errors in data and
 assumptions and possible variations in prices
- the use of decision analysis, and particularly decision trees, to reflect the impact of different decisions at key stages in the progress of a programme
- a review of political, social, public health and environmental considerations, which can be quantified within the economic analysis in some cases or otherwise rated according to their importance in the course of discussions.

3.2. Political, social, public health and environmental impact

The impact of animal health services on these topics would include:

- improved income employment opportunities and living conditions contributing to social and political stabilities
- reduction or contribution to the elimination of the impact of zoonoses on humans;

- the contribution to better working conditions and the decrease in medical expenses incurred in the treatment of zoonoses
- the qualitative and quantitative improvement in human nutrition
- awareness that, although improvements in delivery of animal health services may have an impact on numbers and productivity of livestock, the full benefits of these improvements will only be achieved if the veterinary inputs are associated with better marketing and pricing of animal products

3.3. Strategic planning

The development of a strategic plan should be based on the choice of the endpoint of the programme. The choice of intervention options should be based on their biological effectiveness, ease and cost of implementation to fit the needs of the programme, as well as the benefits that are expected by reaching the objectives of the programme. Value chain analysis helps understand the role of different players within the production system, identify critical control points to target measures and provide an indication on the incentives for and feasibility of implementation of the programme. The decision on the most appropriate intervention options should take into account cost-benefit considerations, in conjunction with the likelihood of success of a particular set of disease control measures.

Institutional analysis examines the organizations involved in delivering services and the processes that govern their interaction. This type of analysis would be helpful to inform the strategic planning process and identify areas where a change would enable better programme implementation and facilitate effective collaboration.

The programme should include a continued review process to assess the effectiveness of the interventions that are being applied, identify gaps in knowledge and adapt the goals, objectives and methods or actions as required.

The programme should take into consideration the distribution of costs and benefits among different stakeholders and understand the factors limiting stakeholder participation in programme activities. These factors can affect the optimal selection of interventions. Programme policies need to include incentives for engagement including, for example, additional services for the producer, appropriate compensation schemes, adding value to the final product and protecting public health. In addition, it may be necessary to include measures to ensure compliance including movement restrictions and fines.

3.4. Implementation plan

A disease control programme should be based on an efficient and effective veterinary service. Countries are encouraged to follow the provisions of Chapter 3.1 of the *Terrestrial Animal Health Code* (*Terrestrial Code*) concerning the quality criteria of the services, as well as to undergo a Performance of Veterinary Services (PVS) evaluation (the PVS analysis path way) and address the recommendations issued following these PVS and PVS-Gap analysis evaluations.

The implementation plan should address the following:

1. Disease surveillance

The underpinning of the disease control programme activities is an effective surveillance system that provides guidance on priorities and targets for the application of interventions. The surveillance system should consist of general surveillance activities reinforced by pathogen specific activities. Surveillance in animal production in covered in detail later.

2. Epidemiological knowledge

The implementation of the programme needs to take into consideration:

- Knowledge of livestock production systems
- Geographical and temporal distribution
- Species affected
- Zoonotic potential

· Risk factors and critical control points

- Vectors
- Carriers
- Reservoirs

3. Diagnostic capability

The successful control of disease depends initially on its timely and accurate recognition and on the presence of sound diagnostic capabilities based on effective working links between laboratories and field services. The programme needs to be supported by diagnostic facilities with adequate capacity. The choice of diagnostic tests applied should ensure detection and confirmation of the disease. The tests should follow the specific requirements in Chapter 1.1.4 on Principles of Validation of Diagnostic Assays for Infectious Diseases and the disease specific recommendations in the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* and *the Manual of Diagnostic Tests for Aquatic Animals*. Diagnostic facilities, either official or accredited, should be under a quality assurance scheme coordinated by the designated national reference laboratory. The latter should establish communication with an OIE reference laboratory for the particular disease. National and subnational laboratories need to ensure that diagnostic results are communicated to the national surveillance system, field veterinarians and producers. National laboratories are also needed to provide independent and impartial quality control of vaccines for confirmation of findings and developing an understanding of the molecular epidemiology of the agent.

The OIE laboratory twinning activities, providing capacity building and networking, links in each twinning project, an existing OIE Reference Laboratory or Collaborating Centre ("parent lab") with a selected candidate laboratory and contributes to a stronger global disease surveillance network.

4. Disease control measures

Disease control measures to be applied in the programme can be implemented by the *Veterinary Authority*, or private entities or a combination of both. In any event, the overall responsibility for oversight of the programme remains with the *Veterinary Authority*. The basic principles of a control programme and the measures to address them include:

- a) Identification of foci of infection
- Early detection and diagnosis
- Disease reporting
- Surveys
- Abattoir surveillance
- · Epidemiological and outbreak investigation

b) Prevention of infection of susceptible hosts

- Vaccination
- Quarantine
- Animal movement control
- Vector control
- Public awareness and communication
- c) Elimination of the infectious agent
- Cleaning, disinfection and rest period
- Animal treatments
- · Treatment of products and by-products
- Test and isolation

- · Test and slaughter
- Stamping-out
- · Early detection and rapid response capacity when needed

The management of the application the disease control measures should follow standard operating procedures including:

- Implementation, maintenance, monitoring of the measures
- Application of corrective actions
- · Verification of the process
- Record keeping

5. Vaccination

a) Role of vaccination

Vaccination is an essential tool in the control of many diseases. However, vaccination on its own will not usually achieve the desired results unless the vaccination programme is part of an integrated control strategy. Depending on the epidemiological situation, the pattern of animal movements, population density and production systems within the country, targeted vaccination may be more effective than systematic mass vaccination. Where appropriate, vaccination campaigns should be serologically monitored for their effectiveness to ensure that herd-level immunity objectives are being met.

b) Vaccine quality

A vaccine quality assurance programme ensures the purity, safety, potency of vaccines as well as measures their efficacy in relation to the circulating strains. Vaccines used within control programmes should be licensed under the authority of the official veterinary services in accordance to international standards and preferably tested independently for safety and potency.

c) Vaccine delivery

Effective delivery of vaccine, including preservation of the cold chain and proper administration, is the cornerstone for reaching an adequate level of population immunity. Governmental and/or private schemes can be established to ensure vaccine distribution at the local level.

d) Vaccine and antigen banks

Banks could be useful to ensure sufficient stocks are available if targeted vaccination is needed. Such banks may be held at national or regional levels.

6. Regulatory framework

The disease control programme should be supported by effective legislation at the primary and secondary levels. Countries are encouraged to follow the OIE Guidelines on Veterinary Legislation².

National legislation should require OIE listed diseases to be notifiable throughout the country. The regulatory framework for the disease control programme should be flexible enough to be adapted to evolving programme needs.

7. Traceability

An effective traceability system facilitates the identification of affected herds or flocks. The existing traceability system may need to be adapted to take into account the epidemiology of the disease particularly the length of the incubation period. The design of the traceability system should follow the provisions of the Terrestrial Code, in particular Chapter 4.1 on General Principles on Identification and Traceability of Live Animals and 4.2 on Design and Implementation of Identification Systems to Achieve Animal Traceability.

2 http://www.oie.int/fileadmin/Home/eng/Support_to_OIE_Members/docs/pdf/A_Guidelines_VetLeg.pdf

8. Emergency preparedness and response

Countries should develop emergency preparedness and response plans to be applied in case of a disease introduction into a formerly free zone or an unexpected increase in incidence in areas that have reached an appropriate level of control or in the case of disasters. These plans are especially important for rapidly spreading diseases. Emergency response plans should be up to date, tested in the real world setting and embedded in the legal framework. Early detection and rapid response mechanism should be in place for all the priority diseases. Emergency funds should be available to cover operational costs and Indemnities where applicable.

The chain of command and coordination with all key players should be well established to ensure control efforts are executed rapidly and with success. Contingency plans need to be in place when immediate response is needed, including critical actions that need to be taken when a sudden outbreak of a disease is notified. Arrangements need to be in place to ensure rapid communication at all times. It is also important that these plans are coordinated on a regional level, particularly for transboundary animal diseases.

When the disease control measures applied have a significant economic impact, appropriate compensation mechanisms are needed to ensure cooperation by farmers. Funding is essential; inadequate compensation of livestock keepers may lead to non-compliance and under- or non-reporting of suspect disease. This aspect is dependent of the national/regional policy and available resources. Partnerships between government and the private sector have proven effective to develop sustainable contingency funds in several parts of the world.

9. Communication and publicity

Communication, awareness programmes and programme ownership need to be in place. Stakeholders should be involved in the development, planning, implementation and management of the programme. Good communication promotes compliance with disease control measures by making all parties aware of the reasons for the controls and the consequences of failure to comply.

10. Programme review and assessment

The programme should include a continued review process to assess the effectiveness of the interventions that are being applied, identify gaps in knowledge and adapt the goals, objectives and methods or actions as required. This process should begin with the establishment of baseline data on the epidemiological, economic and social impact of the disease. The programme should collect data on process and impact indicators. This enables measurement of the effectiveness of interventions on epidemiological indicators such as incidence and prevalence, and identify areas that needing strengthening.

11. Role of research in support of disease control programmes

During the strategic planning and assessment of programmes certain areas needing further research may be identified. Communication with national and international research institutions should be established to address programme needs.

12. Training and capacity building

Institutional capacity building is important in development of systems and infrastructure. The personnel in charge of implementing the measures within the programme need to be adequately trained and updated on the current technical knowledge on the relevant topics and diseases covered by the National Control Program. Veterinary accreditation schemes of private veterinarians and veterinary para-professionals can be a useful tool to increase the veterinary presence in the field, however training and supervision coordinated by the official veterinary service is required. In case of official delegation of activities, a clear definition of the mandate, the scope/type of actions and the control mechanism shall be clearly established.

4. Control of food-borne zoonoses

Food-borne zoonotic diseases are a significant and widespread global public health threat.

The protection of consumers from food-borne zoonoses requires an integrated approach to food safety from the farm to the fork. The approach consists of both risk assessment (e.g. data collection, analysis, recommendations) and risk management (e.g. legislative measures, targets for reduction) measures involving all key actors; national governments, the medical and veterinary professions, livestock producers and the food industry. Measures to control food borne zoonoses may be applied at any point along the production chain. The application of risk analysis and HACCP principles to the entire 'production to consumption' chain is required to identify where risk reduction and mitigation strategies can be applied most effectively. In many cases interventions to protect food safety are best applied at the primary production level in live animals. The nature of such interventions is dependent on scientific knowledge of the biology and epidemiology of the zoonotic agent e.g. biosecutity and vaccination to control Salmonella in poultry, animal feed controls for BSE in cattle.

For some agents of food-borne zoonoses the current level of understanding of the agent in animal populations is inadequate to institute control measures in primary production (e.g. verotoxigenic Escherichia coli) or effective control measures in animal populations have not been developed (e.g. Campylobacter in poultry). In these cases the protection of public health is reliant on interventions and practices further down the food chain. The table below³ outlines the possible control points in animal production for food-borne-zoonoses.

FOOD-BORNE HAZARD	CONTROL POINTS
Introduction of pathogens and	Sources of animals (horizontal and vertical transmission)
contaminants	Sourcing of breeding stock
	Breeding procedures
	Semen and embryo quality
	Bedding
	Feed and water
	Records of acquisitions and animal movements
	Health and hygiene of visitors and personnel
	 Contact with other animals (including wildlife/rodents/in- sects, etc.)
	Vehicles/clothing/instruments/equipment
	Infected/contaminated carcasses, tissues or secretions
Transmission of pathogens and	Animal housing and population density
contaminants	Disease diagnosis (horizontal and vertical transmission)
	 Health and hygiene of visitors and personnel
	Vehicles/clothing/instruments/equipment
	Infected/contaminated carcasses, tissues or secretions
	Bedding management
	Insect or pest vectors
Microbial and parasitic infections on	Pasture management
pastures and paddocks	Microbial/parasite diagnosis

3 Adapted from WHO/FAO Guide to good farming practices for animal production food safety http://www.oie.int/fileadmin/Home/eng/Food_Safety/docs/pdf/GGFP.pdf

FOOD-BORNE HAZARD	CONTROL POINTS
Microbial load on skins	Environment of animals
	Waste management
	Bedding management
	Population density
Airborne infections and contaminations	Farm location
	 Animal housing and ventilation
	Population density
Carrier animals shedding pathogens	Animal management
	Diagnosis
	Population density
Increased susceptibility to pathogens	Animal management (incl. transport)
	Diagnosis
	Population density
Antimicrobial and parasiticide resistance	Diagnosis
	Therapeutic regimes
	Record keeping
Feedborne infections and contaminations	 Feed production, transport and storage
	Feed quality
	Feed equipment
	Record keeping
Waterborne infections and infestations	Water quality
	Effluent management
	Watering equipment

5. Control of chemical contaminants in animal production

A range of chemical substances may be present in live animals and result in the contamination of foods of animal origin:

- · Naturally occurring contaminants from the environment (e.g. heavy metals)
- Naturally occurring feed contaminants (e.g. mycotoxins)
- Industrial contaminants (e.g. dioxins)
- Pesticides and other agrochemicals
- · Residues of veterinary medicines

Although chemical contaminants can cause acute health problems in animals and in humans consuming foods, the main food safety concerns from chemical contamination of foods of animal origin are generally of a long term, chronic nature and result from the prolonged exposure to chemicals in food.

Control strategies for chemical contamination of food are based on assessment of the public health problems caused by chemicals ingested by humans, from which an acceptable daily intake (ADI) of the chemical can be determined. By using dietary information the quantity of food types consumed by humans a maximum residue limit (MRL) can be set for each food commodity.

In addition to providing the health protection benefits, effective pesticide and veterinary drug use and residue control programmes and environmental control programmes enable a country to participate in international food trade with greater confidence; an effective residue and contaminants control programme can serve as the foundation for certifying the safety of the country's exported food products, as well as providing assurance of the safety of food products imported into the country.

In establishing effective residue control programmes, a country should first establish a comprehensive system for determining the safety of pesticides and veterinary drugs. This may be accomplished, for example, through an organization or organizations with suitable technical expertise and administrative authority. Approval of pesticides and veterinary medicines may take into consideration several relevant criteria (quality, efficiency and safety), among which will be the safety evaluation of residues of pesticides or veterinary medicines. Scientific evaluation of the safety of pesticides or veterinary drugs and the acceptable levels for human consumption is a long and rigorous task which may not need to be performed in each country, especially among developing countries.

The elements in establishing an effective national programme for the control of residues of veterinary medicinal products or pesticides in food of animal origin should include the following:

- Establishing the competent authority/authorities for implementing inspection programmes and laboratory analysis, identifying the official testing needs;
- Establishing an integrated inspection programme, including a residue control programme for the inspection
 of food (The organization responsible for implementing the inspection programme should be granted the
 authority to take all the steps necessary to control products when residues exceed the maximum residue
 limits established for a food commodity or when non-permitted residues or contaminants are found)
- A complete database of authorised veterinary medicines and pesticides used in the country, including products manufactured in the country and products imported into the country
- Establishing a clear legal framework concerning the authorisation, distribution use and control of veterinary medicines;
- Providing the relevant guidance concerning the evaluation mechanism and data content of the dossiers, according with the evolution of the scientific data, technical progress and regulatory evolution;

- Elaborating regulations, guidance concerning the distribution of veterinary medicines and pesticides, providing control procedures for authorized sale, manufacture, import, distribution and use of such products;
- Elaborating procedures for determining the safety and efficacy of veterinary medicines and pesticide residues (This should include description of procedures for determining maximum residue limits for veterinary medicinal and phyto-pharmaceutical products in food);
- Establishing control procedures for monitoring through sampling of food products for these residues;
- Selecting the reference methods of analysis to be used for veterinary medicines and pesticides residues where applicable;
- Implementing a laboratory quality assurance programme to ensure the highest quality of analytical and timeless results and
- Developing educational best practices programmes for primary producers and veterinarians, instructing on the rational use of veterinary medicines and proper use of pesticides and encouraging the use of preventive measures to reduce the occurrence of residues in food.

Food production, processing and preparation operations should be analysed with a view to identifying hazards and assessing the associated risks. This should lead to a determination of critical control points and the establishment of a system to monitor production at these points (i.e. the Hazard Analysis Critical Control Point or "HACCP" approach). It is important that care is exercised throughout the whole production-processing and distribution chain, since food safety and quality in other respects cannot be 'inspected into' the product at the end of the chain.

Control measures based on the principles of HACCP may not need to be developed on an individual basis for primary producers but may be developed by experts and recommended to primary producers as "good practice recommendations". Education and training programmes should be relied upon to introduce practices that, in effect, may represent a change in the manner in which farms and other primary food production operations are managed.

5.1. Control of environmental contamination

Pollution of air, water and arable land can result in the contamination of crops grown for food or animal feed, food producing-animals and surface and ground waters used as sources of water for drinking and food production and processing. The relevant national authorities should be informed about actual and potential food contamination problems and encouraged to take measures to:

- control emissions of pollutants from industry, e.g. the chemical, mining, metal and paper industries;
- control emissions from energy generation (including nuclear plants) and means of transportation;
- control the disposal of solid and liquid domestic and industrial waste, including its deposition on land, disposal of sewage sludge and incineration of municipal waste;
- control the production, sale, use and disposal of certain toxic, environmentally-persistent substances e.g. organohalogen compounds (PCBs, brominated flame retardants, etc.), lead, cadmium and mercury compounds;
- ensure that before new chemicals are introduced in the market, and especially if they may eventually be released into the environment in significant amounts, they have undergone appropriate testing to show their acceptability from the health and environmental points of view;
- replace toxic environmentally-persistent substances by products which are more acceptable from the health and environmental points of view.

5.2. Veterinary medicines

CAC guidance⁴ for the use of veterinary drugs in food producing animals recommends that programmes for the control of residues of veterinary drugs in foods should:

- Be based on risk using realistic risk profiles assessed as reasonably likely to be associated with food derived from the relevant productions systems;
- Be prevention focussed based on the realistic risk profiles associated with the probable or known use of approved, non-approved and prohibited veterinary drugs in the production system;
- Include regulatory measures proportionate to the relative human health risk associated with these hazards compared with other food-associated hazards;
- Ensure all parties involved in the production, marketing and processing system of the animals and/or the food products derived from them are held accountable to ensure that unsafe animal products will not be sold as a result of their action or inaction;
- Recognise that pre-harvest controls and practices are the primary means for ensuring safe food;
- Recognise that the primary role of audits and sampling programmes is to verify the implementation and effectiveness of the pre-harvest controls and practices;
- · Focus on system and population based assurances; and
- Be cost effective and have the support of stakeholders.

Business operators/commercial entities involved in the production, processing and marketing of food have the primary responsibility for ensuring food safety. Competent Authorities regulate the use of veterinary medicines, verify that appropriate best practices are applied and that effective measures are in place within the veterinary products distribution and food production system to provide effective protection of consumers and facilitate trade, consistent with the goals of Codex Alimentarius.

Control of residues of veterinary medicines requires an effective regulatory framework to set and enforce rules for the use of medicines.

The competent authority responsible for providing consumer assurances for food safety must ensure that it has the appropriate technical food safety knowledge, the control over veterinary medicines that are in the market and used within the production food chain and that it has sufficient resources to implement the needed measures.

5.3. Antimicrobial resistance (AMR)

The use of antibiotics for treatment of animal diseases has great benefits for animal health and therefore contributes to supporting the livelihoods of livestock owners - particularly those in the poorest countries - and to propel economic development. However, inappropriate use of antimicrobials for treatment and prevention of diseases in food production or companion animals can also lead to the emergence and spread of antimicrobial resistant microorganisms.

The misuse of medicines, such as, for example, under-dosing, uncontrolled use to prevent disease, the use of counterfeit, and poor quality compounds can create the conditions that allow resistant microorganisms to emerge, spread, and persist. From an animal health production perspective, the undesirable outcomes are the likely failure of disease control programmes or clinical recovery, increased severity of diseases, prolonged morbidity, increased mortality, reduced productivity, higher risks of disease spread in animal populations, and increased costs to society as a whole.

Development of resistance to antimicrobial agents renders life-saving treatments ineffective. Many diseases that are infectious to animals and humans could become untreatable. The appearance of AMR in food animals

⁴ Guidelines for the design and implementation of national regulatory Food safety assurance programme associated with the use of veterinary Drugs in food producing animals. CAC/GL 71-2009

poses serious threats to food security and livelihoods. When food animals are unhealthy and unproductive, they are no longer able to make important contributions to efficient food production, to generate food-products of acceptable quality, to contribute to income generation, job creation, economic growth, or the alleviation of poverty. Animals suffering from resistant infections are more likely to perish, leading to loss of income-generating assets and to shortfalls in food supplies.

Humans can also suffer from prolonged illness, treatment failures, and increased severity of diseases or even death caused by food-borne antimicrobial resistant bacteria, for example Campylobacter and Salmonella. The growth of global trade of animals and products of animal-origin and travel of humans allows resistant microorganisms to be spread rapidly to distant countries and continents, in the process threatening public health.

Measures to minimize and contain AMR are thus essential to ensure the continued availability and efficacy of veterinary and human antimicrobial drugs. This ultimately depends on the responsible and prudent use of antimicrobial drugs and requires appropriate actions to be taken by all those involved in the authorization, regulation, distribution, and use of antimicrobials in food-producing animals. At a national level this should include appropriate policies and strategies to regulate the authorization of antimicrobial drugs, to control the quality and usage of antimicrobials, to monitor AMR and quantities of veterinary drugs used, and to regulate the manufacture, importation, and distribution of drugs.

Livestock producers also have an important role in ensuring that veterinary medicines are not used as a substitute for good management and hygiene or other disease prevention methods such as vaccination and effective biosecurity measures. Importantly, they should only use antimicrobials when necessary and in accordance with veterinary advice. Veterinarians play an important role in advising producers on effective disease control measures and good husbandry practices, as well as in promoting responsible and prudent usage of antimicrobials.

6. Surveillance in animal production

6.1. Animal health surveillance

There are many, similar definitions published for animal disease surveillance; two examples are:

- the collection, collation, analysis, interpretation and timely dissemination of information on the presence, distribution or prevalence of risk organisms and the animals that they affect.⁵
- the systematic, continuous or repeated, measurement, collection, collation, analysis, interpretation and timely dissemination of animal health and welfare related data from defined populations, essential for describing health hazard occurrence and to contribute to the planning, implementation, and evaluation of risk mitigation measures.⁶

As these definitions state, surveillance fulfils a range of purposes, both in terms of the type of information obtained and the use to which it can be put. The objectives of surveillance can be divided into two components; the actual information that is obtained and the subsequent use of the information to make policy decisions.

Surveillance purpose

Describes what type of information will be obtained about the occurrence of a health hazard using a particular surveillance activity:

- · Early detection / warning of known (exotic or re-emerging) or unknown (new) disease
- Substantiate freedom from disease or infection
- · Describe the baseline level, distribution and impact of specified disease(s)
- Describe changes in the health of the population, including changes in the occurrence of health indicators or specified diseases
- Describe changes that may threaten the health of the population, this may include changes in the population structure or its exposure to risk factors
- Detect cases to facilitate control

Policy purpose

To inform decisions about how best to support policy objectives such as maintaining a healthy and sustainable food and farming industry, protection of the livelihood of producers, other value chain stakeholders and public health and to support national economic development. The specific decisions that surveillance information can assist policy makers with are:

- Management of outbreaks whether additional control measures are required to limit the spread of an emerging or exotic disease outbreak
- Informing trade whether to permit import or support export of animals or animal products based on evidence about the prevalence and distribution of disease and the risk of disease spread through the commodity being traded thus protecting the indigenous population and facilitating access to international markets
- Prioritisation how to prioritise surveillance and control measures for different health hazards based on their level of occurrence and impact on animal health and welfare, public health, trade and the wider economy using information about relative importance of hazards

⁵ Biosecurity Surveillance Strategy 2020. MAF Biosecurity New Zealand

⁶ http://www.animalhealthsurveillance.org/uploads/Main/ICAHS%20workshop%20-%20final%20report%20December%202011.pdf

• Informing control – how to improve the efficiency of surveillance and risk mitigation measures including an assessment of whether the current control measures should be maintained, changed or stopped

The overall objective of animal disease surveillance is to support the disease control strategy of a country in its aims to protect the livestock, economy, environment and health of the human population of the country by:

- detecting risk organisms early enough to allow for optimal management to occur and to inform choices about appropriate management strategies
- providing evidence to support the demonstration of freedom from risk organisms e.g. to facilitate international trade
- assisting with the detection and monitoring of new and emerging risks and threats to the country
- describing the distribution and prevalence of risk organisms already present within the country, and the animals they affect, to inform choices about appropriate actions;
- providing evidence to inform decision making across the animal disease control system
- · measuring the success of the animal disease control system

6.1.1 Surveillance strategy

The principal objectives of a national veterinary surveillance strategy are to identify surveillance needs to protect the health of livestock and consumers, to set priorities, and to allocate resources effectively and efficiently. An important goal is to achieve a higher benefit-cost ratio with existing or reduced resources. Every country will have its own specific needs for surveillance to support its disease control policies. It is there-

fore essential to develop a national strategy to ensure that surveillance resources are targeted to achieve the greatest benefits for the country.

Factors that should be considered in developing a national surveillance strategy include:

- Prioritisation procedures
 - risk- and impact-based prioritisation of surveillance activities
 - speed of detection to enable early implementation of control measures
- Surveillance partners
 - comprehensive network of surveillance partners
 - standardised and harmonised approach to surveillance
- Information sharing
 - structured surveillance reports
 - user friendly systems
 - rapid dissemination of surveillance information to target groups
 - access to surveillance data for researchers
- Surveillance quality
 - promote confidence in the reliability of surveillance information
 - understanding of significance of surveillance information
 - standardised surveillance mechanisms and denominator data
- Efficiency
 - benefit cost ratio

6.1.2 Types of surveillance

Different types of surveillance activity may be applied depending on the purpose and desired outcomes of the surveillance. Surveillance may be classified in a number of ways according to the disease focus, population studied and desired output, and a wide range of surveillance types and definitions are published⁷; the main categories are scanning (or passive) surveillance and targeted (or active) surveillance.

Passing (Scanning) surveillance

Scanning disease surveillance is the routine gathering of information on disease incidents from readily available sources such as requests for assistance from farmers, reports from private veterinarians, field veterinary officers and livestock officers, submission of diagnostic specimens to laboratories and the results of laboratory investigations. Routine disease reports may also come from other sources such as abattoirs and livestock markets.

The passive surveillance monitors the health of defined animal populations to increase the likelihood of timely detection of undefined or unexpected diseases, or important changes in endemic diseases.

For example, in the UK in recent years the scanning surveillance programme has been responsible for the early detection of pandemic H1N1 influenza in pigs, notifiable avian disease outbreaks, bovine tuberculosis in non-bovine species, antimicrobial resistance in Salmonella and virulent psoroptic mange in cattle, as well as providing reassurance of the national animal health status that has supported trade.

Elements of a scanning surveillance system

Design of the system

Standardised, risk- and objective-based Scanning surveillance systems must be designed on a national level to ensure that they deliver the required outcomes in a cost effective manner.

Information sources

A wide variety of non-random surveillance sources may be available. These vary in their primary purpose and the type of surveillance information they are able to provide. Some surveillance systems are primarily established as early detection systems, but may also provide valuable information to demonstrate freedom from infection. Other systems provide cross-sectional information suitable for prevalence estimation, either once or repeatedly, while yet others provide continuous information, suitable for the estimate of incidence data (e.g. disease reporting systems, sentinel sites, testing schemes).

Surveillance involves the detection of disease or infection by the use of appropriate case definitions based on the results of one or more tests for evidence of infection or immune status. In this context, a test may range from detailed laboratory examinations to field observations and the analysis of production records. The performance of a test at the population level (including field observations) may be described in terms of its sensitivity and specificity and predictive values. Imperfect sensitivity and/or specificity will have an important impact on the conclusions from surveillance.

Disease reporting or notification systems

Data derived from disease reporting systems can be used in combination with other data sources to substantiate claims of animal health status, to generate data for risk analysis, or for early detection mechanism.

Ante-mortem and post-mortem inspections

Sanitary inspection of animals at slaughterhouses (ante and post mortem inspections) may provide valuable surveillance data. The sensitivity and specificity of slaughterhouse inspection for detecting the presence of specified diseases under the inspection system in place should be pre-determined

7 http://www.animalhealthsurveillance.org/uploads/Main/ICAHS%20workshop%20-%20final%20report%20December%202011.pdf

Laboratory investigation records

Analysis of laboratory investigation records may provide useful surveillance information. The coverage of the system will be increased if analysis is able to incorporate records from national, accredited, university and private sector laboratories. Valid analysis of data from different laboratories depends on the existence of standardised diagnostic procedures and standardised methods for interpretation and data recording. As with abattoir inspections, there needs to be a mechanism to relate specimens to the farm of origin.

• Field observations

Clinical observations of animals in the field are an important source of surveillance data. The sensitivity and specificity of field observations may be relatively low, but these can be more easily determined and controlled if a clear standardised case definition is applied. Education of potential field observers in application of the case definition and reporting is an important component. Ideally, both the number of positive observations and the total number of observations should be recorded.

• Farm production records

Systematic analysis of farm production records may be used as an indicator of the presence or absence of disease/infection at the herd or flock level. In general, the sensitivity of this approach may be quite high (depending on the disease), but the specificity is often quite low.

Wildlife data

Specimens from wild animals for disease/infection surveillance may be available from sources including hunters and trappers, road-kills, sanitary inspection of hunted animals, morbidity and mortality observations by the general public, wildlife rehabilitation centres, wildlife biologists and wildlife agency field personnel, farmers and other landholders, naturalists and conservationists.

Partnership networks

Scanning surveillance relies of the collection of information from a wide range of sources and the establishment of networks of stakeholders throughout the animal production chain, including:

- Veterinary services units
- Veterinary diagnostic laboratories
- Food safety inspection services
- Private veterinarians
- Industry groups
- Livestock producers
- · Livestock auction markets
- Public health agencies
- · Wildlife agencies
- Local authorities
- Universities and research establishments
- · Port and border inspectors

Information collection

Field force of accredited veterinarians, producers, wildlife biologists, and border inspection agents who collect observational and biological samples

Standardised case definitions, using OIE Terrestrial Code standards where appropriate

Laboratory testing

A national network of accredited laboratories applying standardised methods should be established.

The performance of a test may be described in terms of its sensitivity and specificity and predictive values. Imperfect sensitivity and/or specificity will have an impact on the conclusions from surveillance. Therefore, these parameters should be taken into account in the design of surveillance systems and analysis of surveillance data.

The values of sensitivity and specificity for the tests used should be specified for each species in which they may be used, and the method used to determine or estimate these values should be documented. Alternatively, where values for sensitivity and/or specificity for a particular test are specified in the Terrestrial Manual, these values may be used as a guide.

Data Collation and Storage

The success of a surveillance system is dependent on a reliable process for data collection and management, and the use of integrated information management systems. The process may be based on paper records or computerised. The consistency and quality of data collection and event reporting in a format that facilitates analysis is critical.

Surveillance Analysis

Surveillance data should be analysed using appropriate methodologies, and at the appropriate organisational levels to facilitate effective decision making, whether it be planning interventions or demonstrating status.

Methodologies for the analysis of surveillance data should be flexible to deal with the complexity of real life situations. No single method is applicable in all cases. Different methodologies may be needed to accommodate the relevant host species, pathogens, varying production and surveillance systems, and types and amounts of data and information available.

The methodology used should be based on the best information available and should also be in accordance with the OIE Terrestrial Code, fully documented and supported by reference to the scientific literature and other sources, including expert opinion.

Communication of results

Summaries and analytical reports

Frequent reports - Weekly, monthly, quarterly, annual reports

Reports should be tailored to the varied needs of the audience - decision-makers, programme managers, field operations, laboratories, other stakeholders including general public

Coordinating body

An 'intelligence hub' of people and IT facilities

- to support data capture, exploration, collation, analysis, reporting and use of surveillance findings,
- to trigger risk mitigation measures or further research
- supported by ready access to relevant population and risk factor data

6.1.3 Active (targeted) surveillance

Targeted surveillance involves examination of selected animals to determine their status for a specific disease over a defined time period. This frequently involves structured surveys of animals in their environment but may also include other activities such as examination of animals at abattoirs.

Targeted surveillance is usually conducted in response to perceived concerns about the status of livestock for a specific disease and is used to fill the gaps in knowledge obtained from scanning surveillance. The strength of targeted surveillance is that it provides information that is scientifically valid. However, targeted surveillance is often costly and may be conducted only for a defined period of time.

Survey design

Surveys should be carefully designed to ensure that they provide statistically rigourous results and answers to the issues they address. The design of a survey will depend on the size, structure and degree of understanding of the population being studied, the epidemiology of the disease or condition and the resources available. Surveys may be conducted on the entire target population (i.e. a census) or on a sample. A sample may be selected in either of the two following ways:

- non-probability based sampling methods, such as:
 - convenience
 - expert choice
- quota
- probability based sampling methods, such as:
 - simple random selection;
 - cluster sampling
 - stratified sampling
 - systematic sampling

Periodic or repeated surveys conducted in order to document disease freedom should be done using probability based sampling methods so that data from the study population can be extrapolated to the target population in a statistically valid manner.

The objective of sampling from a population is to select a subset of units that is representative of the population of interest with respect to the objective of the study. Sampling should provide the best likelihood that the sample will be representative of the population, within the practical constraints imposed by different environments and production system

Surveys are generally conducted either to demonstrate the presence or absence of a factor (e.g. disease agent) or to estimate a parameter (e.g. the prevalence of infection). The method used to calculate sample size for surveys depends on the purpose of the survey, the expected prevalence, the level of confidence desired of the survey results and the performance of the tests used.

Surveillance to demonstrate freedom from disease/infection

Targeted surveillance for specific disease agents can be used by a country to demonstrate freedom from disease (in the country, zone or compartment). For many diseases of major economic importance the OIE Terrestrial Code includes details of surveillance requirements in the specific disease chapters e.g. foot and mouth disease Chapter 8.5.⁸

6.1.4. International animal disease surveillance

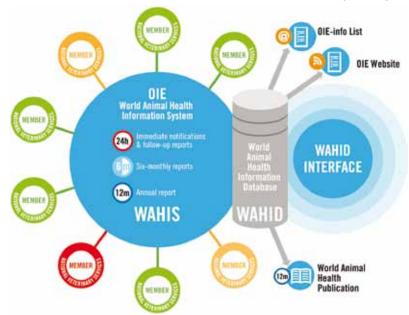
National veterinary authorities should routinely study all sources of information about international animal disease to identify potential threats to the country. These sources include, but are not limited to:

World Animal Health Information Database (WAHID)

OIE is the main source of worldwide information. All OIE Members are required to report instances of notifiable disease outbreaks and other disease information. The World Animal Health Information Database (WAHID) Interface⁹ provides access to all data held within OIE's World Animal Health Information System (WAHIS).

8 http://www.oie.int/index.php?id=169&L=0&htmfile=chapitre_1.8.5.htm

9 http://web.oie.int/wahis/public.php?page=home



The World Animal Health Information Database (WAHID)¹⁰

Global Early Warning System (GLEWS)

GLEWS¹¹ is a joint system that builds on the added value of combining and coordinating alert mechanisms of the World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO) and the World Organisation for Animal Health (OIE), while linking networks from the international community and stakeholders, to assist in early warning, prevention and control of animal disease threats, including zoonoses, through sharing of information of disease events, epidemiological analyses and risk assessments.

FAO Emergency Prevention System (EMPRES)¹²

EMPRES has the mandate to address prevention and early warning across the entire food chain. It promotes the effective containment and control of the most serious epidemic pests and diseases and food safety threats through international cooperation involving early warning, early reaction, coordination and capacity development.

6.2 Surveillance for public health

6.2.1. Food-borne zoonoses

Food-borne zoonotic agents can cause disease in animals (e.g. bovine tuberculosis, Brucellosis) or can be carried asymptomatically (e.g. campylobacter, Salmonella spp). Surveillance for the former group of agents can be captured by animal health surveillance programmes.

For all food-borne zoonoses data collection is essential to identify which animals and foodstuffs are the main sources of infections in humans and to monitor the prevalence of zoonoses. Data analysis supports efforts to prevent and reduce the impact of zoonoses in the food chain. Surveillance for food borne zoonotic agents includes gathering information from human cases of food-borne disease, from foods of animal origin and from animal populations.

¹⁰ http://www.oie.int/animal-health-in-the-world/the-world-animal-health-information-system/the-oie-data-system/

¹¹ http://www.glews.net/

¹² http://www.fao.org/foodchain/empres-prevention-and-early-warning/en/

6.2.2. Chemical contaminants in food of animal origin

An assessment of the presence and levels harmful chemical substances in the diet is important for food safety. Potentially harmful chemical substances include e.g. pesticide or veterinary drug residues, heavy metals, environmental or process contaminants, naturally occurring toxins that can be present in food at levels that might adversely affect the health of consumers. With the development of food chemistry, there has been a rapid development from simple checking of purity and adulteration to sophisticated tests for the presence of a range of chemical substances in food at increasingly lower levels. Today, effective food control systems are considered essential to protect the health and safety of consumers.

Most national surveillance programmes aimed at ensuring that food does not contain unacceptable levels of contaminants are designed to measure selected chemical contaminants in a variety of agricultural commodities. Since the concern for chemical contamination is generally chronic disease rather than acute illness, surveillance for chemical contaminants focuses on ensuring that the level of contaminants is below a predetermined maximum allowable limit rather than linking the contaminant level to an acute illness. When chemical contaminants are below the maximum allowable limit, consumers can be assured that the product has been produced according to good agricultural practices and their exposure to the chemical contaminant will be below the established acceptable daily intake level.

In addition to providing the health protection benefits, effective pesticide and veterinary drug use and residue control programmes and environmental control programmes enable a country to participate in international food trade with greater confidence; an effective residue control programme can serve as the foundation for certifying the safety of the country's exported food products, as well as providing assurance of the safety of food products imported into the country.

The selection of priorities for chemical analysis is part of the official food control system and it follows general scientific principles for protecting the public from potential hazards in the food supply. Individual countries may perceive the selection of these priorities differently in accordance with their own political, economic or cultural practices and traditions.

Food safety risk assessments take account of both toxicological information and estimates of dietary exposure of the population to the chemical substances in order to evaluate benefits and risks for public health. To estimate exposure, it is essential to analyse the food that is eaten for the presence and levels of contaminants then relate the occurrence levels to the amounts of the respective food consumed. Some monitoring or surveillance data focus on individual chemical substances in raw commodities and may not provide a direct link to the dietary exposure assessment of the population.

In an international context, the Codex Alimentarius Commission generates guidance and standards for the management of food safety and consumer protection. CAC publications include guidance on surveillance systems for residues of pesticides and veterinary medicines:

- Recommended Methods of Sampling for Pesticide Residues for the Determination of Compliance with MRLs (CAC/GL 33-1999)
- Guidelines for the design and implementation of national regulatory Food safety assurance programme associated with the use of veterinary Drugs in food producing animals. (CAC/GL 71-2009)

These documents include detailed information about sampling strategies and analytical methods.

In conjunction with these guidance texts, CAC lists MRLs for pesticides in commodities, including food of animal origin and for veterinary drugs:

http://www.codexalimentarius.net/pestres/data/commodities/index.html http://www.codexalimentarius.net/vetdrugs/data/vetdrugs/index.html

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6.2.3. Anti-microbial resistance

In recognition of the concerns about the development of antimicrobial resistance, the CAC Code of Practice to Minimize and Contain Antimicrobial Resistance (CAC/RCP 61-2005) states that veterinary authorities should develop a structured approach to the investigation and reporting of the incidence and prevalence of antimicrobial resistance. Priority should be given to the evaluation of antimicrobial resistance in food-borne microorganisms.

The methods used to establish such programmes (laboratory techniques, sampling, choice of veterinary antimicrobial drugs and microorganisms) should be harmonized as much as possible at the international level (e.g. OIE documents on "Harmonisation of National Antimicrobial Resistance Monitoring and Surveillance Programmes in Animals and Animal Derived Food" http://www.oie.int/eng/publicat/rt/2003/a_r20318.htm and "Standardisation and Harmonisation of Laboratory Methodologies Used for the Detection and Quantification of Antimicrobial Resistance" http://www.oie.int/eng/publicat/rt/2003/a_r20317.htm).

Preferably, epidemiological surveillance of antimicrobial resistance should be accompanied by data on the amounts of veterinary antimicrobial drugs used by veterinarians and other authorized users in food-producing animals. These data could be collected using one or more of the following sources:

- production data from manufacturers;
- importers and exporters;
- if possible, data on intended and actual usage from manufacturers, wholesale and retail
- distributors including feed mills, and veterinary prescription records;
- surveys of veterinarians, farmers and producers of food-producing animals.

Regulatory authorities should have in place a pharmacovigilance programme for the monitoring and reporting of adverse reactions, in particular to veterinary antimicrobial medicines, including lack of the expected efficacy related to microbial resistance. The information collected through the pharmacovigilance programme should form part of the comprehensive strategy to minimize microbial resistance.

In cases, where the assessment of data collected from pharmacovigilance and from other post authorization surveillance including, if available, targeted surveillance of antimicrobial resistance, suggests that the conditions of use of the given veterinary antimicrobials should be reviewed, the competent authorities shall endeavour to achieve this re-evaluation and to take the appropriate measures in conformity with evaluation results.



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- 7 Traceability and Labelling
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EDES is funded by the European Union

Printed on FSC-certified paper with environmentally friendly solvent-free inks. Publication date: September 2012

