

guidelines

REGULATORY FRAMEWORKS FOR CONTROL OF HPAI AND OTHER TADS

A guide to reviewing and developing the necessary policy,
institutional and legal frameworks



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Recommended citation

FAO. 2013. *Regulatory frameworks for control of HPAI and other TADs – A guide to reviewing and developing the necessary policy, institutional and legal frameworks*. FAO Animal Production and Health Guidelines No. 13. Bangkok, Thailand.

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ISBN 978-92-5-107481-7

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Foreword

Animal diseases and zoonoses impact over 800 million people in developing countries, posing direct and indirect risks to actors along the production and marketing chain – from people living in rural areas to the consumers of animal products. Animal diseases disrupt livestock production, rural economies, people’s livelihoods and food security. A robust regulatory framework, comprising sound policy as well as institutional and legal elements, is essential for the control of transboundary animal diseases.

Recent intensive efforts to prevent, contain and eliminate high-impact diseases such as highly pathogenic avian influenza (HPAI) have given a sense of urgency to the development of improved disease control strategies, harmonized across regions, in order to tackle transboundary disease control using more uniform, robust and effective methods. In partnership with the World Organisation for Animal Health (OIE) and the World Health Organization (WHO), FAO has adopted a One Health approach in strengthening the systems to detect and combat new pathogens by creating a coordinated response to disease outbreaks, by implementing effective prevention and containment strategies, and by managing the risks of disease emergence. The One Health initiative builds on the lessons learned from, and the achievements of, the responses to H5N1 HPAI and H1N1 epidemics. This handbook adopts the principles and approach of One Health by creating an understanding of the context in which diseases emerge and by presenting the two key issues – legislation and regulatory frameworks – for the attention of administrators and policy-makers.

The review of regulatory frameworks (policy and institutional) for animal health is a critical but often neglected area. This handbook draws on the veterinary experience of Dr Ian Robertson (a consultant to FAO who is funded by the Asian Development Bank), and the legal expertise of Ambra Gobena and Carmen Bullon (Legal Service Officers, FAO) to facilitate an understanding of the structure and elements of veterinary policy and legislation, the international frame of reference, the interface between veterinary policy, institutions and legislation, and the potential impacts of the national legal tradition on the way that laws are drafted. The production of this handbook reflects the need for close cooperation within countries between people who have technical veterinary expertise and those who have legal and regulatory expertise.

Activities carried out within the context of Phase II of the Asian Development Bank project ‘Strengthening Regional Capacity to Control and Eradicate HPAI in Asia and the Pacific’, and the EU-funded project ‘Improvement of regional capacities for prevention, control, and eradication of highly pathogenic and emerging diseases (HPED)’, including HPAI in Association of Southeast Asian Nations (ASEAN) and South Asian Association for Regional Cooperation (SAARC) countries, have been directed towards the practical implementation of advice on the upgrading of these countries’ veterinary and animal health regulatory frameworks. This handbook provides a compilation of such advice within the Asian context, but has broad applicability for countries seeking regulatory reform on animal health issues.

It is hoped that the handbook will enable governments in countries in South Asia and South East Asia in particular to approach the upgrading of their legislation in a way that results in achieving regional approximation of animal health control provisions in a more informed and objective way. It is also hoped that the handbook will help them to make the recommended revisions independently, and fully in accordance with their own governmental structures and legal systems, with the need for only occasional external support and advice, and that it will give them more complete ownership of both the process and its outcome.

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Acknowledgements

The authors wish to acknowledge a number of people who have provided inputs in the preparation of this handbook.

Dr Juan Lubroth, Chief Veterinary Officer, FAO, is acknowledged for his insights and for urging the need to strengthen legislation to support disease control.

Dr Subhash Morzaria, ECTAD Regional Manager, is thanked as the originator of the concept that a handbook on policy and legislation would be a constructive output of the consultant's assignment.

The enormous efforts of Dr Ian Robertson, the primary author of this handbook, and the legal expertise of Carmen Bullon and Ambra Gobena, who critically read the manuscript, are both recognized and greatly appreciated.

We are grateful to other FAO colleagues, including Dr Carolyn Benigno, Dr Angel Ortiz Peláez, Dr David Castellan and Dr Mary Elizabeth Miranda for giving generously of their time, advice and encouragement in this collaborative publishing endeavour.

Mr Bill Garthwaite, Mr Lalaina Ravelomanantsoa, Mr C.Y. Gopinath and Ms Sissel Brenna are thanked for their inputs and for their review of this handbook.

The inclusion of many constructive suggestions provided by participants in the September 2008 Workshop on the Strategic and Legal Aspects of the Control of Transboundary Livestock Diseases, and also provided by participants in the June 2010 Workshop and Training Course on the Modernization and Approximation of Animal Health Legislation, has added to the validity of the handbook's contents and will surely enhance its practical value. We would like to express our gratitude to Jessica Vapnek in this regard.

Finally, without the financial support provided by the Asian Development Bank during Phases I and II of the project on Strengthening Regional Capacity to Control and Eradicate HPAI in Asia and the Pacific, and the EU HPED project, the production of this handbook would not have been possible.

Abbreviations

ALPAN	African Livestock Policy Analysis Network
CVO	chief veterinary officer
CAH	community-based animal health
CITES	The Convention on International Trade in Endangered Species of Wild Fauna and Flora, also known as the Washington Convention
ECTAD-RAP	Emergency Centre for Transboundary Animal Diseases – FAO Regional Office for Asia and the Pacific
EID	Emerging Infectious Disease
FAO	Food and Agriculture Organization
H1N1	subtype of HPAI
H5N1	subtype of HPAI
HPAI	highly pathogenic avian influenza
HPED	highly pathogenic and emerging diseases
IPPC	International Plant Protection Convention
NGOs	non-governmental organizations
NVS	national veterinary service
OIE	World Organisation for Animal Health
PVS	Performance of Veterinary Services
RIA	regulatory impact assessment
SOP	Standard Operating Procedure
SPS	Sanitary and Phytosanitary (Agreement on the Application of Sanitary and Phytosanitary Measures (WTO Agreement))
WTO	World Trade Organization

Introduction

WHY THE HANDBOOK WAS PREPARED: A REGIONAL FOCUS

2010 saw an increase in the number of countries where the H5N1 virus was reported – rising from 12 countries in 2009 to a total of 18 countries in 2010. Of these 18 countries, 14 were in Asia.¹ By 2009, a great deal of new and more detailed information had been accumulated at global level from multidisciplinary studies on the epidemiology of highly pathogenic avian influenza (HPAI). This information focused largely on the factors that influence the spread of the H5N1 virus and the establishment of the disease as an endemic problem in certain areas; it also focused on the control strategies that may be needed in order to contain and eradicate it. Although the handbook was developed in the context of HPAI, its content, guidelines and message are more broadly applicable to all transboundary animal diseases and, more broadly still, to regulatory frameworks for animal health.

In moving from a phase of containment of the disease towards the more ambitious goal of its complete eradication, global, multisectoral and multidisciplinary coordination and collaboration are crucial. To this end, there are significant benefits in adopting a regional approach to the challenge. Owing to the transboundary nature of HPAI and other animal diseases, and given that many countries share the same disease ecology and epidemiology, long-term national strategies must be linked with cross-border collaboration and regional approaches to disease control.²

One of the guiding principles in the preparation of the *FAO Regional Strategy for Highly Pathogenic Avian Influenza and other Emerging Infectious Diseases of Animals in Asia and the Pacific 2010–2015*, which was published in March 2010, was the “need to strengthen national and international disease prevention and emergency response capabilities”. Regional harmonization of control strategies is difficult in a regulatory environment in which there is diversity in the quality, breadth and comprehensiveness of national animal health legislation.

Governments have too often failed to acknowledge the key role of their veterinary services in protecting human health and contributing to the security of the food supply. This has had serious negative consequences for livestock production and public health, and has posed a threat to the food security, nutrition and income of rural communities who are dependent on livestock. The consequences of high-impact animal diseases have been reported to cost affected governments billions of dollars. Equally, both within governments and among many non-governmental organizations (NGOs) who support the capacity building process, there is a poor understanding of veterinary legislation and its relationship with livestock disease control policies, and the need for regulatory framework support in order to achieve animal health objectives.

¹ FAO, 2011. *Fourth Report on the Global Programme for the Prevention and Control of HPAI* (January – December 2010), Rome

² FAO. 2011. *Approaches to controlling, preventing and eliminating H5N1 Highly Pathogenic Avian Influenza in endemic countries*. FAO Animal Production and Health Paper No. 171. Rome (available at <http://www.fao.org/docrep/014/i2150e/i2150e.pdf>)

This handbook therefore serves to bridge the divide between technical and regulatory issues by outlining key elements of a policy, legal and institutional framework for animal health. It adopts an integrated approach to animal health which recognizes food safety regulation, public health and trade in animals and animal products as some of the related subsectors that affect animal health and the control of animal diseases.

Box 1 provides a distillation of key issues (relating specifically to countries with endemic infections of H5N1 HPAI) under the Food and Agriculture Organization of the United Nations (FAO) and World Organisation for Animal Health (OIE) Global Strategy on H5N1 HPAI and endemically infected countries. The approach and recommendations outlined in this handbook are aligned with this Global Strategy.

Multilateral cooperation among the countries in the region is essential for the successful implementation of the revised Regional Strategy for Highly Pathogenic Avian Influenza and other Emerging Infectious Diseases of Animals in Asia and the Pacific 2010–2015, which it was foreseen would be adopted by each country as the harmonized norm. The key to success, however, still remains with veterinary services at the national level.

OBJECTIVES OF THE HANDBOOK

This handbook, which incorporates the standards, recommendations and guidelines on animal health issued by the OIE, seeks to provide insights into the processes involved in

BOX 1

The FAO/OIE Global Strategy on H5N1 HPAI and endemically infected countries

A medium- to long-term approach (rather than just an emergency response) is needed in order to contain HPAI in endemically affected countries and subregions. This requires:

- the continued building of capacity in key institutions, including better functioning veterinary services with the necessary powers to implement essential control measures and regulations;
- sustainable adjustments to the policy sector, in order to reduce the risks of disease and infection in settings where commercial poultry production and marketing practices carry high risks of HPAI;
- effective engagement of private stakeholders (including industrial poultry producers) in these risk reduction efforts;
- sustained political commitment from the highest level of government, reflected in the provision of appropriate resource allocations and enforceable regulations;
- the application of appropriate interim control measures, including vaccination, in order to contain infection.

Source: FAO. 2011. *Approaches to controlling, preventing and eliminating H5N1 Highly Pathogenic Avian Influenza in endemic countries*. FAO Animal Production and Health Paper No. 171. Rome (available at <http://www.fao.org/docrep/014/i2150e/i2150e.pdf>)

policy development, legislative drafting and the adoption of appropriate strategies for the practical and effective implementation of animal health and disease control initiatives.

The handbook may facilitate an assessment of the comprehensiveness of animal health policies and laws by identifying the key functions of veterinary services in implementing such policies or laws. It aims to provide a range of tools and mechanisms, and explain the ways in which these are applied. It does not aim to prescribe specific actions to be taken by governments, given the diverse national, social, political and legal contexts of countries in the region. Instead, the handbook seeks to outline various policy, institutional and legal issues related to animal health and, in particular, issues related to planning for, and responding to, outbreaks of disease. Therefore, in the first instance, the handbook could serve to strengthen national responses and capacities, while also enabling a degree of harmonization in the region.

SCOPE OF THE HANDBOOK

The handbook begins with a structured discussion on the ways in which various policy options could be used to address an existing or hypothetical problem. Once selected, the relevant policy option must be implemented and legitimized, either by drafting a new statutory instrument or by amending pre-existing law. The handbook traces the elaboration strategies used to achieve the objectives set down in the law and to ensure implementation of the law through effective and feasible actions.

The first part of the handbook, which focuses on the broader context of animal health policy development, provides a summary of technical and policy lessons learned in HPAI-endemic countries. This facilitates an understanding of the tools that can be employed to respond to as well as prevent and control HPAI and other diseases. The second part of the handbook touches on institutional and administrative aspects, while the third and final part provides an overview of the essential features of animal health and disease control legislation.

It should be noted that the term "regulatory framework" is used throughout to refer to a combination of three composite elements: policies, institutions and laws.

Part 1

Policy

1.1 POLICY DEVELOPMENT

Key issues addressed in this section

- **Policy reform in the context of animal health and disease control**
- **The principles and processes involved in policy development**
- **The difference between law and policy**

1.1.1 Policy reform and context

In the context of government, "policy" means, in a broad sense, the basic principles by which a government is guided (and sometimes limited) in its management of public affairs. Policy refers to the stated objectives that a government seeks to achieve and sustain in the interests of the nation and its people.³

The general policy of a government will almost certainly reflect the political ideology from which it derives its principles, and the religious beliefs and social values of the state's citizens. More specific policies are those that are based on a government's guiding principles, and which a government creates for the benefit of the country and its people; such policies may focus on issues such as the economy, health and education. Simply put, policies are necessary in order to prevent and solve problems in a coherent and effective way.

Policies can cover any sphere of public regulation. Within the animal health and production sector, a number of discrete policies may already be in place (for example, policies governing disease outbreaks, livestock production, animal feed and animal welfare). On the other hand, a single overarching policy may apply. Policy may be unwritten and may be inferred from different regulatory tools available to the government and the approach that it takes on particular issues. It is, however, common to explicitly enshrine policy in a text that has been endorsed by stakeholders.

A comprehensive and holistic understanding of the political, economic, social, cultural and environmental context of policy reform is essential, regardless of the policy domain or the scope of the policy. Such a context comprises a number of aspects, including the country's history, constitutional framework, distribution of domestic political power, motivations of political actors and stakeholders, socio-economic positions of stakeholders, and the regulatory environment.⁴ For example, the level of commitment expressed by the livestock sector, the general public and the government will affect animal health policy. Support for

³ BusinessDictionary.com (<http://www.businessdictionary.com/definition/policy.html>); *Better livestock policies for Africa*: January 1985 – ALPAN – African Livestock Policy Analysis Network – paper No. 1 – Stephen Sandford, Livestock Policy Unit, International Livestock Centre for Africa, Addis Ababa, Ethiopia (<http://www.fao.org/wairdocs/ILRI/x5499E/x5499e00.htm>)

⁴ World Bank, 2007. *Tools for Institutional, Political, and Social Analysis of Policy Reform: A Sourcebook for Development Practitioners*

TABLE 1
Cultural and societal factors to be considered in the policy context of responses to HPAI outbreaks

Gender and age	Are the poultry keepers male or female, and have extension and outreach services taken this gender issue into consideration? Are poultry keeping registration requirements a barrier for women's engagement in poultry production? Are other issues a consideration, for example, the presence of widows, or predominantly poor women with children, whose only means of support is their poultry, and who would therefore be reluctant to notify authorities about sick birds? Are children the ones usually taking care of birds?
Hospitality	In some cultures, a visit by an important stranger requires that the host present that person with a gift as a way of expressing their gratitude. Do poultry keepers hesitate to ask a veterinary officer to examine sick poultry because they know that they must then offer a bird or two in recompense for the service provided? Are infected birds given to visitors who then take the birds back to their homes and communities?
Village life	Where are poultry kept and under what conditions are they kept at village level? How free are birds to wander and intermingle with other flocks (for example, was the poultry sector developed without much regulation)? Is equipment ever shared or loaned out? Is it regularly disinfected? Are poultry transported? How and where are they sold? How linked are villages to marketing systems?
Environment	Do certain environmental factors affect the spread of disease and the efficacy of control measures? Are water bodies that are used for domestic needs also used to accommodate potentially ill or infected wild migratory birds? Do free-range poultry use the same water bodies or wetlands as those used by wild birds? Is sufficient land available in an infected zone to quarantine birds or dispose of a large number of dead or culled birds without endangering groundwater supplies?
Cross-border activities	Is there a great deal of contact between groups on either side of a porous national border? Are informal cross-border trade or live poultry markets taking place near the border? Is there a great deal of cross-border movement for weddings, or for cultural or religious events? What is the cultural, political and economic climate on the other side of the border and what would happen in the case of an outbreak of infection? Is it possible to create cooperative agreements and plans between national authorities?
Attitude towards government	What is the reputation of the government and the veterinary services? Do people in the area view government representatives as outsiders or corrupt? Would government officers be able to gain the people's trust in order to implement prevention and response measures? Can government representatives be trusted in carrying out their duties and held accountable for their actions?

Source: Vapnek, 2010. *Regulatory measures against outbreaks of Highly Pathogenic Avian Influenza (HPAI)*.
 FAO Legal Paper Online Series

measures to contain or eradicate animal diseases may be lukewarm unless stakeholders perceive a direct impact on their livelihoods or well-being.

With specific reference to animal health, the regulatory sphere would not be limited solely to keeping animal populations free of disease; rather, it would include generally promoting animal health and placing this priority within the broader framework of economic development, public health, food security, natural resource management, agricultural intensification and trade and marketing systems. In addition, contextual factors may affect a reform process, either positively or negatively; consequences might include, for example, significant opposition from stakeholders, a lack of capacity or lack of political will among the implementing agencies.⁵

⁵ World Bank, 2007. *Tools for Institutional, Political, and Social Analysis of Policy Reform A Sourcebook for Development Practitioners*

In order to reduce and mitigate the impact of diseases, governments should be in a position to change and adapt policies by updating and reviewing control and prevention measures according to the (sometimes very rapidly) evolving situation.⁶ Table 1 illustrates some traditions and practices that are relevant to policy reform in the context of HPAI.

1.1.2 How are policies developed?

A number of principles are involved in the process of policy development⁷ by government ministries: the policy must not be in conflict with the principles or the details set down in the constitution of the country; the legislation of the country must not prevent the policy from being implemented, and the policy must be in line with international treaties, conventions or agreements ratified by the country. Indeed, the constitution, the country's laws or individual international treaties, conventions or agreements may *require* certain policies (and laws which implement such policies) to be put in place.

In addition to the constitutionality and legality of a policy proposal, consideration should be given at an early stage to the rationale and feasibility of the proposal. In other words, does a particular policy make sense and is it capable of being implemented?

The development of policy generally involves research, analysis, consultation and synthesis of information to produce recommendations based on the evidence of the compiled material.

Table 2 provides an overview of the steps to be taken during a policy development scenario where, for example, a zoonotic infection has, without warning, started to cause serious disease in humans.

For effective policy development, it is desirable to have a competent working group or decision-making team in place. Ideally, it should comprise a small number of people (i.e. between five and seven) who have a combination of technical (veterinary) and administrative or policy expertise and decision-making skills. Relevant government agencies and departments should be represented on this team.

Table 3 provides examples of the types of questions that are likely to be posed to, and must be answered by, a decision-making team during the development of a particular policy.

With regard to the importance of research, policies in the veterinary sector must be evidence-based, and must use reliable and up-to-date scientific data. Veterinary policies and tools must also be subject to ongoing critical evaluation according to current scientific evidence. This includes information on a specific virus or disease, its epidemiology in different geographical and regional systems, the efficacy of disease control options, and their impact on the respective livestock subsector and on local communities.⁸ It is therefore important to ensure that the information collected is timely and accurate; furthermore, it must be analysed and disseminated to subnational and supranational regions, allowing sufficient time to enable a prompt response to new incursions of disease. Box 2 shows the different factors that may affect the quality of surveillance and disease reporting for global and regional-level policy approaches.

⁶ FAO, 2009. *Highly Pathogenic Avian Influenza and beyond: FAO's response. Towards One World, One Health*

⁷ Office of the Auditor General, Province of Manitoba, Canada, 2003. *A Guide to Policy Development*: <http://www.oag.mb.ca/reports/PolicyDevelopmentGuide.pdf>

⁸ FAO, 2008. *Global Programme for the Prevention and control of H5N1 Highly Pathogenic Avian Influenza*

TABLE 2
Hypothetical outbreak scenario

1.	<p>Verify, define and detail the problem, i.e. the policy issue A country has endemic brucellosis (<i>Brucella melitensis</i>). In certain areas, attention has been drawn to the problem by the confirmation of cases of the disease in people who were in close contact with sheep flocks or goat herds, and where the human disease has been serious enough for some patients to require hospitalization. The government minister who is responsible for health is deeply concerned and believes that the ministry responsible for agriculture should be doing something about the problem.</p>
2.	<p>Gain a full understanding of the situation The following actions may be taken by the <i>minister responsible for agriculture</i>:</p> <ul style="list-style-type: none"> • Discuss options with the minister responsible for health and keep him/her informed until a policy decision is made. • In conjunction with the minister responsible for health, keep the head of state informed about the action being taken and issue a news release to inform the public. <p>The following actions may be taken by the <i>chief veterinary officer</i>:</p> <ul style="list-style-type: none"> • Take steps to determine the distribution and prevalence of brucellosis in small ruminants. This will involve carrying out a statistically valid serological survey combined with the collation of historical data on the diagnosis of the disease in the human population and in livestock. • Obtain estimates of the seriousness of clinical disease in sheep and goats and the level of the resulting economic loss, possibly from information gathered by questionnaires completed during the collection of samples for the serological survey.
3.	<p>Establish the evaluation criteria Usually, a working group of experts drawn from different fields set the criteria. Specific questions to be addressed in this context would include: What is the extent of the disease in sheep and goats? How many smallholders are involved? What is the risk of disease transmission from animals to humans?</p>
4.	<p>Identify the policy options The chief veterinary officer may chair a working group to consider the avenues available to deal with the problem, having taken into account the results of the surveillance exercise and the information obtained on the extent of the problem at farm level. For example, the options may be to:</p> <ul style="list-style-type: none"> • do nothing; • institute a test and cull programme; • introduce a voluntary or compulsory vaccination campaign; • through the extension services, provide guidance to those who are likely to be exposed to the infection on measures that are approved by the medical authorities and are designed to minimize the risk of contracting the disease; • ensure effective veterinary sanitary controls on the production and processing of milk and dairy products from small ruminants, including pasteurisation. <p>The above options may be mutually exclusive or mutually reinforcing. Therefore, more than one policy option may be implemented.</p>
5.	<p>Describe the policy options and distinguish between them During this first stage of the policy development process the objectives must be clearly defined and prioritized. For example, they may include:</p> <ul style="list-style-type: none"> • prevention of transmission of brucellosis to persons who have contact with infected sheep or goats; • prevention of transmission of <i>Brucella melitensis</i> to consumers of sheep and goat dairy products; • reduction in losses because of brucellosis infection in sheep flocks and goat herds.

(cont.)

Stakeholder opinion is widely recognized as integral to any policy review or development process. Effective consultation, participation and multistakeholder processes are key to developing policies based on partnerships and commitment to action. Different political systems may favour alternative forms of consultation.

Consultation during the policy development process means seeking advice and inputs, debating and clarifying issues, and obtaining reactions from relevant individuals and stakeholder groups, both within government and externally. The aim of such consultation

6. Evaluate the policy options

- The working group should, within an agreed and short time frame, consider the available options on the basis of the experience of other countries in which the control or eradication of brucellosis in small ruminants has been attempted. They should also take into account issues such as the need for registration of all sheep flocks and goat herds, for individual animal identification, and for the imposition of movement restrictions in certain areas and in certain circumstances.
- Estimates of the cost of a range of options should be made. Such options may include compensation for animals culled, the cost of vaccine procurement and whether the vaccine should be made available free of charge to livestock owners. An assessment of the resources required to implement each option should also be calculated – particularly in relation to the manpower resources required.
- Given the limited available resources, at this stage in the policy development process it may be appropriate to consider the possibility that a less important policy could be rescinded in order to allow the brucellosis control policy to proceed. This implies a requirement that veterinary sector policies should be prioritized.
- Funding may be a factor in determining the most appropriate option. For example, a testing and culling programme may be the quickest and most effective method of controlling brucellosis in this particular situation. However, because of the high incidence of the disease, financial resources may not be available to cover the cost of diagnostic procedures and compensation for animal owners. In such circumstances, the vaccination option may be chosen, so as to ensure that the control campaign is sustainable within the available budget, even though the incidence of the disease will be reduced at a slower rate.
- Interest groups, particularly livestock farmers and local health authorities, should be consulted, and their opinions should be sought on the need for action and their preferences in this regard.
- The working group will list the factors that could impact negatively on the implementation of the favoured policy options, and attempts may be made to estimate the probability that the implementation of such options would result in the overall failure of the policy.

7. Prepare for delivery

The working group should, possibly under the chairmanship of the relevant government minister, make an informed decision about what they consider to be the best option. If the minister is not present at the decisive working group meeting, his/her approval of the outcome must be obtained as soon as possible.

Unless the outcome of the decision-making process is to take no action, steps will then be taken to put in place without delay all the elements necessary for the implementation of the new policy.

8. Monitor the implemented policy and adapt it as necessary

During its implementation phase, a policy is under continual review and will be revised on the basis of, for example, refinements to correct weaknesses identified as a result of field experience, or amendments that have been made possible by new or more detailed technical information. The evolution of policy is important, as it allows the fine tuning of the implementation system and makes use of ideas originating at field level through the use of a “bottom up” information transfer mechanism.

is to reach broad agreement at the earliest possible stage of the policy development process. Individuals and groups may collaborate or compete to influence the outcome of the policy-making process.

Institutional or stakeholder mapping is a tool used to identify the positions of relevant institutions, individuals, communities and groups, as well as their respective interests and linkages or relationships at regional, national and local levels. Such mapping is useful because it enables the perspectives of stakeholders who have an interest in, or who are affected by, a particular policy to be identified, and their views to be understood and taken into account. This understanding is considered essential, given that stakeholders can either drive reform or use their influence to reverse or block change; in other words, stakeholder influence or contributions can affect a particular policy.⁹ In addition, consultation provides

⁹ World Bank, 2007. *Tools for Institutional, Political, and Social Analysis of Policy Reform: A Sourcebook for Development Practitioners*

TABLE 3
Types of questions posed to a decision-making team

1.	What precisely is the objective?
2.	What alternative approaches are available to address the issue in question?
3.	Could any of those alternative approaches realistically achieve the objective?
4.	What are the preferences of the government and the preferences of the minister responsible for this area?
5.	Are external influences a factor in making a decision?
6.	Are the available options limited by the effects of external influences?
7.	Is there a deadline for making a decision?
8.	Are adequate resources (i.e. trained, motivated and well-managed staff, equipment and other materials, funding) available to implement the policy?
9.	What particular factors could cause the selected policy to fail?
10.	Are there ways of eliminating or mitigating such negative factors?
11.	Will a regulatory impact assessment (RIA) be necessary?
12.	What type of consultation is required?
13.	Will regulatory changes be necessary in order to enable the policy to be implemented?

an opportunity to examine the relationship between formal (public or private) and informal institutions. Participation in policy reform by all relevant stakeholders is an important democratic principle and has been shown to enhance the legitimacy and transparency of the policy-making process.

Although the decision-making team is likely to be small in terms of the number of participants, various other fora and workshops involving larger numbers of stakeholders can also be used to ensure that broader issues and questions are discussed. In this way, it is possible to work towards ensuring the feasibility and appropriateness of a particular response, and to distil the various policy recommendations made during these discussions. A complementary process may involve the dissemination of objective information, so as to raise awareness, enhance transparency and encourage engagement in the policy-making process.¹⁰

It is important that a concerted effort is made by facilitators to ensure that all stakeholders are heard. This may entail holding special fora targeting women, presenting information in a manner that is understood by, and is accessible to, the local population. In areas where literacy is low, it may entail using other forms of communication. Box 3 summarizes some of the benefits and challenges associated with fostering stakeholder participation.

¹⁰ *ibid*

BOX 2

Factors that affect the quality of surveillance and disease reporting data for HPAI

Surveillance and reporting systems vary markedly between countries. For various reasons, not all cases of disease and infection are detected or reported. Moreover, even within countries, differences exist between veterinary services at the subnational level in terms of their capacity to detect and report infection and disease. Variations also occur in the information that is reported officially to the OIE.

Data on the molecular characteristics of H5N1 HPAI viruses also provide valuable information but remain incomplete.

In certain countries, gene sequence information is often available within a few days of virus isolation or receipt of a swab. As genetic information provides valuable clues to links between outbreaks, as well as clues to the possible origin of viruses, such information should be determined as quickly as possible after any outbreak, using infected samples detected during surveillance testing.

Source: FAO. 2011. Approaches to controlling, preventing and eliminating H5N1 Highly Pathogenic Avian Influenza in endemic countries. FAO Animal Production and Health Paper No. 171. Rome (available at <http://www.fao.org/docrep/014/i2150e/i2150e.pdf>)

BOX 3

Stakeholder participation in regulatory reform – benefits and challenges**Benefits**

- garners consensus, even on contentious issues;
- enhances public awareness and brings together different expertise;
- ideas and solutions are initiated from local stakeholders;
- increases transparency and accountability;
- facilitates implementation of law and policy;
- empowers otherwise neglected stakeholders.

Challenges

- risk of increasing conflicts because it is rarely possible to satisfy all interests;
- perception that the decision-making of official or formal structures is being eroded.

Source: World Bank, 2007. Tools for Institutional, Political, and Social Analysis of Policy Reform: A Sourcebook for Development Practitioners

It is important to note that participation should be informed, free and meaningful. This means that stakeholders should not be coerced into a particular position; their particular methods of communication should be respected and they should be given all the information they need to make an informed decision. Participation governs not only the policy-making process and the law-making process (i.e. by contributing to the formulation of a policy or law), but also the implementation of policy and law. One possible way of ensuring participation is to include specific provisions in the law, such as a requirement for established committees that empower stakeholders to participate in decision-making and management.

1.1.3 Law and policy

In order to understand the regulatory framework as a whole, and to clarify the link between policies for the control and eradication of high-impact diseases of livestock and animal health legislation, it is first necessary to emphasize the difference between law and policy. Policy generally sets out in broad terms the goals, targets and objectives of the government on a particular issue, and it establishes the key methods and mechanisms used to achieve these targets. The law is one of the tools that can be used to implement policy.

Laws are more precisely drafted than policy documents, setting out specific standards, procedures and principles that must be followed. Laws generally establish an institutional framework for enforcement, including the powers and functions of public bodies as well as provisions that can be used to hold both public and private actors accountable.

Policy legitimization, in a broad sense, means widespread social acceptance of a policy. In a more narrow interpretation, it is the official sanction or recognition of a policy, frequently through enactment of a law. It may be necessary to amend the existing regulatory framework or to introduce a new legal instrument to allow a particular policy to be implemented and enforced.

1.2 IMPLEMENTATION OF POLICY

Key issues addressed in this section

- **How are the chosen policies implemented?**
- **How can implementation be approached in a coherent way?**
- **How is a contingency plan different from an action plan?**
- **Why are contingency plans important?**

Focusing on the implementation process facilitates an understanding of how, and under what circumstances, a particular policy intervention may or may not work.¹¹

Common elements in the implementation of a policy generally include: (i) legislative analysis and identification of necessary law reform; (ii) procurement of resources; (iii) elaboration of a written action plan; (iv) training of staff; (v) design and implementation of an awareness campaign; (vi) preparation and distribution of a manual of standard operating procedures (SOPs); and (vii) establishment of a monitoring and evaluation system.

¹¹ World Bank, 2007. *Tools for Institutional, Political, and Social Analysis of Policy Reform: A Sourcebook for Development Practitioners*

Legislative analysis and necessary law reform is examined in detail in Part 3 of this handbook.

1.2.1 Strategy, action plans and contingency plans

A. Strategy

“A strategy is a plan, method, or series of manoeuvres by which a specific goal or result is achieved.” In addition, a strategy can be the “plan that integrates an organization’s major goals, policies, and action sequences into a cohesive whole.”¹² The strategy or plan specifies what action will be taken to deal with a range of events that will occur, or may occur, during the implementation of the policy.

When a policy is inherently complex, such as a policy on the eradication of a disease, a series of inter-related strategies will be necessary for the implementation of the policy components. The range of strategic choices available may be limited by factors such as financial and material resources; staff numbers, competence and motivation; the structure and effectiveness of the management system; political commitment and public opinion.

In addition to prevention mechanisms, disease control strategies commonly contain two additional elements: early detection (preparing for the disease and identifying it at an early stage) and early response (responding effectively in order to contain it). Both the administrative (technical and operational) and legal frameworks must enable the quick identification of, and response to, a disease. The procedures, systems and processes involved in a detection and response structure will be set down in a legal framework, which will facilitate rapid disease reporting, the establishment of a committee or organization with the legal mandate to control the disease, and a series of standard operating procedures.¹³

Countries should have in place long-term technical strategies and action plans that are responsive to local conditions to contain diseases and are designed to modify high-risk practices. With specific reference to H5N1 HPAI, while a number of endemically infected countries currently do not have specific plans for eliminating the virus, most have short- to medium-term plans or strategies for its control and prevention.¹⁴ A programme is a synonym for a plan and may, therefore, also be used to refer to a strategy in the broader sense of that term.

B. Action plans

Action plans are necessary to ensure that all of the strategies for the realization of the policy are fully and consistently applied. In cases where elements of action plans (for existing problems) and contingency plans (for future or potential threats) impose legally binding measures, the plans themselves may need to be given legal status in the relevant legislation. Manuals of procedures, based on these plans, should be compiled. They may serve as comprehensive guides for field staff, and they may also be used as manuals for training and aids for the assessment of staff performance. National animal health legislation should

¹² Strategy: *Reference for Business Encyclopedia of Business*, 2nd edition.
(<http://www.referenceforbusiness.com/small/Sm-Z/Strategy.html>)

¹³ Vapnek, 2010. *Regulatory measures against outbreaks of Highly Pathogenic Avian Influenza (HPAI)*. FAO Legal Paper Online Series

¹⁴ FAO, 2011. *Approaches to controlling, preventing and eliminating H5N1 HPAI in endemic countries*. Animal Health and Production Paper

require that such action plans (for endemic diseases) and contingency plans (for exotic disease outbreaks) are drawn up and that they are always implemented in disease control programmes. The plans should have a legal foundation either explicitly or implicitly, based on the powers of the competent authority to approve such action.

Plans for the prevention, detection, diagnosis, containment and eradication of livestock diseases fall into several categories. Where diseases are already present in a country, specific action plans should be in place for their control or eradication. For example, because a surveillance programme and epidemiological sampling are essential components of the strategy to combat HPAI, the action plan in countries where HPAI is present should incorporate the procedures required for each of these elements. For diseases that are not yet present in a country, but pose a potential threat, specific or generic contingency plans should be in place.

Some important factors in relation to action plans (discussed further in Table 4) include the following:

1. The text of the action plan must be complete in every detail.
2. The plan must be endorsed by all authorities affected by its implementation.
3. The plan must be kept under continuous review.
4. The plan must be amended, as required, following changes in the situation and following receipt of relevant new information about the disease and its behaviour.
5. Up-to-date versions of the plan must be constantly available to those involved in the implementation of the policy and to interested stakeholders.

TABLE 4
Action plan details

1.	The legislation under which the disease control activities will be carried out;
2.	the chain of command and line of communication in the veterinary services and the relationship between the various parts of that organization;
3.	the arrangements that may be necessary for the efficient and effective operation of the national command centre and any regional control centres or local subcentres;
4.	the staffing of the centres, with descriptions of the functions and responsibilities of each post, so as to ensure that there is no confusion about who does what;
5.	the membership, functions and responsibilities of a specialist decision-making group within the national command centre organization;
6.	the arrangements that are in place for the supply of equipment, facilities and services;
7.	the arrangements for the removal and disposal of carcasses in a manner that will avoid any risk of spreading disease or of environmental damage;
8.	emergency vaccination campaigns, if appropriate;
9.	the budgetary lines from which all activities will be funded;
10.	communication within the service and between relevant ministries, disease awareness campaigns, publicity activities and contact with the news media;
11.	programmes for the training of staff.

C. Contingency plans

Contingency planning generally involves the preparation of a response to future events whose occurrence may be difficult to predict. The response is structured in such a way that once the incident has occurred, an attempt can be made to control it using certain planned interventions designed to influence the development and outcome of the event. In this way, an attempt is made to limit the scope and duration of the emergency and to minimize the resulting damage.

Information may be available to help predict, foresee or prevent the occurrence of a disease outbreak. This information may be derived through mechanisms such as international disease notifications, surveillance and early warning, routine animal movement controls and prophylactic measures.

Contingency planning entails consideration of the different types of disease control strategies that are available, the implications for their use and a predetermination of the most appropriate strategy, given different circumstances or disease outbreak scenarios. Box 4 provides an example of the different options considered by the People's Republic of China through the creation of zoning for disease control of HPAI. It should be noted that Box 4 is for illustrative purposes only. Specific responses and options should be considered on a regional, national and subnational level. Such options would also vary according to veterinary system capacities; geographical, ecological and epidemiological environments; poultry production, and marketing practices.

Therefore, in addition to facilitating an orderly response to the emergency, contingency plans may ensure that the available resources can be mobilized quickly and in a coordinated way, thus avoiding the wasteful use of financial resources. Contingency plans would minimize and alleviate the damage resulting from the emergency situation and would ensure that people affected by the emergency are given prompt advice and assistance. Such plans would also enable the quick, regular, accurate and complete transmission of information to news media and the public throughout the emergency.

In contingency planning, it is important to establish where the necessary funding will come from and to ensure that there is a quick, transparent and effective way of accessing and distributing this funding.¹⁵ It is essential to communicate with relevant ministries in advance of outbreaks, so that the additional requirements of the veterinary services in the event of a disease emergency are understood. Emergency funding should be available at short notice. Another key issue relating to funding is the question of compensation. In addition, resource planning entails a determination of the response requirements in terms of staff, expertise and equipment (medical, logistics, IT, etc.). Staff should be trained in advance, so that the requisite skills are available during emergencies and disease outbreaks.¹⁶ Furthermore, simulation exercises are necessary in order to identify shortcomings and flaws in the planned responses, and also to ensure that data, equipment etc. is kept up to date and is in working order.

Contingency plans must take into account the national and local situation in addition to issues such as the structure of the poultry sector, veterinary services capacity, geographic

^{15, 16} FAO, 2009. *Preparing for Highly Pathogenic Avian Influenza*. Animal Health and Production Manual

BOX 4

Options for HPAI control in China

Three zones were planned. These comprised **infected points**, **infected zones** (i.e. within a 3 km radius of infected points) and broader **threatened zones** (i.e. within a 5 km radius of infected zones).

- Stamping out:** All poultry within infected zones would be stamped out.
- Emergency vaccination:** All susceptible poultry in the threatened zones would be compulsorily vaccinated with the vaccines approved by the veterinary services. Only healthy birds would be vaccinated.
- Disposal:** All poultry carcasses and poultry products in infected points, along with excretion material, contaminated feed, litter and sewage from the infected points would be subject to biotreatment or disposal.
- Cleaning and disinfection:** All contaminated items within the infected zones, i.e. transportation vehicles, utensils, poultry counters and grounds would be cleaned and disinfected.
- Movement control:** Warning signs would be widely posted around the infected zones; disinfection stations would be set up at the transportation entrances of infected zones in order to disinfect vehicles and items entering and exiting zones; and movement of all susceptible live birds and their products would be controlled.
- Closing the market:** All poultry and poultry product markets in infected zones as well as live bird markets within a 10 km radius of infected zones would be closed.
- Tracing:** If poultry and poultry products were sold during the incubation or clinical manifestation period, or otherwise moved, tracing would be conducted on the potentially infected or contaminated items to prevent these items from spreading disease.
- Financial support:** Financial support systems would be established for all owners of poultry destroyed because of HPAI.
- Public health:** Surveillance of staff involved in poultry rearing, trade and transportation and processing units, especially staff working in the infected zones, should be intensified and epidemiological investigation should be conducted. Stringent protective measures must be implemented by staff participating in the destruction of infected birds and the cleaning of contaminated premises.

Adapted from: 'Zoning: the case of China'. FAO. 2009. *Preparing for Highly Pathogenic Avian Influenza*. FAO Animal Health and Production Manual No. 3 Revised Ed.

BOX 5
Common elements of contingency plans

1. detailed description of the disease and its status within the country;
2. resource inventory (personnel, equipment and funds);
3. components of an action plan;
4. clear responsibilities for relevant agencies;
5. composition of the emergency committee, responsibility for overall coordination, and clearly defined individual responsibilities.

and environmental considerations, transportation and communication, and state or provincial relationships with central government authorities. Although national plans are highly context specific, some common elements can be distilled to form the basic structure (see Box 5).

FAO's *Manual on the preparation of national animal disease emergency preparedness plans*¹⁷ recommends formulating four sets of complementary technical contingency plans. As follows:

- i. contingency plans (general and specific) detailing the strategies to detect, control and eradicate the disease;
- ii. standard operating procedures;
- iii. enterprise manuals detailing zoonosanitary guidelines for businesses that may be involved in an emergency animal disease outbreak;
- iv. job description cards for all individual veterinary officers.

While revisions to policy will result in the need to amend action plans, contingency plans and manuals of procedures, the latter would require regular review in any event, in order to ensure that data is up to date.

TABLE 5
Designing contingency plans

Considerations that should be taken into account in order to design an effective contingency plan	
1.	Do not wait until the threat is imminent to prepare the plan.
2.	Make use of already existing structures and organizations (do not create new entities unnecessarily).
3.	Give details of the chain of command and line of communication.

(cont.)

¹⁷ Available at <http://www.fao.org/docrep/004/x2096e/x2096e00.htm>

TABLE 5 *cont.d*

4.	Define thoroughly and clearly for all organizations involved the roles and responsibilities of each organization in an emergency. There must be no confusion about who does what. (The organizations involved will include the relevant ministries and departments, the national emergency response unit or its equivalent, the police and the national defence forces).
5.	Avoid gaps or overlaps when defining responsibilities.
6.	Create theoretical structures, including locations, for the central command centre (which may already exist and may be fully equipped) and for local control centres.
7.	Define thoroughly and clearly the relationships between the organizations involved.
8.	Carefully select competent staff to fill the key posts in the central command centre and the local control centres.
9.	Ensure that in the implementation of the emergency measures: <ul style="list-style-type: none"> (i) a functioning mechanism is in place to bring together, at very short notice, the personnel responsible for implementing the measures; (ii) the best possible use is made of the available knowledge, training and experience; (iii) complete descriptions are prepared of the tasks to be carried out by every individual participant in the implementation of the measures; (iv) systematic theoretical and practical group training is provided for all administrative, professional and technical staff who will be involved; (v) the contingency plan is tested during such training exercises and then refined, having incorporated the lessons learned; (vi) the chain of command and line of communication is short and is accepted by all participating individuals and organizations; (vii) there is an effective system of communication in both directions through the chain of command and line of communication; (viii) the process of decision-making is well-informed and properly structured; this requires the availability of advice from experts who are neither part of the decision-making team nor in any way involved in the decision-making process, and the empowerment of an individual team leader to make final decisions when unanimity is lacking.
10.	Establish a small, permanent, but part-time organization to keep the plan up to date, so as to ensure that it can be speedily activated and also in order to guarantee that the trained staff and other necessary resources can be made available without delay.
11.	Strictly and consistently enforce the control measures, which must have the force of law, and apply penalties for offences.

1.2.2 Manual of Procedures

An additional component of an action plan or contingency plan is the Manual of Procedures/Instructions or Standard Operating Procedures (SOPs) for staff who will be implementing the plan. This is a comprehensive technical and practical guide to field activities (see Table 6 for examples of the contents of such a manual). The manual would also be used for the theoretical and practical training of staff and as the basis for the assessment of the effectiveness of staff performance in the implementation of the disease control policies.

TABLE 6
Manual of Procedures

The Manual of Procedures will list the legal responsibilities and powers of veterinary inspectors and other members of the disease control team, and will provide detailed instructions on such matters as:	
1.	actions to be taken when a notifiable/scheduled/listed disease is reported as being present or is suspected of being present: (i) investigation; (ii) clinical examination; (iii) collection and dispatch of diagnostic samples; (iv) temporary movement controls; and (v) preliminary epidemiological enquiry.
2.	reporting to the central command centre;
3.	action to be taken when a scheduled disease is confirmed as present: (i) the establishment of control zones and the enforcement of controls within those zones; (ii) valuation of livestock on the infected holding/epidemiological unit; (iii) humane killing of susceptible animals on the infected holding/epidemiological unit; (iv) safe disposal of the carcasses on the infected holding/epidemiological unit; (v) seizure and destruction of contaminated animal products, waste, feed and other materials; (vi) payment of compensation for animals killed and materials seized; (vii) cleaning and disinfection of buildings, contaminated areas, vehicles, equipment etc.; (viii) reporting all activities associated with the outbreak.
4.	tracing of movements to and from the infected holding or epidemiological unit to determine, if possible, the origin and spread of the infection and also to determine what additional holdings or epidemiological units may be at risk;
5.	the valuation, humane killing and safe disposal of susceptible animals on holdings or epidemiological units considered to have been at particular risk of exposure to the infection, given the available epidemiological information and, where appropriate, after careful risk analysis;
6.	the lifting of restrictions on the holding or epidemiological unit when the outbreak is officially at an end;
7.	repopulation of holdings or epidemiological units and the recovery process;
8.	emergency vaccination campaigns.

1.3 REGIONAL CONSIDERATIONS

Key issue addressed in this section

- **What regulatory considerations have been highlighted in recent meetings for emphasis at a regional level?**

This section takes a closer look at regional harmonization of policies for the control and eradication of HPAI and other emerging infectious diseases, which could be used to set out elements and mechanisms in the law. It is the premise of this handbook that regional and subregional collaboration is instrumental in the creation of a consolidated, robust and

BOX 6

Regional issues for consideration at national level

- Countries should share experiences in order to learn from the successes and failures of others.
- Countries should cooperate in the prevention of illegal cross-border movements of livestock and products of animal origin.
- Countries should take coordinated action when cross-border incursions occur.
- Countries should share epidemiological data that could provide early warnings of possible risks; they should also use all available data to optimize their tactics for disease control and eradication;
- Countries should carry out complete epidemiological investigations of disease outbreaks, in particular to determine putative sources of the infection and its possible dissemination to new foci.
- Countries should adopt successful, universally applicable and harmonized techniques.
- Countries should adopt a multidisciplinary approach to disease control, particularly in the case of zoonotic diseases, for which One Health principles should be applied;
- Countries should look towards the longer-term objective of disease eradication, rather than just settling for the half-way status of containment.

flexible policy and legislative infrastructure through which HPAI and other transboundary diseases of livestock may be more successfully controlled and eradicated.

The *FAO Regional Strategy for Highly Pathogenic Avian Influenza and other Emerging Infectious Diseases of Animals in Asia and the Pacific 2010–2015* advocates a longer-term approach, which should include risk-reduction measures to minimize HPAI transmission, particularly through the enhancement of biosecurity and more effective regulation of the market chain. It proposes addressing threats on a systematic basis, recognizing the complex web of human, livestock and environmental issues involved and the need to address underlying weaknesses in preventive measures. The One Health initiative represents a comprehensive, multisectoral, integrated approach to emerging infectious disease (EID) prevention and control, and must be taken into account in the elaboration of policies in the veterinary sector.

The Strategic Framework set out in the *FAO Regional Strategy for Highly Pathogenic Avian Influenza and other Emerging Infectious Diseases of Animals in Asia and the Pacific 2010–2015*, which was published in March 2010, comprises support by the Emergency Centre for Transboundary Animal Diseases – FAO Regional Office for Asia and the Pacific (ECTAD-RAP) for FAO country teams in developing appropriate, country-specific prevention and control strategies for HPAI, with particular attention paid to the countries represented in these geographic clusters. The major elements of these strategies are as follows:

- Placing a greater emphasis on a long-term approach to HPAI control in endemic countries by applying risk-reduction measures including:
 - preventive vaccination activities that are properly planned and well executed, so as to achieve high coverage; are properly monitored, so as to ensure satisfactory flock protection, and are either economically sustainable or else planned with a particular short-term objective and with an exit strategy;
 - improving biosecurity of poultry production, with particular focus on farming practices in the small-scale commercial sector, including addressing the issue of grazing ducks;
 - improving regulation and management of poultry movement along market chains, including cross-border movements, with appropriate veterinary hygiene measures to minimize the spread of the virus and improved public hygiene in markets to protect consumers from H5N1 infection and other zoonotic and food-borne diseases;
 - promoting engagement between government regulatory authorities and commercial industry, so as to achieve solutions to HPAI control that are technically sound, economically feasible, culturally acceptable and have regard to livelihoods as changes occur in commercial poultry production and marketing practices.
- Advocating and assisting collaboration between countries in geographic clusters by:
 - jointly addressing cross-border livestock trade management; and
 - harmonizing livestock movement and disease control regulations and interventions between countries, as appropriate, in order to minimize undesirable informal trade across international borders.
- Promoting the application of appropriate response activities, so as to limit the risk of human exposure to the H5N1 virus:
 - outbreak response includes culling and disposal of infected poultry and poultry considered to be at high risk of infection, decontamination of the immediate environment, containment of the disease by managing movement from the area, tracing of the source and likely spread of the disease, where possible;
 - improved control activities by the application of standard operating procedures for humane killing, disposal of carcasses and disinfection;
 - deployment of rapid response teams that have received specialized training in HPAI diagnosis and outbreak containment, including community engagement;
 - surveillance in the high-risk control area, and backward and forward tracing from identified outbreaks, so as to determine the source and the extent of spread, and quickly respond to related outbreaks;
 - engendering community participation in suspected outbreak reporting and compliance with outbreak containment activities, including compensation for compulsory slaughter.

Part 2

Institutions

Institutions play the crucial role of implementing policy and legislation within the regulatory framework. In this handbook, the term institutions is used to mean the administrative structure of the government, parastatal bodies and, where expressly stated, private actors. While this part of the handbook is brief, it serves to take a closer look at the institutional structure for animal health and disease control. Greater detail regarding functions, activities and responsibilities of the competent authorities can be found in Parts 1 and 3.

2.1 NATIONAL VETERINARY SERVICE (NVS)

Key issue addressed in this section

- **Structure, role and functions of a national veterinary service (NVS)**

2.1.1 Structure

A well-organized and functioning veterinary service is the first precondition for the development and implementation of a successful animal health policy. Box 7 provides an overview of the rationale for animal health services policy and structure. It provides a useful link between the policy discussions described in Part 1 and the functions of veterinary services outlined in this section.

The national veterinary service (NVS) is the authority designated by a country as responsible for its veterinary services; it can be a self-standing ministry or, more often, a department under another ministry, usually the ministry responsible for agriculture. Key roles of the NVS include promoting animal health and protecting livestock and other animals, and enhancing market access for live animals and animal products. In some countries, the role of the NVS also extends to protecting public health, either from zoonoses or from food-borne diseases that are of animal origin. In other countries, the NVS is also the authority that is responsible for aquatic animal health. The specific functions of the NVS are examined below.

The NVS plays a role in implementing, at national level, the international standards for animal health (recognized in the World Trade Organization (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures – the SPS Agreement – as being those of the World Organisation for Animal Health (OIE)). Therefore, the NVS also contributes towards compliance with international (trade) obligations.

As international technical requirements increase in line with trade growth and higher consumer expectations, a concomitant approach by the NVS is required in order to respond to the needs of national stakeholders and international trading partners. The SPS Agreement endorses the right of each WTO member to impose sanitary and phytosanitary (SPS) measures for the protection of plant, animal and human life or health, provided they are

BOX 7

Animal health services policy

In order to obtain the necessary political, economic and public support, animal health services policy should attempt to contribute effectively to the overall development of a country, aiming at improving the standard of living of its inhabitants.

An effective and desirable animal health services policy should contribute in a practical way to reducing food losses due to animal morbidity and mortality, increasing productivity in animal population/herd yields and draught power, protecting human health against diseases transmissible from animals and ensuring humane treatment of animals.

The variety of animal health policy includes different animal health services organizations and programmes. The spectrum varies from country to country. The activities of the animal health services are carried out by government veterinary services staff (completely or partly free of charge), but certain functions may be delegated to private parties.

Animal health services strategy in developing countries reflects the application of general policy. It identifies the concept, priorities and principal objectives of animal health programmes. The strategy should also determine the systems required to achieve these objectives and to solve animal problems in the most effective way. It should respect the country's needs and conditions and stage of development, as well as economic and organizational possibilities.

Extract from: FAO, 1991. Guidelines for strengthening animal health services in developing countries

transparent, science-based and are based on a risk assessment. Paragraph 4 of Annex A of the Agreement defines risk assessment as:

"The evaluation of the likelihood of entry, establishment or spread of a pest or disease within the territory of an importing Member according to the sanitary or phytosanitary measures which might be applied, and of the associated potential biological and economic consequences; or the evaluation of the potential for adverse effects on human or animal health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs."

(emphasis added)

Even though wider aspects relating to WTO issues generally fall under the mandate of trade authorities, technical requirements of compliance are the responsibility of the NVS.

With specific reference to disease control, arrangements should be put in place to ensure cooperation with the veterinary services of neighbouring countries on the issue of animal disease control in border areas, and also in order to create linkages, information networks and common initiatives for transboundary disease control activities.

The OIE points to the need for the NVS to be independent and objective, providing decisions that are both transparent and science-based; additionally, the resulting findings and consequent activities of the NVS need to be immune to political pressure.¹⁸ In fact, the OIE notes that the credibility of the NVS, from the perspectives of both in-country stakeholders and other countries, is contingent on the effectiveness of domestic animal health programmes and the response of the NVS to animal disease emergencies.¹⁹ Box 8 below sets out the four essential components of an NVS.

In relation to the first point in Box 8, the NVS should be able to demonstrate that it has the capacity, supported by appropriate legislation, to exercise authority over all animal health matters. Attention therefore needs to be paid to allocating resources for staff development and training in animal health matters. Frequently, the law creates an obligation for the NVS to provide training for veterinarians, veterinary paraprofessionals and other staff working on animal health issues, in order to ensure that they have up-to-date knowledge. The provision of training may be restricted by the funding available in the country, but it can still be achieved progressively, based on targeted training according to priorities for implementation of the law.

The structure of animal health services is shaped by the administrative, political and financial framework in the country concerned, and should be such that it is flexible and responsive to disease emergency situations. It should be able to reach the entire geographical territory of the country. With respect to disease control, the nature of action and contingency plans may depend on whether the administrative structure is centralized or decentralized.

A more centralized organization may offer strong national prevention, control and eradication, increased uniformity of rules and methods as well as coordination.²⁰ In this structure, single or unitary plans are frequently used in emergency responses.

BOX 8

The OIE's four fundamental components of an NVS

- human, physical and financial resources to attract resources and retain professionals with technical and leadership skills;
- technical authority and capability to address current and new issues, including prevention and control of biological disasters, based on scientific principles;
- sustained interaction with stakeholders in order to stay on course and execute relevant joint programmes and services;
- ability to access markets through compliance with existing standards and the implementation of new disciplines such as the harmonization of standards, equivalence and zoning.

Source: World Organisation for Animal Health website <http://www.oie.int>

^{18, 19} Available at: <http://www.oie.int>

²⁰ FAO, 1991. *Guidelines for strengthening animal health services in developing countries*

Decentralized or federal organizational structures of services are advantageous for identifying and solving local problems, treating diseased animals, accessing hard-to-reach areas and increasing animal productivity.²¹ Decentralized veterinary services enable closer cooperation with, and access to, farmers and local communities. Depending on the degree of autonomy of the local or regional authority, the latter may develop individual emergency response plans. If this is the case, such plans should be linked to, and be integrated with, national-level coordinated plans. Effective action plans for disease control require that regions, districts or states do not exercise autonomy during an emergency.²² At the various district or provincial levels, subordinate chief veterinary officers (CVOs) supervise provincial diagnostic laboratories, veterinary clinics, storage facilities etc. However, one of the most crucial tiers of the animal health service structure is the field extension service, which is in direct contact with producers, animals and their products, and is carried out at the village, farm, herd/flock and individual animal levels.²³ It is suggested that the animal health and production extension staff operate separately from the agronomy extension services, so as to maintain the distinct expertise required for each position.²⁴

Where animal health staff i.e. veterinarians, veterinary paraprofessionals or veterinary assistants are dispersed throughout the administrative structure, there is a greater likelihood of effective responses in the event of an emergency. However, where these individuals are not present in strategic locations, such as rural areas or linking local and central levels, or where general field staff are assigned to positions without being equipped with the training to recognize animal diseases, the disease response mechanism may be compromised. It is therefore recommended that an assessment be made of how well the chain of command functions in an emergency scenario.²⁵

In order to do this, the government should consider establishing permanent training and awareness programmes to inform veterinarians, veterinary paraprofessionals and certain qualified field staff (either public or private) about various types of transboundary animal disease, how to recognize certain diseases and what steps should be taken where a disease is identified.²⁶ The government may also consider issuing standing orders for field staff detailing (a) the command structure, so as to ensure that the notification process goes from the source of the disease to the CVO and (b) the immediate measures that can be taken to address the disease outbreak in accordance with the action plan, while awaiting further instruction from the central authority.²⁷

2.1.2 Functions

The powers and responsibilities of the NVS should have a basis in law, in order to ensure that its activities are not challenged on legal grounds, and also in order to clearly establish the role of the NVS (this is discussed in detail in Part 3). Implementing regulations and administrative decrees and circulars will also serve to flesh out procedures, processes and manuals. The following functions of a typical NVS are those that would be included in primary legislation, and are enumerated here so as to provide an indication of the parameters of its expertise and activities.

^{21, 24, 26, 27} *ibid*

^{22, 25} Vapnek, 2010. *Regulatory measures against outbreaks of Highly Pathogenic Avian Influenza (HPAI)*.
FAO Legal Paper Online Series

²³ FAO, 1991. *Guidelines for strengthening animal health services in developing countries*

- Prevent and control the entry, establishment or spread of notifiable/listed diseases and other pathogens that can cause disease in animals across the entire territory of a country, including in animals entering and exiting the territory;
- Develop and update a list of notifiable diseases and establish import requirements in accordance with that list;
- Approve the necessary sanitary measures for preserving the animal health status;
- Undertake emergency action for disease and pathogen outbreaks, and inform and collaborate with relevant ministries and departments;
- Carry out and coordinate detection, surveillance and monitoring activities relating to animal health epidemiological matters;
- Issue international veterinary certificates;
- Develop a system of inspection of animals and animal products;
- Regulate the import, export, manufacture, packaging, labelling, storage, transport, distribution, quality, advertising, sale and use of animal feed, veterinary biologicals and veterinary drugs (although this will depend on the respective competences of other responsible authorities, for example, food safety, drugs and pharmaceuticals);
- Develop and implement systems for animal identification and animal traceability;
- Operate quarantine stations and facilities;
- Evaluate equivalence of sanitary measures taken by trading partners;
- Liaise with the competent authorities for food safety, customs, trade, the environment and human health in carrying out activities;
- Make notifications to the OIE in compliance with international obligations (for OIE/ WTO member states) and provide information in response to requests from trading partners;
- Undertake risk analysis or assessment studies;
- Promote the implementation of good veterinary practices;
- Organise awareness-raising and training activities;
- Approve and implement animal welfare standards;
- Coordinate with other competent authorities, such as food safety authorities.

The NVS is normally headed by a national CVO who is responsible for the technical activities and operations of officers under the NVS. He/she is also responsible for the technical supervision of private enterprises and cooperative enterprises in the areas of animal disease control and animal production.²⁸ While private veterinarians play a role in protecting and enhancing animal health, the focus of this part of the handbook is on public veterinary services.

Notwithstanding this, the scope for partnership between the public and private sectors should be considered, particularly where constraints on funding and staff resources impede the ability of the NVS to carry out its work. The active participation and investment of the private sector in ensuring quality standards and evaluation has been recognized by the OIE.²⁹ Under specific arrangements (complete with the necessary legal safeguards explored below), partnerships with private sector producers, traders and enterprises can be useful in surveillance, livestock production and communication and outreach. Non-governmental

²⁸ FAO, 1991. *Guidelines for strengthening animal health services in developing countries*

²⁹ Available at <http://www.oie.int>

organizations, research institutions and reference centres have a role to play in supporting the NVS (for example in cases of disease outbreaks), and also more generally in relation to the broader goal of protecting a country's animal health status. The drafting and implementation of laws or policies should be carried out with the consultation and participation of both public and private stakeholders.

2.1.3 Capacity of veterinary services to prepare and respond to HPAI

Generally speaking, developing countries are hindered by a lack of capacity to identify and respond swiftly and effectively to cases of infection and disease outbreak. The reasons for this lack of capacity with specific reference to H5N1 HPAI include:³⁰

- insufficient budgets;
- an inadequate number of available staff;
- lack of training for frontline staff;
- The drivers of value chains are not well understood by veterinary and animal production staff.
- The skills to design and implement appropriate changes to production and marketing systems are often lacking in veterinary and production departments.
- Countries with strong decentralization have poor communication between provincial or district level activities and poor coordination at national level.

In many countries in Asia and the Pacific region there is a significant reliance on community-based animal health (CAH) workers who are veterinary paraprofessionals. Discussions at national and international level currently centre on the quality of care, accessibility and sustainability of animal health care and the issue of institutionalizing CAH systems in order to achieve wider animal health coverage at village and community levels.³¹ CAH workers are recognized as important players in achieving poverty-reduction development goals for the livestock-dependent poor, given their ability to reach and work in rural (and remote) areas.³²

Nonetheless, CAH services are not well integrated into the activities of the NVS and, traditionally, they have been neglected in the context of wider animal health policy issues. This is particularly the case in regions other than Asia which, when compared with other regions, demonstrates a greater link between CAH workers and government staff.³³ There have been calls to increase the degree of formal institutionalization (i.e. recognition and integration into formal animal health care structure) and to develop standardized curricula with set training periods for CAH workers. This may be particularly important for disease control, as some findings suggest that CAH workers may not have the skills or equipment to recognize disease.³⁴

The quality of veterinary services is also affected by laboratory and diagnostic capacity. Epidemiological surveillance is crucial for rapid detection of HPAI, as is laboratory capacity

^{30, 34} FAO, 2011. *Approaches to controlling, preventing and eliminating H5N1 HPAI in endemic countries*. Animal Health and Production Paper

^{31, 32} Riviere-Cinamon, 2005. *Animal Health Policy and Practice: Scaling-up Community-based Animal Health Systems, Lessons from Human Health*. Pro-Poor Livestock Policy Initiative (PPLPI) Working Paper 22. FAO, Rome

³³ ibid

to detect infection and to establish an accurate diagnosis in a timely manner.³⁵ Countries are encouraged to carry out regular epidemiological studies in order to identify and understand local features that may impact disease emergence and spread.³⁶

2.2 THE OIE PERFORMANCE OF VETERINARY SERVICES (PVS) TOOL

Key issues addressed in this section

- **What is the OIE PVS Tool?**
- **What is it used for?**

The OIE has developed the Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool), which is designed to assist NVS authorities to “assess their current level of performance, to identify gaps and weaknesses in their ability to comply with OIE international standards, to form a shared vision with stakeholders (including the private sector) and to establish priorities and carry out strategic initiatives.”³⁷

The Tool is referenced in this handbook to illustrate the options available to countries in terms of mechanisms to assess and strengthen their NVS. Box 9 below provides a snapshot of the gains to be made by using the OIE PVS Tool.

BOX 9

Benefits and uses of the OIE PVS Tool

- a general assessment of the overall performance for each of the four components (see Box 8 above) and a relative performance rating within each of the critical competencies;
- a basis for comparing the performance of the NVS with that of other relevant government services in the region or globally, in order to explore areas for cooperation or negotiation;
- facilitating the process of verifying compliance with the OIE standards and assessments of the NVS by external or independent bodies;
- where gaps in the legislative framework are identified, the specific actions needed to modernize the veterinary legislation are given;
- through the OIE PVS Gap Analysis, helping countries to identify priorities and present justifications for national or international financial support;
- providing a basis for establishing a routine monitoring and follow-up mechanism on the overall level of performance of the NVS over time;
- helping to determine the benefits and costs of investing in the NVS and identifying the actions and securing the investments that are needed to help improve compliance with the OIE standards for good governance.

Extract from: OIE PVS Tool website. <http://www.oie.int/en/support-to-oie-members/pvs-evaluations/oie-pvs-tool/>
Available at <http://www.oie.int>

³⁵ FAO, 2008. *Global Programme for the Prevention and control of H5N1 Highly Pathogenic Avian Influenza*

³⁶ *ibid*

³⁷ <http://www.oie.int/en/support-to-oie-members/pvs-evaluations/oie-pvs-tool/>

A PVS Gap Analysis mission enables an assessment of the NVS compliance with OIE quality standards, a joint elaboration of expected outcomes for the critical competencies, the activities to be carried out in order to achieve these competencies, and the resources required for this. These activities are carried out while focusing on national needs and priorities. Thus, the PVS Gap Analysis Tool is essentially “a quantitative evaluation of a country’s needs and priorities based on the outcome of the independent external evaluation of the country’s veterinary services using the OIE PVS Evaluation Tool.”³⁸

³⁸ *ibid*

Part 3

Legislation

This part of the handbook summarizes the key elements involved in assessing and drafting national legislation governing animal health and disease control. It is not intended to serve as a comprehensive guide to aid the drafting of animal health legislation. Rather, it is designed to simplify relevant concepts and to create a better understanding of the aspects to consider during legislative reform. This part of the handbook also emphasizes the specific areas in animal disease control that require legal authority or legal basis.

3.1 WHAT IS LEGISLATION AND WHY IS IT NECESSARY?

Key issues addressed in this section

- **Key terms defined**
- **The influence of legal systems in shaping legislation**
- **Why are laws necessary?**
- **What aspects influence a particular law?**

3.1.1 Key legal terms and concepts used in the handbook

A. Law versus law

In some countries, particularly among non-lawyers, the term “law” is commonly understood to mean the main or primary “Law” governing a particular area. In this handbook, “law” (lower case l) is used *generically* to refer to the whole corpus of animal health or related legislation that is legally binding, whereas “Law” (capital L) is used *specifically* to refer to a law passed by the highest legal authority.

Therefore, while a “Law” typically refers to the primary or highest legal instrument, animal health legislation is the *body of laws and implementing regulations* that address issues relating to animal health. Disease control provisions can be found in laws specifically addressing a type of disease, or general animal disease control legislation; alternatively, such provisions can be included in broader animal health legislation or, broader still, in veterinary sector legislation.

Note should be made of the distinct references in this handbook, to veterinary, animal health or disease control legislation (and the varying scope of each).

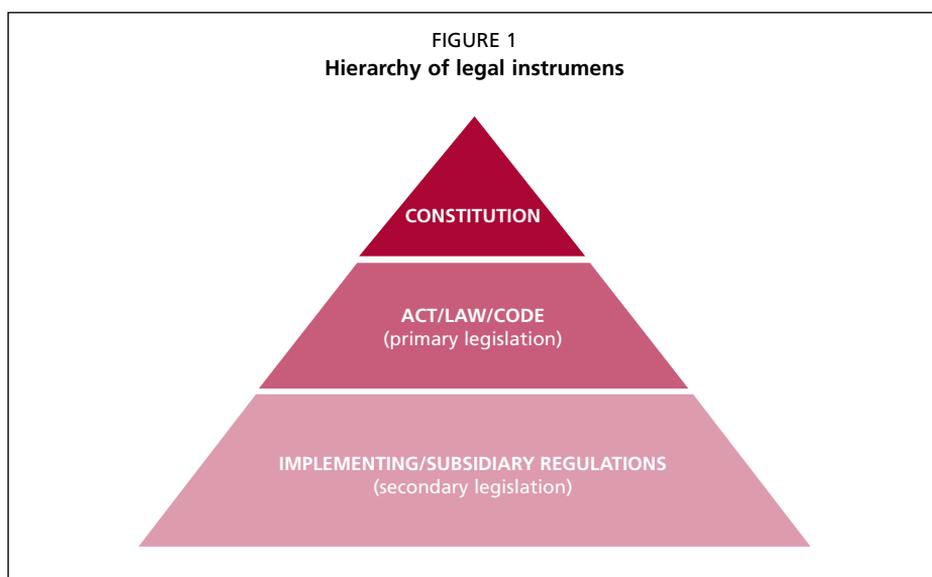
B. Hierarchy of legal instruments

National systems of law establish a hierarchy of norms, based on the particular source from which those norms derive. It is common, therefore, for the fundamental values of society to be given constitutional status and precedence over norms enacted by laws and regulations. In principle, the higher a legislative norm falls within the hierarchy, the greater its level of authority.

Primary Laws, passed by the legislative branch of the state, are the highest laws in a country, subject only to the constitution, which is the ultimate legal authority. A Law (also termed an act or a code in some countries) is approved by the highest law-making authority, commonly referred to as the parliament or national assembly. Some legal systems permit the executive to approve Law-level legislation, for a limited number of areas and on certain conditions.

The implementation of regulations refers to secondary or subsidiary legislation – texts that are based on the primary Law or act that has already been passed. Regulations are frequently approved by a government body (e.g. the cabinet) or a person (e.g. a government minister) who is endowed with this power by the primary Law on which the regulations are based, or by the legal system in the country in question. Secondary legislation therefore expands the primary Law, i.e. detailing aspects such as procedures and technical requirements (see Figure 1). Thus, it is common for one act or Law to have several sets of implementing regulations. When drafting implementing regulations, it is important to ensure that they do not go beyond the scope of the primary Law. In other words, subsidiary legislation cannot confer powers or responsibilities, or govern areas that have not been addressed by the legal instrument on which they are based.

Primary legislation typically lays down the key obligations, powers and responsibilities of public authorities; it specifies institutional arrangements; sets out basic rights and freedoms; and establishes criminal offences and taxes. However, the scope of a primary law may be determined by the constitution or, more generally, by the legal tradition of the country. As discussed briefly in Part 2, section 2.1.2, the powers and functions of inspectors are generally quite significant, as they are granted powers of search and entry, as well as powers to put down diseased animals, take samples, confiscate items and restrict the movement of animals. Accordingly, given that such powers could potentially affect or limit the constitutional rights and freedoms of citizens, these matters should be discussed, and passed by the highest legislative authority.



Powers and functions should not be included in secondary legislation for two main reasons: (a) strictly speaking, these powers could be considered to go beyond the scope of the law if the primary legislation does not refer to them; and (b) such powers can also be challenged in, or be trumped by, primary legislation of other ministries. Primary laws should define the scope of application of a particular Law or act and, therefore, the multisector discussions that are an integral part of parliamentary or national assembly debates should work towards ensuring that there are no overlaps with the mandates of other ministries and departments.

Decisions about what should be addressed in primary legislation and what should be dealt with in the implementing regulations depends on the legal tradition of the country. In Asia, some countries have primary laws that set out very basic principles that are then fleshed out by numerous implementing regulations. Other countries prefer to have greater detail in the primary legislation to establish clear parameters of application.

Aspects that are likely to be amended, such as technical or scientific details, should be left to implementing regulations, due to the fact that scientific advancements can occur rapidly, and require updated legislation to reflect such changes. In Asia and the Pacific region, as is the case elsewhere, primary legislation is subject to protracted and sometimes cumbersome procedures; consequently, such legislation is unable to keep pace with policy and technical advances. In addition, placing detail in subsidiary instruments facilitates the passage of primary legislation because, the more general the law, the less likely it is to be objectionable to other ministries and government authorities.

C. Law and policy

The difference between law and policy has been examined in Part 1, section 1.1.3. Therefore, at this juncture, it is sufficient to reiterate that laws are just one of the tools used to implement policy. Laws establish specific requirements, procedures and principles; they create an institutional framework for enforcement by empowering designated authorities to carry out explicit functions and create rights and obligations that are enforceable.

3.1.2 Legal systems

The predominant legal system in a country will affect the style, manner and content of animal health legislation. Within each system, different roles are played by the legislature, the executive, the judiciary and representatives of civil society in the adoption and implementation of legislation. Table 7 provides an indication of the major legal traditions observed in selected countries in Asia and the Pacific region. Within this region may be found examples of dual systems which present variations of the different types of legal systems and plural legal systems (where customary law based on traditions and customs exists side by side with statute law, whether or not the former is explicitly recognized by the latter). Customary law often affects the operation, implementation of, and compliance with, formal statutory law in that it may create an alternative system for natural resource management (most commonly observed in relation to resources such as land and water, but not commonly observed in relation to disease control).

Government functions are typically divided between the legislature, the executive and the judiciary, with their respective roles dependent on the legal system and political make-

TABLE 7
Examples of legal systems in Asia

Country	Legal System
Bangladesh	Common law and Sharia law
Cambodia	Mixture of civil law and customary law
India	Common law
Indonesia	Civil law, customary (adat) law and Sharia law
Lao, People's Democratic Republic	Civil law
Malaysia	Common law and Sharia law
Nepal	Common law and customary law
The Philippines	Civil law, common law, customary law and Sharia law
Thailand	Civil law
Viet Nam	Civil law

up of the country. The function of legislatures is, by definition, the making of laws but they may also have other tasks, such as supervision of administration, appropriation of funds, ratification of treaties and so on. Legislatures do not monopolize the function of making law because, in most systems, the executive may also have a power of veto over legislation, and even where that does not exist, the executive may exercise original or delegated powers of legislation. The judiciary is responsible for interpreting laws and may also contribute to law-making through *stare decisis* or judicial precedent in common law countries. The executive branch of government has responsibility for the daily administration of the state bureaucracy. The role of the executive is to implement and enforce the law as written by the legislature and interpreted by the judicial system.

3.1.3 Administrative law

Both highly developed countries and less developed countries have experienced a growth in the functions of state and, with each addition to the functions of state, administrative organs have acquired greater powers. Because administration involves the exercise of power by the executive arm of government, administrative law is of constitutional and political, as well as juridical importance.

Administrative law is the legal framework within which public administration is carried out; such law is important for the day-to-day functions, procedures and powers of government. It also defines the rights and responsibilities of officials, the relations between various government bodies, between government bodies and citizens, and between government bodies and non-governmental bodies.³⁹ The organization of the national legislature, the

³⁹ United Nations – Governance and public administration
(http://esa.un.org/techcoop/adserv_detail.asp?ServID=pubadmin)

court structures, the make-up, composition and role of the cabinet, and the role of the head of state are often defined in the constitution, whereas the procedural provisions relating to central and local governments, and the rules for the formulation of policies and the functioning and coordination of the institutions, are considered to be matters of administrative law.

Bureaucratic failures have become increasingly common. Most of these failures can be prevented or eliminated by the application of good management techniques, a clear legal framework and the strategic training of personnel. The outcome of such efforts is better governance. Administrations that work in partnership with those to whom the law applies are more likely to be effective than those that see themselves as mere enforcers of the law.⁴⁰

3.2 INTERNATIONAL AGREEMENTS AND STANDARDS

Key issues addressed in this section

- **Difference between binding and non-binding legal texts**
- **Key principles of the SPS Agreement relevant to animal health**
- **OIE standards, recommendations and guidelines**

International agreements to be incorporated into national legislation should be divided into those that are legally binding and those that are not. Legally binding instruments contain obligations to which countries that are party to an international treaty, agreement or convention must adhere, and are governed by the Vienna Convention on the Law of Treaties (1969). Non-binding instruments, on the other hand, do not impose legal obligations but instead promote international harmonization.

The term “soft law” refers to standards, guidelines or recommendations that do not have a legally binding force, as opposed to “hard law” (for example, international agreements). Countries may decide to align their national legislation with non-binding instruments, with a view to harmonization with trading partners, or they may decide to incorporate international best practice.

The World Trade Organization (WTO) SPS Agreement, a legally binding text on WTO member states, outlines the basic rules for countries establishing food safety and animal and plant health measures. It allows countries to decide on their desired level of sanitary protection, and to approve the requisite sanitary measures to protect human life, animal or plant life or health. The SPS Agreement encourages governments to establish national SPS measures that are consistent with international reference standards, guidelines and recommendations, where they exist, in furtherance of the harmonization principle. The SPS Agreement refers to three international reference-setting bodies: the Codex Alimentarius Commission for food safety and quality matters, the OIE for animal health and the International Plant Protection Convention (IPPC) for plant protection.

OIE member countries and signatories to the SPS Agreement are encouraged to comply with the standards espoused by the OIE in order to harmonize health protection measures in a manner that is least trade disruptive. Among other detrimental effects (such as the risk of the spread of disease), non-compliance with international standards on animal health

⁴⁰ United Nations – Governance and public administration
(http://esa.un.org/techcoop/adserv_detail.asp?ServID=pubadmin)

may create problems of market access for a country's exports of live animals and animal products. Therefore, in addition to compliance with the SPS Agreement, which is legally binding, such member states are encouraged (but not legally bound) to follow the OIE standards, recommendations and guidelines. Consequently, the SPS Agreement allows governments to impose more stringent requirements, provided those measures are based on scientific evidence, are risk-based and transparent, and do not unjustifiably discriminate between countries.

The OIE Terrestrial and Aquatic Animal Health Codes are recognized as scientific references and recommended standards on animal health for countries; as such, they are used to guide the substantive elements to be included in national legislation. The OIE Guidelines on Veterinary Legislation provide the list of areas to be considered when revising national veterinary legislation. In other words, legislation on HPAI and other transboundary animal diseases should be assessed against the standards of the OIE Terrestrial Animal Health Code.

It should be noted that some elements of veterinary legislation addressed in the OIE guidelines go beyond the scope of animal health, and will thus require compliance with the standards of other international organizations (such as the Codex Alimentarius Commission). As a result, certain elements of the guidelines may be regulated through different legislation, such as food safety legislation, drugs legislation, or legislation on livestock production, animal products and products for veterinary use.

3.3 VETERINARY LEGISLATION

Key issues addressed in this section

- **What are the steps involved in law reform?**
- **What are the key elements of laws?**
- **Against what reference points/standards/texts are national laws assessed?**
- **What issues should be considered when drafting legislation?**

Veterinary legislation should incorporate the substantive technical provisions aimed at achieving the law's objectives, which are guided by international and regional standards as well as national veterinary policies. This section highlights a number of important legal considerations to be taken into account during legal review or reform of the veterinary sector.

Table 8 simplifies the steps typically involved in legislative review and reform. The most important aspects of these steps are explored in further detail later in this section.

It is worth highlighting that analysis of existing legislation during review and reform activities should include not only the content and provisions of the law (which is the focus of this part of the handbook), but also the application of the law and its effect in practice. Consideration should be given to the fact that where the existing legislation is ineffective for reasons other than gaps or weaknesses in the law itself, a new, perfectly drafted law may not necessarily work better. In addition to carrying out strict legal analysis and reviews of the legislation, it is important to assess the feasibility of changing the existing non-legal constraints, to identify the priority order for legal change and, finally, to identify options for various legal solutions.⁴¹

⁴¹ *Law and sustainable development in Rio: Legal trends in agriculture and natural resource management*. FAO Legislative Study No. 73

TABLE 8
Simplified steps for legislative review

1.	Establish a small multidisciplinary law reform working group comprising lawyers and veterinarians, as well as a larger working group comprising representatives of the food sector, agricultural sector, customs authorities, environmental and decentralized authorities, and private stakeholders. Consultations with experts should take place throughout the process when explanations or advice are required on technical issues that are outside the knowledge or experience of the members of the working group.
2.	Understand the legal context: legal system, constitution, administrative context.
3.	Understand the socio-economic and political context (and specifically the veterinary sector context).
4.	Research and compile all veterinary legislation.
5.	Identify gaps, overlaps and weaknesses of the legal framework (i.e. relating to animal health). One way to approach this is to use the gap analysis method.
6.	Map institutional mandates according to legislation.
7.	Assess legislation in terms of: quality of drafting, clarity and consistency; clarity and adequacy of administrative/institutional powers and functions; creation of clear rights and obligations; enforcement provisions (offences and penalties) and compliance with international agreements and reference standards (see section 3.3 below).
8.	Discuss and identify gaps, needs and priorities with stakeholders in accordance with the participatory methodology.
9.	Propose and discuss recommendations with stakeholders (initially with national veterinary services, and subsequently and more broadly with other stakeholders).
10.	Draft amendments or new legislation (listing provisions in related legislation that should be revised in order to prevent contradictions).
11.	Circulate the first draft among public stakeholders and revise according to comments and inputs.
12.	Circulate the revised draft among public and private stakeholders, including livestock farmers, consumer groups, and revise according to comments and inputs.
13.	Hold workshops to discuss the working draft – identify potential obstacles to the implementation of the measures in the draft law and attempt to find solutions to those problems during the drafting process.
14.	Final draft to be cleared by the chief veterinary officer (CVO) and minister responsible for livestock and, depending on the legislative process in the country, final draft to be submitted to the ministry for justice and legal affairs or to the national assembly or parliament, as appropriate.
15.	Once the law has been passed, it should be subject to periodic review and evaluation.

3.3.1 Assessment

First and foremost, it is necessary to have an understanding of the national legal system, constitution and general administrative structures. As noted in section 3.1.2, law adoption processes and enforcement systems vary from country to country, as do legal frameworks governing the powers and duties of regional and local authorities. Provisions regarding offences and penalties, liability, legal presumptions and principles of interpretation also differ between countries.

In making assessments of animal health legislation, or indeed in drafting such legislation, countries are required to take into account any obligations assumed at the interna-

tional or bilateral level. International commitments may require a voluntary surrender of a small part of national sovereignty and, as a consequence, the commitments may narrow and shape the policy options available. Bilateral trade agreements often make reference to specific standards and legislation as a condition for trade between the parties.

An analysis of the institutional and legal frameworks for every area related to, or with an impact on, veterinary legislation will be required when reviewing animal health legislation. Consequently, all related areas must be considered in the review process and must not exclusively focus on the specific subject area under review.

One of the important issues to determine when carrying out legislative assessments is a mapping of the institutional framework as it exists in the legislation. Overlapping or contradictory provisions within sector legislation, or within legislation relating to different sectors, may result in two or more government bodies being granted the same power. Duplicate mandates mean added costs for the government (as well as for the private sector), increased bureaucracy and ineffective regulation.

One approach to legislative assessment is to carry out a gap analysis of legislation, using the provisions of the OIE Terrestrial Animal Code as criteria or benchmarks. In this way, by comparing the national legislation with the OIE reference standards, one can determine to what extent the measures in the former match those of the latter. The analysis should focus on the substantive provisions included in the law and not on the legal provisions related to the national governance structure or legislative style generally, which should remain in line with other national legislation and the legal tradition of the country. The analysis of the substantive provisions should be continued, article by article, until all provisions of the law or regulation have been examined and any corresponding gaps have been noted. For each article or section, one should also consider how closely or to what extent the provisions match – not necessarily in terms of wording, but in terms of effect or outcome. As noted above, the analysis may require looking at a number of laws or regulations at national level, as appropriate, to ensure that the gap analysis is carried out accurately. Table 9 below summarizes these steps.

This gap analysis is useful for assessing the technical quality or strength of the draft, for example in terms of the use of the instrument to control diseases or to regulate veterinary drugs. The legal quality of legislation is, however, best addressed by lawyers, which is why step 1 in Table 8 (above) recommends the establishment of a multidisciplinary law reform working group. Some of the aspects of legal quality, and the degree to which legislation is well drafted, are examined in the section below on drafting.

Gap analysis of veterinary legislation in countries in the Asia Pacific region

In order to illustrate the level of compliance of national legislation with international veterinary standards, Annex I provides a general assessment of the legal framework for the veterinary sector in selected Asia and the Pacific region countries. This assessment was carried out in 2008 as part of an Asian Development Bank-funded project (see Foreword).

In Annex I, the criteria for which there is a high level of non-compliance fall into two categories: administrative-organizational and technical. In the case of administrative-organizational provisions, these may be found in other laws not available for review. Such examples would include legal provisions on the structure or delegation of powers within

TABLE 9
Simplified steps for a gap analysis of legislation

1.	Decide whether the assessment will cover the full range of veterinary legislation, or whether it will be limited to consideration of the animal health or disease control measures.
2.	Collect all the relevant statutory instruments, both administrative and technical, that must be subjected either wholly or in part to the gap analysis.
3.	Assess how closely the measures in the statutory instruments match the OIE reference standards.
4.	List the gaps in the legislation and incorporate them into a report explaining the differences.

the ministry responsible for veterinary matters, and budgetary provisions that provide financial support to the veterinary services (also during emergencies). As noted above, comprehensive legal reviews should have access to laws governing these issues. This provides an indication of the types of problems that may arise, and gives emphasis to the need for care in preparing for and carrying out such reviews of legislation. The assessment conducted in 2008 also highlights the advantages of having regulatory assessments carried out at the national level by NVS personnel who are thoroughly familiar with the structure and content of the country's veterinary legislation. It is hoped that this handbook will assist such an exercise.

3.3.2 Drafting

Having identified the deficiencies or weaknesses in the legislation, the next phase will involve either amending the legislation where there are only minor changes, or drafting new legislation where the changes are extensive, in order to bring the regulatory framework into line with international standards.

Ideally, the legal drafting process should be carried out by a multidisciplinary team comprising veterinarians, lawyers and other professionals. While those with veterinary expertise can access technical accuracy, feasibility and priority issues, it should be borne in mind that legal experts are often in a good position to address legal concerns such as consistency with other legislation, to identify gaps and overlaps, and to draft the legal instrument in a clear, precise and accurate manner.

Drafters must first identify the regulatory objective that is to be translated into national legislation. In other words, the questions to be asked are: Do we wish to formulate animal disease control legislation that is narrowly focused on prevention, control or eradication of animal diseases? Or is it preferable to propose a broader animal health Law to cover additional areas with a direct impact on animal health? Is an overarching instrument required – one that addresses animal health and livestock production (and therefore encompasses issues such as animal products, waste, animal breeding, genetic resources)? The answers to these questions will depend on the needs and priorities at national level and the benefits that may be gained by having separate instruments for different areas.

In the same vein, animal health may impact the safety of food products whereas feed safety and quality have a recognized effect on animal health. Veterinary matters may be

found in a number of sectoral laws, most frequently in laws governing the veterinary sector, but also in the provisions of laws governing food safety, trade, import and export, and public health. Veterinary legislation may also incorporate provisions aimed at controlling animal disease-associated risks to food, feed, and human and environmental health. Additionally, animal production activities can impact land and soil quality and, more broadly, the environment and natural resources. Given recent emphasis on greater integration in natural resources management, the concept of sustainable animal production regulates the obligation of governments to approve policies on animal production that take environmental impacts into consideration.

When reviewing the legislative framework for animal health it is, therefore, important to take into account this framework and related legal texts, in order to obtain a complete picture of the mechanisms, provisions and authorities involved in the veterinary sector. Box 10 summarizes the areas that are relevant to animal health.

The various areas related to animal health are discussed further below in the context of the scope and objective of Laws.

In general, legal texts should be drafted in such a way as to create clear, concise and accurate provisions. A balance should be struck between precision and flexibility; this should be approached in a manner that both facilitates implementation and avoids misinterpretation. Care should also be taken to be internally consistent; the provisions in the law should not contradict, overlap or duplicate each other. The law should contain predominantly operative clauses, and it should identify the persons who have either a right or an obligation.

Frequently, drafters in developing countries use developed countries' legislation models as their reference point. While this is helpful, it should be noted that such texts have limited value in terms of guiding the content of new legislation in developing countries. The legislation of neighbouring countries or countries with similar epidemiological or socio-political environments may be more appropriate as sources of inspiration; moreover, the process of examining such legislation may also result in creating ways to help achieve harmonization objectives. In order to strengthen cooperation and protection against disease, countries may decide to develop at the national level common rules that reflect the framework of regional organizations or regional priorities. Regional harmonization can mitigate weaknesses in technical capacity and can create a platform for shared initiatives such as joint risk assessment, early warning systems and contingency responses. This may be useful for streamlining border control procedures.

A. Key elements of animal health legislation

The following discussion seeks to distil key features that may provide general parameters for drafting animal health legislation. It is not intended to provide a definitive checklist of essential elements; rather it is intended to serve as a guide to the overall content and scope of the legislation.

Scope and objectives

Depending on the country's legislation and practice, provisions stating the purpose, objectives or scope of the legislation generally precede all other provisions. The scope of the OIE

BOX 10

Various areas of veterinary legislation that affect the scope of animal health legislation

Consistency between animal health legislation and *food safety* legislation is essential. Food safety laws govern management and controls on all food products in all stages of the food production chain, in order to verify compliance with food safety and quality standards. Potential overlaps exist between animal health legislation and slaughterhouse regulations. In many countries, slaughterhouses are regulated by separate legislation implemented by health authorities or local authorities.

Animal *feed* legislation is another area with strong linkages to food safety and animal health. Based on Codex Alimentarius* standards, feed regulation involves addressing: production; marketing and use; specific aspects such as feed safety, the use of ingredients and additives, and procedures to avoid cross-contamination on the premises; provisions in relation to labelling, packaging and distribution.

Veterinary drugs legislation addresses the production, marketing and prescription of drugs.

Animal welfare legislation addressed in the same instrument or in separate legislation includes references to humane treatment or ethical concerns that exceed the goal of protecting animal health status, incorporating standards and rules to be followed by medical research facilities.

Biosecurity concerns are raised where the deliberate use of pathogens causes disruption of trade or otherwise harms human or animal health.

The veterinary services may assume functions in areas that are usually under the jurisdiction of environmental or rural development authorities; alternatively, they may coordinate animal health controls with these authorities. This is the case for controls on international trade in threatened animals and plants, and specimens derived from them, under CITES (the Convention on International Trade in Endangered Species of Wild Fauna and Flora, also known as the Washington Convention).

Modified extract from: Lubroth J., Bullon C. 2010. *Solutions and Tools to Improve Veterinary Legislation: Drafting National and Regional Veterinary Legislation*

* *Code of Practice on Good Animal Feeding*. Codex Alimentarius [CODEX STAN CAC/RCP 54-2004] and *Code of Practice for the Reduction of Aflatoxins in Raw Materials and Supplemental Feed for Milk Producing Animals* [CAC/RCP 45-1997]

guidelines covers the full range of veterinary matters and, in incorporating the elements of these guidelines, countries may need to determine what can be included in the draft animal health law and what it may be more desirable to include in separate legislation, for example in veterinary drugs laws or feed laws.

Therefore, in establishing the scope of the new draft law, an analysis of the existing legislation will enable identification of the normative areas and, in particular, elements

that may overlap or contradict the new draft instrument. This will facilitate distinguishing between issues that need to be addressed exclusively under an animal health law, and those that are related to animal health but may require separate legislation.

The scope of a law determines the parameters of its application, the institutional actors involved in its implementation and any linkages or overlaps with other areas. Countries seeking legislation on both animal health and production may prefer an integrated law, which will need to be coordinated with the authorities who have the primary responsibility for food safety, feed, drugs and genetic resources. Consideration should be given to inspections and controls with animal health objectives, such as post-mortem inspections for tuberculosis, and these should be differentiated from controls aimed at ensuring the safety of the meat as food. Similarly, milk controls to monitor traces of animal diseases will differ from microbiological safety controls or quality controls for the organoleptic characteristics of the milk.

The composition, raw materials, labelling or storage of animal feed may be relevant to animal health and food safety. This analysis (legal and technical) and consensus building will therefore require close collaboration with the authorities responsible for food safety, industrial production and consumer protection.

Definitions

A list of definitions of the main terms included in the law is a common feature of most legislation. Definitions are important in that they may affect the scope of application of the law. For example, the definition of animal, animal product, disease, should be considered carefully, so that no gaps or overlaps or other unintended consequences are created. A definition of *animal* would consider whether the law applies only to terrestrial animals and not, for example, to aquatic animals. If it applies to the latter, then this may require the regulation of aspects relating to aquatic animal health, such as aquatic feed and drugs, handling of fish and aquaculture. When formulating definitions, there has been a clear trend in recent years for countries to closely refer to internationally agreed sources such as the OIE and the Codex Alimentarius, as well as other national legislation on related issues. Aligning the definitions of terms goes some way towards bringing the national text closer to the text of international instruments; similarly, consulting other national legislation on related issues enables countries to deliver a consistent approach and to identify any possible gaps and overlaps.

Institutional/administrative structure

In most jurisdictions, primary legislation should set out the powers and functions of the responsible authorities. This is particularly important with respect to animal health, where the veterinary services should be empowered to kill diseased animals where necessary. The power to confiscate items, carry out disinfection and enter property, as well as limit the constitutional rights and freedoms of citizens, should be subject to debate by the highest authority in the country. See Box 11 for a checklist of key powers necessary for disease control.

The legislation should address the powers delegated to the minister responsible for animal health matters, to the director of veterinary services or CVO, and to veterinary

BOX 11

Checklist of key powers and responsibilities necessary for disease control

It should be noted that corresponding powers and functions would not necessarily be included at primary law level, but rather in accordance with the hierarchy of laws and application of principles that require broad powers to be addressed at national level and more specific or technical responsibilities to be set out in subsidiary instruments.

- Does the minister or the CVO have the authority to initiate a country-wide serological surveillance campaign for a specific infection or disease?
- Does the minister or the CVO have the authority to call on the veterinary diagnostic laboratory system to carry out serological testing on the samples collected in the serological surveillance campaign?
- Does the CVO have the authority to order the retention of sera in a serum bank for possible subsequent testing for other diseases?
- Do veterinary inspectors have the power of entry to premises to determine whether certain animals are present?
- Do veterinary inspectors have the power to clinically inspect and take samples from animals for diagnosis?
- If not, do veterinary inspectors have the power, for the purposes of individual identification, to mark animals from which samples are taken during the surveillance campaign?
- Does the CVO have the authority to impose movement restrictions on infected herds and flocks?
- Do veterinary inspectors have delegated authority to impose such restrictions?
- Does the NVS have the authority to kill animals in case of infection?
- Does the NVS have the authority to requisition equipment for the destruction of carcasses of infected animals after a pre-emptive killing?
- Does the NVS have the authority to requisition land for the incineration or burial of the carcasses of animals killed in a disease control and eradication campaign?
- Does the CVO have the authority to initiate a compulsory vaccination campaign?
- Are legal provisions in place to approve sanitary measures preventing the entry of animals from countries infected with, or at risk of, a disease, or to ensure that such imports may be carried out safely?
- Is there a legal requirement for the government to notify the confirmed presence of a notifiable/scheduled disease to the OIE, other international organizations, neighbouring countries and trading partners?
- Is there a legal requirement for the ministry responsible for veterinary matters and the ministry responsible for human health to share information and to cooperate as necessary in the event of the suspected or confirmed presence of a notifiable/scheduled zoonotic disease?

inspectors. Details of the general structure of the NVS, its management, as well as the chain of command and line of communication, can be detailed in subsidiary regulations, in plans, or in any instrument that is flexible enough to incorporate frequent changes.

The role of the private veterinary sector (including veterinary paraprofessionals) in official duties should also be considered. Increasingly, countries opt to use private veterinarians to alleviate financial, technical and human resources limitations. This can be particularly useful for disease control. Such devolvement to the private sector should expressly state the functions that can or cannot be delegated. Rules and regulations governing delegation should entail important particulars, such as an agreement in writing, delineation of the scope, nature and duration of the delegation, as well as any conditions or reporting duties.

Therefore, an animal health law should specify the nature and the limits of the powers of relevant authorities and should expressly state who may exercise such powers. Of considerable importance to effective disease control is the degree to which functions are decentralized to regions and provinces (this is discussed in Part 2 section 2.1.1). Central government should not erode or duplicate the power or function of decentralized authorities; instead, it should respect the administrative and constitutional make-up of the executive branch that is specific to each country. However, effective disease control must also recognize chains of command, communication and response actions that may require central coordination. An issue related to decentralization is the use of community-based animal health workers who may be empowered to carry out certain extension activities and treatments or to assist during disease emergencies, especially in rural areas where there is no permanent NVS presence.

If the law goes beyond disease control, and if it encompasses additional aspects within its ambit, the role of other authorities should be recognized; moreover, the mechanisms for cooperation between these authorities should be explored, both at the centralized and decentralized levels.

The law should also refer to the veterinary officers' inspection function (including taking samples), in addition to their other tasks. Subsidiary regulations or manuals (see Part 1 section 1.2.2) may contain operational, technical and procedural details.

Substantive provisions

Listed/scheduled diseases: Animal disease control legislation should contain provisions for a list of diseases that would trigger a declaration of quarantine or disease area. Detailing the list of diseases in an annex or schedule to the Law is desirable in order to provide the NVS with the flexibility to modify the list whenever it is appropriate. While the NVS is responsible for animal diseases in general, it should be noted that *listed* or *scheduled* diseases would activate particular responses.

Declaration of infected zones: An animal health law must provide the minister with the power to declare certain zones infected or under quarantine; it must also stipulate the restrictions and obligations in effect in that area including, for example, the movement of animals or animal products. Restrictions applicable in a quarantine or disease area must be proportionate, they must be technically justified and they must be based on a risk assessment. The law should also contain provisions for a review of areas under quarantine and

the lifting of quarantine where the risk of spread of disease is no longer present or has been reduced as necessary.⁴²

Power to declare an animal disease emergency and approve emergency measures: The responsible minister should be empowered to declare an animal disease emergency which would set in motion the activities and actors identified in contingency plans. Emergency measures and contingency plans should be given a basis in law. They should receive fiscal support, i.e. adequate funds should be specifically allocated for this purpose and it should be possible to access such funds immediately following the declaration of an emergency.

Reporting requirements: Animal disease laws should impose a duty on both public officials (veterinary officers, extension agents, border guards) and the private sector (farmers, private veterinarians) to report the appearance of certain diseases, even before the presence of the disease can be diagnostically confirmed.⁴³ The law should also refer to the duty of the NVS to report all notifiable diseases to the OIE.

Movement controls, including import and export: Animal health legislation should include within its scope restrictions or prohibitions on the movement of animals and animal products within the country, particularly from an infected zone to anywhere outside it; it should also include controls on the import and export of live animals and certain animal products. Where there is a disease outbreak, the law should enable the establishment of post-import quarantine of animals and animal products or, where necessary, a total, temporary ban on imports.⁴⁴ However, any measures that restrict imports should be compliant with the principles of the WTO in general and the SPS Agreement in particular. Most relevant in this case would be the principles of non-discrimination and the obligation to base import measures on scientific justification.

Surveillance: A key function of the NVS in disease prevention and control is surveillance, which is essentially the detection and monitoring of a disease or infection. Surveillance programmes also help to support claims of disease-free areas or zones and are essential for producing the data required to carry out risk analysis and undertake effective risk management.

Culling: Where management of a disease is best achieved through culling of animals to prevent further spread, or where there is no cure, the legislation should empower veterinary officers to kill animals without incurring any liability on behalf of the government or the NVS as a result of implementing disease control measures.

Disposal: The law should enable veterinary officers to effectively dispose of dead animals in a manner that destroys the causative pathogen and in a location approved by environmental authorities. The law may direct the animal owner to follow the instructions of a veterinary officer with respect to disposal.

Compensation: Providing swift and adequate compensation to farmers whose animals have died, or have been slaughtered, may be an effective way to prevent the spread of disease in certain cases, as it may reduce the disinclination of such animal owners to report the disease. The content and nature of compensation schemes are generally at the discretion of the government. Should governments decide to assume such an obligation with regard to farmers, the law should address the conditions for receiving compensation, how and by

^{42, 43, 44} *Law and sustainable development in Rio: Legal trends in agriculture and natural resource management.*
FAO Legislative Study No. 73.

whom it should be authorized and distributed, and in what form it is to be paid (in cash or in kind).⁴⁵ While the latter details, together with other particulars such as how to calculate compensation can be detailed in regulations or other subsidiary instruments, an overarching provision for the option of compensation would be required in primary legislation.

Collection of epidemiological data: Under the animal diseases law or its accompanying regulations, provision should be made for the collection and analysis of epidemiological data, so that the disease status can be monitored, and, where relevant, such findings can be shared at regional or international level.⁴⁶

Identification and traceability of animals: Countries may wish to establish systems for the identification and traceability of animals. Such systems may differentiate between species and may introduce progressive obligations and recording mechanisms. The systems may be regulated by implementing legislation or by private standards in the form of co-regulation or self-regulation under public supervision. Identification and traceability are essential elements in disease control. It should be noted, however, that developing countries may have difficulties in setting up such systems, given resource and communication constraints.

Assistance from law enforcement personnel: Where the legislative instrument is of a high enough order, the responsible minister may be empowered to request the assistance and presence of the forces of public order in carrying out control measures (imposition of quarantine, inspection, slaughter, roadblocks, etc.). Where these measures are set out in implementing regulations, the minister who issues the regulations can only request, but not direct, the assistance of law enforcement personnel as he/she would not have the mandate to legally compel another ministry to provide such assistance.

Duty to cooperate: Disease control legislation often contains a legal requirement for owners and keepers of animals to cooperate in various ways with a veterinary inspector, for example, confining animals, restraining them for examination and sample collection, providing information on clinical history and animal movements. Additionally, with a view to fostering collaboration, a useful provision to include in the law is a legal requirement for owners and keepers of animals to be informed of the results of diagnostic tests performed on samples from their animals.

Offences and penalties: Depending on the legal system in place, a good legislative practice is to indicate the specific acts or omissions that constitute an offence under the law, together with penalties commensurate with the offence. Distinctions should be made between administrative breaches and corresponding fines and penalties, and criminal offences that would trigger the involvement of prosecution authorities and fiscal or incarceration penalties. Penalties should be both proportionate to the offence and sufficient to act as a deterrent. A recent trend in some laws is to apply the concept of “penalty units” rather than fixed amounts, so that inflation will not erode the punitive and deterrent value of penalties as the legislation ages.⁴⁷

^{45, 46, 47} *Law and sustainable development in Rio: Legal trends in agriculture and natural resource management.*
FAO Legislative Study No. 73.

Miscellaneous legal provisions

One of the legal options available is to establish an appeals system in accordance with the legal system of the country. Under this appeals system, animal owners would be entitled to have decisions made by veterinary officers reviewed. In the first instance, the appeal would be made to the CVO and thereafter to the minister responsible for animal health matters. Another option would be to include clauses which indemnify public officials for actions carried out in good faith during the course of their work. Legislation that makes significant changes to an existing system may require the repeal of existing legislation, although some laws may contain a savings clause which stipulates that certain existing regulations may still have effect.

Finally, for illustrative purposes, Box 12 outlines the role of the law in preventing and responding to HPAI.

B. A key element in the development of legislation – participation

One final aspect to consider, and one of the most important tenets of legislative drafting, is the participation of stakeholders. Steps 8-13 in Table 8 emphasize the importance of participation. The participatory methodology for legal drafting works towards building consensus and has been shown to improve implementation and enforcement of the law. Participation in the drafting of legislation raises awareness of various technical concepts as well as policy matters among diverse groups of stakeholders. Legislative drafting that involves extensive consultation with all stakeholders allows the latter to make informed choices and contribute to decision-making and, in the process, increases transparency and accountability.

BOX 12

The importance of legislation in the context of HPAI

Laws and regulations empower authorities to carry out the following actions (and create the mechanisms, rights and obligations to ensure that such actions are carried out):

- Proclaim a notifiable disease.
- Enter a poultry enterprise to inspect birds or collect specimens.
- Define infected areas and disease control zones.
- Institute a quarantine of affected or suspect premises.
- Place movement controls on poultry, poultry products and potentially contaminated materials.
- Destroy and dispose of infected or potentially infected birds and contaminated materials.
- Undertake other disease control operations, such as compulsory vaccination.
- Place controls on the operation of enterprises, such as poultry processing plants.

Extract from: FAO, 2009. Preparing for Highly Pathogenic Avian Influenza. Animal Health and Production Manual

Annex I

Regulatory compliance in selected Asia and the Pacific region countries

In relation to the data included in this Annex, the following points should be noted. Not all pieces of legislation relevant to veterinary matters were available and could not, therefore, be reviewed. In some cases, this was due to the fact that English translations, even unofficial versions, were not available.

I General provisions					
1.	*Objectives/purposes of the law are listed	6	1	0	0
2.	*Scope: specifies to whom and to what the law applies	2	2	3	0
3.	*Terms used are fully defined to international standards	0	7	0	0
II Rights, powers and responsibilities of participants					
4.	*Power to implement the law is granted to government	2	3	2	0
5.	*Participants in the veterinary system are listed	1	2	4	0
6.	*Responsibilities of government are specified	1	3	3	0
7.	*Powers are given to the minister responsible for animal health matters	4	3	0	0
8.	*Rights and duties of private veterinarians are specified	2	1	4	0
9.	*Duties of animal owners and keepers are specified	1	4	2	0
III Organization of the official veterinary service and the practice of veterinary medicine					
10.	*Structure of the national veterinary service is described	0	3	4	0
11.	*Responsibilities of the national veterinary service are listed	2	1	4	0
12.	*Veterinary inspectors are provided where required	2	0	5	0
13.	*Specific duties of veterinary inspectors are listed	5	1	1	0
14.	*Specific powers of veterinary inspectors are listed	3	2	2	0
15.	*Duties of border veterinary inspectors are listed	3	3	1	0
16.	Animal breeding centres may be officially provided	2	1	3	1
17.	*The role of local authorities in animal health is defined	4	1	2	0
18.	*Funding is provided for running the veterinary services	0	1	5	1

* Asterisks denote the criteria that are essential for disease control

19.	*Funding is provided for emergency veterinary measures	0	1	5	1
20.	Fees may be charged for official veterinary services	1	1	5	0
21.	*Official duties of veterinary technicians and paraprofessionals	1	1	5	0
22.	*Training and monitoring of veterinary inspectors	1	0	6	0
23.	A veterinary chamber/statutory body is provided for	2	1	4	0
IV Development and implementation of veterinary sanitary measures					
24.	*Objectives of official veterinary measures are listed	2	2	2	1
25.	*WTO sanitary and phytosanitary principles included	0	0	6	1
26.	*Control, inspection and approval procedures	0	1	5	1
V Protecting animal health and human health in relation to animal disease					
27.	*Protection of animal health	3	4	0	0
28.	*Protection of humans from zoonoses	3	3	1	0
29.	*List of prescribed notifiable diseases	3	2	2	0
30.	*Ability to deal with previously unrecognized diseases	1	2	4	0
31.	*Early detection and diagnosis of listed diseases	1	4	2	0
32.	*Annual measures to control/eradicate endemic diseases	1	2	4	0
33.	*Duties of owners regarding prevention and control measures	1	4	2	0
34.	Payment by owners for prevention and control measures	0	2	4	1
35.	*Contingency plans/preparations for disease emergencies	1	2	4	0
36.	*Management of epidemiological data	1	1	5	0
37.	*Equipment and materials for disease prevention and control	0	0	7	0
38.	*Funding of disease prevention and control measures	0	2	4	1
39.	*Action on suspected presence of a listed disease	1	6	0	0
40.	*Setting up/activating central and local disease control centres	1	1	5	0
41.	*Measures for control of outbreaks of serious animal disease	2	5	0	0
42.	*Diagnosis of listed serious animal diseases	0	2	5	0
43.	*Criteria for the confirmation of disease	1	2	4	0
44.	*Action on confirmation of a listed serious animal disease	1	4	2	0
45.	*International notification of listed disease outbreaks	1	1	5	0
46.	*Role of police and defence forces in enforcing controls	1	2	4	0
47.	*Compensation to owners for loss or damage	3	1	3	0
48.	*The end of an outbreak – lifting of restrictions	2	1	4	0
49.	*Epidemic-free zones – compartmentalization	0	0	7	0
VI Veterinary sanitary control in facilities					
50.	*Facilities subject to official control, inspection and approval	2	1	0	4

* Asterisks denote the criteria that are essential for disease control

51.	Criteria for licensing	1	1	1	4
52.	Control numbers for licensed facilities	1	0	2	4
53.	Suspension or revocation of operating licences	1	0	2	4
54.	Official veterinary control for export facilities	1	0	2	4
55.	*Record-keeping by facilities under veterinary sanitary control	0	0	3	4
VII Raising, producing and circulating animals and reproductive materials					
56.	*Registration of livestock holdings and other entities	2	3	1	1
57.	*Identification of animals	0	0	6	1
58.	*Control of circulation of animals	4	1	1	1
59.	Licences for gatherings of animals	0	0	6	1
60.	*Slaughter of animals in licensed slaughterhouses	3	1	0	3
61.	*Official veterinary control during slaughter	3	1	0	3
62.	*Record-keeping by slaughterhouses	1	1	2	3
63.	Provisions for inspection of game	0	0	4	3
64.	Licensing of animal breeding centres	1	1	2	3
VIII Producing and circulating products of animal origin					
65.	Circulation of products of animal origin	3	1	0	3
66.	Vehicles used in circulation	1	1	2	3
67.	Official veterinary control for edible animal products	2	0	1	4
68.	Marking animal products as fit for human consumption	1	1	2	3
69.	Animal products not fit for human consumption	1	1	2	3
70.	*Records kept by facilities producing edible animal products	0	0	4	3
71.	Requirements for circulation of edible animal products	1	2	1	3
72.	Licence to produce and circulate milk or milk products	0	1	3	3
73.	*Licensing and record-keeping by rendering facilities	0	0	4	3
74.	Registration of facilities using non-edible animal products	0	0	4	3
IX Producing and circulating animal feed					
75.	Licensing animal feed producers	1	2	1	3
76.	Registering animal feed circulators	1	2	1	3
77.	Compliance with technical standards and hygiene of animal feed	1	2	1	3
78.	Sampling and testing of animal feed	1	2	1	3
79.	*Use of waste food (swill) for feeding animals	0	0	4	3
X Circulating veterinary medicinal products, disinfectants and products for insect and rodent control					
80.	Licensing of veterinary medicinal products	1	2	1	3

* Asterisks denote the criteria that are essential for disease control

81.	Licensing veterinary pharmacies	1	0	2	4
82.	Recording the use of veterinary medicinal products	0	0	3	4
83.	*Disinfectants for disease control	0	0	4	3
XI Veterinary sanitary control in international trade					
84.	*Protecting the country from the importation of disease	4	2	0	1
85.	*Requirements for import and transit consignments: animals	4	1	0	2
86.	*Requirements for import and transit consignments: products	4	1	0	2
87.	*Import and transit licences	3	1	1	2
88.	*Import of exotic animals	0	0	5	2
89.	*Designated border inspection posts	3	1	1	2
90.	*Notification to the veterinary inspectorate of imports	3	1	1	2
91.	*Risk-based approach to official veterinary controls	2	0	3	2
92.	*Customs must not clear before veterinary inspection	2	1	2	2
93.	*Import blocked if listed disease in export or transit country	2	2	1	2
94.	*Quarantine requirements for imported animals	2	2	1	2
95.	Conditions for export consignments	4	1	0	2
96.	Issue of international veterinary certificates for export	3	1	1	2
XII Protecting the environment					
97.	General requirements for environmental protection	2	1	1	3
98.	*Prohibition on dumping animal carcasses	2	0	2	3
XIII Protecting animal welfare					
99.	General and specific animal welfare issues	3	3	1	0
XIV Penal provisions					
100.	*Punishments	5	2	0	0

* Asterisks denote the criteria that are essential for disease control

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Availability: February 2013

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The *Handbook on regulatory frameworks for the control and eradication of HPAI and other transboundary animal diseases* adopts the principles and approach of One Health by creating an understanding of the context in which diseases emerge, and by presenting the two key issues – legislation and regulatory frameworks – for the attention of administrators and policy-makers. The Handbook explains the critical role of regulatory frameworks (policy and institutional) on animal health and the need for close cooperation within countries between people who have technical veterinary expertise and those who have legal and regulatory expertise. It further defines the structure and elements of veterinary policy and legislation, the international frame of reference, the interface between veterinary policy, institutions and legislation, and the potential impacts of the national legal tradition on the way that laws are drafted specifically on animal health matters.

ISBN 978-92-5-107481-7 ISSN 1810-0708



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I3192E/1/01.13