

# **PVS Evaluation Report**

## JAPAN



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# **OIE PVS Evaluation report of the**

# **Veterinary Services of Japan**

## 11 – 26 October, 2016

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Disclaimer

This mission has been conducted by a Team of OIE PVS Pathway experts authorised by the OIE. However, the views and the recommendations in this Report are not necessarily those of the OIE.

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## List of acronyms, abbreviations and/or special terms

ADI	Allowed Daily Intake
AI	Avian Influenza
AFFRC	Agriculture, Forestry and Fisheries Research Council
ALIC	Agriculture and Livestock Industrial Corporation
AMR	Antimicrobial Resistance
AMR	
	Agricultural Mutual Relief (generally followed by "Associations")
APSD	Animal Product Safety Division
AQS	Animal Quarantine Service
AW	Animal Welfare
BIP	Border Inspection Post
BOUSAI	Japan's disaster preparedness programme
	(see http://www.bousai.go.jp/1info/pdf/saigaipanf_e.pdf)
BSL3	Bio Security Level 3
BVDV	Bovine Virus Diarrhoea Virus
CAA	Consumer Affairs Agency
CBPP	Contagious Bovine Pleuropneumonia
CC	Critical Competency
CCRVN	Council for the Certification of Registered Veterinary Nurses (CCRVN)
CE	Continuing Education
CIQ	Customs, Immigration and Quarantine
CJDv	Creutzfeldt-Jacob Disease variant
CSF	Classical Swine Fever
CVL	Central Veterinary Laboratory
CVO	Chief Veterinary Officer
DNA	Deoxyribonucleic Acid
EBL	Enzootic Bovine Leucosis
EIA	Equine Infectious Anaemia
EU	European Union
FAMIC	Food and Agricultural Materials Inspection Centre
FAO	Food and Agriculture Organisation
FMD	Foot and Mouth Disease
FSCJ	
	Food Safety Commission of Japan
FSCAB	Food Safety and Consumer Affairs Bureau
GCP	Good Clinical Practice
GDP	Gross Domestic Product
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
GoJ	Government of Japan
GPSP	Good Post-release Surveillance Practice
GQP	Good Quality Practice
HACCP	Hazard Analysis and Control of Critical Point
HPAI	Highly Pathogenic Avian Influenza
HR	Human Resources
ISO	International Standardisation Organization
IT	Information Technology
JA	Japan Agriculture
JAB	Japan Accreditation Board (http://www.jab.or.jp/en/)
JAS	Japan Agricultural Standard (Law)
JICA	Japan International Cooperation Agency
JLIA	Japan Livestock Industry Association
JLTA	Japan Livestock Technology Association
JPY	Japanese Yen
JRL	Japanese Racing and Livestock Promotion Foundation
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JSVS	Japanese Society for Veterinary Science
JVARM	Japanese Antimicrobial Resistance Monitoring System
JVMA	Japanese Veterinary Medical Association
LIMS	Laboratory Information Management System
LMO	Living Modified Organism- referred to for VMPs (aka GMO)
LPAI	Low Pathogenic Avian Influenza
LOOP	'Loop' mediated isothermal amplification for DNA
MAFF	Ministry of Agriculture, Forestry and Fisheries
MEXT	Ministry of Education, Sports and Technology of Japan
MHLW	Ministry of Health, Labour and Welfare
MoC	Memorandum of Cooperation
MRLs	Maximum Residue Levels
NACCS	Nippon Automated Cargo and Port Consolidated System
NAIA	National Agricultural Insurance Association (also as NOSI)
NIAH	National Institute for Animal Health (within NARO)
NAR	National Association of Racing
NARO	National Agriculture and Food Research Organisation
NGO	Non-Governmental Organisation
NIID	National Institute of Infectious Diseases
NVAL	National Veterinary Assay Laboratory
NLBC	National Livestock Breeding Centre
NOSI	National Agricultural Insurance Association (Nogyo Kyosai)
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
PASC	Pharmaceutical Affairs and Food Sanitation Council
	(also given as the Pharmaceutical Affairs Sub-Council in E136)
PCR	Polymerase Chain Reaction
PED	Porcine Epidemic Diarrhoea
PHC	Public Health Centres
PMWS	Post Weaning Multisystemic Wasting Syndrome
PPR	Peste des petits ruminants
	I Contraction of the second
PPRS	Porcine Respiratory and Reproduction Syndrome
PVS	Performance of Veterinary Services
PVS Tool	OIE Tool for the Evaluation of Performance of Veterinary Services
QA	Quality Assurance
QS	Quarantine Stations
SOPs	Standard Operating Procedures
SPS	Sanitary and Phyto Sanitary agreement of the WTO
SRM	Specified Risk Material
TADs	Trans boundary Animal Diseases
TB	Bovine Tuberculosis
UN	United Nations
VICH	
	International Cooperation on Harmonization of Technical Requirements for
	Registration of Veterinary Medicinal Products) (see <a href="http://www.vichsec.org">http://www.vichsec.org</a> /)
VMP	Veterinary Medical Products
VPH	Veterinary Public Health
VS	Veterinary Service(s)
VSB	Veterinary Statutory Body (see OIE Code definition)
WAHID	World Animal Health Information Database
WAHIS	World Animal Health Information System
WHO	World Health Organisation
WTO	World Trade Organisation

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The PVS Evaluation Team wishes to express its thanks to the Vice Minister for International Affairs, Hiromichi Matsushima, of the Japan Ministry of Agriculture, Fisheries and Forestry (MAFF) for his support of the PVS Evaluation of Japan.

The Team would particularly like to thank Dr Kumagai (CVO and Director of the Animal Health Division of MAFF), and Dr Ito, (OIE delegate and Director of the International Affairs Office of the Animal Health Division) for their strong leadership and commitment to the mission and all the ongoing support they provided. We would also like to thank Dr Kawashima, former OIE delegate and now Director General of the Food Safety Commission of Japan, for his longstanding leadership and support to the OIE, including in relation to Japan's recent PVS engagement.

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The team were also able to meet with a wide array of external stakeholders which provided an excellent opportunity to review the role of the Japan Veterinary Services and to conduct the PVS Evaluation. The mission would like to thank all those who met with us and supported our mission – we apologise for our many requests for further meetings which occasionally departed from the original schedule; this was not intended to be critical but merely to enhance our understanding of certain complex aspects of a strong and developed Veterinary Service such as Japan's. We also thank the many skilled language translators who supported us during our many meetings, both in Tokyo and in the other prefectures visited.

Finally, we should like to acknowledge the excellent logistic support of Dr Mari Kamogawa and Dr Saki Segami, staff of the Animal Health Division of MAFF. Our many requests for additional information were always met with good will and expeditious delivery.

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John Weaver

Julie Punderson

John Stratton

## **PART I: EXECUTIVE SUMMARY**

## I.1 Introduction

Following a request to the OIE from the Government of Japan, an evaluation of the Veterinary Services based on the OIE PVS (*Performance of Veterinary Services*) methodology was conducted from 11 – 26 October 2016 by independent OIE certified PVS evaluators.

The evaluation began with meetings with the Director of the Animal Health Division, the Chief Veterinary Officer (CVO), Dr Kumagai, and the senior staff at the Ministry of Agriculture, Fisheries and Forestry (MAFF), followed by courtesy meeting with Vice Minister for International Affairs, Hiromichi Matsushima. Meetings were held with officers from other sections of MAFF including the Animal Quarantine Service (AQS), the National Institute for Animal Health (NIAH) and the National Veterinary Assay Laboratory (NVAL) and from Competent Authorities including the Ministry of Health, Labour and Welfare (MHLW) and the Ministry of Environment (MoE). Discussions were also held with the Veterinary Council.

The OIE PVS Team visited sites and institutions in a number of prefectures, cities and rural areas of Japan and discussed the management of Veterinary Services (VS) with government officials, public and private sector veterinarians, livestock producers, traders, consumers and other stakeholders.

Preliminary findings of the evaluation were presented at a closing meeting held at the MAFF office in Tokyo. The meeting was attended by the Director of the Animal Health Division, Dr Kumagai and senior staff, with representatives from AQS and the Veterinary Council.

## I.2 Key findings of the evaluation

The VS of Japan are very well developed with excellent policies, well developed systems and very adequate resources to carry out effective animal health and veterinary public health prevention and control programmes.

A summary of the PVS Evaluation mission findings are presented here further details are provided in the main body of the report.

In section, I.3 Recommendations, the PVS Evaluation mission presents recommendations for the further strengthening of the Veterinary Services of Japan

## I.2.A Human, physical and financial resources

The VS have very high levels of resources: human, physical and financial, at all levels. The large number of registered veterinarians (approximately 40,000) allow almost all aspects of the V S to be delivered by veterinarians including in the field, at abattoirs and at the border posts. Veterinary technical skills are consistently high with national qualifications and registration, and well established and resourced veterinary schools. Veterinary paraprofessionals are little used in Japan as the number of veterinarians is so high.

Internal coordination and the 'chain of command' between central MAFF (animal health) or MHLW (veterinary public health) and their prefecture divisions is well established with regular meetings, and frequent informal contacts. There is a logical pattern of programme design and implementation with policy setting undertaken centrally and implementation by the prefectures and their Livestock Hygiene Service Centres for animal health, and Meat Hygiene Inspection Centres and Public Health Centres for food safety.

External coordination with other ministries and agencies operates effectively with MAFF (animal health) working closely with MHLW (animal food safety), MoE (wildlife and animal welfare) and other commissions and centres such as the Food Safety Commission of

Japan and Food and Agricultural Materials Inspection Centre (FAMIC) for agricultural product safety). A number of activities are managed by other government or (quasi) government supported agencies including livestock traceability (National Livestock Breeding Centre), vaccination programmes (Livestock Industry Federations/Associations), livestock markets (Farmer Cooperatives) and clinical veterinary services (Bureau of Consumer Affairs, via the NOSAI mutual aid insurance scheme). There is an opportunity to increase data sharing between these groups to strengthen epidemiology and risk management to assign priorities and develop programmes and to promote effective and efficient programme delivery; the various Competent Authorities have defined roles and responsibilities defined in Ia or by MoUs. The diagram below indicates the complex delivery of animal health services to farmers in Japan.

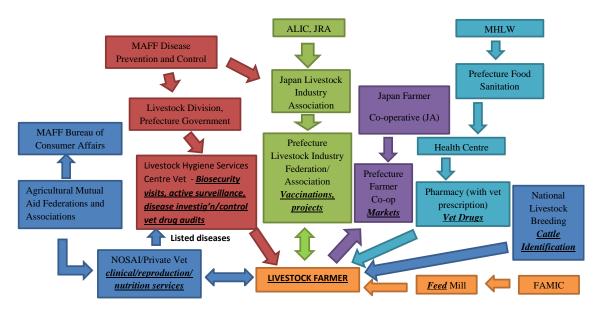


Figure 1: Flow diagram of field veterinary services in Japan

Operational funding of the VS is well defined and regular. Funding of regulatory animal health services is provided largely by central government and is at a level that allows the VS to undertake all core activities and to design and implement new disease prevention and control programmes as required. The NIAH reported that they faced some budget constraints to their operations. Additional financial support is provided through the industry associations. Capital investment is on an 'as needed' basis and is generously applied with excellent facilities and equipment available throughout the country.

The VS have a number of longstanding disease prevention and control programmes such as the mandatory rabies dog registration and vaccination programme. Programmes are generally reviewed and developed as situations change, e.g. Bovine Spongiform Encephalopathy (BSE) testing and Highly Pathogenic Avian Influenza (HPAI) surveillance and response.

Staff are regularly 'rotated' through positions in the VS and though this provides greater understanding of the service there is a risk of loss of critical corporate knowledge in key areas. Staff promotion is often based on seniority and length of service, and not on merit.

MAFF and MHLW do not have longer term strategic plans for the national VS, indicating how they expect to develop animal health, veterinary public health and livestock production in Japan, and considering the challenges being faced including the evolving international trade environment, food safety and security, production levels, farm sizes, and part time and aging farmers.

## I.2.B Technical authority and capability

Japan has an extensive network of veterinary diagnostic and research laboratories which cover animal health, food safety, animal feed safety, veterinary drugs and residues. The laboratories have excellent facilities with high standards of modern equipment and well trained staff. The laboratories are well used with a high throughput of diagnostic and monitoring samples. Only the main NIAH, AQS and FAMIC laboratories have formal quality assurance accreditation; a number of other laboratories are developing quality management programmes. NIAH, the Research Centre for Zoonosis Control, Hokkaido University and the National Research Centre for Animal Protozoal Diseases are examples of recognised OIE Reference Laboratories.

Import risk and food safety analysis by MAFF, MHLW and the Food Safety Commission of Japan is well resourced and technically strong. Measures applied are often more stringent than those specified by international standards. Quarantine and border security is rigorously managed through policies set by MAFF (animal health) and MHLW (veterinary public health) and implemented by AQS. Quarantine facilities and activities are of a very high standard. The programme for border control has a strong awareness and communication element and strong commitment and understanding from the public and industry.

The passive surveillance system operates well through the extensive and active field network of the Livestock Hygiene Service Centres, and the NOSAI and private veterinary clinics; the procedures and response to suspected disease outbreaks are well defined. The Livestock Hygiene Service Centres veterinarians also conduct annual biosecurity inspections of all livestock farms resulting in very high levels of producer contact and awareness. Compensation is well established and this protection for producers further supports the delivery of an effective passive surveillance system. To support the sensitivity of the early detection of emerging and foreign animal diseases it is critically important to conduct regular testing of suspected clinical cases using a broad case definition to avoid premature 'exclusion' of a serious disease occurrence. There is currently a lack of recent exclusion testing for possible Foot and Mouth Disease (FMD) cases and this absence weakens the overall confidence in the passive surveillance programme (see CCII.5A for more details).

Active surveillance programmes are well designed and undertaken continually for priority diseases and disease control programmes. The combination of active and passive surveillance activities results in a highly sensitive surveillance programme and an excellent real time understanding of Japan's animal health status.

Emergency response arrangements are fully developed in Japan as demonstrated by a number of recent successful eradications of FMD and Highly Pathogenic Avian Influenza (HPAI). There is a full range of technical contingency planning, legislative and financial arrangements, and the response systems are very well practiced through at least annual simulation exercises in every prefecture, including with those outside the Veterinary Authority such as the police and emergency services.

Diseases are classified into Category A diseases where the objective is eradication and Category B diseases where monitoring and disease containment is the target. Priority disease control programmes include: Enzootic Bovine Leucosis (EBL), Johne's disease, bovine tuberculosis and brucellosis, BSE, Bovine Virus Diarrhoea (BVD) in cattle; Porcine Epidemic Diarrhoea (PED), Porcine Reproductive and Respiratory Syndrome (PRRS), Aujeszky's disease and Classical Swine Fever (CSF) in pigs; and Avian Influenza (AI), Newcastle disease and avian mycoplasma in poultry.

The lack of MAFF direct line authority over some aspects of disease control including vaccination, livestock traceability and markets complicates the coordination of disease control activities. Although good progress seems to be being made against most targeted

diseases based on active surveillance, no substantive reviews of disease control activities and no reports on any studies of effectiveness and efficiency were available.

Veterinary public health is a very high priority and is led by MHLW working in association with MAFF. Food safety is well managed through producer and abattoir programmes that monitor food borne zoonoses. All slaughter premises are inspected and registered and *ante* and *post mortem* inspection is undertaken by certified inspectors, almost all of whom are veterinarians. Food processors and distributors are similarly required to be registered and are regularly inspected.

Traceability of cattle and cattle products is exemplary with individual animal identification from farm to the end user (retailer and restaurants); a website allows the public access to enter the product code and to trace back to the processor, abattoir and the farm of origin of the source animal. It was reported that pigs and poultry products are generally traceable back to the abattoir and the batch sent from the farm based on consignment records kept at the slaughterhouse.

Japan has a robust and rigorous programme for the registration, manufacture or import, distribution and use of veterinary medicines and biologicals. An effective functional pharmaco-vigilance programme for monitoring adverse events is in place. An effective national residue testing programme is operating; no records of non-compliance were available – a finding that should be formally reviewed to assess sensitivity. Similarly animal feed safety is strictly managed through FAMIC but again the lack of any reported non-compliance issues suggests the need for review.

Animal welfare legislation is in place and active programmes are operating. There is an opportunity to review and strengthen both legislative and compliance aspects of livestock welfare management in line with OIE standards.Records of non-compliance are publicised by the Minstry of Environment including numbers arrested by the National Police Agency, and relevant website links were provided subsequent to the mission.

#### *I.2.C* Interaction with interested parties

Communications with stakeholders is strong in Japan. Both MAFF and prefecture government Livestock Divisions have websites that are updated regularly, and AQS also has a social media presence to promote quarantine practices (by importers and passengers). Prefecture monthly newsletters are sent to producers via email or fax to keep them informed of animal health issues and can also be used immediately for outbreaks; these include information on "BOUSAI" (Japan's disaster preparedness and response system).

Stakeholder consultation is somewhat unusual in Japan as there is no clearly representative industry association organised to influence government policy or programmes. Farmer cooperatives represent industry in principal but their leadership is not democratically representative and their role is more as a mechanism to support rather than to influence. The higher level industry groups, such as the Japan Livestock Industrial Association, do influence high level policy decision making through membership of the Animal Health Advisory Committee, which reports directly to the Minister.

Japan is a very strong contributor to international organisations including the OIE and Codex Alimentarius, including as an active meeting participant, in standards development, in hosting the OIE Regional Representation office and through the development of regional initiatives.

Japan does officially delegate tasks to non-government veterinarians as well as nongovernment veterinary laboratories, in the few areas where government capacity is lacking. The process of delegation is well defined and monitored.

The Veterinary Affairs Council, as the Veterinary Statutory Body, regulates the veterinary profession under appropriate legislation. High standards of education, technical

performance and behaviour are well maintained. As the Veterinary Affairs Council is part of government its independence could be questioned and alternative options should be considered to more fully comply with OIE guidelines. Veterinary registration is one-off, for life, and there is no linkage to continuing education. Evidence of disciplinary action to maintain the technical standards of the veterinary profession is lacking.

## I.2.D Access to markets

Japan has comprehensive, well-structured legislation with the necessary subordinate 'Ordinances'. The legislation is revised as necessary and in alignment with international OIE and other standards. There is a strong extension programme of the requirements set down in legislation with high levels of awareness and compliance by producers and owners to most government programmes. The exception being the low rate of annual vaccination of dogs against rabies; this requirement should, in any case, be reviewed given the length of time since rabies occurred in Japan and the strong border control measures in place. As an overall theme, there are virtually no reported cases of legislative non-compliance or how these cases were handled – this situation is unsatisfactory as it provides no indication of the sensitivity of the enforcement programmes or assurances as regards to their benefit-cost.

International certification is handled by AQS for both animal health (MAFF) and veterinary public health (MHLW). The evidence required for reliable certification is readily available and the certification process is well defined and managed. There were no reports of any major certification problems – minor typographical errors were recorded.

Japan has a strong policy of protecting its high animal health status and an established programme of international sanitary agreements, e.g. to allow imports from HPAI and FMD disease free zones. Japan has few 'equivalence' agreements understandably as the national policy of low levels of acceptable risk precludes such arrangements.

Japan complies fully with international requirements, as laid down in OIE standards, for the immediate notification of outbreaks of emergency animal diseases or unusual events and periodic updates on the endemic disease situation.

Japan currently has no legislation or plans for disease zoning or compartmentalisation.

#### Japan

PVS summary results of Japan	Result
I. HUMAN, PHYSICAL AND FINANCIAL RESOURCES	
I.1.A. Staffing: Veterinarians and other professionals	5
I.1.B. Staffing: Veterinary paraprofessionals and other	5
I.2.A. Professional competencies of veterinarians	5
I.2.B. Competencies of veterinary paraprofessionals	5
I-3. Continuing education	4
I-4. Technical independence	5
I-5. Stability of structures and sustainability of policies	5
I-6.A. Internal coordination (chain of command)	5
I-6.B. External coordination	4
I-7. Physical resources	5
I-8. Operational funding	5
I-9. Emergency funding	5
I-10. Capital investment	5
I-11. Management of resources and operations	4
II. TECHNICAL AUTHORITY AND CAPABILITY	
II-1.A. Access to veterinary laboratory diagnosis	5
II-1.B. Suitability of national laboratory infrastructures	5
II-2. Laboratory quality assurance	3
II-2. Laboratory quality assurance	4
II-4. Quarantine and border security	5
II-5.A. Passive epidemiological surveillance	4
II-5.B. Active epidemiological surveillance	5
	5
II-6. Emergency response II-7. Disease prevention, control and eradication	5
II-7. Disease prevention, control and eradication II-8.A. Regulation, authorisation and inspection of establishments	5
II-8.B. Ante and post mortem inspection	5
II-8.C. Inspection of collection, processing and distribution	5
II-9. Veterinary medicines and biologicals	5
II-9. Veterinary medicines and biologicals	5
II-10. Residue testing	5
II-12.A. Animal identification and movement control	5
II-12.A. Animal identification and traceability of animal products	5
II-12.B. Identification and traceability of animal products	3
III. INTERACTION WITH INTERESTED PARTIES	3
III-1. Communications	5
III-2. Consultation with interested parties	3
III-3. Official representation	5
III-4. Accreditation/authorisation/delegation	5
III-5.A. Veterinary Statutory Body Authority	4
III-5.B. Veterinary Statutory Body Capacity	3
III-6. Participation of producers and other interested parties in joint programmes	5
IV. ACCESS TO MARKETS	5
IV. ACCESS TO MARKETS IV-1. Preparation of legislation and regulations	5
IV-1. Preparation of registration and regulations IV-2. Implementation and compliance with legislation and regulations	4
IV-2. International harmonisation	5
IV-3. International narmonisation	5
	4
IV-5. Equivalence and other types of sanitary agreements	4
IV-6. Transparency	
IV-7. Zoning	NA NA
IV-8. Compartmentalisation NA - Not assessed	INA

NA - Not assessed

## I.3 Conclusions and key recommendations

A number of weaknesses were identified in the VS, and a number of opportunities where the service might be further strengthened and more fully aligned with OIE guidelines. These opportunities are presented below as key recommendations – further recommendations are made under each Critical Competency where appropriate.

An overarching recommendation is that MAFF, with MHLW, should consider developing a longer term, 5 year strategic plan for the national Veterinary Services, that clarifies how they should support the broader directions for animal health, veterinary public health and livestock production in Japan, considering its various challenges including the evolving international trade environment, the priority of food safety and food security and livestock production with increasing exports.

## I.3.A Human, physical and financial resources

Staff levels and technical capabilities are generally strong. A more structured approach to developing specialist skills in key disciplines such as epidemiology, risk assessment and animal health economics, should be developed with the strengthening of staff development programmes and continuing education. The system of using 'terms of reference' for staff focuses on six month targets for staff work plans which would benefit from longer timelines for staff planning and development. Opportunities to enhance, transparent merit-based promotion within the government veterinary services should be explored.

Continuing education is currently largely unstructured following no overall strategic plan. Comprehensive staff development plans should be developed targeting key technical and management abilities as required at organisational and individual levels.

The Veterinary Affairs Council should consider adopting the internationally recognised practice of 'specialist colleges' for accredited disciplines in a range of topics such as epidemiology, pathology, cattle medicine, poultry health, etc. The Council should also consider changing its policy on one-off registration to include a requirement for annual re-registration with continuing professional development being mandatory.

Animal and veterinary public health programmes could be made more sustainable by undertaking regular formal reviews considering the long term strategic plans for the livestock industry and including the use of economic assessments such as cost-benefit and cost effectiveness analyses. In particular long standing programmes such as the requirement to vaccinate dogs annually against rabies and the ongoing programme of monitoring for CSF and mandatory testing for BSE should be reviewed.

Emergency preparedness and response is of the highest standard and well-practiced; running national simulation exercises involving all sectors of government, would further strengthen emergency preparedness.

A review of external coordination mechanisms with other agencies and the private sector should be undertaken. This review should consider the benefit of establishing systems for the clearer coordination of activities and data from markets and slaughterhouses as inputs to the early detection of outbreaks, disease monitoring and control activities.

## I.3.B Technical authority and capability

The veterinary laboratory network is of a very high standard. Consideration should be given to undertaking a comprehensive review of the laboratory network, its resources, capabilities and capacity, as there appears to be an opportunity to consolidate, specialise and rationalise services to make the service more cost-efficient.

NIAH's role as the national reference laboratory for animal diseases should be strengthened with a greater leadership role in quality assurance and proficiency testing and increasing submission of samples for differential diagnostic and reference testing.

Quality assurance programmes in many laboratories are only just starting. More emphasis and support of quality management and formal quality assurance accreditation should be strongly considered in priority laboratories. The would better ensure that the laboratory results produced in Japan can be interpreted with full confidence, including internationally.

The use of risk management to design and monitor disease prevention and control programmes should be increased. A number of diseases, especially those absent from the country, are being over managed with restrictive practices being imposed that are unsupported by current scientific evidence and international standards. A risk analysis approach should also be applied to feed safety measures, including the very high levels of audit and testing with very low non-compliance rates being detected and the monitoring of restrictions on swill feeding. The specialised capacity for post-graduate training in risk assessment within Japan should be developed.

Japan could consider undertaking a review of AQS priorities taking into account the change in international animal health and its risks, including conducting a risk and costeffectiveness analysis to identify limitations and surplus capacity and review the allocation of resources to activities accordingly.

The passive surveillance programme, with the early detection and reporting of suspect animal diseases is generally operating well. A concern is the lack of samples being sent to the national reference laboratory, NIAH, for differential diagnostic testing of significant transboundary animal diseases such as FMD, due to a policy requiring initial clinical and epidemiological analysis. It is strongly recommended that increased numbers of samples from disease outbreaks are submitted for differential diagnostic testing immediately upon any suspicion.

Currently outbreak data is largely managed on a case-by-case basis and only entered into a simple spread sheet. With modern information technology there is an opportunity to develop an integrated animal health information system operating in real-time to capture the reporting and investigation of suspect diseases and the results of diagnostic testing. Such a system for data capture from all levels of the Veterinary Services should use recent advances in information technology and data integration such as SMS, phone apps, spread sheets and other data formats. The system would allow the integration of data in real time and could be used to provide automated reports and mapping with trigger points being set for follow up activities. This approach would immensely strengthen animal and veterinary health programmes and the provision of real-time information on animal health in Japan.

Periodic reviews of the disease control programmes should be undertaken based on the results of surveillance activities, epidemiological risk assessment and economic costbenefit analysis.

Japan's active surveillance and endemic disease control programmes are operating effectively with the prevalence of most diseases declining over time, though the control of porcine epidemic diarrhoea and enzootic bovine leucosis continues to be a challenge. In general, there is an opportunity to better integrate control activities including the use of compensated culling, tracing, quarantine, vaccination, disinfection, inspection and follow up testing/surveillance. Not having direct control over the livestock vaccination and animal

identification programmes or of animal inspection at livestock markets makes this task harder.

Emergency preparedness and response systems are well established and resourced. There is an opportunity to further strengthen these by running a large, national scale, simulation exercise to clarify agency roles and responsibilities. Such exercises should also involve disease tracing nationally and participation by other stakeholders such as transporters, abattoir owners and livestock markets.

Food safety is a priority and well managed nationally. Periodic formal audits at slaughterhouses should be undertaken to further strengthen disease surveillance and the food safety inspection programmes.

The dispensing of veterinary medicines without direct examination of the affected animal by a veterinarian runs the risk of misdiagnosis or delayed detection of major disease outbreaks. Dispensing of medicines in this way should follow a clearly defined protocol, be well documented and regularly audited.

Animal feed safety management and monitoring is very strong through FAMIC. It is a concern that no non-compliance has been detected in five years. The approach to testing and sampling should be reviewed using a risk analysis approach and then the site visit and sampling protocols amended to achieve the desired sensitivity.

Individual animal identification through to end user is in place and operating well for cattle. There is an opportunity to increase animal and product traceability in poultry and pigs. The approach to these should be developed in close collaboration with industry – as is already being piloted.

Animal welfare legislation and guidelines exist for many sectors and activities however some gaps remain such as for livestock transport and slaughter. It is recommended that a national review is undertaken, referring to the OIE international standards, and then steps are taken to address the outstanding activities.

## *I.3.C* Interaction with interested parties

Communications with stakeholders are already of a very high standard; consideration might be given to increasing the use of social media beyond its current use by AQS.

There is an opportunity for the Veterinary Services to increase industry and/or farmer inputs into the design and development of animal health policies and programmes, particularly targeting efficiency and effectiveness. Consideration should be given to establishing a 'peak', highest level, industry body, with representative governance, that can coordinate input from all industry and producer sectors and advocate policies and programmes to government.

Little delegation and accreditation currently takes place in Japan – as the government systems are so strong they are not generally required. Emergency preparedness and response 'surge' capacity could be increased through the development of a programme of delegating supporting response activities to private veterinarians and laboratories.

Options should be explored for the Veterinary Affairs Council, the Veterinary Statutory Body, to be more independent of government, including the selection of Council members and independent funding through annual re-registration fees. Also veterinary nurse training and licensing should be more rigorous with a comprehensive licensing programme, preferably through the Veterinary Affairs Council.

## I.3.D Access to markets

Legislation is of a uniformly high standard and is generally revised and updated as necessary. Notwithstanding this some programmes and supporting legislation would benefit from review; most particularly this applies to the longstanding Rabies Prevention Act and its mandatory requirements. Acts relating to rabies and BSE could also be revised into generic animal health and public health acts, given the declining risks.

Compliance rates are extraordinarily high with virtually no reports of non-compliance from any activity sector – import requirements, implementation of disease surveillance and control, veterinary medicine use, animal welfare and professional standards. The lack of any non-compliance data is a concern as it suggests that the programme of enforcement may be weak or inefficient. It is recommended that a review of enforcement activities and compliance is undertaken across the whole domain of the Veterinary Services – veterinary professional standards and disciplinary actions, and the prudent use of veterinary medicines. Some additional information on animal welfare compliance data and reporting, including publication on websites, was provided after the mission.

Consideration should be given to developing policies for disease zoning and compartmentalisation to protect export markets and reduce the economic impact in cases of emergency disease outbreaks.

## PART II: CONDUCT OF THE EVALUATION

At the request of the Government of Japan, the Director General of the OIE appointed an independent OIE PVS team consisting of Dr John Weaver (Team Leader) and Dr Julie Punderson and Dr John Stratton (Technical experts) to undertake an evaluation of the Veterinary Services of Japan. The evaluation mission took place from 11 - 26 October 2016.

The evaluation was carried out with reference to the OIE standards contained in Chapters 3.1., 3.2., 3.3. and 3.4. of the OIE *Terrestrial Animal Health Code* using the OIE *PVS Tool* (6<sup>th</sup> edition, 2013) to guide the procedures. Relevant Terrestrial Code references are quoted for each critical competency in Appendix 1. A glossary of terms used is provided in Appendix 2.

This report identifies the strengths and weaknesses of the Veterinary Services of Japan compared with the OIE standards. The report also makes general recommendations for actions to improve performance.

## **II.1** OIE PVS Tool: method, objectives and scope of the evaluation

To assist countries to establish their current level of performance, form a shared vision, establish priorities and carry out strategic initiatives, the OIE has developed an evaluation tool called the OIE Tool for the Evaluation of Performance of Veterinary Services (OIE PVS Tool<sup>1</sup>) which comprises four fundamental components:

- Human, physical and financial resources
- Technical authority and capability
- Interaction with interested parties
- Access to markets.

These four fundamental components encompass 47 critical competencies, for each of which five qualitative levels of advancement are described. For each critical competency, a list of suggested indicators was used by the OIE PVS Team to help determine the level of advancement.

The report follows the structure of the OIE PVS Tool and the reader is encouraged to consult that document to obtain a good understanding of the context in which the evaluation was conducted.

The objective and scope of the OIE PVS Evaluation includes all aspects relevant to the OIE Terrestrial Animal Health Code and the quality of Veterinary Services.

# **II.2** Country information (geography, administration, agriculture and livestock)

Japan is an island country in East Asia. Located in the Pacific Ocean, it lies to the east of the Sea of Japan, the East China Sea, China, Korea and Russia, stretching from the Sea of Okhotsk in the north to the East China Sea and Taiwan in the south. Japan is a stratovolcanic archipelago of 6,852 islands. The four largest are Honshu, Hokkaido, Kyushu and Shikoku, which make up 97% of Japan's land area.

The country is divided into 47 prefectures in eight regions (see Maps 4 and 5). The population of 126 million is the world's tenth largest. Japanese people make up 98.5% of Japan's total population. Approximately 9.1 million people live in the core city of Tokyo, the capital city of Japan, which is the sixth largest city proper in the OECD and the fourth leading global city in the world. The Greater Tokyo Area, which includes Tokyo and several surrounding prefectures, is the world's largest metropolitan area with over 35 million residents and the world's largest urban agglomeration economy.

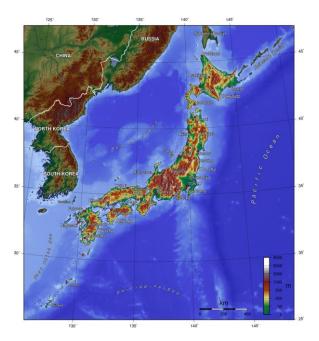
<sup>&</sup>lt;sup>1</sup> Available at <u>http://www.oie.int/eng/oie/organisation/en\_vet\_eval\_tool.htm?e1d2</u>

Map 1: Japan location in East Asia



Since adopting its revised constitution in 1947, Japan has maintained a unitary constitutional monarchy with an Emperor and an elected legislature called the National Diet. Japan is a member of the UN, the G7, G8, and G20 and is considered a great power. The country has the world's third-largest economy by nominal GDP and the world's fourth largest economy by purchasing power parity. It is the world's fourth-largest exporter and fourth-largest importer.

Japan is a developed country with a high standard of living and Human Development Index. Japan enjoys the highest life expectancy and the third lowest infant mortality in the world. It is the world's fifth largest donor of official development assistance (US\$9.2 billion in 2014).



Map 2: Japan topography

Japan's climate varies from subtropical in the south to temperate in the north. The Köppen climate classification describes Japan as four climate types: warm/humid continental and temperate/humid continental, warm oceanic/humid subtropical and temperate/humid continental.

Map 3: Japan climate types

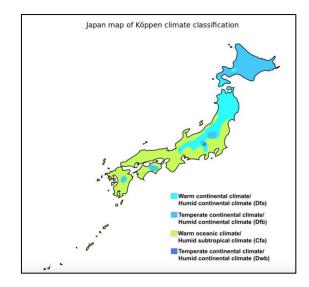


Figure 2: Annual temperatures in four locations in Japan

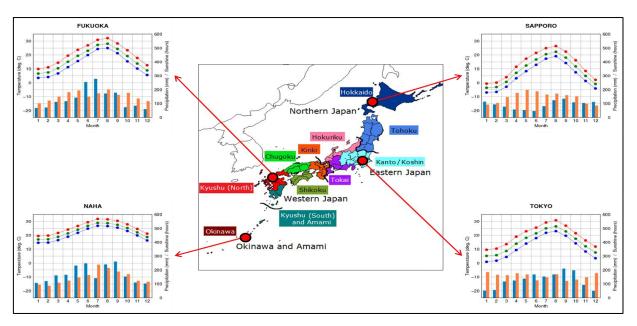


 Table 2: Demographic data

Human population		Livestock households/farms <sup>2</sup>		
Total number	127.3 million (2013)	Beef	57,500	
Average density / km2	336.33	Dairy	18,600	
% of urban	>90%	Pigs	5,270	
% of rural	<10%	Layers	2,560	
		Sheep/goats	Few - not available	
		Total number	86,310	

NOTE - The average farm size in Japan (livestock and cropping/horticulture) is 26 hectares. Most livestock farmers in Japan are part time.

 $<sup>^{\</sup>rm 2}$  Provided by MAFF, data as of Feb 2014.

### Table 3: Current livestock census data

Animals	Total Number	Production system
species		
Beef Cattle	2.57 m	Virtually all systems are
Dairy Cattle	1.4 m	intensive
Pigs	9.54 m	
Sheep & goats	<50,000	
Layers	172 m	]
Broilers	136 m	

#### Table 4: Animal and animal product trade data

	Average annual imports (2011-2015)		Average annual exports (2011-2015)	
Animal, animal products	Quantity tons (heads)	Value (million JPY) meat/heads	Quantity ton	Value (000s <i>JPY</i> )
Meat, cattle	516,000 (11,700)	268 (2.08)	1,041	6,690
Meat, chickens	463,000 (605,000)	127 (0.85)	8,010	1,260
Meat, pigs	810,000 (923)	425 (0.22)	208	401
Meat, sheep	18,000 (13)	13.6	0	0
Eggs, whole*	880	0.30	1.1	280
Milk products**	302,000	128	394	529
TOTAL	-	962m JPY	-	9.16m JPY

\*thousand tons of fresh whole chicken eggs (imports), tons of fresh whole chicken eggs (exports) \*\*thousand tons of butter, whey, and cheese

(Ref: Trade Statics of Japan)

## Table 5: Economic data

National GDP	487,000 b JPY (2014)
National budget	96,700 b JPY (2016 FY) <sup>3</sup>
Livestock GDP	0.3% of National GDP (estimated)
Economic value of livestock population	2,945 b JPY (2014 FY) (estimated)
Annual public sector contribution to	National public sector budget (2015 FY):
agriculture	1,655 m JPY Department of Food Safety
	9,298 m JPY Quarantine Stations
Annual budget of the Veterinary	8,427 m JPY MAFF (Animal Products Safety Division and
Authority	Animal Health Division)
	822 m JPY Animal Quarantine Service
	8,968 m JNY MAFF Quarantine Stations
	13 m JPY MHLW (Tuberculosis and Infectious Diseases
	Control Division)
	1,553 m JPY MHLW (Department of Food Safety)

<sup>&</sup>lt;sup>3</sup> Note the fiscal year (FY) in Japan runs April to March and is referred to by the starting year

## **II.3** Context of the evaluation

## II.3.A Availability of data relevant to the evaluation

A list of documents received by the OIE PVS Team before and during the PVS Evaluation mission is provided in appendix 6. All documents and pictures listed in Appendix 6 are referenced to relevant critical competencies to demonstrate the levels of advancement and related findings.

The following table provides an overview of the availability of the main categories of documents or data needed for the evaluation, taking into account the information requirements set out in the OIE Terrestrial Animal Health Code.

		Data	Data	
		Data available in	Data accessible	Data
	Main document categories			not available
		the public domain	only on site or on request	
$\rightarrow$	Animal census:	uomam	or on request	
~		v		
		X		
		X		
	o per animal species	X		
<u> </u>	<ul> <li>per production systems</li> </ul>	Χ		
$\rightarrow$	Organisations charts	V		
	• Central level of the VS	X		
	• 2 <sup>nd</sup> level of the VS	X		
L	• 3 <sup>rd</sup> level of the VS	Х		
$\rightarrow$	Job descriptions in the VS	X		
	Central levels of the VS	X		
	• 2 <sup>nd</sup> level of the VS	Х		
	<ul> <li>3<sup>rd</sup> level of the VS</li> </ul>	Х		
$\rightarrow$	Legislations, regulations,			
	decrees			
	<ul> <li>Animal health and public health</li> </ul>	Х		
	<ul> <li>Veterinary practice</li> </ul>	Х		
	<ul> <li>Veterinary statutory body</li> </ul>	Х		
	<ul> <li>Veterinary medicines and biologicals</li> </ul>	Х		
	<ul> <li>Official delegation</li> </ul>	NA		
$\rightarrow$	Veterinary census			
	<ul> <li>Global (public, private, veterinary, para-professional)</li> </ul>	Х		
	<ul> <li>Per level</li> </ul>	Х		
$\rightarrow$	Census of logistics and	X		
	infrastructures			
$\rightarrow$	Activity reports		Х	
	Financial reports		X X	
	Animal health status reports	Х		
$\rightarrow$			Х	
$\rightarrow$			X X	
	letters			
		•		

## Table 6: Summary of data available for evaluation

## **II.3.B** Organisation of the Veterinary Services

The Veterinary Services of Japan have a strong chain of command for their core activity of delivering national animal health policies and programmes through the Ministry of Agriculture, Fisheries and Forestry (MAFF). The chain of command operates directly from the central MAFF to its prefecture Animal Health Divisions and the delivery of government field services through their Livestock Hygiene Service Centres and onto the NOSAI and private veterinary clinics.

The main partner Competent Authorities are the Ministry of Health, Labour and Welfare (MHLW) for veterinary public health and food safety and the Ministry of Environment (MoE) for animal welfare and wildlife health. The ministries have similar direct line authority over their prefecture operations.

A short summary of the complex array of ministries and agencies that make up the Japanese Veterinary Services is provided here.

#### **Veterinary Authority**

The Animal Health Division of MAFF is the Veterinary Authority of Japan. Organisationally, the Animal Health Division works alongside the Animal Products Safety Division under the Food Safety and Consumer Affairs Bureau of MAFF<sup>4</sup>.

The Animal Health Division is made up of quarantine, planning and inspection units under the CVO (the Division Director), and the Animal Disease Control and Prevention Office and International Animal Health Affairs Office. The Director of the International Animal Health Affairs Office is the OIE delegate for Japan.

The Animal Disease Control and Prevention Office ('domestic') is made up of units covering 'general affairs' (oversight and review), epidemiology planning and control, hygiene and health, pathogen control and survey analysis.

The International Animal Health Affairs Office has units for risk analysis, quarantine, global animal health and OIE affairs and also a 'general affairs' unit.

The mandate of the Animal Health Division is to provide policy and guidance on 'animal disease control to the prefectural governments, the National Institute of Animal Health and other relevant organisations including the Animal Quarantine Service of MAFF'.

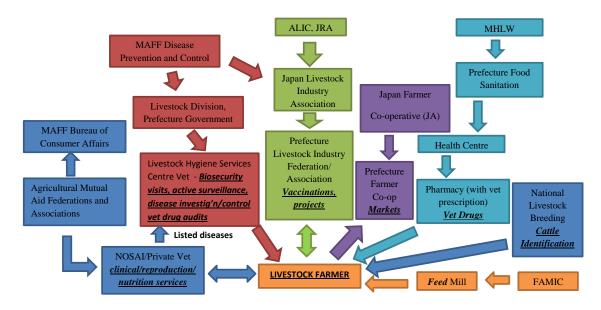


Figure 3: Flow diagram of field veterinary services in Japan

<sup>&</sup>lt;sup>4</sup> For organisation chart see: <u>http://www.maff.go.jp/e/about/organ/att</u> ach/pdf/index-11.pdf.

#### Other Relevant Competent Authorities

A number of partner Competent Authorities work with the Animal Health Division, the main Veterinary Authority, and provide broad coverage of the veterinary domain. The relationship and responsibilities between the Veterinary Authority and other Competent Authorities is well defined, in most cases in law or in formal MoUs. Other Competent Authorities include:

- Animal Products Safety Division, MAFF feed safety, veterinary drugs regulation, traceability, aquatic animal health, veterinary education, licensing of veterinarians and pet animals.
- Animal Quarantine Service, MAFF import risk management
- Consumer Affairs Bureau, MAFF food safety and mutual aid program
- Food Safety Commission of Japan food safety and risk assessment
- Ministry of Environment animal welfare and wildlife health
- Ministry of Health, Labour and Welfare food hygiene, control of zoonoses
- Food and Agricultural Materials Inspection Centre animal feed safety
- National Veterinary Assay Laboratory and National Institute of Animal Health veterinary medicines and biologicals control and veterinary diagnostics and research respectively
- National Livestock Breeding Centre live cattle and beef traceability systems

Further complicating the delivery of the Veterinary Services are two semi-independent national bodies. Despite their names and a perception of being outside government, their governance mechanisms do not reflect traditional forms of industry or other stakeholder representation (e.g. election by subscription paying members). For example, the Japan Livestock Industry Association is largely funded and controlled by government (e.g. MAFF and ALIC<sup>5</sup>). These influential groups are:

- Japan Livestock Industry Association funded by MAFF, ALIC and the Japan Racing Industry. This body has animal health responsibilities in the area of livestock vaccination and emergency disease preparedness.
- Japan Agricultural Cooperative Association (JA) this body plays an influential role in achieving economies of scale for inputs and prices for Japan's farmers, most of whom only work part time. It plays a small role in animal health.

## Subnational

MAFF delivers its national operations through eight regions via Regional Agricultural Administration Offices or directly via the 47 prefecture Animal Health Divisions. Within the 47 prefectures there are 170 Livestock Hygiene Service Centres that provide the field animal health services.

The Regional Agricultural Administration Offices have a limited role in administering the core activities of the Veterinary Services working largely to develop and stabilise product supply and market prices and to facilitate livestock production through support of biosecurity/farm hygiene.

The main delivery of local veterinary services for MAFF is through the prefecture Animal Health Divisions and their Livestock Hygiene Service Centres. The prefecture Animal Health Divisions operate as a number of sections, typically Livestock Hygiene, and

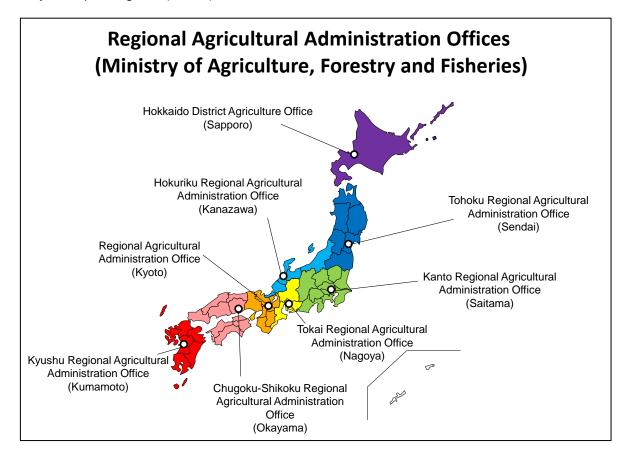
<sup>&</sup>lt;sup>5</sup> The Agriculture and Livestock Industries Corporation (ALIC) is a semi-autonomous body that ensures the "stability for food supply to consumers" including by "management stability measures" and "market adjustment and price stabilization measures" targeting agricultural producers, including livestock farmers. They play a small role in animal health especially for emergency management. See <a href="http://www.alic.go.jp/english/who.html">http://www.alic.go.jp/english/who.html</a>

variously others such as an animal welfare, wildlife/environment and a feed section; sometimes specific groups operate for specialist areas such as for horse racing. These operational sections are supported by a management/coordination group.

The Livestock Hygiene Service Centres are tasked with the planning, coordination and implementation of animal health field operations (disease surveillance and control and emergency response) in their area including communications and awareness of producers and the community, the prevention and diagnosis of disease, support of breeding (e.g., artificial insemination, embryo transfer) and the licensing of drug shops and veterinary clinics. Disease control is focused on early detection, preparedness and response for emergency diseases (e.g, HPAI, FMD, CSF, African swine fever) and surveillance and control of priority endemic diseases (e.g, tuberculosis, brucellosis, Johne's disease, salmonellosis, PRRS, PED).

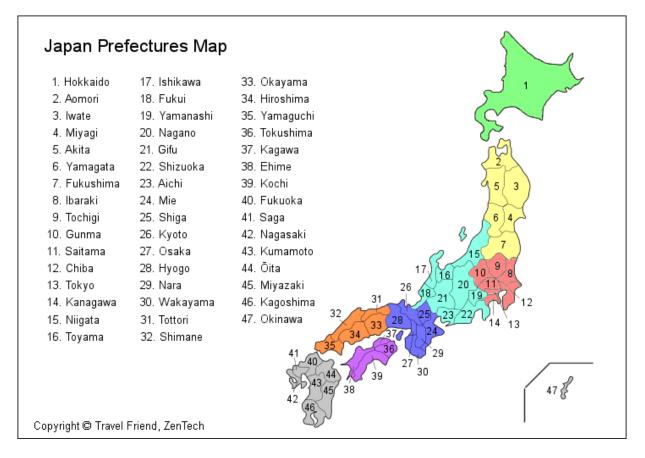
The Livestock Hygiene Service Centres also support AQS by undertaking post release examination of imported livestock and when horses or chicks are being held in designated quarantine stations.

Map 4: Japan regions (MAFF)





Map 5:	Japan	regions	and	prefectures



## **Private sector**

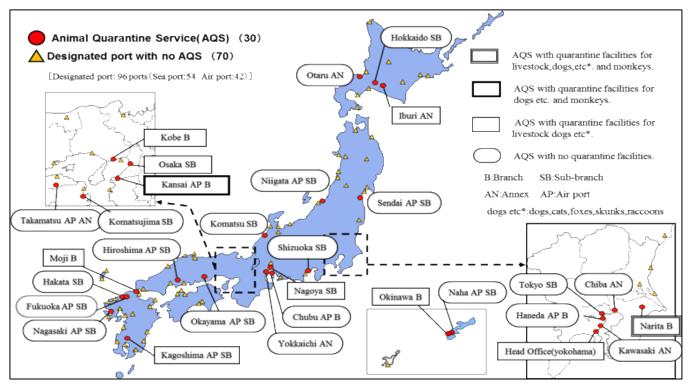
The MAFF system of service delivery is supported by the cooperatives/private sector. Local veterinary clinics, the NOSAI clinics, provide day-to-day veterinary services through a mutual aid insurance scheme for members and through fee-for-service for non-members. Private veterinarians also operate clinics across the country, mostly for companion animals but some also provide livestock health services.

#### **Animal Quarantine**

The Animal Quarantine Service (AQS) operates nationally to control the import of live animals and animal products (see Map 6). The Animal Health Division set the policy on live animal and animal product imports and exports; AQS implement the policy for imports and exports. AQS have an extensive national network of border inspection posts and quarantine stations and supporting laboratories. There are 70 designated ports with no AQS presence; AQS manages quarantine activities at these ports by coordinating and delivering activities with Customs officers.

AQS also store protective equipment for emergency response and disease control including personal protective equipment, decontamination tents, culling equipment and machines, vehicle disinfection units, mobile incinerators and rendering equipment.

## Map 6: AQS facilities



## Food safety

The primary responsibility for inspection of foods of animal origin is with the Ministry of Health, Labour and Welfare (MHLW). Health authorities in each prefecture provide services through 101 Meat Inspection Centres and 472 Public Health Centres within their Food Sanitation Divisions; reports are prepared and provided to MAFF.

MHLW develops the technical guidance at the national level to be implemented at the local level, including methods and procedures for meat inspection and laboratory analysis. MHLW also manages the recall process for products found to be in violation of food safety standards for both domestically produced and imported foods.

MHLW uses their eight regional offices to oversee the registration, approval and inspection of food business operators in consultation with the prefecture public health authorities, with inspections of relevant premises implemented by Health Centres and Meat Inspection Centres.

The Food Safety Commission of Japan is an independent commission that provides risk assessments in the area of food safety for MAFF and MHLW. The Food Safety Commission of Japan assesses human health risks associated with food and monitors food safety policies and helps develop emergency responses for food safety crises. The Food Safety Commission of Japan utilises some 200 external technical experts and provides hazard-specific assessment guidelines. MHLW and MAFF coordinate risk management in the area of food safety.

## Laboratories

Japan's veterinary diagnostic laboratories operate at two levels – the National Institute of Animal Health (NIAH) and other relevant central laboratories and the prefectural Livestock Hygiene Service Centre laboratories. Other central veterinary laboratories include the National Veterinary Assay Laboratory (NVAL) for the registration and control of veterinary medicines, the Animal Quarantine Service (AQS) laboratories for live animal and animal product inspection and the Feed and Agricultural Materials Inspection Centres (FAMIC) for monitoring animal feed safety.

Livestock Hygiene Service Centres Laboratories provide first level diagnostic testing. The 171 Centres each have a well-equipped laboratory for first line diagnostic services; 52 are designated as 'advanced diagnostic laboratories' (one or more per prefecture) with more sophisticated facilities and equipment suitable for molecular testing and virology. Eight laboratories are designated as BSE testing laboratories.

NIAH has four laboratories that provide higher level testing and act as the national reference laboratory. NIAH has its headquarters at Tsukuba, just outside Tokyo, with additional facilities at the Exotic Disease Research Station (Kodeira, Tokyo), Hokkaido Research Station and Kyushu Research Station. These laboratories also undertake research and produce veterinary biologicals. NIAH provides training for other laboratories and animal health staff, particularly from the prefectures and Livestock Hygiene Service Centres.

NVAL provides assurance that veterinary medical products are safe and efficacious, managing product registration with marketing approval, marketing authorisation, distribution and post release evaluation. NVAL also maintains a database for pharmacovigilance recording reports of adverse events. At its site in Tokyo, NVAL operates a series of well-equipped laboratories and has two BSL3 facilities; it also conducts animal experiments to assay veterinary medicines and biologicals in animals and fish. NVAL has taken the lead in the monitoring of antimicrobial resistance (AMR) with a programme to review the use of antimicrobials and the levels of antimicrobial resistance in animals. NVAL works internationally to develop capacity for AMR monitoring.

AQS operates 23 laboratories which undertake pathology/histopathology, microbiology and serology including PCR and virus isolation. Two laboratories have BSL3 facilities for specialist diagnostics and research (eg electron microscopy and gene sequencing). Two other laboratories have BSL3 facilities for quarantine of non-human primates.

#### OIE Reference Laboratories

NIAH is recognised as an OIE Reference Laboratory for BSE, CSF, Equine Infectious Anaemia (EIA), swine influenza, epizootic haemorrhagic diseases and rinderpest; it is a laboratory accredited to hold rinderpest virus and to manufacture rinderpest vaccine. NIAH actively participates in international programmes and trainings.

Two other laboratories are recognised as OIE Reference Laboratories for animal health in Japan:

- Research Centre for Zoonosis Control, Hokkaido University HPAI and LPAI
- National Research Centre for Animal Protozoal Diseases babesia, surra, equine piroplasmosis.

Other Japanese laboratories are recognised as OIE Collaborating Centres

- FAMIC Animal feed safety and analysis
- Research Centre for Food Safety food safety<sup>6</sup>
- NIAH & NVAL diagnosis and control of animal diseases and veterinary product assessment
- National Research Centre for Animal Protozoal Diseases surveillance and control of protozoal diseases

#### Other laboratories

The Ministry of Health, Labour and Welfare operates a number of laboratories inter alia for veterinary public health and food safety including the National Institute of Infectious Diseases (NIID) and at its Public Health and Meat Inspection Centres. Some residue testing is also conducted at the Research Centre for Food Safety.

<sup>&</sup>lt;sup>6</sup> <sup>6</sup> <u>http://www.ag.kagawa-u.ac.jp/english/?page\_id=1377</u>

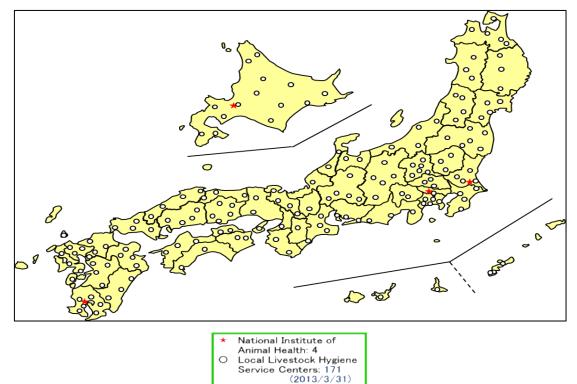
### Private laboratories

MAFF do not formally authorise any private laboratories for the purpose of supporting official animal health programmes including the import and export of animals and animal products. MHLW has authorised 103 private laboratories for the purpose of monitoring import and export food safety. A number of private laboratories exist and some undertake specific tests for MAFF – e.g. EBL and some PPRS testing.

#### Universities

University laboratories are well equipped for teaching and can perform diagnostic testing. Some Livestock Hygiene Service Centres cooperate with nearby veterinary school laboratories sharing samples and technologies where appropriate. This is particularly so in Osaka where the Osaka Prefecture Veterinary School and Livestock Hygiene Service Centre are in adjacent buildings.

Map 7: Location of National Institute of Animal Health and Livestock Hygiene Service Centres



#### Veterinary public health

The Animal Health Division of MAFF works with the Tuberculosis and Infectious Diseases Control Division of MHLW for the mandatory reporting of defined zoonoses under the the Act on the Prevention of Infectious Diseases and Medical Care for Patients suffering from Infectious Diseases.

The policy for importing certain species of animals considered of higher zoonotic risk is controlled by MHLW and implemented by AQS. For some specified species all imports are prohibited outright (e.g. masked palm civets, bats, monkeys), others must be approved by MHLW (e.g. monkeys from approved countries), others are entirely managed by AQS (e.g. dogs, livestock) and others are notified (mammals and aves other than those quarantined by MAFF) to MHLW. The risk of rabies incursion and any required response is jointly

Japan

managed by the Animal Health Division and MHLW. Preventative, surveillance and response measures are defined.

Food safety is a recognised priority for Japan. MHLW has a 'Department of Environmental Health and Food Safety' in its 'Pharmaceutical and Environmental Health Bureau'. Within this department are a number of divisions responsible for food safety including planning and communications, standards and evaluations, inspections and safety and subordinate offices for international food safety, quarantine, new foods, imported food safety, Hazard Analysis and Critical Control Points, (HACCP) and food borne disease surveillance.

The Food Safety Commission of Japan was established in 2003 by direct authority of the Cabinet Office. It is an independent agency that undertakes risk assessments working with MAFF and MHLW. The relationship between the Food Safety Commission of Japan and other ministries is shown in the figure below (Figure 4). The Food Safety Commission of Japan work is managed by a Planning Committee with reviews by Scientific Panels. The Scientific Panels on Veterinary Medicinal Products, Microorganisms and Viruses and Prions are particularly relevant to the veterinary domain. The Food Safety Commission of Japan undertakes science based risk assessments with full transparency including open meetings and reviews.

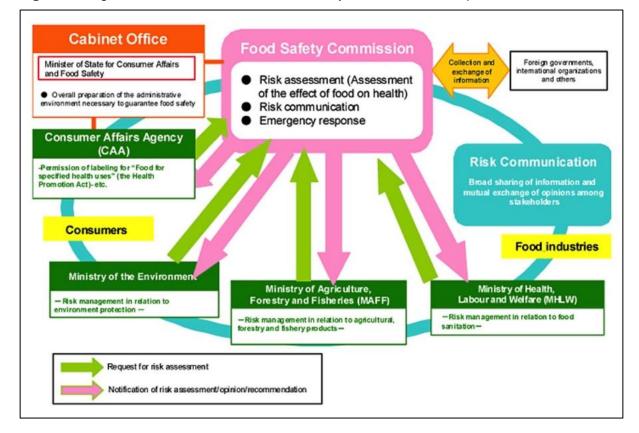


Figure 4: Organisational relations the Food Safety Commission of Japan

Local governments are responsible for meat inspection under MHLW legislation. The 101 'Meat Inspection Centres' are responsible for meat hygiene including the food safety management of slaughterhouses and processors.

#### Animal Feed

The Fertilizer and Feed Inspection Department Agricultural Materials Inspection Centre (FAMIC) has the responsibility to audit and test animal feeds and feed additives for safety. Site visits and samplings are undertaken. Analytical methods in use include HPLC, microbiological assays, spectrometry, BSE analyses (microscopy, ELISA and PCR),

identification of dioxins, assessment of contamination with radioactive isotopes and melamine and the presence of GMOs.

Human food and animal feed safety is further supported by the Governors of the Prefectures who are responsible for the inspection of livestock producers, processors, distributors and vendors.

#### Wildlife and Animal Welfare

The Ministry of Environment (MoE) has the legal mandate for the welfare and management of animals, operated by the Nature Conservation Bureau, Animal Welfare and Management Office.

MoE has set specific standards for the care (keeping, selling, training and exhibiting) of animals. Business owners are required to be registered by prefectural governors or mayors. Prefecture or city officers undertake on-site welfare inspections of facilities. MAFF's role in animal welfare and its coordination with the MoE was not clear, particularly in relation to livestock welfare.

MoE also has the mandate for wildlife with a focus on restoration of the natural environment, conservation of biodiversity and 'maintaining a rapport with nature' through its national parks and with promotional activities. MoE monitors wildlife health and works with Animal Health Division of MAFF and its supporting laboratories to undertake surveillance and diagnostic testing; the main activity is in avian influenza wild bird surveillance.

#### Veterinarians

In 2014 there were 39,098 veterinarians registered under the Veterinary Council in Japan. Of these 9,456 are public officials (agriculture, public health and education), 4,113 work for commercial organisations and 17,569 work in private practice (4,317 in farm animal practice, 15,205 in small animal practice); there are 4,550 registered as 'others' (retired etc.).

There are 16 veterinary schools in Japan – ten national, one prefecture and five private schools. To become registered as a veterinarian the veterinary school graduates must pass a professional entry examination held by the Veterinary Council.

## Table 7: Veterinarians in Japan

	Number of Veterinarians
Central Government	518
Agriculture, Forestry and Fisheries	297
Administrative Organisations including Animal Health	134
Division	-
Research Institutes	0
Inspection and Guidance Agencies	163
Public Health	159
Administrative Organisations	37
Research Institutes	91
Inspection and Guidance Agencies	31
Environment	7
Others	55
Prefectural Governments	7,121
Agriculture, Forestry and Fisheries	3,078
Administrative Organisations	427
Livestock Hygiene Service Centres	2,217
Research Institutes	341
Others	93
Public Health	3,828
Administrative Organisations	369
Health Centres	1,529
Research Institutes	142
Slaughterhouses/Abattoirs or Food Hygiene Laboratories	1,589
Others	199
Education	46
Environment	90
Others	79
Municipal Governments	1,887
Agriculture, Forestry and Fisheries	128
Administrative Organisations	58
	70
Veterinary Hospitals Public Health	1,531
Administrative Organisations	77
Health Centres Slaughterhouses/Abattoirs or Food Hygiene Laboratories	<u>817</u> 487
Others	150
Education	
Environment	<u> </u>
Others	188
Nongovernmental Organisations	7,623
Agricultural Cooperative Associations	302
Veterinary Practice	178
Others	124
Agricultural Mutual Aid Associations	1,903
Veterinary Practice	1,716
Others	187
Pharmaceutical or Feed Companies	2,407
Inspection or Research	174
Veterinary Practice	233
Pharmacy	1,006
Feed	156
Others	838
Independent Administrative Agencies	1,011
Universities/Collages	740
Others	271
Horse Racing Related Organisations	224
Private School	686
Incorporated Associations or Foundations	798
Others	292

## II.3.C Animal disease occurrence

Disease	Domestic		Wild		
	Notifiable	Status	Notifiable	Status	Note
Acarapisosis of honey bees	1	Disease present			
American foulbrood of honey bees	r	Disease present			
Avian infectious bronchitis	1	Disease present	×	Absent (since Unknown)	
Bovine viral diarrhoea	V	Disease present	×	Absent (since Unknown)	
Duck virus hepatitis	1	Disease limited to one or more zones			
Enzootic bovine leukosis	V	Disease present	X	Absent (since Unknown)	
Epizootic ulcerative syndrome	X	Disease limited to one or more zones	×	Absent (since 09/2012)	
Equid herpesvirus-1 (EHV-1) (Infection with)	¥	Disease limited to one or more zones	×	Absent (since Unknown)	
European foulbrood of honey bees	4	Disease present			
Highly path. avian influenza	V	Disease present	×	Disease present	
Inf.bov.rhinotracheit. (IBR/IPV)	1	Disease present	×	Absent (since Unknown)	
Infec bursal disease (Gumboro)	V	Disease present	×	Absent (since Unknown)	
Infect. haematopoietic necrosis	X	Disease present	×	Absent (since 09/2014)	
Infection with Xenohaliotis californiensis	r	Infection/infestation limited to one or more zones	r	Infection/infestation limited to one or more zones	
Japanese encephalitis	¥	Disease limited to one or more zones	X	Absent (since Unknown)	
Koi herpesvirus disease	1	Disease present	V	Disease limited to one or more zones	
Mycoplasmosis (M. gallisepticum)	1	Disease present	×	Absent (since Unknown)	
Paratuberculosis	1	Disease present	×	Absent (since Unknown)	
Porcine reproductive/respiratory syndr.	K	Disease present	×	Absent (since Unknown)	
Red sea bream iridoviral disease	×	Disease present	X	Absent (since Unknown)	
Varroosis of honey bees	V	Disease present			
Viral haemorrhagic septicaemia	r	Disease present	V	Absent (since Unknown)	
White spot disease	X	Disease present	×	Absent (since Unknown)	

Table 8: Diseases present in Japan (2015) from the OIE-WAHIS website<sup>7</sup>

## II.4 Organisation of the evaluation

## II.4.A Timetable of the mission

Appendix 3 provides a list of persons met; Appendix 4 provides the timetable of the mission and details of the facilities and locations visited by the OIE PVS Team and Appendix 5 provides the international air travel itinerary of team members.

## II.4.B Categories of sites and sampling for the evaluation

Table 5 lists the categories of site relevant to the evaluation and the number of each category of site in the country. It indicates how many of the sites were visited, in comparison with the suggested sampling framework ("ideal" sampling) recommended in OIE PVS Manual.

Appendix 4 provides a detailed list of sites visited and meetings conducted.

<sup>&</sup>lt;sup>7</sup> <u>http://www.oie.int/wahis\_2/public/wahid.php/Countryinformation/Animalsituation</u>

# Table 9: Site sampling

Table 1. Site sampling	Terminology of the country	Number	"Ideal"	Proposed
		of sites	sampling	sampling
	TIVE ORGANISATION OF THE COUNT		1	4
1st administrative level 2nd administrative level	National Regional Agricultural	1	1	1
	Administration Office	9	9	2
3rd administrative level	Prefectures	47	10	6
Municipal entities (Cities)	Cities/ towns/ villages	1,718	40	6
Sub-municipal	Wards	23	10	0
	RVICES ORGANISATION AND STRUC		10	
Central (Federal/National) VS	National/Central government	1	1	1
1 <sup>st</sup> level of the VS	Ministry (MAFF, MHLW, MoE)	3	3	3
2 <sup>nd</sup> level of the VS	Prefecture	47	10	6
	City	69	10	6
	Ward	23	10	0
3 <sup>rd</sup> level of the VS	Livestock Hygiene Service Centres	170	10	6
	Public Health Centre	480	21	2
	Meat Inspection Centres	101	10	2
Veterinary organisations (VSB, unions)	Veterinary Council, Japan	2	2	2
	Veterinary Medical Association,			
	D ANIMAL HEALTH NETWORK		T	
Field level of the VS (animal health)	Livestock Hygiene Service Centres	170	10	6
Private veterinary sector	National Agricultural Insurance	47	6	5
	Associations (NOSAI)			
	NARY MEDICINES & BIOLOGICALS	0	T	r
Producers/manufacturers	Licensed factories of manufacture	267	16	3
Importers and retailers	Licensed dealer of medicine for	10,270	100	6
	animal use			
	TERINARY LABORATORIES	-	-	-
National labs	National Veterinary Assay Lab	4	4	4
	National Institute of Animal Health			
	National Institute of Infectious			
	Diseases			
Designal and least labo	Animal Quarantine Service	50	10	<u> </u>
Regional and local labs	Prefectural animal health laboratory	50 ~30	10 5	6
Associated, accredited and other labs	FAMIC, others NIMAL PRODUCTS MOVEMENT CON		5	4
Bordering countries	None		1	_
Airport entry points	None	42	10	6
Seaport entry points		42 54	10	-
Animal Quarantine Service	Head Office		10	6
Animal Quarantine Service		7	7	3
	Branch Sub-branch	17	10	3
Quarantina stations for import	AQS sub-office	31	10	1
Quarantine stations for import Live animal markets		144	10	3
	PECTION OF ANIMALS AND ANIMAL			3
Export slaughterhouse	Beef export establishment	77	<b>3</b>	3
LAPOIT SIAUGITETTIOUSE	Pork export establishment	110	10	3
	Poultry meat export establishment	98	10	3
National market slaughterhouses	Slaughterhouses	183	13	3
	AND RESEARCH ORGANISATIONS	105	15	5
Veterinary & para-professional schools	Veterinary Universities	16	4	3
Veterinary research organisations	National Agriculture Research	10	4	1
	Organisation			
STA	(EHOLDERS' ORGANISATIONS	I	I	1
Agricultural Chamber / organisation	National Federation of Agricultural	1	1	1
	Co-operative Associations			
National livestock farmers organisations	Japan Livestock Industry	1	1	1
			1 .	
National investock farmers organisations	Association			
Consumer organisations	Association National Liaison Committee of	1	1	1

# PART III: RESULTS OF THE EVALUATION & GENERAL RECOMMENDATIONS

This evaluation identifies the strengths and weaknesses of the veterinary services, and makes general recommendations.

### **FUNDAMENTAL COMPONENTS**

- 1. HUMAN PHYSICAL AND FINANCIAL RESOURCES
- 2. TECHNICAL AUTHORITY AND CAPABILITY
- **3 INTERACTION WITH INTERESTED PARTIES**
- 4. ACCESS TO MARKETS

The activities of the Veterinary services are recognised by the international community and by OIE Members as a 'global public good'. Accordingly, it is essential that each country acknowledges the importance of the role and responsibilities of its Veterinary Services and gives them the human and financial resources needed to fulfil their responsibilities.

This OIE PVS Evaluation examined each critical competency under the 4 fundamental components, listed strengths and weaknesses where applicable, and established a current level of advancement for each critical competency. Evidences supporting this level are listed in appendix 6. General recommendations were provided where relevant.

The current level of advancement for each critical competency is shown in cells shadowed in grey (15%) in the following tables.

# III.1. Fundamental component I: human, physical and financial resources

This component of the evaluation concerns the institutional and financial sustainability of the VS as evidenced by the level of professional/technical and financial resources available and the capacity to mobilize these resources. It comprises fourteen critical competencies:

#### **Critical competencies:**

Section I-1	Professional and technical staffing of the Veterinary Services A. Veterinary and other professionals (university qualification) B. Veterinary para-professionals and other technical personnel
Section I-2	Competencies of veterinarians and veterinary para-professionals
	A. Professional competencies of veterinarians
	B. Competencies of veterinary para-professionals
Section I-3	Continuing education
Section I-4	Technical independence
Section I-5	Stability of structures and sustainability of policies
Section I-6	Coordination capability of the VS
	A. Internal coordination (chain of command)
	B. External coordination
Section I-7	Physical resources
Section I-8	Operational funding
Section I-9	Emergency funding
Section I-10	Capital investment
Section I-11	Management of resources and operations

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Terrestrial Code References:

Points 1-7, 9 and 14 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / Independence / Impartiality / Integrity / Objectivity / Veterinary legislation / General organisation / Procedures and standards / Human and financial resources. Point 4 of Article 3.2.1. on General considerations.

Point 1 of Article 3.2.2. on Scope.

Points 1 and 2 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.

Point 2 of Article 3.2.4. on Evaluation criteria for quality system: "Where the Veterinary Services undergoing evaluation... than on the resource and infrastructural components of the services".

Article 3.2.5. on Evaluation criteria for human resources.

Points 1-3 of Article 3.2.6. on Evaluation criteria for material resources: Financial / Administrative / Technical.

Points 3 and Sub-point d) of Point 4 of Article 3.2.10. on Performance assessment and audit programmes: Compliance / In-Service training and development programme for staff.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 1-5 and 9 of Article 3.2.14. on Organisation and structure of Veterinary Services / National information on human resources / Financial management information / Administration details / Laboratory services / Performance assessment and audit programmes.

I-1 Professional and	Levels of advancement
technical staffing of the	1. The majority of veterinary and other professional positions are not
Veterinary Services	occupied by appropriately qualified personnel.
The appropriate staffing of the VS to allow for veterinary and	2. The majority of veterinary and other professional positions are occupied by appropriately qualified personnel at central and state /
technical functions to be undertaken efficiently and effectively.	<ul><li>provincial levels.</li><li>3. The majority of veterinary and other professional positions are occupied by appropriately qualified personnel at local (field) levels.</li></ul>
A. Veterinary and other professionals (university qualification)	4. There is a systematic approach to defining job descriptions and formal appointment procedures for veterinarians and other professionals.
	5. There are effective management procedures for performance assessment of veterinarians and other professionals.

*Evidence* (see Appendix 6): E106, 140, 142, 149, 152, 168, 173, 174, 182, 183, 185, 187, 207

#### Findings:

Japan has a large number of registered veterinarians working for government (animal and public health), commercial organisations, in research and teaching, and in the private sector.

The need to provide veterinary care for small animals and livestock is recognised and promoted. MAFF have a 'basic policy' (2010) to secure livestock clinicians and official veterinarians for the prefectural governments. Each prefecture implements the policy and programmes of central MAFF developing its own programme and objectives which it publishes and reports against; prefectures set target numbers of veterinarians required, considering their local situations and the needs of livestock owners. At Central level, the Planning Committee under the Veterinary Affairs Council develops policies and support programmes to try and support these needs.

Incentives for veterinary graduates include providing clinical training in livestock medicine and production and scholarship loans for high school and veterinary school students. Veterinary students receive career guidance and job experience.

Type of veterinarian	Number (%)
Livestock practice	4,300 (11)
Small animal practice	15,200 (39)
Government	9,500 (24)
Universities and commerce	5,600 (14)
Unknown (not working as a vet)	4,600 (12)
TOTAL	39,100

**Table 10**: Number of veterinarians by type (2014)

Since 2006 the total number of veterinarians has increased from 35,800 to 39,100, an increase of some 9%. The largest increase in numbers has been in small animal practice (15%) followed by public officials (5%); while large animal practitioners have decreased (-3%).

There is no 'job description' as such for government veterinary staff as their tasks are directed by the ministry policy and priority setting. Following high level policy setting at the ministry level the target areas are broken down into the activity areas of the Bureaus and then by Division; within the Animal Health Division the Offices are assigned objectives by the Director and in turn assign objectives (i.e. task lists rather than job descriptions) to their staff. The division has designated staff responsible for legal affairs. Each staff member meets with his/her line manager every six months to review the next period's programme and set their individual objectives; at this time some training and development needs may be identified.

Recruitment to government positions is through a public competitive process with technical assessment/examination and a civil servant examination. All staff undergo a twice yearly work review, 'a Personal Assessment' that records ranked priority areas for action and development and sets targets for achievement; records are maintained by the individual and the division.

Prefecture Animal Health Division and Livestock Hygiene Service Centre staff also have a 'terms of reference approach' and undergo a personal review twice yearly.

AQS is a core part of the Veterinary Services with its focus on managing the risk from live animal and animal product imports; AQS is also responsible for certification of exports. AQS now employs 153 veterinarians, out of a staff of over 400, for their operations across the country; staff numbers have increased dramatically from 122 in 1975 with a proportional increase in the number of veterinarians. AQS staff have a similar approach using 'terms of reference' rather than 'job descriptions', identifying the objectives of the unit or group and then breaking this down into a work plan; from the work plan, staff tasks are assigned. As above, this process takes place every six months and staff work with their managers to set targets and identify any development needs.

Considerable numbers of veterinarians are also employed by the other Competent Authorities particularly by MHLW and MoE with others at independent agencies and institutes such as NIAH, NVAL and the Food Safety Commission of Japan. MHLW employs a large number of veterinarians within its Department of Environmental Health and Food Safety and Tuberculosis and Infectious Diseases Control Division, at NIID and at the prefecture Public Health Centres and Meat Inspection Centres. The nature conservation bureau of the MoE centrally also employs veterinarians though this is regarded as being incidental rather than a requirement.

NIAH has a staff of 265 of which 88 are veterinarians. NIAH is the reference laboratory for the diagnosis of exotic infectious animal diseases (FMD, HPAI, BSE etc.); it also undertakes research and training for MAFF and other agencies.

Veterinary medicines and biologicals registration is managed by the National Veterinary Assay Laboratory (NVAL). NVAL employs 102 staff with 38 veterinarians, 6 pharmacists and 38 technical staff (graduates working as animal managers, auditors and inspectors) at its facility in Tokyo. The regulation of veterinary medicines and biologicals including the inspection of premises and processing to GLP, GMP, GCP and GPSP standards and pharmacovigilance is further supported by approximately 20 staff at MAFF and more than 2,000 working in the prefectures.

MAFF encourages female veterinarians to return to work with refresher training and 'up-skilling' on latest knowledge. It is considered important to allow female veterinarians to make full use of their training and so contribute to rebalancing the uneven distribution of veterinarians both geographically and occupationally. This is a real and potentially increasing problem as nearly 50% of veterinarians under 40 years of age are female. Currently 22% of veterinary staff of the MAFF central Animal Health Division are female; there are no female veterinary managers.

The Veterinary License Act (1949), most recently amended in 2013, defines what a veterinarian can do covering and covers General Provisions, Licensing, Examinations Operations, the Veterinary Affairs Council, Penal and Supplementary Provisions

#### Strengths:

Large numbers of well-trained veterinarians working at all levels of the Veterinary Services.

- The system of using 'terms of reference' focuses on six month targets for staff work plans and their development – this could be improved by developing longer timelines for staff planning and development;
- To promote a more dynamic organisation with stronger human resources, MAFF should explore merit based recruitment and promotion based on performance and not only on the years of government experience.

I-1. Professional and	Levels of advancement
technical staffing of the	1. The majority of technical positions are not occupied by personnel
Veterinary Services	holding appropriate qualifications.
The appropriate staffing of the	2. The majority of technical positions at central and state / provincial
VS to allow for veterinary and	levels are occupied by personnel holding appropriate qualifications.
technical functions to be	3. The majority of technical positions at local (field) levels are occupied
undertaken efficiently and	by personnel holding appropriate qualifications.
effectively.	4. The majority of technical positions are effectively supervised on a
	regular basis.
B. Veterinary para-	5. There are effective management procedures for formal appointment
professionals and other	and performance assessment of veterinary para-professionals.
technical personnel	

#### Evidence (see Appendix 6): none specific

#### Findings:

Japan has a very large number of registered veterinarians, nearly 40,000, especially relative to its livestock population, and therefore veterinary para-professionals are little used in the Veterinary Services. The main exception is the use of veterinary nurses in companion animal clinics. Other categories of veterinary para-professional include artificial inseminators, meat inspectors at some small poultry slaughterhouses and 'technicians' at the Meat Inspection Centres, who mostly work in the laboratories. Where they are working, given their small relative numbers, they receive strong technical supervision by veterinarians.

#### Veterinary Nurses

Most private companion animal veterinary practices employ veterinary nurses. Their role is to support the various clinical and surgical procedures being undertaken.

A Council for the Certification of Registered Veterinary Nurses (CCRVN) was set up in 2012 with the aim of consolidating and standardising the veterinary nursing activities of a range of independent associations and educational colleges including the Japanese Society of Veterinary Science, the Japanese Veterinary Medical Association, the Japan Animal Health Technicians Association, the Japanese Animal Hospital Association, the Japan Small Animal Veterinary Association, the All Japan Veterinary Co-operative (private veterinary practitioners) and the Japanese Society of Animal Nursing.

CCRNN has developed a core curriculum for training veterinary nurses with courses provided over two to four years. CCVRN will grant a 'license' to graduates of these courses, but it is noted that this is not yet a 'National License'. 15,814 CCVRN nurses were registered in June 2016.

#### Artificial Insemination technicians

A license to be a domestic animal inseminator is granted by prefectural governments based on the 'Act on Improvement and Increased Production of Livestock'. Candidates must complete a course of lectures and practical training and then pass an exam to check whether he/she has obtained sufficient knowledge and techniques to be an artificial inseminator. Most artificial inseminators are veterinarians but not all. Non-veterinarians working as artificial inseminators are required to be supervised by veterinarians.

#### Meat inspectors at small chicken slaughterhouses

Following training veterinary para-professionals are able to undertake meat inspections at smaller chicken slaughterhouses (less than 300,000 per year). Veterinary supervision is required.

#### Strengths:

- Almost all veterinary activities are undertaken by registered veterinarians;
- Tasks are defined that can be undertaken by a veterinary para-professional;

Veterinary nurse training and licensing is being developed into a coherent national programme.

#### **Recommendations:**

MAFF should support the national programme for the formal recognition of veterinary nurse training and licensing by working with the Council for the Certification of Registered Veterinary Nurses or another certifying body.

I-2 Competencies of	Levels of advancement
veterinarians and veterinary	1. The veterinarians' practices, knowledge and attitudes are of a
para-professionals	variable standard that usually allow for elementary clinical and
The capability of the VS to	administrative activities of the VS.
efficiently carry out their	2. The veterinarians' practices, knowledge and attitudes are of a
veterinary and technical functions;	uniform standard that usually allow for accurate and appropriate
measured by the qualifications of	clinical and administrative activities of the VS.
their personnel in veterinary and	3. The veterinarians' practices, knowledge and attitudes usually
technical positions.	allow undertaking all professional/technical activities of the VS (eg
	epidemiological surveillance, early warning, public health, etc.).
A. Professional	4. The veterinarians' practices, knowledge and attitudes usually
competencies of veterinarians	allow undertaking specialised activities as may be needed by the
including the OIE Day 1	VS.
competencies	5. The veterinarians' practices, knowledge and attitudes are subject
	to regular updating, or international harmonisation, or evaluation.

*Evidence* (see Appendix 6): E98, 99, 137, 177, 178, 203, 207

#### Findings:

There are 16 veterinary schools in Japan – ten national, one prefecture and five private schools. To become registered as a veterinarian, veterinary school graduates must pass a professional entry examination held by the Veterinary Council with MAFF endorsement. The pass rate is estimated at greater than 85%.

The basic veterinary course in Japan is six years with the first year or two dedicated to general subjects, a foundation period. Following the six year course veterinary studies may be continued in a graduate school in a specialist subject to achieve a PhD. There are very few veterinary Masters Degree courses provided in Japan. There is also no designated non-academic pathway for accrediting veterinary specialisation, such as the 'College of Veterinary Surgeons' memberships and fellowships available in other developed countries (eg US, Great Britain, Australia and New Zealand). The Society for Veterinary Pathology has some form of further recognition.

The veterinary schools face a number of challenges. In particular the schools are generally small -11 of the 16 schools graduate 40 or fewer veterinary students per year; the private veterinary schools are larger – one school graduates 80, the other four 120 students each per year. The veterinary schools are also mostly part of larger faculties of agriculture and this is believed to reduce their autonomy and ability to deliver the best veterinary education and also to limit their access to research budgets and scholarships. The veterinary schools visited reported the absence of support staff with almost all teaching, preparation and administrative tasks being provided by the academic staff.

The veterinary schools are undertaking a series of innovations to address some of their challenges. Innovations include reviewing the national 'model core curriculum', certifying students as legally able to participate in veterinary clinical activities prior to graduation, assessment by the Japan University Accreditation Association, international academic exchanges and the sharing between universities of resources and materials. There are semiannual meetings of the veterinary school deans.

The draft core curriculum is broad based covering the OIE 'Day 1' competencies including topics such as basic pre-clinical subjects, applied environmental and veterinary public health, veterinary medicine and surgery and practical application of knowledge. It was reported that approximately 70-80% of the veterinary curricula is core or common, with the remainder allowing flexibility for some specialisation between schools. The curriculum includes specific topics on veterinary epidemiology, environmental and veterinary hygiene, public health, zoonoses and food hygiene.

The facilities and standards of teaching provided were observed to be excellent. In some situations the schools had no immediate access to livestock (e.g. cattle, pigs and poultry) but this problem was addressed by bringing in some animals for examination and practice surgery and by sending

students out to undertake clinical examinations and observe farm management in nearby rural areas. Veterinary schools often work closely with the Livestock Hygiene Service Centres and with the NOSAI clinics allowing students to develop skills in livestock diagnostics and medicine.

In the Veterinary Authority, the central MAFF Animal Health Division, there are 41 veterinarians of which three have PhDs and three Masters Degrees. Development training in specialist skills is generally provided 'on the job' with skill development being determined by the staff member's line manager. Some staff are also seconded to NIAH for further training and development.

Under the MHLW, the Meat Inspection Centres provide a Meat Inspector Training Programme with a defined curriculum and fixed schedule to incoming staff. Note that the vast majority of meat inspectors are veterinarians. Training covers legislation, public health, pathology and microbiology with 'apprentice' practical sessions. Short term supplementary training programmes are also provided for meat inspectors.

MAFF has access to a sponsorship programme to support staff training overseas. For example, an employee of the Animal Health Division has just completed Masters courses in epidemiology in the UK.

#### Strengths:

- High quality veterinary education compliant with OIE 'Day 1' competencies;
- Review of national veterinary curriculum underway; there is already a sound curriculum including good ratios of animal and veterinary public health and other subjects;
- Specialist and other training programmes for veterinarians available as required (e.g. meat inspection);
- > A national veterinary examination that ensures veterinary educational standards.

- Consider developing additional certificate and postgraduate training options within Japan, such as Masters Degrees in specialist areas such as epidemiology, risk analysis, animal health economics, programme monitoring and evaluation;
- Consider developing a 'College of Veterinary Surgeons' style specialisation pathway, using the many models available in other countries;
- Review needs and consider further specialist postgraduate training at overseas institutes to address current national limitations, e.g. epidemiology, risk analysis.

B. Competencies of	Levels of advancement
veterinary para-professionals	1. The majority of veterinary para-professionals have no formal entry-level training.
	2. The training of veterinary para-professionals is of a variable standard and allows the development of only basic competencies.
	3. The training of veterinary para-professionals is of a uniform standard that allows the development of only basic specific competencies.
	4. The training of veterinary para-professionals is of a uniform standard that allows the development of some advanced competencies (eg meat inspection).
	5. The training of veterinary para-professionals is of a uniform standard and is subject to regular evaluation and/or updating.

#### *Evidence* (see Appendix 6): 179, 193, 203

#### <u>Findings:</u>

As veterinary para-professionals are little used in the Veterinary Services there is limited training provided. Some universities have animal science courses (or equivalent) of shorter length than veterinary degrees (i.e. 4 years or less), with some teaching assistance from those based in veterinary faculties.

Veterinary CCRVN nurses take a training course for two to four years and are then granted a 'license'.

To become an artificial inseminator candidates must complete a course of lectures and practical training and then pass an examination to check whether they have obtained sufficient knowledge and technical skill to be an artificial inseminator. Most artificial inseminators are veterinarians but not all.

Following short course training, veterinary para-professionals are able to operate as meat inspectors at smaller chicken slaughterhouses.

All veterinary para-professionals work under good levels of veterinary supervision.

#### Strengths:

- Well defined veterinary para-professional roles with standardised training required and strong veterinary supervision;
- Few veterinary para-professional positions exist in Japan as veterinarians are available to conduct most technical tasks.

- Clearly define and document activities and roles that may be undertaken by a veterinary para-professional, as opposed to untrained non-technical staff (Note that legislation, Veterinary License Act 1949, clearly defines what a veterinarian can do);
- Promote the central registration of all veterinary para-professionals by category with appropriate training requirements.

I-3 Continuing	Levels of advancement
education (CE) <sup>8</sup>	1. The VS have no access to veterinary, professional or technical CE.
The capability of the VS to maintain and improve the competence of their	2. The VS have access to CE (internal and/or external programmes) on an irregular basis but it does not take into account needs, or new information or understanding.
personnel in terms of relevant information and understanding;	3. The VS have access to CE that is reviewed annually and updated as necessary, but it is implemented only for some categories of the relevant personnel.
measured in terms of the implementation of a relevant training programme.	<ul> <li>4. The VS have access to CE that is reviewed annually and updated as necessary, and it is implemented for all categories of the relevant personnel.</li> <li>5. The VS have up-to-date CE that is implemented for all relevant personnel and is subject to regular evaluation of effectiveness.</li> </ul>

*Evidence* (see Appendix 6): 133, 158, 198, 199

#### Findings:

There is no overall, formal, defined programme for the continuing education of government veterinarians. Staff undergo twice yearly 'Personal Assessments' from which training needs may be identified, but this is not systematic or formalised. Training is most often by mentoring or 'on the job' experience. Staff line managers have the authority to determine what staff training will be provided, guided by their business unit and its policies and programmes.

Ad hoc training takes place through attendance at conferences, short courses and seminars; these occur quite frequently. There is no consolidated programme to review overall training and development needs and to design and implement the required training programmes.

NIAH delivers an extensive training programme approved by MAFF, though it is mostly targeted to prefectural and field veterinarians and laboratory personnel. Sometimes seconded staff from MAFF are involved in development and training. Training at NIAH covers basic and advanced diagnostics, and disease diagnosis and epidemiology by species – cattle, pig, poultry and 'foreign animal diseases'. Training courses are provided by the four NIAH centres. NIAH also runs a series of workshops on animal health topics, approved by MAFF, including virology, bacteriology, pathology and biochemistry. Some universities are also approved by MAFF or prefectures to deliver supported training programmes.

Attendance at international meetings is recorded but there is no consolidated record of other staff training and development.

MAFF has had a policy of providing support for individual's needs since 2015. Under this policy experienced prefectural or Livestock Hygiene Service Centre veterinarians are provided with training in clinical or laboratory services, disease control and farm management in order to apply sanitary controls. Female veterinarians who have been out of work for some time may receive support for refresher training courses.

The main prefectural NOSAI clinic, often referred to as a Production Medicine Centre run courses for other NOSAI staff or private veterinarians in their prefecture. This includes training for existing staff and new recruits in disease diagnosis, artificial breeding and other technical aspects of their work.

JVMA develops and hosts a variety of continuing education offerings including an annual national 3-day conference covering a broad range of topics. They have recently initiated a continuing education points system where those veterinarians meeting requirements can be certified by JVMA. There is no link to registration (which is one-off, lifetime registration), uptake is low and primarily targets small animal veterinarians; only those courses delivered by JVMA count as eligible towards certification. Although there are no requirements for continuing education within

<sup>&</sup>lt;sup>8</sup> Continuing education includes Continuous Professional Development (CPD) for veterinary, professional and technical personnel.

government service, MAFF and MHLW provide a range of trainings on a regular basis for their staff, including annual conferences on HPAI and FMD.

#### Strengths:

- Staff mentoring by line managers;
- Frequent access to meetings and conferences.

#### Weaknesses:

- Lack of strategic plan for staff continuing education and ongoing development;
- Limited access to key specialist skills such as epidemiology, risk analysis and animal health economics;
- No consolidated records of staff continuing education;
- > No requirement to undertake continuing education to maintain veterinary registration.

- Develop a rolling five-year plan for staff development and training, and integrate training needs into work plans and performance management at all levels, including for individual staff;
- Formalise feedback for all forms of official continuing education to monitor staff development and progress and to update training content and delivery;
- Increase access to training in specialist skills such as epidemiology, risk analysis and animal health economics;
- Consider linking compulsory continuing education requirements to ongoing veterinary reregistration (see CCIII.5 on Veterinary Statutory Body) as is being implemented in most other developed countries.

I-4 Technical	Levels of advancement
independence	1. The technical decisions made by the VS are generally not based on
The capability of the VS to	scientific considerations.
carry out their duties with	2. The technical decisions take into account the scientific evidence, but
autonomy and free from	are routinely modified to conform to non-scientific considerations.
commercial, financial,	3. The technical decisions are based on scientific evidence but are
hierarchical and political	subject to review and possible modification based on non-scientific
influences that may affect	considerations.
technical decisions in a	4. The technical decisions are made and implemented in general
manner contrary to the	accordance with the country's OIE obligations (and with the country's
provisions of the OIE (and of	WTO SPS Agreement obligations where applicable).
the WTO SPS Agreement	5. The technical decisions are based only on scientific evidence and
where applicable).	are not changed to meet non-scientific considerations

#### Evidence (see Appendix 6): none specific

#### <u>Findings:</u>

Public health and food safety is a clearly identified priority for Japan, aligned with extremely high consumer expectations. Strong commitment is also made to increasing the quality of livestock production and the improvement of animal health to support this.

To ensure all aspects of veterinary public health are well delivered there is strong legislation and resourcing available for animal and human health and supporting legislation for wildlife health and animal welfare. Priority plans and activities focus on BSE and rabies control and a range of other activities to identify and control zoonoses (eg HPAI, brucellosis) and food borne zoonoses. Guidelines have also been developed for major transboundary animal diseases – FMD, BSE, CSF, notifiable AI and ASF.

MAFF manages priority disease control programmes directly with the prefectures and their Livestock Hygiene Service Centres. Financial oversight is provided at regional level. Technical decisions made remain independent of interference on non-scientific grounds, though levels of acceptable risk are set very low based on consumer expectations.

A senior level Animal Health Advisory Committee comprises wide representation and their deliberations on high priority animal health and veterinary public health issues are usually open to the public, promoting openness and transparency and supporting technical independence. All the Food Safety Commissions decisions are similarly open to public scrutiny, as are any legislative changes in animal or veterinary public health.

Animal health and veterinary public health programmes are well supported by political leaders and senior managers at all levels of government. Although there is room to explore epidemiological risk and cost-benefit analyses to better target priorities and improve efficiency (eg reviewing costbenefit of rabies vaccination, feed safety testing, mandatory BSE testing and active CSF surveillance) there is no indication of technical decisions being based on non-scientific considerations.

There is a general policy with supporting legislation for the management of conflicts of interest of public officials through the National Public Service Ethics Board and an Ethics Supervisory Officer (e.g. declarations and the reporting/disclosure of gifts). However staff knowledge of the 'Ethics Board' was limited. Salary levels are sufficient to fully support technical independence in all relevant official veterinary activities.

The Veterinary Services comply with the OIE Terrestrial Animal Health Code, Chapter 3.1.2 and specifically articles 3, 4 and 5 on impartiality, integrity and objectivity respectively.

#### Strengths:

- > Well resourced, ongoing programmes for disease prevention and control;
- > Open, transparent and consultative legislative and policy development;
- High international profile supports the rigour required with ongoing commitments by Japanese OIE Reference and Collaborating Centres.

- Develop skills in animal health economics and undertake cost-benefit, cost-effectiveness studies to support commitment and sustainability;
- Ensure conflict of interest and related obligations are widely known amongst all staff of the VS.

I-5 Stability of	Levels of advancement
structures and	1. Substantial changes to the organisational structure and/or leadership of the
sustainability of	public sector of the VS frequently occur (eg annually) resulting in lack of
policies	sustainability of policies.
The capability of the VS structure and/or	2. Sustainability of policies is affected by changes in the political leadership and/or the structure and leadership of VS
leadership to	3. Sustainability of policies is not affected or is slightly affected by changes in the
implement and sustain policies over time.	political leadership and/or the structure and leadership of VS.
	4. Policies are sustained over time through national strategic plans and frameworks and are not affected by changes in the political leadership and/or the structure and leadership of VS
	5. Policies are sustained over time and the structure and leadership of the VS
	are stable. Modifications are based on an evaluation process, with positive
	effects on the sustainability of policies.

*Evidence* (see Appendix 6): none specific

#### <u>Findings:</u>

The Veterinary Services have a strong record of developing high quality, comprehensive health programmes to support human and animal health.

The VS define and set out their policy, objectives and commitment to quality systems and standards. The role and responsibility of the Chief Veterinary Officer/Veterinary Director is clearly defined and the lines of command are well described.

A number of programmes have been in place for many years and have achieved their goals. One example is the rabies prevention and control programme under the Rabies Prevention Act (1950, amended 1998). No case of rabies has been detected in Japan for more than 50 years. The programme continues to operate with mandatory vaccination of dogs and tight border controls for the import of all animals including dogs.

Japan has had recent incursions of FMD and HPAI and has responded effectively and efficiently to eliminate these disease outbreaks. Following disease outbreaks a review process is undertaken and any recommendations followed up. For example, following the FMD outbreak in Miyazaki in 2010, the legislation was changed to strengthen the requirements for farm biosecurity, to allow the rapid implementation of ring vaccination, to allow culling of non-infected animals and to require more timely reporting of suspect cases. Disease control guidelines are also reviewed and updated every three years to ensure currency of information.

The major and effective response to the detection of BSE in 2001 resulted in major changes in policy and operations which continue to this day. Since the last BSE case was identified in January 2009 the policy on animal surveillance and testing has slowly evolved in response to improved understanding of the epidemiology of BSE and the situation globally and in Japan. Risk analysis has been undertaken by MAFF, with advice from Food Safety Commission of Japan, and has resulted in animals only over the age of 48 months being routinely tested. Japan was classified as a country of 'negligible BSE risk' in 2013.

Japan has a sound policy for animal and veterinary public health emergency preparedness and response with the provision of the necessary legal mandate and operational resources.

Programmes are underway and making progress for the control of priority diseases such as Johne's disease, tuberculosis, brucellosis and Aujeszky's disease. There is no clear, well documented strategic plan for animal and veterinary public health that clearly sets out policies and priorities.

It is apparent that the VS have polices that are sustained over time.

The structure of the VS is stable over time. Prior to the current veterinary leadership, the CVO/OIE Delegate had been the same person for an extended period. The organisational structure is stable,

although staff are routinely rotated through the organisation every two years or so, including within central MAFF, within AQS, within NIAH and within the prefectures.

The Veterinary Services substantially comply with the OIE Terrestrial Animal Health Code, Chapters 3.2.3 point 1 and 3.2.14 point 9.

#### Strengths:

- Longstanding robust and effective disease prevention and control programmes;
- Ongoing review and revision of programmes;
- > Post outbreak response reviews and revisions.

- MAFF with MHLW should consider developing a longer term 5 year strategic plan for the national VS, that clarifies support for the broader animal health, veterinary public health and livestock production in Japan, considering its various challenges including the evolving international trade environment, food safety and food security, livestock production, farm sizes, and the prevalence of part time and aging farmers;
- Staff training in specialist skills to provide evidence and support for disease prevention and control policies;
- Strengthen current disease prevention and control programmes further with risk analysis, epidemiology and animal health economics (cost-benefit and cost-effectiveness analysis);
- Undertake a cost-benefit analysis of the mandatory rabies vaccination of dogs using a risk assessment approach and considering international 'best practices'.

I-6 Coordination capability of the	Levels of advancement
Veterinary Services	1. There is no formal internal coordination and the chain
A. Internal coordination (chain of	of command is not clear.
command)	2. There are internal coordination mechanisms for some
,	activities but the chain of command is not clear.
The capability of the VS to coordinate its	3. There are internal coordination mechanisms and a
resources and activities (public and private	clear and effective chain of command for some activities.
sectors) with a clear chain of command,	4. There are internal coordination mechanisms and a
from the central level (the Chief Veterinary	clear and effective chain of command at the national level
Officer), to the field level of the VS in order	for most activities.
to implement all national activities relevant	5. There are internal coordination mechanisms and a
for the Codes (i.e. surveillance, disease control	clear and effective chain of command for all activities and
and eradication, food safety and early detection and rapid response programmes).	these are periodically reviewed/audited and updated.

*Evidence* (see Appendix 6): 30, 74, 111, 120, 134, 143, 149, 151, 174, 190 213, 214, 215, 216

#### <u>Findings:</u>

The Veterinary Services have effective internal coordination mechanisms and a chain of command from central to field for all activities. Recent emergency responses to BSE, FMD and HPAI have tested and demonstrated the overall effectiveness of the coordination mechanisms of the VS when facing animal health emergencies.

In animal health, MAFF have a strong, defined, direct chain of command between headquarters in central government to the Prefecture Animal Health Divisions and their Livestock Hygiene Service Centres. Operational capacity for the prevention and control of infectious diseases in the field is provided primarily by the Livestock Hygiene Service Centres under the Prefecture Animal Health Divisions with a focus on biosecurity and the prevention of disease transmission. This structure is defined in the comprehensive and still relevant 'Act on Domestic Animal Infectious Diseases Control' (1951).

MAFF is directly involved in quarantine and border security at air and seaports via AQS.

Coordination takes place between central MAFF and the prefectures through a number of mechanisms:

- A series of national meetings are convened annually between central level and the Prefecture Animal Health Divisions. These meetings may be focused on a single issue such as HPAI or BSE, or more general issues such as infectious disease prevention and control.
- A series of disease control guidelines have been developed against priority infectious diseases such as BSE, CSF, ASF, HPAI and FMD and a set of biosecurity standards have been developed for the major livestock species, both of which set out operational requirements, including disease surveillance sampling and annual biosecurity inspections for all livestock farms.
- National disease control programmes from MAFF such as for Johne's disease, brucellosis, Aujeszky's disease and salmonellosis set down the implementation and coordination arrangements that prefectures and their Livestock Hygiene Service Centres need to implement.
- National level animal health and veterinary public health relevant legislation supports the chain of command.

Extensive informal communication also takes place between the Prefecture Animal Health Divisions and central MAFF – commonly by email but also by phone. Staff at central and prefecture level have a strong common vision for the promotion of animal health and veterinary public health, know each other well and have well-established lines of communication. Some MAFF central staff

are rotated to positions in the prefectures and vice versa increasing understanding between the different levels of MAFF.

Prefecture Animal Health Divisions work closely with their prefecture Livestock Hygiene Service Centres with formal meetings held monthly with minutes recorded; this coordination is further strengthened with frequent visits, often weekly, and daily contact as needed through phone calls and emails. Livestock Hygiene Service Centres are well connected to their local NOSAI and private veterinary clinics with any suspicions of notifiable diseases reported across for investigation.

The MAFF regional offices support the development of agriculture including livestock production in their regions. These offices play a mostly non-technical role in financial administration and oversight between MAFF and the prefectures and have only a more minor role in the control of infectious diseases and the promotion of animal health. Regional offices focus on improved farm hygiene biosecurity and generally the control of lower priority production limiting endemic diseases.

The central Animal Health Division operates in three sections – the CVO/Director and his support staff, the Domestic Animal Health Office (Disease Prevention and Control) and the International Animal Health Office. The whole Animal Division is located in one large open plan office and informal communications take place easily. Animal Division have weekly meetings of Deputy Director staff and above to plan activities and to develop workplans.

AQS have formal meetings as required (1-2 per week at different levels such as section chief, deputy director, etc.). Informal communications and cooperation take place frequently with good support and empathy for needs.

In veterinary public health, a similar clear chain of command also exists between MHLW, its prefectural Hygiene Divisions with their Public Health Centres (for food processing/retail, drug and animal welfare inspection) and Meat Inspection Centres (for abattoir inspection). There is regular ongoing formal coordination (planning and programme design and implementation) and dynamic informal coordination between MAFF and MHLW.

Across the core Veterinary Services (Animal Health Divisions at central MAFF and in the prefectures and their Livestock Hygiene Service Centres) there is excellent ongoing formal and informal communication with effective setting of priorities and the development of annual budgeted work plans. The same is in place for veterinary public health between MHLW and its prefectural Hygiene Divisions and their local Health Centres and Meat Inspection Centres.

#### Strengths:

- Strong chain of command facilitated legislatively and financially with clear understanding of roles, commitment and lines of communication;
- Effective formal communication and coordination mechanisms with budgeted annual work plans vertically in MAFF for animal health and between MAFF and MHLW for veterinary public health, including for food safety and surveillance activities;
- Strong personal networks for communications and develop of support and prioritisation of activities.

- Formal reviews should be undertaken periodically to identify any gaps or weaknesses that should be addressed in national coordination;
- Consider a national whole of government emergency response simulation exercise to review coordination mechanisms operating in a high intensity situation involving multiple prefectures.

B. External coordination	Levels of advancement
The capability of the VS to coordinate its resources and activities (public and private sectors) at all levels with other relevant authorities as appropriate, in order to implement all national activities relevant for OIE Codes (i.e. surveillance, disease control and eradication, food safety and early detection and rapid response programmes). Relevant authorities include other ministries and Competent Authorities, national agencies and decentralised institutions.	<ol> <li>There is no external coordination.</li> <li>There are informal external coordination mechanisms for some activities, but the procedures are not clear and/or external coordination occurs irregularly.</li> <li>There are formal external coordination mechanisms with clearly described procedures or agreements for some activities and/or sectors.</li> <li>There are formal external coordination mechanisms with clearly described procedures or agreements at the national level for most activities, and these are uniformly implemented throughout the country.</li> <li>There are national external coordination mechanisms for all activities and these are periodically reviewed and updated.</li> </ol>

*Evidence* (see Appendix 6): 87, 88, 89, M92, 97, 107, 109, 116, 117, 118, 119, 132, 134, 143, 151, 174, 190

#### <u>Findings:</u>

External coordination mechanisms are well developed in the Veterinary Services with an array of Competent Authorities operating with good coordination, collaboration and cooperation. (See also II.3B Organisation of the VS)

Extensive coordination takes place with MHLW and the independent Food Safety Commission of Japan to identify food safety risks and to eliminate or minimise these risks. The identification of BSE cases in 2001 resulted in major policy changes across animal and human health. In consultation with MHLW, new legislation was passed to set official standards for animal feeds and the need for the removal of specified risk materials (SRMs). No BSE positive animals have been detected since 2009.

MHLW undertook a comprehensive review of BSE control measures in the light of the reducing risk of infection (2015). MHLW with MAFF requested Food Safety Commission of Japan to undertake a science based risk assessment and as a result some control measures were revised – e.g. animals were only required to be BSE tested if over 48 months (about 20% of cattle slaughtered) and the removal of SRMs required are tonsils and distal ileum in cattle of all ages; and then head (excluding tongue, cheek meat and skin), vertebral column (including dorsal root ganglia) and spinal cord, of cattle aged 30 months or over. There are further moves to stop mandatory BSE testing of cattle... Import restrictions were also lifted for some countries. MAFF sets import restrictions and they are being implemented by AQS.

Following outbreaks of HPAI, MAFF has been working closely with MoE to undertake wild bird surveillance with sample collection and testing. Guidelines have been developed for the response to HPAI detections which include visual inspection within a 3km radius and enhanced surveillance sampling within a 10km radius and the early warning of at risk producers to enhance their level of biosecurity. An AI Advisory Committee involving academic experts in ornithology and virology meets regularly to discuss AI in wild birds; MAFF and MHLW staff are invited.

Coordination mechanisms between the Competent Authorities are through a combination of relatively infrequent formal meetings (usually only a few times per year – unless an issue is identified) and very frequent personal and informal communications (many times per week).

Tri-ministerial cooperation is in place between MAFF/MHLW/MoE under the 'Act on Domestic Animal Infectious Diseases Control' which requires MAFF, MHLW and MoE mutually to provide information for the smooth implementation of animal disease control as needed.

Livestock markets are managed by local governments with attendance by contracted veterinarians. Animal welfare and health issues are managed at the markets by contracted veterinarians under the control of the markets under the Livestock Transaction Act. There is no programme for ongoing reporting of market activities and data on animal diseases present.

NOSAI veterinarians and the private clinics implement effective vaccination programmes as set down by MAFF; currently there is little recording of individual animal identification data, with activities recorded at the herd or flock level.

Overall coordination with the NOSAI veterinarians works well with direct alerts made to the local governments for any animal health or welfare issues identified.

The MoE implements national animal welfare programmes. There is some effective formal and informal external coordination operated at national level between MoE and MAFF on animal welfare. However, based on field visits by the team, it seems only limited programme planning and coordination at field level on animal welfare activities takes place between MoE and prefecture animal health staff.

#### Strengths:

- Identified Competent Authorities with formal and informal coordination mechanisms established;
- Strong common commitment to veterinary public health and the support of animal health.

#### Weaknesses:

- Limited coordination of inspection activities and reporting from markets and slaughterhouses;
- Only limited data/information exchange between the vaccination and animal traceability programmes;
- Management and coordination of animal welfare programmes between MoE, MAFF and MHLW exists but could be further improved.

- Improve coordination of inspection activities and reporting from markets and slaughterhouses with integration of data to support early detection of outbreaks, disease monitoring and response;
- Improve links with and between the vaccination and animal traceability programmes to provide better information for disease control and risk management;
- Strengthen coordination on the implementation of animal welfare programmes by MoE and with MHLW, identify gaps and increase MAFF activities to address these in coordination with MoE and MHLW.

I-7 Physical	Levels of advancement
<b>resources</b> The access of the VS to relevant physical resources including buildings, transport, telecommunications, cold chain, and other relevant equipment (e.g. computers).	<ol> <li>The VS have no or unsuitable physical resources at almost all levels and maintenance of existing infrastructure is poor or non-existent.</li> <li>The VS have suitable physical resources at national (central) level and at some regional levels, and maintenance and replacement of obsolete items occurs only occasionally.</li> </ol>
	3. The VS have suitable physical resources at national, regional and some local levels and maintenance and replacement of obsolete items occurs only occasionally.
	4. The VS have suitable physical resources at all levels and these are regularly maintained.
	5. The VS have suitable physical resources at all levels (national, sub-national and local levels) and these are regularly maintained and updated as more advanced and sophisticated items become available.

*Evidence* (see Appendix 6): E152, 162, 168, 169, 174, 182, 185

#### <u>Findings:</u>

The Veterinary Services have appropriate to exceptional physical resources at all levels. Facilities, vehicles, equipment, IT/computers are generally new or relatively new and are well maintained. Asset registers are available with lists of items, purchase dates and prices, maintenance schedules and replacement dates.

The facilities of the 170 Livestock Hygiene Service Centres are generally of a high to very high standard with good office accommodation, meetings rooms, laboratories, post mortem rooms and other facilities. Supporting infrastructure is also usually provided – including garaging, car washing facilities, incinerators and/or large cold stores for carcasses pending their removal for rendering. The build quality of the facilities is high and they are well maintained. There is an average of one car for two veterinarians in most of the Centres – also new, well maintained and washed after every use.

The laboratories of the Livestock Hygiene Service Centres vary with some having higher capabilities than others but generally with very highly functionality for local access laboratories (e.g. Hokkaido has BSE testing capable laboratories); see also CC II.1A Laboratory access. These laboratories have the necessary facilities and equipment to provide diagnostic services in pathology/histopathology, parasitology, microbiology, serology, virology including the use of cell lines for virus isolation, molecular diagnostics (real time PCR, Mediated Isothermal Amplification for DNA (LOOP)) and haematology/clinical pathology. All equipment is high quality, new/well maintained and in regular use. Equipment of the Livestock Hygiene Service Centres is recorded on an asset management register with dates and costs of purchase, maintenance schedule and time for replacement.

The MAFF offices have a high level of IT and communications equipment. The central Animal Health Division is well placed in a single large room. Though convenient there is little space and there is an opportunity to review how best to operate in the limited space. Paper filing at the Animal Health Division is unwieldy and large numbers of files on desks create an impression of clutter, disorganisation and overwork.

AQS have 30 offices situated across the country covering 54 seaports and 43 airports. These offices are busy but functional with rather limited desk space. Ancillary quarantine facilities are well provided for with kennels both for the inspector dogs and for the quarantine of imported animals. Facilities are also provided for imported non-human primates at the two designated import sites (Narita and Kansai). Incinerators are available on site and formal contracts established with private contractors for the waste disposal of aircraft/ship garbage etc.; these contractors are required to follow established protocols covering transfer and incineration and are regularly assessed and formally audited.

The AQS Laboratory Department operates laboratories at, or nearby, all designated entry points. These laboratories are equipped to undertake pathology and physicochemical examinations and microbiology with PCR/LOOP technology.

The AQS also operate two BSL3 facilities under their 'Microbiological Examination Division' and 'Exotic Disease Inspection Division' – at Yokohama and Chubu. These laboratories are used for diagnosis and research on agents including bovine, equine and porcine diseases; rabies and influenza viruses. The facility at Chubu was visited and found to be designed and built to the high standard required for a BSL3 laboratory. Very extensive diagnostic and the necessary supporting equipment was available including large volume pass through autoclaves, -80°C freezers, BSL2 cabinets, fluorescence microscopes, ELISA readers, PCR/LOOP and a gene sequencer. The high security laboratories have been accredited to ISO17025. In addition, the AQS has other two BSL3 facilities for quarantine of non-human primates in Narita and Kansai airports for the diagnostic laboratory tests for Ebola and Marburg viruses.

AQS have animal quarantine facilities at 13 locations. All these locations are equipped with facilities designed for companion animals; large animals (cattle) are mainly imported through Moji and Kobe. After on-arrival inspection at the airport, high health horses, day-old-chicks and non-human primates can proceed directly to designated, non-government, quarantine sites.

Facilities and equipment have been purchased by MAFF in preparedness for mounting an emergency response. This equipment has been funded by various sources primarily MAFF and JLIA and is now stored by AQS at their Nozeki Quarantine Station as they have the required warehousing space, and it is centrally located in the country. Equipment includes a mobile rendering plant, mobile incinerators, a 'poultry foam depopulation system' and a 'wide area controller' (a disinfection unit). Consumable supplies are also stored by AQS including protective clothing, tarpaulins and other miscellaneous items. Most prefectures have their own large stockpile of a full range of emergency animal health equipment (including disinfectants and lime, personal protective equipment, roadblocks and signs, shovels and wheelbarrows) all stored for ready access and use.

The main national laboratories of the VS are NIAH, AQS and NVAL. NIAH is recognised as an OIE international reference laboratory. NIAH has a complex of buildings including a BSL3 laboratory. Its biosafety/biocontainment has been recognised by OIE and it is one of the few laboratories internationally to be granted permission to hold and work on rinderpest virus; it also is the only site worldwide to continue to make rinderpest vaccine (made annually and held in reserve).

Other Competent Authorities such as FAMIC are also well resourced with a series of laboratories equipped to undertake different analyses. Core equipment at FAMIC includes radioassay to detect radioactivity (particularly following the 'Great East Japan Earthquake' in 2011), HPLC and a range of spectrometers for detect residues, microbiological assays, microscopy and simple detection kits such as ELISA.

Equipment at the university veterinary schools is of a very high standard. Two universities visited (in Osaka and Miyazaki Prefectures) had MRI and CAT scanners alongside the more traditional radiography and ultrasound – students were seen to be using the equipment. In Osaka a high quality, oncology treatment room was available with a radiation probe – records showing a high rate of use (6 - 7 animals per day). Other facilities at these schools were also well designed and constructed with excellent lecture and laboratory rooms for student teaching and good facilities for students to undertake surgery, handle and examine large animals and for holding large and small animals. The Osaka Prefecture Veterinary School is next door to the Livestock Hygiene Service Centre for the Prefecture and this allows the exchange of materials for teaching and advanced diagnosis.

Osaka Prefecture is implementing a development plan to improve their capabilities in holding stray dogs and cats. A design has been finalised for a main animal centre of 2,500m<sup>2</sup> at a cost of 2.1 billion JNY; building is due to begin. Three further secondary centres are planned.

#### Strengths:

- > Exceptional facilities and levels of equipment at all levels of the VS;
- > All facilities and equipment are well maintained and replaced as necessary.

#### **Recommendations:**

Review physical facilities and resources as there are some duplicated systems that might lead to uncertainty of which facility is to take the lead in certain activities (e.g. the provision and storage of emergency response equipment and the number of high biosecurity laboratories operated under MAFF and AQS).

I-8 Operational	Levels of advancement
funding	1. Funding for the VS is neither stable nor clearly defined but depends on
The ability of the VS	resources allocated irregularly.
to access financial	2. Funding for the VS is clearly defined and regular, but is inadequate for their
resources adequate	required base operations (i.e. disease surveillance, early detection and rapid
for their continued	response and veterinary public health).
operations,	3. Funding for the VS is clearly defined and regular, and is adequate for their
independent of	base operations, but there is no provision for new or expanded operations.
political pressure.	4. Funding for new or expanded operations is on a case-by-case basis, not
	always based on risk analysis and/or cost benefit analysis.
	5. Funding for all aspects of VS activities is adequate; all funding is provided
	under full transparency and allows for full technical independence, based on risk
	analysis and/or cost benefit analysis.

#### *Evidence* (see Appendix 6): E204, 210

#### <u>Findings:</u>

Operational funding is adequate for all aspects of the Veterinary Services activities at a level that provides for full implementation of programmes and transparency of accounting.

Table 10: VS funding (2014)

Budget holder	2014 funds (JPY)
MAFF (Animal Products Safety Division and Animal Health Division)	8,427m
AQS	822m
MHLW (Tuberculosis and Infectious Disease Control Division)	13m
MHLW (Department of Food Safety)	1,553
Quarantine stations	8,968m
NIAH	3,757m
Prefecture funding unavailable for animal health	Not available

Risk analysis is used to identify priority activities in some situations such as for the prioritisation of the inspection of imported animal products and in passenger profiling. Risk analysis is not generally used for field activities as the level of operational funding provided is exceptional allowing high levels of communication, disease surveillance, the effective implementation of control programmes and the promotion of animal health, veterinary public health and animal welfare. For example, LHSC staff conduct annual biosecurity inspections of *all* livestock farms.

Funding is provided to the prefectures from central government through a process of budget application by each prefecture to the MAFF Financial Department; following review and consolidation the overall draft budget for national animal health is provided to the Ministry of Finance. Approved funds are provided from the Ministry of Finance for core animal health activities direct to the prefecture finance departments; in addition funds are provided to the MAFF Regional Offices who support animal production and promote market stability. No constraints on animal health activities based on limited funding were identified. Detailed budgets are available at all levels of MAFF. There is room for greater efficiency via the prioritisation of activity using a systematic application of risk analysis and/or benefit cost analysis of activities.

Some local funds are also available to the prefectures from registration and licensing fees, including from private veterinary clinics, livestock markets and businesses selling veterinary drugs. These funds are not used for core animal health/infectious disease control, funded by national government, but for 'livestock hygiene'. Livestock hygiene covers activities such as improving and supporting livestock production and promoting the distribution of some products such as fresh milk.

The prefecture animal health division budgets are adequate for all their animal related activities including animal health, through the Livestock Hygiene Service Centres, for animal production and animal welfare. Funding allows for the attendance at national meetings and for the coordination meetings held within the prefecture. Prefecture Animal Health Divisions are well staffed, some 60%

are typically veterinarians, 35% are 'technical' (eg capturing stray animals, wild animals and caring for animals).

The field service is provided by the 170 Livestock Hygiene Service Centres. These centres provide disease surveillance, both passive and active, disease control and animal welfare programmes with supporting laboratory diagnostic services. The budget for these centres seems very adequate and no issues were raised to the mission of the inability to undertake certain activities through a lack of funding.

Clinical, reproductive and nutritional veterinary services are provided via the Agricultural Mutual Aid Federations/Associations (NOSAI) system, managed centrally by the by the MAFF Management Improvement Bureau under the Agricultural Disaster Compensation Act, and delivered in the field through 257 NOSAI clinics across the country. Livestock farmers pay a fee to be 'insured' and access these VS, which are well subsidised by government. Insured farmers can also use private veterinarians if they choose under their insurance scheme. The uptake is much higher for dairy and beef cattle producers than other species. If notifiable diseases are suspected, NOSAI veterinarians contact their local Livestock Hygiene Service Centres for further investigation.

The Japan Livestock Industry Association at national level is funded almost equally from ALIC, MAFF and the Japan Racing Industry. At prefectural level, the Livestock Industry Associations play a key role in supporting vaccination programmes and some special commissioned animal health projects which are delivered outside government. Local 'Self Prevention Promotion Associations' at municipal level determine the numbers of farmers interested in vaccination. Farmers are required to contribute to vaccine costs and the Livestock Industry Associations contract the NOSAI veterinarians for field delivery.

No analyses of cost-benefit or cost-effectiveness were available.

#### Strengths:

- Budget process is well documented and transparent;
- Operational budgets are not a constraint to VS activities, including subsidising and collectivising veterinary activities generally involving only individual private fee-based delivery in other countries e.g. clinical and reproductive services through the government supported NOSAI insurance system;
- The operating budget is adequate to allow ongoing support of international programmes and support to OIE.

#### Recommendations:

Undertake a review of the cost-effectiveness of some major activities that may benefit from revision such as BSE surveillance, feed safety testing and the rabies prevention programmes.

I-9 Emergency funding	Levels of advancement
I-9 Emergency funding The capability of the VS to access extraordinary financial resources in order to respond to emergency situations or emerging issues; measured by the ease of which contingency and compensatory funding (i.e. arrangements for compensation of producers in emergency situations) can be made available when required.	Levels of advancement         1. No funding arrangements exist and there is no provision for emergency financial resources.         2. Funding arrangements with limited resources have been established, but these are inadequate for expected emergency situations (including emerging issues).         3. Funding arrangements with limited resources have been established; additional resources for emergencies may be approved but approval is through a political process.         4. Funding arrangements with adequate resources have been established, but in an emergency situation, their operation must be agreed through a non-political process on a case-by-case basis.         5. Funding arrangements with adequate resources have been established and their rules of operation documented and agreed with interested parties.

*Evidence* (see Appendix 6): E6, E16, 17, 201

#### Findings:

The 'Act on Domestic Animal Infectious Diseases Control' (1951, amended 2012), requires the national government to be responsible for funding emergency preparedness and response.

This Act (Articles 58 – 60) covers allowances to be paid to the owner for any loss of animals or objects caused by the response to an infectious animal disease. Provision is made for the allowances to be reduced or cancelled if the owner or manager of the animals has failed to report as required to the health authorities. MAFF is required to consult with the governors of affected prefectures before deciding on the proper appraised value and prefectural governors are required to consult with at least three appraisers to assess the value of the lost assets.

Under this Act, the State is required to compensate for the slaughter of specified domestic animals and to pay the full cost of burial or incineration of domestic animal carcasses that have been required to be culled; provision is made for the burden of compensation to be modified by Cabinet Order. The value to be paid out is set at one third of the animal value before they became 'affected' (100% if FMD or HPAI); for suspect affected animals and objects destroyed the appraised value is set at one four fifths (100% if FMD or HPAI). Compensation paid for the cost of disposing of carcasses is set at one half.

MAFF provides fully comprehensive compensation to affected farmers, for culling as a direct result of an outbreak. For indirect losses caused by movement restrictions MAFF subsidises prefectures for 50% of this cost of compensation. For the loss of income/production and restocking a Mutual Fund set up through the Japan Livestock Industry Association pays out to eligible farmers who have contributed to it. Due to strong political pressure during the 2010 FMD outbreak in Miyazaki, MAFF ended up also providing compensation to the farmers who were not part of this Mutual Fund. The case was highly exceptional given the circumstances and the firm MAFF policy is not to provide compensation in this way again.

Further support is to be provided to affected prefectures including 100% of the cost of traveling expenses incurred by prefecture animal health inspectors, variable support for medicines and biologicals, hygiene equipment, disinfection stations and support for economic loss.

Further the state is required to take the necessary financial measures in order to provide the reserves to accurately and promptly prevent the spread of domestic animal infectious disease in the early stages of an outbreak, or suspected outbreak.

Prefecture governments may elect to provide further support to their livestock sector by compensating loss of business, loss of production and loss of business continuity.

The Japan Livestock Industrial Association (JLIA) with the Agriculture and Livestock Industries Corporation (ALIC) and the Japan Racing and Livestock Promotion Foundation supports various

aspects of livestock production including ensuring that prefecture governments have adequate supplies for an effective and timely emergency response.

AQS has a primary role in managing the risk from imported animal products but also holds emergency response materials and uses some of its facilities to store emergency equipment such as mobile renderers and incinerators.

Emergency preparedness and response is supported by multiple simulation exercises that are run each year in every prefecture

#### Strengths:

- Legal mandate for the funding of emergency preparedness and response;
- Clearly defined funding sources for the payment of compensation including for loss of income;
- Support from other stakeholders in funding the purchase and/or storage of emergency equipment and materials;
- > Annual prefecture level simulation exercises.

- Review the simulation exercise programme and revise to deliver cost-effective training and development of the emergency response system and the understanding of MAFF staff and stakeholders;
- Consider a desk top national simulation exercise for a worst case scenario to test the funding limits and options;
- Consider options for increased funding support for emergencies from industry and the NOSAI programme.

I-10 Capital	Levels of advancement
investment The capability of the VS to access funding for basic and additional investments (material and non material) that lead to a sustained improvement in the VS operational infrastructure.	1. There is no capability to establish, maintain or improve the operational infrastructure of the VS.
	2. The VS occasionally develops proposals and secures funding for the establishment, maintenance or improvement of operational infrastructure but this is normally through extraordinary allocations.
	<ol> <li>The VS regularly secures funding for maintenance and improvements of operational infrastructure, through allocations from the national budget or from other sources, but there are constraints on the use of these allocations.</li> <li>The VS routinely secures adequate funding for the necessary</li> </ol>
	<ul><li>maintenance and improvement in operational infrastructure.</li><li>5. The VS systematically secures adequate funding for the necessary</li></ul>
	improvements in operational infrastructure, including with participation from interested parties as required.

*Evidence* (see Appendix 6): none specific

#### <u>Findings:</u>

The Veterinary Services are routinely able to upgrade and improve their facilities, vehicles, specialist and other equipment. Budgets are proposed and reviewed for the further investment in capital items both within the core animal health services run by MAFF and its agencies, such as AQS, NIAH and NVAL, and for activities undertaken by Competent Authorities including MHLW and MoE and other entities such as FAMIC and the Food Safety Commission of Japan.

Almost all building facilities at all levels are appropriate. Facilities are often modern or at least regularly maintained with refurbishment as necessary. Office accommodation is sometimes a little cramped with limited storage space – this is particularly so in the central animal health division of MAFF; prefecture animal health divisions generally have very good accommodation.

The Livestock Hygiene Service Centres not only have excellent office accommodation but also provide clinical examination, laboratory, autopsy, garaging with car washing and other facilities. Incinerators are provided on-site or nearby. Public Health Centres and Meat Inspection Centres are similarly well equipped for their veterinary public health roles.

Modern vehicles are available in all offices to all staff. The Livestock Hygiene Service Centres typically have one car per two veterinarians.

Computing and IT systems are available at all sites with modern equipment, large capacity printers and copiers, and some large format document printers ('plotters'), and ready access to the Internet. A number of databases have been developed for the management of assets, operations, and the handling of animal health data. AQS use a national database to assess risk and to schedule the investigation of shipments.

Laboratory facilities and equipment are generally excellent, established in purpose-built buildings with multiple rooms for the full array of laboratory diagnostic and research activities as designated. High levels of biosecurity are available ranging from BSL2 cabinets at the Livestock Hygiene Service Centres to pressure controlled HEPA filtered rooms with shower in/out at more specialist facilities. Laboratory equipment is modern, well maintained and calibrated regularly. The laboratories have a wide range of diagnostic techniques and equipment available including, depending on the laboratory, PCR, gene sequencing, ELISA readers, electron microscopes, HPLC, spectrometers, etc. Ancillary equipment necessary for the preparation and sterilisation of diagnostic equipment and materials is always available. Novel technologies such as the loop real-time turbidity meter, a novel gene amplification method, have been introduced to even base level laboratories.

Funding for capital investment is generally provided by the national budget. Prefectures support this with direct funding of additional local facilities.

One prefecture's budget was such that they were able not only to provide their core functions of animal welfare, animal hygiene and wildlife but also to invest in a new purpose built 2,500m<sup>2</sup> premises for the care and management of animal welfare at a cost of 2.1 billion JPY.

Funding for capital investment is maintained at a high level and there are no apparent constraints on purchasing/replacing/refurbishing capital items. Although there was evidence of ongoing investment no medium/longer term plans were available.

#### Strengths:

- > High quality extensive facilities in place at all levels of the VS;
- Extensive equipment in place and replaced/updated as needed;
- > Asset registers with maintenance and replacement schedules.

#### **Recommendations:**

As part of overall strategic policy development and planning there is an opportunity to develop a medium/long term budget for capital investment at central and prefecture levels.

I-11. Management	Levels of advancement
of resources and	1. The VS do not have adequate records or documented procedures to allow
operations	appropriate management of resources and operations
The capability of the VS	2. The VS have adequate records and/or documented procedures but do not
to document and	use these for management, analysis, control or planning.
manage their resources	3. The VS have adequate records, documentation and management systems
and operations in order	and use these to a limited extent for the control of efficiency and effectiveness
to analyse, plan and	4. The VS regularly analyse records and documented procedures to improve
improve both efficiency	efficiency and effectiveness
and effectiveness.	5. The VS have fully effective management systems, which are regularly
	audited and permit a proactive continuous improvement of efficiency and
	effectiveness.

#### *Evidence* (see Appendix 6): E197, 203, 204

#### <u>Findings:</u>

The Veterinary Services have effective management systems based on data capture of programme implementation of animal health and veterinary public-health operations with analysis, review and reporting.

Resources are plentiful and operations appear never to be constrained by any shortage.

An asset register of buildings, vehicles and equipment is maintained at all locations. This asset register itemises resource by purchase date, maintenance schedule and replacement date.

Operations undertaken in the field to promote animal health follow the national guidelines for the prevention and control of infectious diseases. Such operations include regular and often frequent testing of animals for target diseases – often all animals are tested rather than a random representative proportion as resources are not limiting.

Veterinary public health is a priority with major programmes to reduce the risk from foodborne and zoonotic diseases such as BSE, HPAI and rabies; there doesn't seem to have been any cost-effectiveness study of any of these programmes. In the context of the Japanese VS and the very high priority given to public health and consumer safety the ongoing stringent methods for the prevention of these diseases and the earliest detection of any further cases is considered as a clear objective.

The AQS system for managing imported live animals and animal products is efficient and effective. The NACCS programme used for the management of shipments, initial risk assessment and the need to investigate is used across the quarantine services (animal, plant and human) and by Customs. The NACCS system allows the prioritisation risk and its immediate investigation.

The use of detector dogs by AQS at all major airports is an efficient system for promoting awareness of the need for compliance with import regulations and the effective detection of illegal imports.

The VS publish annual reports on their activities, their budget and objectives; copies of such reports are made available to other countries and trading partners.

The disease control guidelines provide the policy and direct the activities required for programme implementation; the prefectures base their operational plans on these guidelines. Annual reports are prepared and sent both to central MAFF and to all the other prefectures. Operations are well documented and described – the utilization of budgets and resources less so.

There are no mandated national vaccination programmes in Japan, apart from rabies. Instead the prefectural Livestock Industry Associations manage voluntary vaccination programmes for farmers who are required to contribute financially to vaccine costs. NOSAI clinics are contracted to administer vaccinations by the Livestock Industry Association.



The Ministry of Internal Affairs and Communications conducts periodic surveys of the policies and administrative procedures of all government departments including MAFF. The latest review was conducted in 2014, as a result of this review recommendations were provided on the improvements required and actions taken to implement them. Recommendations included:

• Recommendation: Improve farmer awareness of biosafety.

*Response*: MAFF directed prefecture governments to increase activities and to develop monitoring activities

• Recommendation: Review effectiveness of passenger hand luggage checks

Response: Risk analysis undertaken and priority activities revised

• Recommendation: Review wild bird surveillance activities

Response: Prefecture governments reviewing their surveillance programmes

• *Recommendation*: Develop rapid response programme for any FMD incursions in worst case scenarios

*Response*: Prefectures are developing mobilisation plans with coordination of human resources

• *Recommendation*: Prepare disposal sites for emergency response

Response: Prefectures working with farmers to identify sites and to prepare alternatives

Annual Animal Health Division reports are available. There is no ongoing or continual or review or audit of activities and so no striving for continuous improvement of efficiency and effectiveness. There is no long-term strategic plan for the VS, and how they will contribute to major goals and a strategic vision for the livestock industries in Japan. The VS deliver effective disease control programmes, a high national animal health status and excellent food safety with minimal risk to the public, and with no financial or operational constraints, there is no incentive to improve efficiency or effectiveness.

#### Strengths:

- Strong well documented programme guidelines with defined activities and operations;
- Annual reports shared across MAFF of operational activities;
- Budgets drafted and approved through a formal review process.

#### Weaknesses:

- No/limited cost-benefit and cost-effectiveness studies of disease control programmes their operations and their use of resources (Note that in the low risk, highly resourced VS of Japan, efficiency is not a priority);
- No long term strategic plan for the VS, and how they will contribute to major goals and a strategic vision for the livestock industries in Japan.

- Undertake cost-benefit and cost-effectiveness studies of disease control programmes their operations and their use of resources;
- Review the cost-benefit of current measures targeting exotic diseases such as active surveillance for CSF and mandatory vaccination for rabies, the testing protocols for animal feeds when no detections have been made for multiple years, and the mandatory BSE testing of non-clinically suspect cattle;
- Consider developing a 5-year plan for the VS that sets out how they will actively contribute to the strategic direction of the Japanese livestock industries in the medium to longer term, especially recognising the desire to increase exports and the reducing numbers of farmers, small farm sizes, part time farming and decreasing outputs.

#### Japan

## **III.2** Fundamental component II: Technical authority and capability

This component of the evaluation concerns the authority and capability of the VS to develop and apply sanitary measures and science-based procedures supporting those measures. It comprises eighteen critical competencies.

For all sections of this chapter, the critical competency includes collaboration with relevant authorities, including other ministries and Competent Authorities, national agencies and decentralised institutions that share authority or have mutual interest in relevant areas.

Section II-1	Veterinary laboratory diagnosis			
	A. Access to veterinary laboratory diagnosis			
	B. Suitability of national laboratory infrastructures			
Section II-2	Laboratory quality assurance			
Section II-3	Risk analysis			
Section II-4	Quarantine and border security			
Section II-5	Epidemiological surveillance and early detection			
	A. Passive Epidemiological surveillance			
	B. Active Epidemiological surveillance			
Section II-6	Emergency response			
Section II-7	Disease prevention, control and eradication			
Section II-8	Food safety			
	A. Regulation, authorisation and inspection of establishments for production, processing and distribution of food of animal origin			
	B. Ante and post mortem inspection at abattoirs and associated premises			
	C. Inspection of collection, processing and distribution of products of animal origin			
Section II-9	Veterinary medicines and biologicals			
Section II-10	Residue testing			
Section II-11	Animal feed safety			
Section II-12	Identification and traceability			
	A. Animal identification and movement control			
	B. Identification and traceability of products of animal origin			
Section II-13	Animal welfare			

#### Critical competencies:

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Terrestrial Code References:

Chapter 1.4. on Animal health surveillance.

Chapter 1.5. on Surveillance for arthropod vectors of animal diseases.

Chapter 2.1. on Import risk analysis.

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General Organisation / Procedures and standards. Point 1 of Article 3.2.4. on Evaluation criteria for quality systems.

Point 3 of Article 3.2.6. on Evaluation criteria for material resources: Technical.

Points 1 and 2 of Article 3.2.7. on Legislation and functional capabilities: Animal health, animal welfare and veterinary public health / Export/import inspection.

Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems. Points 1-5 of Article 3.2.9. on Veterinary public health controls: Food hygiene / Zoonoses / Chemical residue testing programmes / Veterinary medicines/ Integration between animal health controls and veterinary public health.

Sub-point f) of Point 4 of Article 3.2.10. on Veterinary Services administration: Formal linkages with sources of independent scientific expertise. Points 2 and 5-7 of Article 3.2.14. on National information on human resources / Laboratory services / Veterinary legislation, regulations and functional capabilities / Animal health and veterinary public health controls.

Article 3.4.12. on Human food production chain.

Chapter 4.1. on General principles on identification and traceability of live animals.

Chapter 4.2. on Design and implementation of identification systems to achieve animal traceability.

Chapter 4.12. on Disposal of dead animal.

Chapter 6.2. on Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection.

Chapter 6.3. on Control of hazards of animal health and public health importance in animal feed.

Chapters 6.6. to 6.10. on Antimicrobial resistance.

Chapter 7.1. Introduction to the recommendations for animal welfare.

Chapter 7.2. Transport of animals by sea.

Chapter 7.3. Transport of animals by land.

Chapter 7.4. Transport of animals by air.

Chapter 7.5. Slaughter of animals. Chapter 7.6. Killing of animals for disease control purposes.

II-1 Veterinary	Levels of advancement		
laboratory diagnosis	1. Disease diagnosis is almost always conducted by clinical means only,		
	with no access to and use of a laboratory to obtain a correct diagnosis.		
A Access to veterinary	2. For major zoonoses and diseases of national economic importance,		
laboratory diagnosis	the VS have access to and use a laboratory to obtain a correct		
The outbority and	diagnosis.		
The authority and	3. For other zoonoses and diseases present in the country, the VS have		
capability of the VS to have access to laboratory	access to and use a laboratory to obtain a correct diagnosis.		
diagnosis in order to	4. For diseases of zoonotic or economic importance not present in the		
identify and record	country, but known to exist in the region and/ or that could enter the		
pathogenic agents,	country, the VS have access to and use a laboratory to obtain a correct		
including those relevant for	diagnosis.		
public health, that can	5. In the case of new and emerging diseases in the region or world, the		
adversely affect animals	VS have access to and use a network of national or international		
and animal products.	reference laboratories (eg an OIE Reference Laboratory) to obtain a		
and animal products.	correct diagnosis.		

Evidence (see Appendix 6): E144, 200, 201

#### Findings:

The Veterinary Services have a very extensive number of national, prefecture and specialist veterinary diagnostic and research laboratories; there are also a number of private laboratories (see table 8). The VS participate, often leading, international and regional laboratory networks to support the development of new and/or improved diagnostic tests for known and emerging infectious diseases. A number of facilities are recognised internationally as OIE Reference Laboratories or OIE Collaborating Centres.

Table 11: Laboratories permitted to handle domestic animal diseases and notifiable animal diseases

			12-Aug-16
	Laboratories handling the pathogens of the domestic animal infectious diseases ※1	Laboratories handling the pathogens of the notifiable infectious diseases %2	total of $\%1$ and $\%2$
Total	52	113	127
Reference Laboratories涨3	3	3	3
Public : Private	31:19	68:45	77:50
BSL3:BSL2	45:7	3:110	14:113

Note: that there are 13 OIE Reference Laboratories listed in Japan as many of these are co-located they only count as one permit; others are not included as they deal with aquaculture or parasites and no permit is required.

#### NIAH

NIAH is the national reference laboratory for animal health. NIAH operates under the National Agriculture Research Organisation, the 'core institute' in Japan for conducting research and development in food and agriculture, an independent agency of MAFF. NIAH undertakes 'research for diagnosis' and so supports animal health in Japan. NIAH is an OIE International Reference Laboratory for BSE, CSF, EIA, swine influenza and rinderpest; NIAH, together with NVAL, is recognised as an OIE Collaborating Centre for the 'Diagnosis and Control of Animal Diseases and Veterinary Product Assessment in Asia'; it is also one of the very few laboratories worldwide designated by the FAO and OIE to hold rinderpest virus.

NIAH's role is to lead the national laboratory network, operating as the national reference laboratory; NIAH supports laboratory quality assurance throughout the national network, including

activities such as proficiency testing. NIAH currently receives few samples for confirmatory/differential diagnosis – this is largely as other laboratories have the required testing capability; virtually no samples are sent for FMD differential testing at NIAH with a consequent concern that passive surveillance/early detection for an FMD outbreak may be compromised.

NIAH operates at four sites – Tsukuba (headquarters, disease control, epidemiology, TADs, bacterial and parasitic disease and pathology), Kodeira (exotic disease research and diagnosis), Kagoshima (subtropical disease control) and Hokkaido (dairy research). BSL3 facilities operate at Kodeira and Tsukuba. NIAH has a staff of 265 with 88 veterinarians. This has declined significantly in recent years from 355 staff in 2010.

NIAH undertakes a range of research projects (62 peer reviewed research papers in 2014-15) and provides high level, advanced technology diagnostic services as well as producing biological products where there is market failure; it also provides training programmes for MAFF but mostly targeting prefectural and Livestock Hygiene Service Centre staff. NIAH is the only institution in Japan that provides 'definitive diagnosis' for FMD, BSE, CSF, ASF, HPAI/LPAI and CBPP. Livestock Hygiene Service Centres are required to send samples for confirmation if these diseases are suspected.

NIAH is funded mainly by MAFF but with increasing support from other agencies.

### NVAL

NVAL is included here for completeness though it is not a diagnostic laboratory. NVAL is tasked with researching and regulating the development, production (including imports), distribution and use of animal medicines, biologicals, quasi-drugs, regenerative and cellular therapy, gene therapy products and medical devices. Though diagnostic testing is not the remit of NVAL it does have the capacity and capability to undertake pathology, bacteriology, serology and virology. See also CC II.8 Veterinary medicines and biologicals.

NVAL provides assurance that veterinary medical products are safe and efficacious. NVAL manages product registration through a process of marketing approval, marketing authorisation, distribution and post release evaluation. NVAL runs a database for pharmacovigilance recording any reports of adverse reactions. NVAL also manages the Antimicrobial Resistance Monitoring System.

At its site in Tokyo, NVAL operates a series of well-equipped laboratories and has two BSL3 facilities; it also conducts animal experiments to validate veterinary medicines and biologicals in animals and fish. NVAL has taken a lead in the monitoring of antimicrobial resistance (AMR) with a programme reviewing the use of antimicrobials and the levels of antimicrobial resistance. NVAL works internationally to develop capacity for AMR monitoring.

# Livestock Hygiene Service Centres

Each of the 170 Livestock Hygiene Service Centres has a functional and well used laboratory; 52 of these laboratories are designated for advanced diagnosis with specialist facilities and technologies available. Each prefecture has one or more advanced laboratory – Hokkaido has five to cover its wide geographic area and large livestock populations.

At the advanced laboratories, facilities and diagnostic equipment are available to provide services in pathology and histopathology, haematology, biochemistry, serology and virology including PCR (mostly real time but some also have conventional), LOOP, virus isolation; some laboratories have gene sequencers. BSL2 facilities are available in all laboratories. The remaining Livestock Hygiene Service Centre laboratories provide services in pathology/histopathology, parasitology, bacteriology and serology – they do not usually have access to PCR technology.

The Livestock Hygiene Service Centres laboratories are well used with a high throughput of submissions from the monitoring of disease prevalence for control programme activities and outbreak investigations. The Livestock Hygiene Service Centres advanced laboratories are legally mandated to undertake testing of suspect outbreaks of AI or rabies; laboratories of the prefecture

cooperative federations are required to pass on any suspect cases of these diseases. This close collaboration works well with good personal communications and ongoing contact.

# AQS

AQS have a nationwide network of laboratories at their designated border entry points, or nearby, to provide testing for incoming live animals and animal products. The AQS laboratories provide bacteriology, serology and virology tests using standard techniques and with access to PCR and sometimes LOOP DNA amplification technologies. BSL2 cabinets are available.

AQS also have two BSL3 laboratories (Yokohama and Chubu) for the research and advanced diagnostics of high-risk diseases. These laboratories have more advanced technologies available including gene sequencers.

The general throughput for the AQS laboratories is often low. The laboratories continue to be well maintained with staff available and remain functional.

# FAMIC

FAMIC operates laboratories at one central and five regional sites. Its primary task is the safety of feed and other agricultural products. Under the mandate of the Feed Safety Law it undertakes site inspections of feed manufacturing establishments and collects samples for further testing. These samples may be tested for microorganisms such as salmonella and a wide range of other tests including radioactivity, toxins/mycotoxins and BSE/animal derived proteins. There are very low levels of non-compliance for feed testing in Japan (one in the last seven years).

### Universities

University laboratories are well equipped for teaching but do not generally perform diagnostic testing.

Some Livestock Hygiene Service Centres cooperate with nearby veterinary school laboratories sharing samples and technologies where appropriate. This is particularly so in Osaka where the Osaka Prefecture Veterinary School and Livestock Hygiene Service Centre are in adjacent buildings.

### Private laboratories

MAFF do not authorise any private laboratories for the purpose of supporting official animal health programmes for the import and export of animals and animal products. MHLW has authorised 103 private laboratories for the purpose of monitoring import and export food safety. Prefectures use some private or university laboratories where additional official laboratory testing capacity is sought. See CCIII.4 Official Accreditation/Delegation for examples.

### NOSAI laboratories

NOSAI laboratories are operated under the Agricultural Mutual Aid Federations and Associations at the prefecture level. Some prefectures have one or more of these laboratories, the main ones being at the Production Medicine Centre hubs in some prefectures. As laboratories funded, they are funded in part by 'insured farmers pays' and inpart by government subsides.

These laboratories offer most of the same services as the Livestock Hygiene Service Centres laboratories but do not test for notifiable diseases as this testing is referred to the Livestock Hygiene Service Centres. Services provided by NOSAI laboratories include pathology and histopathology, haematology, biochemistry, serology and virology with a more limited range of PCR and virus isolation. These laboratories undertake monitoring and case investigation diagnostics for most diseases including salmonella, IBD, ND, PRRS and PED. The commercial industry also relies on these laboratories to carry out post vaccination monitoring.

### National JA laboratory

The national laboratory develops vaccines, diagnostics and feed additives as part of their technical support activities.

# Strengths:

- > Excellent facilities with high quality modern diagnostic and support equipment;
- Excellent testing capabilities from local NOSAI laboratories to the Livestock Hygiene Service Centres, some operating at 'advanced level';
- > Excellent capacity available at the national reference laboratories of NIAH;
- > 13 OIE reference laboratories.

- Undertake a national review of the laboratory network, resources and capacity as there is an opportunity to consolidate, specialise and rationalise services to make the service more efficient – some laboratories are little used (e.g. some AQS laboratories);
- NIAH's role in leading and developing a functioning national laboratory network should be reviewed; greater emphasis should be given to its role as the national reference laboratory and its support for laboratory quality assurance throughout the national network, including activities such as proficiency testing and on the need to receive adequate samples for rule out testing of e.g. CSF and FMD (see CCII.5A - passive surveillance);
- As an international reference laboratory, NIAH should explore closer collaboration with neighbouring countries with less laboratory capabilities providing increased training and support and also through the testing of samples from overseas.

II-1 Veterinary laboratory	Levels of advancement
diagnosis	1. The national laboratory infrastructure does not meet the need of the VS.
<b>B. Suitability of national</b> <b>laboratory infrastructures</b> <i>The sustainability,</i> <i>effectiveness and efficiency</i>	2. The national laboratory infrastructure meets partially the needs of the VS, but is not entirely sustainable, as organisational deficiencies with regard to the effective and efficient management of resources and infrastructure (including maintenance) are apparent
of the national (public and private) laboratory infrastructures to service the needs of the VS	3. The national laboratory infrastructure generally meets the needs of the VS. Resources and organisation appear to be managed effectively and efficiently, but their regular funding is inadequate to support a sustainable and regularly maintained infrastructure
needs of the VS	4. The national laboratory infrastructure generally meets the needs of the VS and is subject to timely maintenance programmes but needs new investments in certain aspects (eg accessibility to laboratories, number or type of analyses).
	5. The national laboratory infrastructure meets the needs of the VS, and is sustainable and regularly audited.

*Evidence* (see Appendix 6): E3, 4, 5, 6, 85, 144, 159, 166, 185, 211

### Findings:

The national veterinary diagnostic and research laboratories have high quality and well-maintained infrastructure appropriate to their needs and capabilities.

NIAH, AQS and some universities have BSL3 facilities operating with modern well-designed, accredited facilities allowing for advanced diagnostic testing and research activities.

The Livestock Hygiene Service Centre laboratories vary in their infrastructure and capacity. Each prefecture has an 'advanced diagnosis centre' with BSL2 facilities; these are situated in facilities of varying age but often refurbished and fully functional allowing the use of molecular techniques (PCR, LOOP, etc.) and virus isolation. The other Livestock Hygiene Service Centre laboratories have lesser but still functional facilities providing more basic testing in pathology/histopathology, bacteriology, serology, haematology, etc. but not usually molecular testing or virus isolation.

The other AQS laboratories (not their BSL3 laboratories) have facilities that are variable with some being rather older and cramped. The AQS facilities are all adequate and fully operational for the range and number of tests being undertaken.

Biocontainment and waste management is well managed usually by incineration on site, sometimes by transfer to an off-site facility. BSL3 and BSL2 facilities have air handling and HEPA filters and water treatment/autoclaving of all waste.

FAMIC has its main very extensive laboratory in a modern high rise building providing a wide array of high technology analytical tests including radioactive assays. The regional FAMIC laboratories are understood to have excellent facilities available.

NVAL and NIAH both have extensive facilities with a range of laboratories for their various activities. Both NVAL and NIAH have BSL3 facilities available on site.

Few formal audit programmes of laboratory facilities and capacities were reported as currently being undertaken. Informal laboratory checks are undertaken by the Animal Health Division, Deputy Director of General Services of the Livestock Hygiene Service Centres.

AQS has a formal laboratory quality management programme since 2007 and based on the Directors guideline, Quality Assurance Division annually performs on-site audit of facilities and capacities of the AQS laboratories.

The laboratory service meets the needs of the VS and is sustainable and there are ongoing reviews and assessments.

### Strengths:

- > Excellent fully functional laboratory facilities are available at all levels of the VS;
- > Informal reviews take place of laboratory capacity and capability;
- Laboratory surge capacity is available and planned for if needed in an emergency response.

### Weaknesses:

No reviews or audits of the national laboratory capabilities and capacity considering their efficiency and cost-effectiveness.

- Undertake a review and audit of national laboratory capabilities and capacity considering efficiency and cost-effectiveness;
- Develop a formal review programme to be undertaken periodically to monitor laboratory capabilities and to identify where capacity can be consolidated, should be maintained or needs to be developed.

J	a	D	а	n	
-	-	r	-		

II-2 Laboratory quality	Levels of advancement
assurance	1. No laboratories used by the public sector VS are using formal
The quality of laboratories (that	QA systems.
conduct diagnostic testing or	2. Some laboratories used by the public sector VS are using
analysis for chemical residues,	formal QA systems.
antimicrobial residues, toxins, or	3. All laboratories used by the public sector VS are using formal
tests for, biological efficacy, etc.) as	QA systems.
measured by the use of formal QA	4. All the laboratories used by the public sector VS and most or all
systems including, but not limited	private laboratories are using formal QA systems.
to, participation in relevant	5. All the laboratories used by the public sector VS and most or all
proficiency testing programmes.	private laboratories are using formal QA programmes that meet
	OIE, ISO 17025, or equivalent QA standard guidelines.

# *Evidence* (see Appendix 6): 166, 167, 191

# Findings:

The higher level diagnostic and research laboratories at NIAH, AQS and FAMIC are formally accredited by the Japan Accreditation Board or Perry Johnson Laboratories for ISO17025, ISO/TC 34 series or other quality assurance programmes. NVAL has a quality management programme and the team was informed that it is to be formally accredited under the Perry Johnson Laboratories for ISO17025 after evaluation.

AQS started developing laboratory SOPs soon after establishment of a division in charge of quality management (QM) in 2003 and initiated its formal laboratory QM programme in 2007. As part of the established programme, AQS's ISO 17025 accredited laboratories participate in foreign proficiency tests and those of the head office organize proficiency tests for the branch laboratories such as by inter-laboratory comparison of *Salmonella*.

The Livestock Hygiene Service Centres advanced diagnostic laboratories are at various stages of developing quality management systems with some having quality managers, and quality manuals and SOPs being developed or merely considered; other Centre laboratories have no quality programme established.

Proficiency testing of the Livestock Hygiene Service Centre laboratories is led by NIAH with periodic rounds of testing. NIAH also provides training in general diagnostic testing at basic and advanced levels to MAFF staff, and more specialised training in exotic disease testing and diagnosis at its four centres.

Livestock Hygiene Service Centres are provided with a manual of diagnosis and laboratory techniques. The more advanced Livestock Hygiene Service Centres may provide training for the other Centres in their prefectures.

Notwithstanding the lack of formal quality management and quality assurance at lower level laboratories, all laboratories operate at high standards with excellent facilities and equipment, manuals of procedures, good record keeping and review and high throughputs.

# <u>Strengths:</u>

- Formal quality assurance programmes developed and operating at leading laboratories AQS, NIAH and NVAL;
- Livestock Hygiene Service Centres understand the concept and need for laboratory quality assurance – some programmes are now being developed.

### Weaknesses:

> Few laboratories with quality assurance accreditation/formal quality management.

### Recommendations:

Formal quality assurance programmes should be developed and accredited for all MAFF and associated laboratories;

- The quality assurance programmes should adopt a stepwise approach to quality assurance with the development of:
  - Quality management programmes established at all MAFF laboratories;
  - Formal quality assurance accreditation increasingly achieved by all laboratories;
  - Undertake proficiency testing nationally for priority diagnostics to standardise and validate testing methods and quality.

II-3 Risk analysis	Levels of advancement
The authority and capability of the	1. Risk management measures are not usually supported by risk
VS to base its risk management	assessment.
measures on risk assessment.	2. The VS compile and maintain data but do not have the capability
	to carry out risk analysis. Some risk management measures are
	based on risk assessment.
	3. The VS compile and maintain data and have the capability to
	carry out risk analysis. The majority of risk management measures
	are based on risk assessment.
	4. The VS conduct risk analysis in compliance with relevant OIE
	standards, and base their risk management measures on the
	outcomes of risk assessment.
	5. The VS are consistent in basing sanitary measures on risk
	assessment, and in communicating their procedures and outcomes
	internationally, meeting all their OIE obligations (including WTO
	SPS Agreement obligations where applicable).

*Evidence* (see Appendix 6): E34, 35, 86, 1-2, 103, 104, 120, 139, 141, 209, 215

### Findings:

The Veterinary Services conduct detailed risk analysis, particularly in food safety, and use the results to prioritise risk management measures.

Import risk and food safety analysis by MAFF, MHLW and the Food Safety Commission of Japan is well resourced and technically strong; Japan has adopted a very low level of acceptable risk in animal and veterinary public health. To minimise risk, Japan adopts mitigation measures that are often more stringent than those specified by international standards.

The ongoing success of globally applied measures to control BSE/vCJD and the ongoing lack of a credible link between bovine Johne's disease and human Crohn's Disease are two examples where evolving risk assessment could be better reflected in risk management and risk communication policies. The current programmes of mandatory BSE surveillance over 48 months, mandatory rabies vaccination of dogs and undertaking CSF serological testing of pigs, despite the fact Japan has been free of each of BSE, rabies and CSF for a long period and has strong border protection measures, indicates the low levels of risk accepted by MAFF and MHLW.

Animal feed safety measures are stringent relating to feed composition including high levels of audit and testing by FAMIC with virtually zero non-compliance detected; interestingly although comprehensive guidance is provided there are no formal legislative/compliance measures for managing the risk of swill feeding to pigs, even during active FMD outbreaks. This risk may be significant with a number of endemic pig diseases such as PRRS, PMWS and Aujeszky's, and ongoing threats from FMD and CSF, and growing risks of ASF internationally.

The farm biosecurity programme uses a risk management approach to identify and manage- onfarm risks. This is also supported by early notification of animal health issues to poultry farmers if Al is suspected in wild birds in the area. Farmer compliance with risk mitigation measures such as vaccination programmes and farm biosecurity is very high.

AQS use a risk approach to prioritising inspections of incoming flights, live animal and animal product imports. The Nippon Automated Cargo and Port Consolidated System (NACCS) system is used routinely by AQS and Customs for every consignment to identify higher risk shipments for inspection.

Food safety is managed through a dynamic risk analysis programme. The Food Safety Basic Law of May 2003 was enacted to enhance the public trust in food safety following the occurrence of BSE in 2001 and introduced the risk analysis approach to food safety. The Food Safety Commission of Japan was established under the Japanese Cabinet Office as an independent entity from the risk managing ministries such as MHLW and MAFF.

The Food Safety Commission of Japan is tasked with conducting risk assessments and supporting the establishment of standards for food, food additives and veterinary medical products. Independent scientific panels, expert committees, and *ad hoc* working groups are used to inform the basis of the Food Safety Commission assessments using external experts.

Specific scientific panels are in place for: Food Additives, Pesticides, Veterinary Medicinal Products, Contaminants in Foods, Microorganisms and Viruses, Prions and Natural Toxins and Mycotoxins. There is a working group on antimicrobial-resistant bacteria.

Transparency is central to the function of the Food Safety Commission; meetings are open to the public, supporting documents and minutes are made available on their website. Risk assessments are published for public comment prior to final decision. To date, they have completed over 2,000 assessments including 505 assessments for veterinary products, 16 for food borne antimicrobial-resistant bacteria and 52 related to prions. The request for risk assessment may come from government agencies (e.g. MAFF, MHLW), the general public or from the Food Safety Commission itself.

The Food Safety Commission has Memorandums of Cooperation (MoCs) with a variety of international risk assessment agencies including the European Food Safety Authority (EFSA) and Food Standards Australia New Zealand (FSANZ).

Within MAFF, risk assessment efforts have used informal discussions with consumers, explanatory meetings for industries and other meetings to develop policies incorporating the viewpoint of consumers and other stakeholders. The Animal Health Division, International Animal Health Affairs Office includes positions for risk analysis and periodically holds public meetings to exchange views about activities of the OIE and OIE Terrestrial Code with producers, consumers, and experts including veterinarians and other stakeholders. Risk assessment is used to inform import management and quarantine decisions.

The National Institute for Animal Health (NIAH) has a position, the Bio-risk Manager, for the management of exotic diseases and its Department of Planning and General Administration has a Risk Management Section.

Import risk analyses for imported livestock and livestock products are thorough and the responsibility of the International Animal Health Affairs section of MAFF, although scientific inputs from the Food Safety Commission of Japan can be used (e.g. BSE risk from beef products).

There is no formal training programme in risk analysis in Japan; training is provided 'on the job'. Though effective there is an opportunity to develop more formal training programmes in risk analysis and to provide training to all levels of the VS.

# Strengths:

- Risk analysis is effectively used to manage animal quarantine risks by AQS;
- Robust disease control programmes based on very low levels of acceptable risk.

### Weaknesses:

- No specialised capacity for post-graduate training in risk assessment within Japan;
- Risk management measures are very strict and do not always reflect current scientific evidence and international standards;
- > No use of cost-benefit analysis in risk analysis and the application of risk mitigation.

- Review risk management measures being applied in Japan against diseases such as BSE, Johne's disease, rabies and CSF are currently very strict and there is an opportunity review these analyses to reflect current scientific evidence and international standards and also to consider cost-benefit analysis;
- Review risk management and cost-benefit relating to feed safety measures, as managed by FAMIC, including the very high levels of audit and testing with very low non-compliance rates being detected and the lack of a compliance programme on swill feeding;
- > Develop specialised capacity for post-graduate training in risk assessment within Japan.

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II-4 Quarantine	Levels of advancement
and border security The authority and capability of the VS to prevent the entry and spread of diseases	<ol> <li>The VS cannot apply any type of quarantine or border security procedures for animals or animal products with their neighbouring countries or trading partners.</li> <li>The VS can establish and apply quarantine and border security procedures; however, these are generally based neither on international standards nor on a risk analysis.</li> </ol>
and other hazards of animals and animal products.	<ol> <li>The VS can establish and apply quarantine and border security procedures based on international standards, but the procedures do not systematically address illegal activities9 relating to the import of animals and animal products.</li> <li>The VS can establish and apply quarantine and border security procedures which systematically address legal pathways and illegal activities.</li> </ol>
	5. The VS work with their neighbouring countries and trading partners to establish, apply and audit quarantine and border security procedures which systematically address all risks identified.

*Evidence* (see Appendix 6): E37, 44, 75, 95, 140, 163, 164, 165, 167, 169, 170, 209, 217

# <u>Findings:</u>

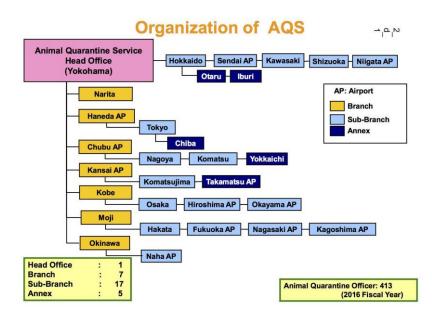
Japan has established an extremely rigorous and effective animal quarantine and border security programme.

Policies for live animal and animal product quarantine are developed by the Animal Health Division within the MAFF Food Safety and Consumer Affairs Bureau, with implementation by the MAFF Animal Quarantine Service (AQS).

The International Animal Health Affairs Office within the Animal Health Division develops the detailed policies through its various units (Quarantine Affairs Unit, Risk Analysis Unit and Global Animal Health Planning Unit).

AQS is well resourced with 30 offices – a head office in Yokohama, 7 regional branches, 17 subbranches and 5 annexes. There are currently 413 quarantine officers, of which 153 are veterinarians. AQS functions are supported by laboratories and quarantine stations.

Figure 4: Organization chart of the AQS



<sup>&</sup>lt;sup>9</sup> Illegal activities include attempts to gain entry for animals or animal products other than through legal entry points and/or using certification and/or other procedures not meeting the country's requirements.

Animal quarantine is legally mandated under a series of acts primarily the Act of Domestic Animal Infectious Disease Control, the Rabies Prevention Act and the Act on the Prevention of Infectious Diseases and Medical Care for Patients Suffering from Infectious Diseases. These acts provide AQS with the necessary powers to prevent, investigate, control, seize and dispose of live animals and animal products.

AQS operates a risk assessment programme to determine allowed, managed or prohibited imports of animals and animal products. This control extends to animal fodder products such as grain straw and forage.

AQS have a history of suspending imports following changes to animal health and assessed risk. The response to BSE was to ban the import of cattle, goats and sheep and their products with exceptions then made for specified countries. Poultry products and live bird imports have been prohibited following outbreaks of HPAI, likewise pig products after outbreaks of CSF.

Importing live animals is strictly managed with pre-notification and health certification required. Import is only allowed through designated ports where animals will be examined, tested and held or released depending on species and their country of origin. Quarantine procedures follow a strict protocol – which is published on their website.

On arrival animals are first inspected before unloading – providing the opportunity for animals to be rejected before ever reaching Japan. Animals inspected and meeting the import criteria for Japan from approved countries will typically be held in quarantine for 10 days (horses, poultry), 15 days (cattle, pigs and sheep) or one day for rabbits and honey bees. Approved private quarantine facilities are available for day-old chicks and high health horses – these are inspected and monitored.

Animal products similarly go through a checking procedure on the product per consignment, its prior notification and health certificate with further investigation if needed; the AQS website provides guidance on comprehensive details on import requirements. The decision to investigate further, including sampling, is based on compliance with the process and risk assessment using the Nippon Automated Cargo and Port Consolidated System (NACCS) integrated database for the recording and approval of imported goods operated by Customs and used by AQS and others to manage import risks. The NACCS system is efficient and effective in tracking products and identifying risks. Product inspection facilities are provided with strict control of entry of people and vehicles and control of any pests and wild birds. Product maybe released or not released in which case it may be reshipped or destroyed by incineration – either on site or taken in sealed trucks to a contracted incinerator; reports are available on all consignments and their handling. Most non-compliance is due to problems with the certificate/product identification.

All AQS locations have on site, or nearby, laboratories. These laboratories conduct viral, bacterial and parasite testing of products and live animals. The laboratories are well equipped with PCR level testing and the necessary supporting equipment and materials. Some of the laboratories are a little cramped but functional. AQS also operates two BSL3 facilities (Yokohama and Chubu) for diagnostic testing and for research into improving test technologies and sensitivity (eg Aujeszky's disease, EIA, AI); the laboratory in Chubu mostly works on zoonoses such as influenza virus and rabies but also other exotic disease such as babesiosis and ehrlichosis. AQS has two BSL3 facilities in case one ceases to be operational from a disease outbreak in the area. The BSL3 facilities have ISO17025 accreditation.

The risk from the illegal import of products is mitigated by an active awareness and extension campaign with posters, children's badges, 'giant detector dog dress-up suits', fliers and signage at entry/exit ports. Quarantine detector dogs operate at all eight major airports and their numbers are being increased. Flights are assessed on risk based on their origin and the history of detections and dog activity is increased as required.

AQS effectively manage other quarantine threats such as ensuring that all aircraft and ship waste is destroyed, either by incineration or by deep burial. Animal products imported through international mail are all inspected at the five designated post office entry points. AQS also manages the export of animals and animal products – monitoring importing country requirements, checking documentation, inspecting products/animals and 'permitting' their export.

AQS collects and maintains extensive data on the origin, volume and type of imported and exported goods and animals and develops as needed *ad hoc and* annual reports. The data captured is used for analysis and risk assessment to prioritise activities.

AQS maintain stockpiles of protective equipment – disinfectant mats, protective clothing, syringes and needles, disinfectants etc. AQS also store emergency equipment for their own use and on behalf of the Animal Health Division of MAFF including mobile rendering plants and incinerators and wide area disinfectant units.

AQS work with MHLW 'Quarantine' sections, the human heath quarantine service, to manage the risk to public health from importing animals. Under this protocol certain animals are banned by MHLW (such as monkeys, prairie dogs, masked palm civets, bats), others are allowed entry under specified circumstances (such as livestock, poultry, dogs, rabbits, monkeys from approved countries to be quarantined by AQS), for others only notification is required (mammal and aves other than those quarantined by AQS). The rationale for this approach is the *a priori* need of public health and the specific policy on preventing rabies and other major zoonoses (Ebola etc.).This approach appears to be based on a rather arbitrary distinction as any species may pose some risks to both animals and man, particularly when considering emerging infectious diseases. A defined process is laid down for notification and health certification.

# Strengths:

- Legally mandated well-resourced and effective quarantine service;
- Risk analysis is used to identify risk and implement mitigation measures;
- Strong public awareness and information campaigns;
- > AQS activities address informal movement of animals and animal products.

- Undertake a review of AQS priorities considering the change in international animal health and its risks;
- Conduct a risk and cost-effectiveness analysis of AQS to identify limitations and surplus capacity and review the allocation of resources and activities accordingly;
- Consider consolidating responsibility for live animal import quarantine and inspection for all species within one agency (MAFF).

II-5 Epidemiological	Levels of advancement
surveillance and early	1. The VS have no passive surveillance programme.
detection	2. The VS conduct passive surveillance for some relevant diseases and
	have the capacity to produce national reports on some diseases.
The authority and	3. The VS conduct passive surveillance in compliance with OIE standards
capability of the VS to	for some relevant diseases at the national level through appropriate
determine, verify and	networks in the field, whereby samples from suspect cases are collected
report on the sanitary	and sent for laboratory diagnosis with evidence of correct results obtained.
status of the animal	The VS have a basic national disease reporting system.
populations, including	4. The VS conduct passive surveillance and report at the national level in
wildlife, under their	compliance with OIE standards for most relevant diseases. Producers and
mandate.	other interested parties are aware of and comply with their obligation to
	report the suspicion and occurrence of notifiable diseases to the VS.
A. Passive	5. The VS regularly report to producers and other interested parties and the
epidemiological	international community (where applicable) on the findings of passive
surveillance	surveillance programmes.
Terrestrial Code reference	(s): Appendix 1

# *Evidence* (see Appendix 6): E24, 31, 110, 113

# Findings:

The field veterinary services network within Japan provides full national coverage with all livestock producers in regular contact with the very high number of fully qualified field veterinarians operating within one of three systems of field livestock health delivery.

### Livestock Hygiene Service Centres

The prefecture government Livestock Hygiene Service Centres are responsible for surveillance and risk management targeting Japan's notifiable diseases, listed as Category A and Category B which together cover 99 diseases compared with the current OIE list of 116 diseases; the diseases unlisted in Japan are mostly arthropod-born diseases present in Africa and/or the Americas. MAFF has developed biosecurity standards targeting each of the major livestock species and the Livestock Hygiene Service Centre veterinarians are responsible for conducting annual inspections of every cattle, pig and poultry farm for awareness and compliance, as well as conducting disease investigations and disease control activities (other than vaccination) for the listed diseases.

There are clear legal provisions on listed notifiable diseases and the requirement to report Under the Act on Domestic Animal Infectious Diseases, Surveillance (livestock) Diseases (1951, most recent amendment 2012) are defined as Domestic Animal Infectious Diseases (n = 28) and Notifiable Infectious Diseases (n = 71).

There is a disease reporting system to central government but this is based largely on case reports. There is no a real-time system for data capture from the various levels of the VS

Disease control activities (such as culling for Category A diseases and loss of income) are covered by a strong compensation scheme which mitigates any loss and so encourages early reporting of suspect disease outbreaks.

Livestock Hygiene Service Centre veterinarians also undertake official inspections relating to veterinary drug distribution and use, and feed safety.

### NOSAI veterinary clinics

A network of NOSAI clinics operates providing on-call clinical and reproductive health services for cattle and pig farmers. This service also provides farmer training and extension in nutrition and general husbandry and provides veterinary services to livestock markets. Farmers may choose to subscribe to this mutual aid insurance scheme that provides them with access to these services. Coverage is good with typically 80-90% of cattle farmers involved in these insurance schemes nationally, though coverage for other species is much lower. Premiums are based on the number of animals and type of livestock system, level of coverage, the health and claims history of the farmer

etc. The government heavily subsidises the service, especially covering capital costs. Uninsured farmers can also access these services on an as needed basis but must pay the full cost.

#### Private veterinarians

Private veterinarians are also available in some areas. Farmers are also able to claim through their mutual aid insurance for services using private veterinarians, but at a capped cost.

There is a clearly stated requirement that for any suspected or confirmed notifiable diseases the NOSAI or private veterinarians must refer the cases to their local Livestock Hygiene Service Centre.

Further complicating the field services delivery system in Japan are the Livestock Industry Associations which are not actually industry representative bodies, but rather a mechanism for the government, ALIC and Japan Racing Association to fund specific programmes, most significantly vaccination campaigns for the major endemic diseases. These industry associations do not have field staff as such, though they do have local industry associations that determine with the Livestock Hygiene Service Centres the number of vaccinations required annually for a given district for each disease control programme. Vaccination delivery is contracted out to the NOSAI and/or private veterinarians. Farmers are required to contribute some of the costs of vaccination, and this level has been increasing in recent years based on government policy. Little post vaccination sero-surveillance is undertaken.

With the very large number of veterinarians operating at field level and in regular contact with producers, a strong compensation scheme and excellent awareness amongst farmers, Japan's passive surveillance system is generally strong. For example, HPAI detections have been made immediately following the first clinical signs and have contained the outbreak to a single farm. Clusters of HPAI cases were caused by point introductions from wild birds on each farm rather than any spread between farms as a result of delayed detection or epidemiological contact.

Poultry farmers monitor mortality, morbidity and production rates daily and are required to contact their veterinary service if changes above a certain threshold occur – typically this is a doubling of the mortality from the baseline. This monitoring system is effective and sensitive and appears to be working well. Poultry farms also undertake routine post vaccination monitoring to manage their disease risks and also to provide a high health environment to support the early detection of emerging problems.

HPAI passive surveillance has been refined and is now at impressive levels reflecting strong farmer awareness and reporting. Data was provided on point source HPAI cases detected in December 2015 and January 2016 that showed that very early detection had taken place with only very small number of dead birds at the time of notification, followed by laboratory confirmation in less than 24 hours and immediate response.

Detection of the FMD outbreak in 2010 was delayed by approximately one month due to delayed reporting from the index farm and atypical clinical signs on the first farm where the disease was investigated (diarrhoea in a buffalo). This resulted in a delay in sending samples to NIAH for confirmatory testing and significant early spread of FMD within the Miyazaki prefecture early in the outbreak.

There are a number of improvements that should be considered, particularly relating to FMD surveillance.

#### 1. Rule-out diagnostic testing

Despite some notifications of suspect FMD, no samples have been sent to NIAH for diagnostic testing since 2011. This lack of rule-out testing is based on advice from NIAH that samples should only be sent when there is a high level of suspicion of FMD such as that photographs have been reviewed by NIAH experts and the disease is spreading among animals.

This lack of exclusion testing is inadequate to demonstrate freedom; a level of diagnostic testing with negative results is necessary to demonstrate that the passive surveillance system is operating effectively with a high level of sensitivity. Emergency response will be delayed as the required

quarantine and control measures cannot be undertaken without the legal authority provided by a laboratory confirmation. It is also noted that recent FMD outbreaks (Miyzaaki 2010) did not show the classical disease signs of FMD so over-reliance on text book signs and reviewed photographs may also result in delayed detections and response.

# 2. Routine diagnostic testing

All suspect cases of FMD or other priority Category A diseases do not currently result in immediate sample collection and submission to NIAH for diagnostic testing. The excellent field VS network for early disease detection is compromised if policies do not support rapid sampling at any level of suspicion with immediate laboratory confirmation or exclusion of disease.

#### 3. Livestock markets

Livestock markets, as aggregation points, provide a high risk point to monitor for the presence of disease and so support a passive surveillance system for early detection. Currently, NOSAI veterinarians may be contracted to provide services to livestock markets; these markets are usually managed by local farmer cooperative groups.

NOSAI veterinarians currently undertake little if any inspection activity, either clinically (passive surveillance) or in relation to livestock traceability or transport welfare; their primary role at markets appears to be to provide antibiotic and vitamin injections as part of preparations for livestock transport after sale. (Assurances were provided that the treated livestock were not destined for slaughterhouses.)

#### 4. Slaughterhouses

Protocols for animals rejected at ante-mortem inspection at abattoirs should be made more specific with a requirement to collect and submit samples routinely for diagnostic testing, rather than merely sending the animal back to its place of origin.

### 5. Veterinary supervision

Veterinarians can supply drugs to farmers based on their knowing the farm and on a verbal discussion without seeing the affected animals; though practical, the protocols for when this is permitted are not clear. For example, a condition may be set that 'veterinary medicines may only be supplied to treat specified clinical problems present on the farm that have previously been confirmed by veterinary examination and/or laboratory diagnosis within a specified time period'. This would reduce the loss of sensitivity of the passive surveillance system by supplying veterinary drugs in the absence of clinical examination with the potential delay in detecting notifiable diseases such as FMD.

### Strengths:

- A very impressive field veterinary network with full national coverage, regular farm visits, high levels of farmer awareness and the availability of compensation;
- Impressive early detection, as demonstrated particularly for AI in poultry.

#### Weaknesses:

- Limited sampling and laboratory differential diagnostic testing at NIAH for suspected outbreaks of category A diseases on farms – especially for suspect FMD;
- Limited passive surveillance at abattoirs and livestock markets;
- No integrated animal health information system operating in real-time to capture the reporting and investigation of suspect diseases and the results of diagnostic testing.
- Recommendations:
- Encourage immediate sampling and laboratory testing at NIAH for any levels of disease suspicion of category A diseases on farm – especially for suspect FMD;

- Enhance passive surveillance at abattoirs and livestock markets with protocols for sampling of animals rejected on the basis of poor health;
- Strengthen veterinary drug control by further limiting the dispensing of medicines without clinical examination of the affected animals;
- Develop an integrated animal health information system operating in real-time to capture the reporting and investigation of suspect diseases and the results of diagnostic testing. Such a system for data capture from all levels of the VS should use recent advances in information technology and data concatenation such as SMS, phone apps, spread sheets and other data formats. The system would allow the integration of data in real time and could be used to provide automated reports and mapping with trigger points being set for follow up activities;
- Increase dissemination of animal health surveillance information to all relevant parties such as Japan Agriculture (JA) and other livestock associations (i.e. ensure that the VS regularly report to producers and other interested parties and the international community (where applicable) on the findings of passive surveillance programmes);
- Livestock Hygiene Service Centres should consider providing a veterinary presence at markets with a focus on inspection and passive surveillance, or this activity could be officially delegated to NOSAI or private veterinarians, with clear obligations for inspection activity and reporting to government, with associated training.

II-5 Epidemiological surveillance and early	Levels of advancement
detection	1. The VS have no active surveillance programme.
The authority and capability of the VS to determine, verify and report on the sanitary status of the animal populations, including wildlife, under their mandate. B. Active epidemiological surveillance	<ol> <li>The VS nave no active surveillance programme.</li> <li>The VS conduct active surveillance for some relevant diseases (of economic and zoonotic importance) but apply it only in a part of susceptible populations and/or do not update it regularly.</li> <li>The VS conduct active surveillance in compliance with scientific principles and OIE standards for some relevant diseases and apply it to all susceptible populations but do not update it regularly.</li> <li>The VS conduct active surveillance in compliance with scientific principles and OIE standards for some relevant diseases, apply it to all susceptible populations, update it regularly and report the results systematically.</li> <li>The VS conduct active surveillance for most or all relevant diseases and apply it to all susceptible populations. The surveillance programmes are evaluated and meet the country's OIE obligations.</li> </ol>

*Evidence* (see Appendix 6): E18, 19, 20, 22, 21, 22, 23, 31, 83, 113, 120, 122, 126, 127, 128, 129, 130, 131, 146, 189

### Findings:

There are well planned and implemented national active surveillance programmes for an impressive number of priority animal diseases in Japan; these programmes are updated annually. This provides a very strong and detailed understanding of Japan's animal health status.

Priority listed diseases requiring active surveillance are classified into diseases where eradication/elimination is the target (Johne's disease, bovine TB and brucellosis, BSE and other TSEs, EIA) and monitored infectious diseases reported in Japan as a severe threat where the aim is: to monitor prevalence (BVDV, PED, PRRS, Aujeszky's disease, pullorum disease); to predict outbreaks (CSF and notifiable AI), and to predict epidemics (arboviruses including Akabane, Aino, Ibaraki and Bovine Ephemeral Fever). Prefectures also have the flexibility to conduct their own regional surveillance programmes for other diseases as they wish.

Supportive legislation and ordinances clearly set out requirements for the design and implementation of risk-based active surveillance programmes, and for the collection, collation and analysis of data. National active surveillance guidelines for all priority diseases are developed by the Animal Health Division of MAFF (often with technical input from NIAH), and prefectural governments align and develop their annual plans for active surveillance surveys by their Livestock Hygiene Service Centres. The surveillance results provide monitoring for the national disease control programmes and the preparation of progress reports.

MAFF with the NIAH Division of Virology and Epidemiology develop sampling frames for the active surveillance programmes. For example, MAFF currently require once in five-year testing of farms for TB/brucellosis and Johne's disease. Prefectures require their Livestock Hygiene Service Centres to divide the farms they cover into five areas which will then be sampled annually in rotation to achieve the required active surveillance of the target population. For other diseases, such as PRRS and BVDV, specific guidance to prefectures/Livestock Hygiene Service Centres on the numbers of farms and numbers of animals to be tested to achieve given confidence levels for detection at certain infection rates are provided.

As one example, the detailed design of the active surveillance programme targeting BVDV in guidelines from MAFF to the prefectures for fiscal year 2015/16 is provided below:

# Number of farms

In each prefecture, 10 farms that are raising breeding beef cattle shall be selected without regional imbalance; estimated to enable antibody detection with a confidence interval of 95% when the disease prevalence is 30%.

### • Number of animals

In each farm, 10 animals (born on the farm, aged 6 to 18 months old, not inoculated with BVDV vaccine) shall be selected; estimated to enable antibody detection with a confidence interval of 95% when the disease prevalence is 30%. When the number of animals that meet the requirements does not reach 10, nulliparous cows that were born on the farm shall be selected with priority.

# (3) Inspection method and judgment of the result

Serological tests (neutralization tests) shall be conducted. Antibody titres of up to 1:1000 shall be determined.

Most active surveillance testing is undertaken at the Livestock Hygiene Service Centres laboratories though some testing is officially delegated to universities (EBL) and private laboratories. Results of active surveillance surveys are reported annually, both nationally and by prefecture and analysis is undertaken by MAFF. Full details by prefecture and over time were available. A large number of tests are conducted each year.

Disease	Number of tests	Number positive
Br abortus	229,297	33
Bovine TB	218,344	nil
Johne's disease	395,830	3,053
BSE	92,131	nil
VDV	951	206
Akabane	10,894	2,076
Aujeszky's disease	123,301	5,999
PRRS	44,415	9,491
PED	30,481	2,617
EIA	36,482	nil

**Table 12**: Reported laboratory tests for priority diseases (2014)

Only very limited post vaccination sero-surveillance monitoring is being undertaken to assess the effectiveness of the vaccination programmes managed by the Livestock Industry Associations.

# <u>Strengths:</u>

- A large number of tests for a wide variety of diseases are undertaken nationally as part of Japan's active surveillance programmes, resulting in a very detailed and updated knowledge of Japan's livestock health status;
- Active surveillance programmes are well planned with statistical requirements being considered;
- Veterinary competence in sampling and diagnostic testing is high.

- The cost-benefit of undertaking high levels of active surveillance for lower priority endemic diseases should be reviewed, including the ongoing active surveillance for CSF, given the established national freedom from CSF and the rigorous quarantine measures in place;
- Periodically review the design of ongoing surveillance and control programmes based on the results of the active surveillance programme;
- > Develop post vaccination sero-surveillance monitoring programmes to monitor the effectiveness of industry-led vaccination programmes.

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II-6 Emergency	Levels of advancement
response	1. The VS have no field network or established procedure to determine
The authority and capability of the VS	whether a sanitary emergency exists or the authority to declare such an emergency and respond appropriately.
to respond rapidly to a sanitary	2. The VS have a field network and an established procedure to determine whether or not a sanitary emergency exists, but lack the necessary legal and financial support to reasonal appropriately.
emergency (such as a significant disease outbreak or food safety emergency).	<ul> <li>financial support to respond appropriately.</li> <li>3. The VS have the legal framework and financial support to respond rapidly to sanitary emergencies, but the response is not coordinated through a chain of command. They may have national contingency plans for some exotic diseases but they are not updated/tested.</li> <li>4. The VS have an established procedure to make timely decisions on whether or not a sanitary emergency exists. The VS have the legal framework and financial support to respond rapidly to sanitary emergencies through a chain of command. They have national contingency plans for some exotic diseases that are regularly updated/tested.</li> </ul>
	5. The VS have national contingency plans for all diseases of concern, including coordinated actions with relevant Competent Authorities, all producers and other interested parties through a chain of command. These are regularly updated, tested and audited

*Evidence* (see Appendix 6): E7, 8, 9, 19, 11, 13, 14, 15,16, 17, 25, 30, 31,80, 89, 90, 91, 110, 112,117, 118,152, 192

# <u>Findings:</u>

Japan has comprehensive and technically sound national contingency plans for the major emergency animal disease threats including FMD, CSF, ASF and HPAI.

Japan has demonstrated capacity to rapidly respond and successfully eradicate recent emergency disease outbreaks including FMD (Miyazaki – 2010) and HPAI (several outbreaks over the last decade).

There was a delay of approximately one month in detection of the FMD outbreak in Miyazaki in 2010, which allowed significant spread in the dense livestock population of the prefecture (See also CCII.5A passive surveillance). This resulted in some major challenges but these were overcome and the overall the response was effective and the outbreak was restricted to Miyazaki; the outbreak continued for 75 days, with 292 farms infected and a total of 290,000 livestock were culled.

The decision to undertake emergency FMD vaccination was made approximately five weeks after first confirmation, as the capacity to remove culled animal carcases was limited. Vaccination of all susceptible animals was carried out within a 10km radius of infected premises; a total of 77,000 doses were delivered on 1,011 farms. All these animals were later culled to achieve FMD freedom without vaccination, as per the OIE guidelines. With the benefit of hindsight, the decision to vaccinate might have been taken earlier, however it still proved an effective disease control measure.

A major review of the Miyazaki FMD outbreak identified delayed detection and some confusion between the roles and responsibilities of MAFF and the prefectures, limited legislative power to allow culling of healthy, non-infected livestock (e.g. preventive culling or culling of vaccinates), and a major problem in identifying sufficient burial sites for carcase disposal. Significant progress has been made since with strengthened emergency preparedness measures undertaken in all regions since the outbreak, including annual simulation exercises in all prefectures.

There have been sporadic outbreaks of HPAI since 2004. In almost all cases these have been point source outbreaks from infected wild birds and have been limited to a single farm. Between November 2010 and March 2011, more widespread HPAI H5N1 outbreaks affected 24 farms across nine prefectures and resulted in 1.8 million birds being culled. Most recently, from December 2015 to January 2016, HPAI H5N8 affected five farms across three prefectures with

351,000 birds being culled. These farms were reported as not being linked epidemiologically, but rather each being a series of point source outbreaks from wild birds.

In all HPAI cases quarantine measures are implemented immediately following laboratory confirmation with the restriction of movement of birds, at risk products (feed, waste, etc.) and personnel, immediate mass culling (within 24 hours), safe disposal (burial/incineration within 72 hours) and cleaning/disinfection; surveillance is enhanced in the surrounding areas (testing within a 3km radius, daily reporting within a 10km radius) or from contact tracing. Compensation is generous for direct and indirect costs, but only for farmers that have complied with the law, including notification, and have cooperated with the eradication effort.

Legislation provides the veterinary authorities with strong powers to control disease including mandatory reporting, investigation and sampling, movement control, quarantine, culling, compensation, closure of businesses, seizure of products, carcase disposal and disinfection. Following the 2010 FMD outbreak, legislation to permit preventive culling has been put in place.

Emergency funding is immediately available with formal government commitment and a defined process for the release of additional funds laid down in law. Emergency funding also provides for farmer compensation. (See CCI.9 - Emergency funding)

Multiple simulation exercises are conducted in all prefectures annually and include the involvement of those outside of the prefectural veterinary services (e.g. police, emergency services). The simulation exercises vary in format but tend to be largely discussion/information sessions and fewer focused operational and field exercises. Prefectures provide reports on their exercises to the Animal Health Division at MAFF.

There is an impressive array of equipment in prefectures, warehoused and 'ready to go', including for movement control (i.e. roadblocks) culling, disposal and disinfection. AQS store additional equipment purchased by JLIA and others including protective clothing and disinfectants, mobile incinerators and active surveillance programme plants, poultry culling foam systems and wide area disinfectant foggers.

# <u>Strengths:</u>

- Demonstrated success in eradication of disease outbreaks (e.g. FMD, HPAI);
- Strong legislative provisions and financial arrangements, including for compensation;
- High levels of farmer awareness and cooperation, reflecting recent high profile cases of FMD and HPAI, but also the annual biosecurity visits;
- Regular simulation exercises in all prefectures;
- 'Ready to go' emergency response equipment warehoused at prefectural level and centrally by AQS,

- MAFF should develop a medium term strategy for assessing and strengthening emergency preparedness and response focusing on management systems and staff training;
- Consider developing a multi-day national simulation exercise to clarify roles, including its own leadership and coordination role in managing an emergency animal disease response affecting many prefectures at once. Such an exercise should also involve disease tracing nationally and the implementation of a livestock standstill, with the participation of other stakeholders such as transporters, abattoir owners and the livestock markets,

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II-7 Disease	Levels of advancement
prevention, control	1. The VS have no authority or capability to prevent, control or eradicate
and eradication	animal diseases.
The authority and capability of the VS to actively perform actions	2. The VS implement prevention, control or eradication programmes for some diseases and/or in some areas with little or no scientific evaluation of their efficacy and efficiency.
to prevent, control or eradicate OIE listed diseases and/or to	3. The VS implement prevention, control or eradication programmes for some diseases and/or in some areas with scientific evaluation of their efficacy and efficiency.
demonstrate that the country or a zone are free of relevant	4. The VS implement prevention, control or eradication programmes for all relevant diseases but with scientific evaluation of their efficacy and efficiency of some programmes.
diseases.	5. The VS implement prevention, control or eradication programmes for all relevant diseases with scientific evaluation of their efficacy and efficiency consistent with relevant OIE international standards.

*Evidence* (see Appendix 6): E2, 7, 8, 9, 10, 11,13, 14,15, 25, 28, 31, 36, 57, 85, 88, 89, 90, 91, 110, 111,113,117, 118, 123, 124, 127, 128, 129, 130, 131, 134, 143, 144, 146, 148, 150, 153, 154, 155, 156, 158, 159, 160, 161, 164, 165, 166, 167,169, 176, 183, 185, 186, 187, 189,192, 194, 210, 211, 219

# <u>Findings:</u>

Endemic disease control planning and implementation in Japan is well resourced and comprehensive. Diseases are categorised into Category A diseases where eradication, including via testing and culling is the target, and Category B diseases where monitoring and disease containment is the objective. Priority diseases include: EBL, Johne's disease, bovine tuberculosis/brucellosis, BSE and BVD in cattle, PED, PRRS, Aujeszky's and CSF in pigs, LPAI, Newcastle disease and avian mycoplasmosis in poultry and EIA in horses.

Livestock Hygiene Service Centres conduct annual inspections to ensure biosecurity measures are in place on all livestock farms. A recently introduced 'Farm HACCP Programme' has been launched although uptake is still low (91 certified farms) due largely to the high costs (300,000 JPY).

A summary of the national disease control programmes, operated in tandem with the active surveillance programmes (see CCII.5B) by disease is provided below:

### Johne's disease in cattle (Category A)

Guidelines for Johne's disease control were established in 2006 and a screening test system introduced in 2013, as described under CCII.5B on Active Surveillance. On laboratory confirmation, quarantine and culling of the infected cattle is undertaken, as is disinfection of the farm based on the Act on Domestic Animal Infectious Diseases Control. All other cattle on the farm over 6 months of age are tested. Given some issues with testing accuracy, voluntary culling of cattle housed with infected cattle is encouraged. If an introduced animal is tested positive follow-up testing is undertaken on the farm of origin. Affected farms are tested at least three times per year until found to be clear. Farmers require certificates of Johne's disease negative test results when introducing new cattle.

### Brucellosis and tuberculosis in cattle (Category A)

Cattle are regularly TB (caudal fold tuberculin testing) and brucella (milk and/or blood) tested with a frequency depending on the history of disease prevalence in the area. Positive animals are slaughtered and laboratory confirmation undertaken; affected herds are placed under quarantine with a retesting programme under the authority of the Act on Domestic Animal Infectious Diseases Control. The prevalence of brucellosis in Japanese cattle is now very low, and of tuberculosis is almost zero.

# Bovine Spongiform Encephalopathy (Category A)

BSE has not been found in cattle born since January 2002 after the feed regulations were implemented. Japan was classified by the OIE as a country with negligible BSE risk in May 2013. MHLW removes all specified risk materials and undertakes mandatory BSE testing of all cattle over 48 months at slaughterhouses. MAFF prohibits the use of meat and bone meal in cattle feed with manufacturing line separation, which FAMIC regularly audits to verify compliance. All fallen stock 48 months or over are required to be reported and tested for BSE. If BSE infected carcases were to be detected incineration is required and the cohort of cattle is quarantined and then culled.

# Equine Infectious Anaemia (Category A)

All racing horses, sires and mares are tested every five years. On confirmation, quarantine and culling of the affected horse based on the Act on Domestic Animal Infectious Diseases Control. Movement restrictions for horses, if necessary, would be undertaken if the disease occurred in a housing facility such as a racing stable. EIA antibodies were found in a wild horse population in 2011, though there have not been any detections for several years.

# Aujeszky's disease (Category B)

A programme under the Guidelines for control measures for Aujeszky's disease has been being implemented since 1991 with revisions in 2008. The basic policy is to enhance biosecurity, distribute disease free pigs, promote vaccination to prevent clinical disease and reduce the risk of spread, encourage all-in all-out production systems, identify affected swine by antibody testing and encourage the slaughter of affected pigs. Eradication has been achieved in most regions in Japan, but infection still persists in pig populations in some areas of four prefectures.

# Enzootic Bovine Leukosis (Category B)

Recently, the animal-level prevalence of EBL infected dairy and beef cattle in Japan was assessed at 41% and 29% respectively, a significant increase. In order to prevent the spread and lower the within-herd prevalence, MAFF developed Guidelines for control measures for EBL. The basic policy of herd management consists of the use of disposable needles and separate gloves for rectal examinations, only milk from EBL-negative cows or milk replacer to be fed to calves, the implementation of a fly control programme and the adoption of a 'test and slaughter' strategy or 'test and separate' strategy.

# Porcine Epidemic Diarrhoea (Category B)

PED was confirmed in Japan in 2013 for the first time in seven years. It has since spread nationwide, having been confirmed at 817 farms in 38 prefectures up to August 2014. In October 2014, MAFF published the Guideline for control measures for PED. These guidelines encourage farmers to strengthen biosecurity in order to prevent the occurrence and conduct appropriate vaccination in order to minimize the losses especially to suckling pigs. In order to prevent the spread, it urges each prefecture to obtain epidemiological information on affected farms (tracing), and to alert the 'at risk' farms and to instruct farmers whose pigs are showing clinical signs not to transport the pigs to slaughterhouses or to other farms. Since the publication and implementation of disease control guidelines in October 2014, the prevalence has been reduced to 233 farms in 28 prefectures in 2014-15, and 107 farms in 16 prefectures in 2015-16.

MAFF's line authority over some aspects of disease control is indirect and results in some complexity and potential delays in programme management and control; indirectly delivered activities include vaccination (the Livestock Industry Associations), livestock traceability (Livestock Breeding Centres) and markets (Farmer Cooperatives) complicates the direct contribution of these activities to nationally coordinated disease control activities.

Another practice that presents a high risk pathway for the introduction or spread of many listed diseases including FMD, CSF, ASF, Aujeszky's, PRRS, and PED is swill feeding (see also CC II.11 Feed safety). Although there are guidelines which specifically state that swill must be appropriately treated (e.g. cooked) Japan could strengthen control via a risk assessment and a stronger national compliance programme.

#### Strengths:

- Strong effective national programmes for disease control;
- > Good government industry partnership in implementing disease control programmes;
- Successful control programmes have reduced the prevalence levels of a number of endemic diseases including bovine tuberculosis and brucellosis, Johne's disease, Aujeszky's disease, salmonellosis and PRRS.

### Weaknesses:

- Lack of direct line management by MAFF of some aspects of the disease control programmes – such as the delivery of vaccination programmes and animal traceability
- > No reviews of the efficiency and effectiveness of disease control programmes;
- Limited post vaccination sero-surveillance undertaken to measure the effectiveness of vaccination programmes.

- Review the efficiency and effectiveness of disease control programmes and consider opportunities for their further strengthening including how best to integrate vaccination, livestock market inspections and livestock traceability;
- Undertake annual reviews of the disease control programmes and revise as necessary using evidence derived from increased epidemiological analysis with increased use of tracing and risk analysis;
- Carry out post vaccination sero-surveillance to measure the effectiveness of vaccination programmes;
- Extend the farm biosecurity programme to require the temporary isolation of newly introduced and sick livestock;
- Review the management of swill feeding of pigs and consider strengthening measures for the control of this high-risk activity in line with the OIE Terrestrial Animal Health Code.

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II-8 Food safety	Levels of advancement
A. Regulation, authorisation and inspection of establishments for production, processing and distribution of food of animal origin The authority and capability of the VS to establish and enforce sanitary standards for establishments that produce, process and distribute food of animal origin	<ol> <li>Regulation, authorisation and inspection of relevant establishments are generally not undertaken in conformity with international standards.</li> <li>Regulation, authorisation and inspection of relevant establishments are undertaken in conformity with international standards in some of the major or selected premises (eg only at export premises).</li> <li>Regulation, authorisation and inspection of relevant establishments are undertaken in conformity with international standards in all premises supplying throughout the national market.</li> </ol>
	4. Regulation, authorisation and inspection of relevant establishments (and coordination, as required) are undertaken in conformity with international standards for premises supplying the national and local markets.
	5. Regulation, authorisation and inspection of relevant establishments (and coordination, as required) are undertaken in conformity with international standards at all premises (including on-farm establishments).

*Evidence* (listed in Appendix 6): E26, 27, 29, 70, 71, 111, 112, 212, 218

# Findings:

All facilities involved in the production, processing and distribution of foods of animal origins, including abattoirs, are under the control of the MHLW.

The process for the approval and licensing of facilities and businesses that process or distribute foods of animal origin is carried out at the prefecture or municipal level based on national criteria established by the MHLW. Once the license is issued there is regular and risk-based inspection by the local authorities, which includes laboratory testing and is unannounced. MHLW authority extends to all entities engaged in the production, processing or distribution of foods of animal origin from slaughter through to retail and restaurant distribution.

The legislative authority for these functions is based on the longstanding Food Sanitation Law (1947, last amended 2005), Slaughterhouse Law (1953, last amended 2007), Poultry Inspection Law (1990 as amended 2007), and the Food Safety Basic Law (2003). Regulations and more specific ordinances under these national laws, such as relating to premises hygiene, exist at national and/or the prefectural level.

There are 186 registered slaughterhouses. In 2013, 1.2 million cattle, 17 million pigs, 14,000 horses and 8,478 small ruminants were slaughtered under inspection; for poultry, 157 slaughterhouses slaughtered 663 million broilers and 76 million other birds.

The process for the licensing of facilities for the processing and distribution of food of animal origin is carried out at the local level based on regional oversight and national standards. Once a license is issued there is an annual inspection by the local authorities.

Within MHLW, each prefecture has Public Health Centres (494) and Meat Inspection Centres (101). Within the Public Health Centre the work is divided between Environmental Hygiene and Food Sanitation sections. The Public Health Centres have oversight of milk processing, food labelling and sanitary inspection of facilities. Meat Inspection Centres have the specific responsibility for meat inspection and processing facilities.

Inspection frequency by the Public Health Centres for establishments is based on a risk assessment. In one prefecture relevant premises could be inspected from twice a year reducing to only once every five years depending on a risk rating, based on premises type and inspection history. Meat Inspection Centres have the specific responsibility for abattoirs and meat processing facilities, for both premises inspection (general building and hygiene compliance) and *ante* and *post-mortem* inspection (inspection targeting specific animal health and food safety risks).

Further processing and retail/restaurant premises are ranked and inspection frequency is based on the risk assessment.

There are no records of residue violations etc. HACCP inspections are undertaken and local Public Health Centre or Meat Inspection Centre staff work with the owners/operators to correct any minor issues detected.

Rendering plants are registered under the authority of local prefecture government under the MoE with additional oversight by the MHLW Environmental Hygiene unit. Any rendered products to be used as animal feed are inspected and samples by FAMIC for BSE etc.; samples are collected by the Livestock Hygiene Service Centres.

There are very few instances of non-compliance resulting in licenses being revoked or other penalties being administered. Some strict instructions/warnings have been issued and rates of inspection increased.

Note that on-farm slaughtering can only be carried out for personal consumption (no off-farm sales).

# Strengths:

- > MHLW is the designated Competent Authority for food safety in Japan;
- Long standing programme of registering all facilities involved in the production, processing and distribution of foods of animal origin;
- > Risk based, regular inspections required for continued licensing to operate.

# **Recommendations:**

> None.

B. Ante and post	Levels of advancement
mortem inspection at	1. Ante- and post mortem inspection and collection of disease
abattoirs and associated	information (and coordination, as required) are generally not undertaken
premises (eg meat	in conformity with international standards.
boning/cutting	2. Ante- and post mortem inspection and collection of disease
establishments and	information (and coordination, as required) are undertaken in conformity
rendering plants).	with international standards only at export premises.
	3. Ante- and post mortem inspection and collection of disease
The authority and capability	information (and coordination, as required) are undertaken in conformity
of the VS to implement and	with international standards for export premises and for major abattoirs
manage the inspection of	producing meat for distribution throughout the national market.
animals destined for	4. Ante- and post mortem inspection and collection of disease
slaughter at abattoirs and	information (and coordination, as required) are undertaken in conformity
associated premises,	with international standards for export premises and for all abattoirs
including for assuring meat	producing meat for distribution in the national and local markets.
hygiene and for the	5. Ante- and post mortem inspection and collection of disease
collection of information	information (and coordination, as required) are undertaken in conformity
relevant to livestock	with international standards at all premises (including family and on farm
diseases and zoonoses.	slaughtering) and are subject to periodic audit of effectiveness.

*Evidence* (see Appendix 6): E26, 27, 29, 70, 71, 140, 142, 187, 188, 212

# Findings:

Ante and post mortem inspection and collection of disease information are undertaken in conformity with international standards at all premises and are subject to periodic reviews; effectiveness is monitored through regular reporting and follow up investigations.

MHLW, under the authority of the Slaughterhouse Law (1953, last amended 2007), Poultry Inspection Law (1990 as amended 2007), and the Food Safety Basic Law (2003) provides the technical specifications for meat inspection. Related ordinances are at prefectural level.

The Competent Authority, the MHLW provides guidelines and the technical specifications for the implementation of *ante* and *post mortem* inspection, which are undertaken by the prefecture and municipal government authorities. The specifications include meat inspection and laboratory methods, data analysis and reporting requirements. Inspection is based on the Prefectural Plan for Monitoring and Guidance on Food Sanitation in compliance with the defined national standards. Meat Inspection Centres are responsible for *ante* and *post mortem* inspections.

All plants slaughtering cattle and pigs must have at least one veterinarian for on-site inspection and most have several operating at the same time. Veterinary inspectors undergo at least six months of theoretical and on-the-job training before they can be certified by the prefecture as an inspector and be able to work alone. For exports, additional measures are undertaken based on the importing country requirements (e.g. residue testing specifications and increased certification of animal welfare including for humane handling and stunning) and these are certified for export by the Director of the Meat Inspection Centre, a veterinarian.

MHLW has 101 Meat Inspection Centres throughout Japan with 2,076 trained official veterinarians to conduct the *ante* and *post mortem* inspections. These units are part of the MHLW Department of Environment Health and Food Safety, or equivalent. Inspection at poultry processing facilities may be delegated to an inspection agency if resources at the prefecture level are not adequate to provide inspectors. In the case of Iwate prefecture, the Iwate Veterinary Medical Association provides some inspectors for large-scale poultry slaughter and processing facilities on a contractual basis but under the oversight of the Meat Inspection Centre.

Inspections at smaller poultry slaughterhouses, those processing less than 300,000 birds annually, may be conducted either by the Meat Inspection Centre, Food Sanitation of the Public Health Centre or by a designated inspection agency delegated with inspection authority. Generally, if

delegated, the inspection is conducted by veterinary para-professionals have a minimum of three years' experience; however they only receive three days of specific training.

Animals in the lairage that are found to be unfit for slaughter do not enter the food chain. At one pig abattoir, *ante mortem* inspection had resulted in 14 rejections over the previous 12 months with swine erysipelas cited as the main reason that pigs were rejected. These pigs were separated, treated and sent back to their farm of origin.

Slaughterhouse and processing inspection is fee based.

Results of the *ante* and *post mortem* inspection are reported weekly to the prefecture and national MHLW and MAFF authorities with exceptional reports being provided in real time. If any notifiable diseases are suspected at ante-mortem, the Livestock Hygiene Service Centre is contacted immediately. Reports are also prepared on non-compliance with SOPs and HACCP procedures. Records of inspection, including numbers slaughtered and all *ante* and *post mortem* findings are reported weekly to the central government authorities by the prefecture agencies.

MHLW has a well-established training programme for its meat inspectors covering meat inspection, animal health, BSE, HACCP, food safety training programme and a laboratory proficiency programme.

Note: on-farm slaughtering can only be done for personal consumption (no off-farm sales).

# Strengths:

- MHLW is the designated Competent Authority for food safety in Japan;
- Well established, documented and resourced programme for ante and post mortem inspection;
- > High numbers of veterinarians involved in ante and post mortem inspection;
- Routine reporting to prefecture and central governments.

- Review the training programme for veterinary para-professionals undertaking meat inspection at small poultry slaughterhouses;
- Undertake regular formal reviews of the ante and post mortem inspection programme with periodic formal audits of effectiveness.

C. Inspection of	Levels of advancement
collection, processing and distribution of products of	1. Implementation, management and coordination (as appropriate) are generally not undertaken in conformity with international standards.
animal origin	2. Implementation, management and coordination (as appropriate) are
The authority and capability of the VS to implement,	generally undertaken in conformity with international standards only for export purposes.
manage and coordinate food safety measures on collection, processing and distribution of products of	3. Implementation, management and coordination (as appropriate) are generally undertaken in conformity with international standards only for export purposes and for products that are distributed throughout the national market.
animals, including programmes for the prevention of specific food- borne zoonoses and general	4. Implementation, management and coordination (as appropriate) are generally undertaken in conformity with international standards for export purposes and for products that are distributed throughout the national and local markets.
food safety programmes.	5. Implementation, management and coordination (as appropriate) are undertaken in full conformity with international standards for products at all levels of distribution (including on-farm establishments).

[Note: This critical competency primarily refers to inspection of processed animal products and raw products other than meat (eg milk, honey etc.). It may in some countries be undertaken by an agency other than the VS.]

# Terrestrial Code reference(s): Appendix 1

*Evidence* (see Appendix 6): E26, 27, 29, 70, 71,140, 141, 142, 212

# Findings:

The Competent Authority, the MHLW, implements and coordinates food safety measures for the processing and distribution of products of animals, including milk, honey and eggs, and for general food safety programmes in full compliance with international standards.

MHLW officials have defined legal authority (Food Sanitation Law (1947, last amended 2005) the Food Safety Basic Law (2003) cover the processing and distribution of foods of animal origin. The inspection of processing facilities and distribution is conducted by official veterinarians or related professionals from the prefecture and municipal Public Health Centres. Inspection frequency and level of oversight is risk-based and relies on established processes and procedural controls such as HACCP. There is also a high level of inspection and interaction with the retail and restaurant trade with frequent inspection by the local Food Sanitation Unit of the MHLW authorities.

### Strengths:

- > National standardisation of food safety programmes for animal products by the MHLW;
- Ample local resources (Public Health Centres) to conduct inspection and control activities for all relevant animal products for human consumption;
- > Oversight at the prefecture level to support and coordinate local inspection activities.
- Recommendations:
- > None.

II-9 Veterinary medicines	Levels of advancement
and biologicals	1. The VS cannot regulate veterinary medicines and veterinary
The authority and capability of the VS to regulate veterinary medicines and veterinary biologicals, in order to ensure their responsible and prudent use, i.e. the marketing authorisation, registration, import, manufacture, quality control, export, labelling, advertising, distribution, sale (includes dispensing) and use (includes prescribing) of these products.	<ul> <li>biologicals.</li> <li>2. The VS have some capability to exercise regulatory and administrative control over veterinary medicines and veterinary biologicals in order to ensure their responsible and prudent use.</li> <li>3. The VS exercise regulatory and administrative control for most aspects of the regulation related to the control over veterinary medicines and veterinary biologicals, including prudent use of antimicrobial agents in order to ensure their responsible and prudent use.</li> </ul>
	<ul> <li>4. The VS exercise comprehensive and effective regulatory and administrative control of veterinary medicines and veterinary biologicals.</li> <li>5 The control systems are regularly audited, tested and updated when necessary.</li> </ul>

*Evidence* (see Appendix 6): E33, 34, 35, 52, 53, 72, 73, 79,80, 81, 83, 84,102, 103, 113, 119, 135, 136, 139, 141, 166, 186, 205, 206, 211

### <u>Findings:</u>

MAFF is the lead authority in the control of veterinary medicinal products (VMPs) including vaccines and devices under the broad authority of The Act for Ensuring the Quality, Efficacy, and Safety of Drugs, Medical Devices and Other Products (Law No.145, 1960). Specific ministerial ordinances cover the controls and use of VMPs (Ministerial Ordinances No. 107, 2004, as updated in 2013) on the restriction for the usage of VMPs and medicinal products. The Veterinary License Act provides the framework for the use of VMPs by licensed veterinarians and under Article 18 requires that a veterinarian must examine an animal before administering or prescribing prescription VMPs; veterinarians are permitted to dispense veterinary medicines for recurrent clinical problems without examining the affected animals.

MAFF through its agency, the National Veterinary Assay Laboratory (NVAL), established the procedures for marketing approval of veterinary medicinal products with reference to GLP/GCP and GMP standards (see Figure 5). MAFF consults with the Ministry of Health, Labour and Welfare to establish maximum residue limits (MRLs) for the active ingredients (AIs) of the VMPs intended for use in food-producing animals and the Food Safety Commission of Japan to establish Acceptable Daily Intake (ADI) for the AIs. MAFF can then approve placement of the VMPs on the market of Japan.

Initial approval of all VMPs is for six years; all VMPs are required to undergo review based on postmarketing pharmacovigilance and thereafter the approval is permanent.

Veterinary medicines, biologicals and other 'active products' are approved for placement on the market under one of two categories - VMPs requiring prescription or instruction of a veterinarian (antibiotics, hormones, anaesthetics, etc.) and others (anthelmintics, vitamins, medicated topical treatments, medical shampoos, etc.).

NVAL monitors VMP quality and develops the necessary pharmaceutical standards, assays and reference standards for VMPs and vaccines. NVAL confirms the safety and effectiveness after approval based on re-evaluation of veterinary drugs, collects adverse event reports and analyses nationwide outbreaks of drug-resistant bacteria. NVAL operates a database for pharmacovigilance record keeping and reporting.

NVAL is also responsible for monitoring and controlling for antimicrobial resistance (AMR), monitoring labelling and advertising to ensure the safety of animal products for food. NVAL assays all veterinary biological products except for some seed-lot vaccines and diagnostics before distribution. NVAL works in collaboration with FAMIC conducting assays for the presence of VMPs in feed.

NVAL are an OIE Collaborating Centre for Veterinary Product Assessment in Asia and actively participate in the VICH programme. At its site in Tokyo, NVAL operates a series of well-equipped laboratories and has two BSL3 facilities; it also conducts animal experiments to validate veterinary medicines and biologicals in animals and fish.

MAFF grants the facilities/premises a manufacturing authorization. NVAL conducts technical examinations, inspections and investigations of veterinary medicines and facilities/premises, and provides manufactures with technical guidance to ensure their efficacy and safety.

Japan is a member of the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and works to promote the implementation of internationally harmonized test methods used in the approval of VMPs.

Antimicrobial resistance (AMR) data is collected under JVARM (Japanese Antimicrobial Resistance Monitoring System), an ongoing monitoring programme in place with sampling onfarms and in slaughterhouses. Data has been collected monitoring AMR and sales of veterinary antimicrobials since 1999; findings are reported regularly. Prudent use guidelines have been developed.

The Food Safety Commission of Japan has carried out a number of risk assessments for VMPs and has published the 'Assessment Guideline for the Effect of Food on Human Health Regarding Antimicrobial-Resistant Bacteria Selected by Antimicrobial Use in Food Producing Animals' (2004).

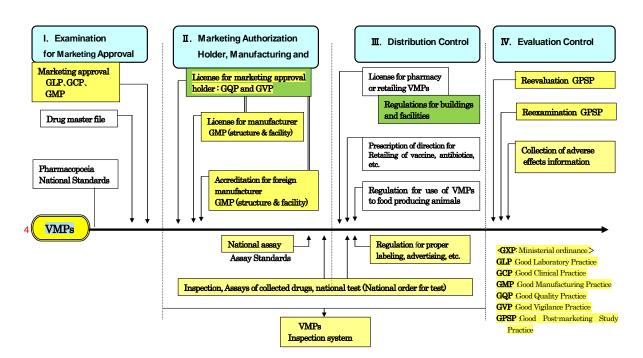
The Food Safety Commission of Japan has a standing expert committee for Veterinary Medical Products and a working group on AMR. The Food Safety Commission of Japan ranked human antimicrobials commonly used in Japan considering their relative importance in human medicine. The Commission has published a number of risk assessments on the use of antibiotics in food producing animals; examples include fluoroquinolone antibiotics for cattle and swine – medium risk (2010, 2015), tulathromycin pharmaceuticals for swine – medium risk (2012), pirlimycin antibiotics for cattle – low risk (2013), fluoroquinolone antibiotics for poultry – medium risk (2013), ceftiofur antibiotics for cattle and swine – medium risk (2015) and florfenicol antibiotics for cattle and swine – negligible risk (2016).

MAFF devotes considerable resources to the control of VMPs in the field. At central level MAFF has 20 'pharmaceutical affairs inspectors' and some 50 'pharmaceutical affairs inspectors' are based at NVAL. Approximately 2,000 'pharmaceutical affairs inspectors' work in the prefectures conducting local area inspections and control activities of retail and wholesale distributors, veterinary clinics, and farms. All 'pharmaceutical affairs inspectors' are veterinarians.

Japan has a high number of sales points for VMPs; data from 2013 indicates 1,562 'retail outlets', 1,075 wholesale outlets and 7,622 'exceptional retail outlets'. Exceptional sellers are allowed only to sell products not needing expertise to dispense or use (e.g. shampoos, disinfectants). Retailers with a pharmacist on staff can sell any type of VMP with a veterinary prescription but retailers with only a 'registerd salesclerk' are restricted to handling and supplying only VMPs not approved as VMPs requiring instruction. The local Public Health Centres have Health and Pharmaceutical Units (or equivalents) that are responsible for inspecting pharmacies, including their sales and storage of veterinary drugs.

VMPs requiring instruction are made available directly to farmers following a veterinary examination from the consulting veterinarian or from a retailer with a veterinary prescription or instruction; veterinarians are permitted to dispense veterinary medicines to their clients for recurrent clinical problems without examining the affected animals. VMPs may also be dispensed by a veterinarian or with a prescription from a drug seller without any clinical examination of animals on the basis of close and frequent veterinary supervision of the production enterprise; Japan producers and veterinarians seem to have a very close relationship which should protect the integrity of this approach.

Figure 5: Flow chart of approval/authorization process by Japanese competent authorities



# Strengths:

- > Well established, comprehensive management of veterinary medicines and biologicals;
- Requirement to meet GCP, GMP, GLP, GQP GPSP standards;
- > Pharmacovigilance and active AMR monitoring and reporting programmes in place.
- Recommendations:
- Review and audit the frequency and nature of field use of antimicrobials in livestock <u>without</u> accompanying veterinary examinations to ensure that this practice is not presenting risks to the early detection/passive surveillance for animal diseases, antimicrobial resistance, and/or the application of withholding periods;
- Review the risk of conflict of interest and the risk to prudent drug use by the 'free' provision of veterinary services to producers by veterinarians employed by drug and feed additive companies, particularly to pig producers.

II-10 Residue testing	Levels of advancement
The capability of the VS to undertake residue testing programmes for veterinary medicines (eg	<ol> <li>No residue testing programme for animal products exists in the country.</li> <li>Some residue testing programme is performed but only for selected animal products for export.</li> <li>A comprehensive residue testing programme is performed for all animal products for export and some for domestic consumption.</li> </ol>
antimicrobials and hormones), chemicals, pesticides, radionuclides, metals, etc.	<ul> <li>4. A comprehensive residue testing programme is performed for all animal products for export and domestic consumption.</li> <li>5. The residue testing programme is subject to routine quality assurance and regular evaluation.</li> </ul>

### *Evidence* (see Appendix 6): E102, 103, 104, 119, 125, 139 E104

#### Findings:

The residue testing programme for veterinary medicines is active and comprehensive and subject to routine review and evaluation.

MHLW has the legal authority to regulate, plan, and execute activities aimed at preventing and controlling the presence of residues of veterinary drugs and contaminants in the tissues of animal products for human consumption. The MHLW maintains oversight of its residue laboratory system through an annual audit of residue laboratories conducted by regional auditors. The MHLW 'Manual on how to manage examination, etc. at testing laboratories' outlines requirements for operational procedures and laboratory audit criteria including an annual review of laboratory facilities, equipment, and personnel qualifications.

The meat inspection system of Japan has regulatory requirements that are necessary for a chemical residue control programme that is organised and administered by the national government. The programme includes random sampling of internal organs, muscle, and fat of carcasses for chemical residues, and the programme is adjusted on a yearly basis to address emerging concerns.

MHLW with MAFF establishes Allowable Daily Intakes (ADIs) and Maximum Residue Limits (MRLs) for agricultural chemicals such as pesticides, feed additives and veterinary medicines in animal-derived foodstuffs under the authority of the Food Sanitation Law. It is prohibited to import or sell foodstuffs which contain chemicals at levels above the MRL or in the case where an MRL has not been established, at a level of more than 0.01 ppm.

The residue laboratory network consists of the Japan Food Research Laboratories, which is an independent, private institution accredited by the MHLW as a testing laboratory system for conducting analysis of government samples for the presence of chemical residues – pesticides, antibiotics, heavy metals, environmental contaminants, and food additives in meat products. Japan Food Research Laboratories has seven locations across Japan.

The Food and Agricultural Materials Inspection Centre (FAMIC) annually monitors chemicals in feed according to the Annual Surveillance and Monitoring Plan for Hazardous Chemicals for Food Safety established by MAFF, based on previous results of the monitoring.

Each prefecture develops an annual food hygiene monitoring programme which includes chemical residue monitoring. The Public Health Centres collect large numbers of samples at slaughterhouses and on farms – all were reported to be in full compliance with residue limits.

Auditors in 2015 verified that the control programme is designed and conducted in accordance with Japan's Food Sanitation Law. The programme contains provisions that, in accordance with Food Sanitation Law Article 54, the Health, Labour and Welfare Minister or the governor of the prefecture is in charge of disposing of the food or orders businesses to take the necessary actions to eliminate food hazards. In addition, to prevent the violations from re-occurring, the cause of the residue violation is investigated using national standards.

USDA-FSIS's review indicated that Japan's national testing plan for 2014 was effectively implemented as designed, and that the 2015 plan was on schedule. Inspection personnel within the slaughter facilities collect samples that include muscle, fat, and organ tissues of randomly selected slaughtered animals in accordance with the prescribed methodology provided by the MHLW based on Japan's Food Sanitation Act. USDA-FSIS's review of documentation at the six local inspection offices audited showed that in-plant officials were collecting samples of the required matrices for detection of specific analytes and adhering to the prescribed sample collection schedule. The USDA-FSIS review of the monitoring results for 2013, 2014, and 2015 found that no violative samples were detected.

Carcasses are not held pending the result of any residue testing, unlike the requirement to hold carcases pending results of BSE testing. MHLW have the right to seize and destroy contaminated product and with their effective individual (cattle) or batch (pigs and poultry) tracing systems a test positive carcass would be able to be traced/recalled. Note that no contamination residues have ever been detected.

# Strengths:

- Effective national residue testing programme operating;
- Technologies and new tests developed as required;
- Legal and administrative provisions for both voluntary or mandatory product recalls are available;
- > No non-compliance issues identified.

# Weaknesses:

- No annual report from the residue testing programme;
- > No records of non-compliance.
- Recommendations:
- Publish annual summary report of all residue sampling;
- Develop a policy and associated procedures to determine what actions are to be undertaken if contaminated products are detected.

II-11 Animal feed safety	Levels of advancement
The authority and capability	1. The VS cannot regulate animal feed safety.
of the VS to regulate animal feed safety eg processing,	2. The VS have some capability to exercise regulatory and administrative control over animal feed safety
handling, storage, distribution and use of both commercial	3. The VS exercise regulatory and administrative control for most aspects of animal feed safety
and on-farm produced animal feed and feed ingredients.	4. The VS exercise comprehensive and effective regulatory and administrative control of animal feed safety.
	5. The control systems are regularly audited, tested and updated when necessary.

*Evidence* (see Appendix 6): E78, 82, 83, 147, 160, 172, 185, 194, 196, 211

# Findings:

MAFF has the authority and resources in place for animal feed safety assurance from production to consumption. MAFF has broad authority over the safety and quality control of agricultural production materials (fertilizers, pesticides, feed, etc.) and the promotion of proper feed labelling.

Longstanding legal authority for this function was established in the Law Concerning Safety Assurance and Quality Improvement of Feeds (1953, last amended 2003). Additional specific authority is the Food Safety Basic Act, Feed Safety Law, the Pet Food Safety Act and specific Cabinet Orders and Ministerial Ordnances. Guidelines on Good Manufacturing Practices (GMP) for Feed (2015) and the 'Guide concerning requests, etc. related to establishment and revision of residue standards in feed pertaining to pesticide/herbicide used outside of Japan' (2010) was issued to provide guidance to feed manufactures and establish residue standards for animal feeds using imported ingredients. These standards included the establishment of standard values for radioactive contaminants of crops and feeds in 2012. Mycotoxin, heavy metals, and other contaminants guidelines for compound feed and feed ingredients were established in 2015. FAMIC provides laboratory support in advanced and well-equipped central and regional laboratories and on-site inspection and sample collection.

MAFF interacts with the Agricultural Materials Council and the Food Safety Commission of Japan to approve the specific conditions for use of additives in feeds. Based on this consultation MAFF instructs FAMIC regarding the scope of testing methods needed. On-farm inspection is coordinated by the Regional Agricultural Administration Offices. On-site inspection of feed manufactures, vendors and farms is conducted by prefectural Animal Health Division officers.

The standards for quantities of feed additives and labelling of quantities of feed additives have been established by MAFF. Feed additives are permitted, including the use of antimicrobials, under the oversight of feed company veterinarians.

FAMIC has the authority to control a variety of designated feed additives (157 items, including vitamins and antibiotics) in livestock species and to monitor feed safety for salmonella, pesticide residues, mycotoxins and heavy metals, and to assay ruminant feeds to detect animal protein.

In financial year 2015 FAMIC processed 130 samples for specification of material standards, 443 for meat and bone meal, 1,481 samples for harmful substances and 307 samples were tested for the presence of pathogens (salmonella).

Ministerial Ordinances establish the criteria for testing for the presence of pesticides/herbicides in grains and fodder, especially for imported feedstuffs. Manufacturers and importers of specified feed additives such as antibiotics are required to have FAMIC assay their products before entering the market unless the product is registered as GMP compliant.

Swill feeding to pigs is regulated under Guidelines (2006) based on Ministerial Ordinance (No. 1570 of 2003). This ordinance requires specified heat treatment of food waste prior to feeding to pigs. There was little evidence of a compliance programme in the field relating to this heat treatment requirement; from discussions it was believed that this heating process was largely undertaken on individual farms rather than commercially.

FAMIC is an OIE Collaborating Centre for Animal Feed Safety and Analysis and actively participates in the ISO technical sub-committees for animal feeds and management systems for food safety.

The JA cooperative imports bulk grain and produces/mixes feed at a number of sites; it has its own laboratory to support quality assurance and safety of their feed production businesses. JA reported finding feed safety regulations and standards relating to audit and testing very onerous, noting they were similar to requirements for food safety. They expressed an interest in having the feed standards revisited.

## Strengths:

- Comprehensive animal feed safety programme that is regularly audited, tested and updated when necessary;
- > Philosophy of the importance of animal feed safety.

## Weakness:

- > No reports or audits on the control of animal feed safety;
- > No reports on compliance with specified requirements for the heat treatment of swill;
- > No review of the risks from swill feeding.
- Recommendations:
- Review the testing programme to ensure sensitivity the whole range of FAMIC inspections and testing have not identified any positives or non-compliances in the last five years
- Undertake an epidemiological risk assessment and cost-benefit analysis of the national feed safety inspection programme, considering both audit and testing regimes and noncompliance levels targeting feed composition, as well as risks from swill feeding practices and the lack of any rigorous compliance programme for heat treatment of swill.

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II-12. Identification and	Levels of advancement
traceability	1. The VS do not have the authority or the capability to identify
A Animal identification and	animals or control their movements.
movement control	2. The VS can identify some animals and control some
	movements, using traditional methods and/or actions designed
The authority and capability of the	and implemented to deal with a specific problem (eg to prevent
VS, normally in coordination with	robbery).
producers and other interested	3. The VS implement procedures for animal identification and
parties, to identify animals under	movement control for specific animal subpopulations as required
their mandate and trace their	for disease control, in accordance with relevant international
history, location and distribution for	standards.
the purpose of animal disease	4. The VS implement all relevant animal identification and
control, food safety, or trade or any	movement control procedures, in accordance with relevant
other legal requirements under the	international standards.
VS/OIE mandate.	5. The VS carry out periodic audits of the effectiveness of their
	identification and movement control systems.

*Evidence* (see Appendix 6): E38, 56,148

## Findings:

The Animal Products Safety Division of the Food Safety and Consumer Affairs Bureau of MAFF are responsible for the individual cattle identification system in use for all cattle in Japan from birth, through all production phases, slaughter, processing and distribution of final products. The system was implemented by the Beef Traceability Law in response to the detection of BSE in Japan to both help identify and trace cohort animals of positive BSE animals and improve consumer confidence in the safety of the beef supply.

The system database is maintained by the National Livestock Breeding Centre and uses an individual 10-digit number on a visual ear tag; the individual number is used to record the date and prefecture of the animal's birth, all its movements, its death or slaughter date and prefecture location. Individual farmer identification can be based on their prefecture however 90% of farmers allow their name and location to be publicly available. Data is entered by cattle owners, livestock handlers, slaughterhouses and product wholesalers and is accessible on the internet through a simple interactive website. There is no formal checking of cattle traceability by government staff or others at livestock markets with the updating of movements being made by individual buyers/sellers or their agents. The database includes slaughter data that identifies the name and location of the slaughterhouse.

At the wholesale level product is identified with the place of origin and identification number; individual cuts of beef retain the 10-digit identification number that consumers can verify at the retail level or restaurants through the publicly accessible database available in seven languages. Batch identification for mixed product (e.g. ground beef) is retained by the processing facility.

DNA samples are taken at slaughter from all cattle and identified by the animal's 10-digit identification number; the samples are stored for future analysis.

Currently there are no other official animal individual identification systems in place. The commercial pig and poultry industry supplies animals in batches which are recorded at the slaughterhouse and product traceability becomes part of product movement (i.e. one-step forward, one-step backward traceability). A pilot project for the voluntary identification of individual pigs is being developed by industry with some government support, and at present around 2,000 producers is involved, with hopes for expansion. The poultry industry is large scale, highly intensive and vertically integrated – commercial companies manage their production and processing closely with a high level of through chain traceability by batch.

Livestock Hygiene Service Centres review animal movements and undertake annual censuses. A database is used and monitored closely and would be expected to detect any inconsistencies.

## Strengths:

- Whole of life traceability for cattle (birth death) and derived products to the retail or restaurant level, immediately accessible on the internet to members of the public;
- Batch identification of pigs and poultry.
- Weaknesses:
- > No audit of the accuracy of livestock traceability against performance standards;
- > Limited checking of livestock movements and traceability at livestock markets.

- Continue to support industry-led, livestock identification system for individual pigs;
- Audit the accuracy of livestock traceability against performance standards for each species, such as would be required during a widespread disease outbreak;
- Ensure the more effective checking of livestock traceability at livestock markets, through contracting and training the attending NOSAI veterinarians, or through inspections by Livestock Hygiene Service Centre veterinarians.

B. Identification and	Levels of advancement
traceability of products of	1. The VS do not have the authority or the capability to identify or trace
animal origin	products of animal origin.
The authority and capability of the VS, normally in coordination with producers	2. The VS can identify and trace some products of animal origin to deal with a specific problem (eg products originating from farms affected by a disease outbreak).
and other interested parties, to identify and trace products of animal origin for	3. The VS have implemented procedures to identify and trace some products of animal origin for food safety, animal health and trade purposes, in accordance with relevant international standards.
the purpose of food safety, animal health or trade.	4. The VS have implemented national programmes enabling them the identification and tracing of all products of animal origin, in accordance with relevant international standards.
	5. The VS periodically audit the effectiveness of their identification and traceability procedures.

*Evidence* (see Appendix 6): E93

## <u>Findings:</u>

The cattle/beef traceability system extends to the retail meat/restaurant level with capacity to trace products back to the individual animal based on the 10-digit identification number that is retained with the carcass and onto individual cuts of beef sold at retail; batch identification for mixed product (e.g. ground beef) is retained by the processing facility. The cattle/beef history is publicly accessible via the internet in the National Livestock Breeding Centre database in a transparent process.

The pork industry is working on a similar system on a voluntary basis using a bar code system applied to pig products at the slaughterhouse.

MHLW manages the traceability and recall of both domestic and imported foods of animal origin to identify and trace affected product. The recall process is managed by local governments working with manufacturers and retailers. In the case of recalling imported products, national authorities communicate the scope of the recall to the field for local authorities requesting product tracing. Extensive laboratory resources are available throughout the country to support the testing of potentially affected product.

MHLW has the authority to trace back from food-borne disease investigations but none have been reported related to foods of animal origin in the past 10 years. Records kept by slaughterhouses, and food business operators allow the traceability of products.

## Strengths:

- Cattle/beef system allows individual animal whole of life/product traceability down to the retailer or restaurant;
- Established process for product tracing and recall.
- Recommendations:
- Regularly audit product traceability systems, and continue to work on enhancing systems for pig and poultry products;
- Investigate and verify the claim that no food safety outbreaks have been reported in the past 10 years.

II-13 Animal welfare	Levels of advancement		
	1. There is no national legislation on animal welfare		
The authority and	2. There is national animal welfare legislation for some sectors		
capability of the VS to implement the animal	3. In conformity with OIE standards animal welfare is implemented for some sectors (eg for the export sector)		
welfare standards of the OIE as published in the	4. Animal welfare is implemented in conformity with all relevant OIE standards.		
Terrestrial Code.	5. Animal welfare is implemented in conformity with all relevant OIE standards and programmes are subjected to regular audits.		

*Evidence* (see Appendix 6): E39, 40, 41, 61, 62, 94, 96, 114, 173, 176, 190, 202, 222, 223, 224, 225, 226, 227, 228

## <u>Findings:</u>

The Act on Welfare and Management of Animals (1973, last amended in 2012) provides the government with broad authority over animal welfare policy and management; the Ministry of the Environment is the Competent Authority and MAFF has an important role to establish guidelines in cooperation with livestock organisations for each species of livestock. Effective external coordination mechanisms operate between MoE and MAFF with formal meetings and informal communications at central level. The PVS mission was unable to validate during the mission the effective coordination between MoE and MAFF at the field level, though it is understood that welfare guidelines have been disseminated to farmers and a self assessment animal welfare checklist is being used. The Japan Livestock Technology Association has undertaken publicly funded fact-finding via a farmer questionnaire which assessed knowledge, attitudes and practices relating to animal welfare, and which found generally good compliance with the livestock farming welfare guidelines. At the local level, oversight of animal welfare related issues in small animals is managed by the municipalities or prefectures.

Management of stray animals and pet welfare is well resourced and staffed by veterinarians at the local level where the government performs all functions, including those more usually carried out by NGOs such as Societies for the Protection of Animals. MoE has the resources in all prefectures to undertake awareness and communication programmes; the focus is more on promoting welfare through responsible pet ownership through education at schools and in the community, rather than a specific role to investigate complaints relating to animal cruelty or breaches of animal welfare legislation. Local governments usually have a designated animal welfare group which supports the capture and holding of strays.

There is national animal welfare legislation and there are animal welfare standards for the livestock sector. The animal welfare legislation lacks specific articles on animal transport and humane slaughter, as per the OIE Terrestrial Animal Health Code. However, there are notes (general standards) on transfer and humane slaughter of livestock under the Act on Welfare and Management of Animals. Animal welfare on-farm for livestock is monitored as part of their ongoing programmes by the Livestock Hygiene Service Centres, in cooperation with industry and farmers.

The Japan Livestock Technology Association and the Japan Equine Affairs Association have developed and published a series of animal welfare oriented management guidelines for the onfarm management of beef cattle, dairy cattle, swine, horses, broiler chickens and laying hens in cooperation with MAFF since 2009, referring to the OIE guidelines established in 2005 and has updated them based on changes to the OIE Guidelines. These species specific animal welfare guidelines set out the objectives of animal welfare, the need for the five freedoms and cover animal management including handling, surgery/interventions, cleanliness and hygiene, disease control, nutrition and the necessary training of animal handlers. MoE and MAFF have a clear policy to distribute these guidelines to relevant farmers or animal keepers, excluding livestock transporters and slaughterhouse owners.

The Japan Racing Association has supported the preparation of a guide for animal welfare in slaughterhouses (2014). The Japan Meat Technology Institute also established guidelines for the

treatment and slaughter of animals with the funding support, based on the OIE guidelines, and distributed them to slaughter houses and relevant parties in 2011.

As per the legislation animal welfare standards are in place at slaughterhouses where 'slaughter is to minimise pain and distress', though appropriate methods are not specified and stunning is not mandated. It was noted that at a Meat Inspection Centre that covered export abattoirs the specific handling and slaughter welfare requirements relating to exports were very well known and implemented (e.g. calm environment in the lairage, availability of water, confirmed lack of consciousness after stunning, use of sharp knives for rapid exsanguination).

There is no legislation specifically addressing farm animals, though there is a national standard for the killing of animals generally.

In 2006 the national animal welfare policies were broadly revised with the participation of many government agencies. Transport is covered by a Notification from the Prime Minister's Office (1987) as revised in a Notification from the MoE (2013). It is noted that the typical travel distances for animals being taken to market or slaughter are relatively short. There is a possible exception in Hokkaido where horses may travel longer distances to auction but are provided with housing, feed and water overnight prior to auction and movement to slaughter. As the land area of Japan is relatively small and it's land infrastructure is well developed, there is limited cases of animal transportation by sea and by air. Research and diagnostic laboratories including NIAH, NVAL, NIID and the AQS research laboratories use a range of laboratory animals. Ethical approval for the use of live animals in research is managed in-house within each facility by a board responsible for the ethical use of animals; the declared intention is to minimise the use of animals in research. Similarly the veterinary schools use live animals in their teaching, which includes surgery performed by students - animal welfare is monitored in-house and the management and distress of the animals controlled; after any major surgery animals are euthanised. MoE establishes notes (national general regulations) for laboratory animals under the act Act on Welfare and Management of Animals. In addition, each Ministry has separate guidelines for their stakeholders.

Animals are used by some commercial pharmaceutical companies for their product research and development. These companies have 'animal use review committees' to monitor the use of live animals, to avoid unnecessary use and to ensure animal welfare is maintained. It was understood that no national standards were available for this sector and no inspections or oversight was being provided by government or other external parties.

As the responsible Ministries for pharmaceutical companies or Universities in Japan, MAFF, MHLW and the Ministry of Education, Culture, Sports, Science and Technology have guidelines to ensure animal welfare on laboratory animals. Further more, the Science Council of Japan institute developed 'Guidelines for Proper Conduct of Animal Experiments' in 2006. These guidelines included inspections by external parties as one of the non binding targets, and this was reported as starting to be implemented, though this was not evident during field visits during the mission.

## Strengths:

- > Well established animal welfare programme covering companion animals;
- Review of animal welfare for livestock underway (producer questionnaire) and further work on the development of welfare standards is underway;
- Actual practices seem generally aligned with OIE standards in the areas of farming, transport and slaughter;
- Mechanisms in place for a national livestock welfare compliance programme, given the close contact with livestock in the field for animal health purposes;
- Animal use in laboratories and universities is managed through a process of in-house ethical review.

## Weaknesses:

- Animal welfare legislation could be strengthened by reducing the current over-reliance on animal welfare guidelines, particularly for animal transport and slaughter.
- Can further improve clarity in roles and coordination between MoE and MAFF on animal welfare.

- Review OIE Code recommendations on animal welfare and officially incorporate into national legislation, standards or policy document, as appropriate, particularly for livestock transport and slaughter, where they do not already exist;
- Develop further formal cooperation between MoE, MAFF and MHLW on animal welfare, particularly for livestock, and undertake targeted coordination to link legislation, policy and implementation.
- Consider how the mechanism of public reporting/complaints could be more formally used to monitor and investigate animal welfare cases and ensure community compliance with welfare legislation for both companion animals and livestock;
- Develop a livestock welfare compliance system based on the national laws and standards, involving implementation by local governments such as the Livestock Hygiene Service Centres on farms (welfare checks as part of annual biosecurity visits to farms), Meat Inspection Centres for humane slaughter (as already done for export requirements) and contracted veterinarians in livestock markets (check welfare standards for transport and handling);
- Develop Good Agricultural Practice (GAP) programme to implement and audit on-farm animal welfare practices;
- Review OIE standards for animals used in research and education and update legislation, standards and an external audit programme as required.

# **III.3** Fundamental component III: Interaction with interested parties

This component of the evaluation concerns the capability of the VS to collaborate with and involve stakeholders in the implementation of programmes and activities. It comprises seven critical competencies

# Critical competencies:

Section III-1	Communication	
Section III-2	Consultation with interested parties	
Section III-3	Official representation	
Section III-4	Accreditation / Authorisation / Delegation	
Section III-5	Veterinary Statutory Body (VSB)	
	A. VSB authority	
	B. VSB capacity	
Section III-6	Participation of producers and other interested parties in joint programmes	

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Terrestrial Code References:

- Point 9 of Article 3.2.1. on General considerations.
- Points 2 and 7 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.

Sub-point b) of Point 2 of Article 3.2.6. on Administrative resources: Communications.

Article 3.2.11. on Participation on OIE activities.

Article 3.2.12. on Evaluation of the veterinary statutory body.

Points 4, 7 and Sub-point g) of Point 9 of Article 3.2.14. on Administration details / Animal health and veterinary public health controls / Sources of independent scientific expertise.

Chapter 3.3. on Communication.

Points 6, 7, 9 and 13 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards / Communication.

III-1 Communication	Levels of advancement
The capability of the VS to keep interested parties informed, in a transparent, effective and timely manner, of VS activities and programmes, and of developments in animal health and food safety. This competency includes collaboration with relevant authorities, including other ministries and Competent Authorities, national agencies and decentralised institutions that share authority or have mutual interest in relevant areas	<ol> <li>The VS have no mechanism in place to inform interested parties of VS activities and programmes.</li> <li>The VS have informal communication mechanisms.</li> <li>The VS maintain an official contact point for communication but it is not always up-to-date in providing information.</li> <li>The VS contact point for communication provides up-to- date information, accessible via the Internet and other appropriate channels, on activities and programmes.</li> <li>The VS have a well-developed communication plan, and actively and regularly circulate information to interested parties.</li> </ol>

*Evidence* (see Appendix 6): E96, 104, 105, 114, 157, 176, 217

# <u>Findings:</u>

The Veterinary Services have well developed communications plans with designated staff and units; regular updates on animal health are provided.

Both MAFF and prefectural government Animal Health Divisions have websites that are updated regularly. AQS also has a social media presence to promote quarantine practices (by importers and passengers).

The Planning Unit within the Animal Health Division of MAFF provides media releases and answers queries, particularly to the agricultural media, in liaison with a MAFF Public Affairs Unit. For example, just prior to the mission, the agricultural media sought a briefing on EBL which was provided by the Planning Unit and published in the rural press.

Large annual conferences on FMD (February each year) and on HPAI (every September) are conducted and a wide range of government, industry and academic stakeholders are invited to discuss the latest animal health situation. Presentations and discussions are held on existing and proposed policies and the implementation of programmes.

Prefectural government Animal Health Divisions provide monthly emailed newsletters to farmers with information on national and local disease surveillance and control, international animal health events and general livestock health information. These newsletters also cover emergency preparedness and response and can also be issued immediately if needed (e.g. relating to a disease outbreak). The newsletters are faxed to those farmers without an email address.

Assorted, well-designed and well-focused posters, brochures and leaflets promoting or informing on animal health programmes are produced by Animal Health Divisions and Livestock Hygiene Service Centres at the prefecture level, and also for food safety and animal welfare in the Public Health Centres and Meat Inspection Centres.

AQS runs an extensive awareness campaign using electronic media (websites, social media) and print media (posters, flyers, stickers, badges, etc.) AQS also run a public familiarisation programme with open days and visits to and by schools; these sessions are well set up and use iconic images of their detector dogs including full size dog suits for their staff.

# <u>Strengths:</u>

- Updated, detailed websites and the use of social media (AQS);
- Regular prefectural communication with farmers through newsletters;
- Regular national conferences on HPAI and FMD with stakeholders.

# **Recommendations:**

Consider broadening the use of social media for stakeholder communications beyond AQS.

III-2 Consultation with	Levels of advancement
interested parties	1. The VS have no mechanisms for consultation with interested
The capability of the VS to consult effectively with interested parties on VS activities and programmes, and on developments in animal health and food safety. This competency includes collaboration with relevant	parties. 2. The VS maintain informal channels of consultation with
	interested parties.
	3. The VS maintain a formal consultation mechanism with interested parties.
	4. The VS regularly hold workshops and meetings with interested
authorities, including other	parties.
ministries and Competent	5. The VS actively consult with and solicit feedback from
Authorities, national agencies and	interested parties regarding proposed and current activities and
decentralised institutions that share	programmes, developments in animal health and food safety,
authority or have mutual interest in	interventions at the OIE (Codex Alimentarius Commission and
relevant areas	WTO SPS Committee where applicable), and ways to improve
	their activities.

## Evidence (see Appendix 6): E157

## Findings:

The mechanisms for consultation with industry on animal health policies or programmes in Japan are complex and lack clear commitment to being representative. This is a reflection of high levels of ongoing support provided by government to farmers and so a lack of critical issues to be faced. This support includes financial assistance through price stabilisation and tariffs, and also subsidised animal health programmes delivered through a number of mechanisms.

The Japan Livestock Industry Association, despite their name, does not represent the livestock industry, and is rather an independent government agency, funded by Japan's horse racing industry and the Agricultural Livestock and Industries Corporation (ALIC). The Japan Livestock Industry Association is dedicated to livestock industry support.

Japan Agriculture and at local levels, the Farmer Cooperatives are governed more along the lines of traditional industry representation but are more focused on attaining economies of scale for bulk feed and drug purchasing and marketing, managing livestock markets and providing husbandry services, rather than influencing government policies and programmes in animal health; they do have significant programmes supporting emergency preparedness and response in animal health. Japan Agriculture is largely funded from commissions earned from the sale of bulk feed and other supplies. They are very well resourced with an impressive asset portfolio, including real estate in central Tokyo.

In the meat sector, various companies have grouped together (eg South Kyushu Meat Producing Council and a National Meat Exporters Council) but again the mandate of such industry groupings is focused on sharing information, estimating yield, reviewing market conditions etc., rather than influencing government policy or being actively consulted by government.

Comment was made in several areas that industry receives information, direction or even instructions from the government and works with them to implement their policies and programmes, rather than any reflection of a more active participation in a consultative process for the development of policies and programmes.

One mechanism where industry can influence high level policy decision making is through its membership on the Animal Health Advisory Committee, which reports directly to the Minister. This Committee has representatives including academics, dairy farmers, a beef farmer, a pig farmer, a poultry farmer, two NIAH staff, a Hokkaido prefecture government representative, a NOSAI veterinarian, a food journalist, and a meat processing company representative. The Division of General Affairs, MAFF provides the secretariat, funds members' participation and typically initiates issues and drafts papers for the Committee's consideration. The farmer representatives are nominated through MAFF seeking a nominee from the Japan Livestock Industry Association (also government affiliated) who is then confirmed by the chairman. The selection of these members is

not independent of government and, as such, are not democratically representative of industry. The Committee oversees three technical subcommittees, devoted to poultry diseases, cattle/pig diseases and BSE. The first two subcommittees meet regularly to discuss issues; the BSE subcommittee has not met since September 2014. These technical committees do not have representation from industry.

All major animal health policies or programmes are considered by the Animal Health Advisory Committee, which typically delegates to its relevant technical sub-committee for advice before taking decisions. Topics are generally also publicised for community consultation by providing minutes on line and allowing a public comment period. It was reported that it was pig farmers that pushed for CSF eradication in the 1990s via this mechanism.

The Animal Health Advisory Committee is active at a high level within MAFF. It recently confirmed changes to the BSE testing of fallen stock over 48 months of age based on OIE standards, they are commissioning biosecurity standards reviews (every five years) and the update of the CSF/ASF contingency plan; they have also recently agreed to trade regionalisation (zoning) for HPAI from the US, and are considering the resumption of pork trade with Poland following an ASF outbreak there.

## Strengths:

- Farmer representation on the high level decision making body, the Animal Health Advisory Committee, and opportunities for public comment;
- > A farming sector so compliant with government regulations, policies and programmes in animal health that customary forms of audit and oversight are not considered necessary.

## Weaknesses:

- Limited representation in national industry associations from producers and smaller operators;
- Little farmer input into the design and development of animal health policies and joint programmes.

- Consider how Japan can develop stronger consultations with representation from across the industry sectors in particular as the livestock sector in Japan becomes more deregulated;
- Increase industry and/or farmer inputs to the design and development of animal health policies and programmes, particularly targeting efficiency and effectiveness.

III-3 Official	Levels of advancement
representation	1. The VS do not participate in or follow up on relevant meetings of
The capability of the VS to	regional or international organisations.
regularly and actively	2. The VS sporadically participate in relevant meetings and/or make a
participate in, coordinate and	limited contribution.
provide follow up on relevant	3. The VS actively participate <sup>10</sup> in the majority of relevant meetings.
meetings of regional and	4. The VS consult with interested parties and take into consideration their opinions in providing papers and making interventions in relevant
international organisations including the OIE (and Codex	meetings.
Alimentarius Commission and	5. The VS consult with interested parties to ensure that strategic issues
WTO SPS Committee where applicable).	are identified, to provide leadership and to ensure coordination among national delegations as part of their participation in relevant meetings.

## Evidence (see Appendix 6): none specific

## Findings:

Japan actively participates at all major international meetings through international representation. The VS develop initiatives and provides leadership at international and regional levels.

The International Affairs team at MAFF hosts a meeting with all interested parties via an open invitation before the OIE General Session to discuss the Code Chapters and discuss Japanese inputs. This meeting is typically attended by colleagues from MAFF, academia, prefectures and sometimes consumer representatives. The Domestic Animal Health Office also checks to ensure international standards and Japanese inputs align with their internal animal health policies and programmes.

Japan VS are well represented at OIE international and regional meetings. Typically, the annual OIE General Session is attended by the OIE delegate and three or more other staff and one or two staff accompany the OIE delegate to the OIE Regional Commission conference held every two years; one additional staff member often accompanies the OIE delegate to the Global Framework for TADs (GF-TADs) Regional or Sub-Regional Steering Committee annual meeting.

Japan generously hosts the OIE Regional Representation for Asia, the Far East and Oceania in Tokyo, and provides numerous secondees to both this regional office and to the OIE headquarters in Paris.

Japan has shown leadership in progressing the core group of the OIE Regional Bureau, including the innovative development of an OIE regional roadmap. Japan provides an expert member to the OIE Code Commission.

The development of an East Asia forum for animal health is a recent innovation that was initiated and is being led by Japan. MAFF has been working closely with China and South Korea to develop a MoU on TADs control – now signed by Ministers from each of the three countries.

Food safety is covered by MHLW who are heavily involved in Codex Alimentarius issues and standards setting; the Food Safety Commission of Japan may be requested to also provide inputs.

## Strengths:

Excellent commitment and leadership shown at all major international meetings, conferences and forums.

## Recommendations:

None.

<sup>&</sup>lt;sup>10</sup> Active participation refers to preparation in advance of, and contributing during the meetings in question, including exploring common solutions and generating proposals and compromises for possible adoption.

III-4 Accreditation /	Levels of advancement
authorisation / delegation	1. The public sector of the VS has neither the authority nor the capability to
The authority and	<ul><li>accredit / authorise / delegate the private sector to carry out official tasks.</li><li>2. The public sector of the VS has the authority and capability to accredit /</li></ul>
capability of the public	authorise / delegate to the private sector, but there are no current accreditation / authorisation / delegation activities.
sector of the VS to accredit / authorise / delegate the private sector (eg private veterinarians and laboratories), to carry out official tasks on its behalf.	3. The public sector of the VS develops accreditation / authorisation / delegation programmes for certain tasks, but these are not routinely reviewed.
	4. The public sector of the VS develops and implements accreditation / authorisation / delegation programmes, and these are routinely reviewed.
	5. The public sector of the VS carries out audits of its accreditation / authorisation / delegation programmes, in order to maintain the trust of their
	trading partners and interested parties.

*Evidence* (see Appendix 6): none specific

# <u>Findings:</u>

Japan has a very extensive, well resourced Veterinary Service with large numbers of well qualified government veterinarians and excellent government laboratory facilities. In this context, there are few occasions when it is appropriate to accredit/authorise/delegate to the private sector. In the very few instances where delegation does take place there is a process documenting what is to be undertaken and the requirements/abilities of those undertaking it and the reporting required. Reports are retained to monitor the quality of service delivered.

Some Livestock Hygiene Service Centres have insufficient veterinarians to conduct the annual biosecurity inspections required for all farms; this activity is sometimes officially delegated via a contract to NOSAI clinic veterinarians.

NOSAI veterinarians currently may undertake veterinary activities at livestock markets as contracted by the local farmer cooperatives, but this does not involve official tasks such as inspection, and has no involvement of the relevant animal health authorities (MAFF, prefecture Animal Health Division or Livestock Hygiene Service Centres).

A number of private laboratories are used, including universities, where the capacity does not exist at the local Livestock Hygiene Service Centre laboratory. For example, EBL testing and some virology and molecular analysis for PPRS are undertaken at a private Japanese veterinary laboratory. Residue testing is also conducted at the non-government Food Safety Research laboratories.

For poultry meat inspection, official delegation to a third party agency can be undertaken where there is not capacity within the local Meat Inspection Centre. The poultry law 'Authorization of Designated Inspection Agencies for Poultry Inspection' Article 21 states that 'The Governor may authorise any juridical person designated by the Minister of Health, Labour and Welfare (hereinafter referred to as "designated inspection agency") to conduct, wholly or partly, the poultry inspections required hereunder.' The law also says that the name of the inspector or agency must be made public and MHLW must approve the inspector or agency and provide inspection services if the contractor withdraws services.

# Strengths:

- > With the large cadre of official veterinarians few activities need to be delegated;
- > Contracts and quality management of the delegated activities are in place.

- Opportunities to increase 'surge capacity' further using the private laboratories should be explored – in preparation for any major animal health emergency;
- Prefecture Animal Health Divisions and Livestock Hygiene Service Centres should explore the nature and benefit of current veterinary activities at livestock markets as performed by contracted NOSAI veterinarians considering official tasks (inspection for passive surveillance, traceability and welfare), with the option of officially delegating these to the NOSAI veterinarian after training and under official contract.

III-5 Veterinary Statutory	Levels of advancement
Body (VSB)	1. There is no legislation establishing a VSB.
A. VSB authority	2. The VSB regulates veterinarians only within certain sectors of the veterinary profession and/or does not systematically apply disciplinary
The VSB is an autonomous	measures.
regulatory body for veterinary	3. The VSB regulates veterinarians in all relevant sectors of the veterinary profession and applies disciplinary measures.
para-professionals.	4. The VSB regulates functions and competencies of veterinarians in all
	relevant sectors and veterinary para-professionals according to needs.
	5. The VSB regulates and applies disciplinary measures to veterinarians
	and veterinary para-professionals in all sectors throughout the country.

*Evidence* (see Appendix 6): E54, 55, 64, 65, 76, 77, 81, 137, 179,208,

## <u>Findings:</u>

Japan's Veterinary Affairs Council operates with adequate legislative powers to regulate the veterinary profession under the Veterinary Licencing Act.

The Veterinary Affairs Council has three subsidiary committees, the Examination Committee, the License Committee and the Planning Committee.

The Examination Committee administers the national veterinary examination for graduates or overseas applicants and provides lifetime registration to all veterinarians who pass for a one-off fee. The Examination fee is 13,900 JNY and the registration fee is 32,000 JNY. The fees do not specifically fund the activities of the Council but rather go into consolidated government funds (Ministry of Finance). The Veterinary Affairs Council is therefore not an independent body, but is essentially part of government, being managed and funded within MAFF (Veterinary Affairs Division). This raises risks of technical independence if the Council is considering disciplinary measures against one or more of the many MAFF employed veterinarians. To date, there is no evidence that this has presented any issues in relation to professional negligence or misconduct by MAFF veterinarians. Strong alternative government oversight of standards of public service behaviour and performance are also in place.

The membership of the Veterinary Affairs Council is reasonably representative across relevant sectors but new or replacement members are generally recruited and nominated by the outgoing member. There are some very generic guidelines on selection of members of such government affiliated Council bodies.

No re-registration is required from registered veterinarians, just biennial notification of location and working status; it was reported that the compliance rate for such notification was not high. There is no requirement for registered veterinarians to maintain veterinary continuing education in any form – such as the common international adoption of compulsory points systems. The JVMA has just started a continuing education points system, but it is voluntary and currently focuses on small animal veterinarians; points can only be accrued from participation in JVMA's own training programmes.

## Strengths:

- Strong legislation regulating the veterinary profession based on high standards of education, technical performance and behaviour.
- A functional and adequately resourced Veterinary Affairs Council, with appropriate broadbased representation, and three active committees.
- Competent administration by the Veterinary Affairs Council of a national veterinary examination, with a pass compulsory for registration, to maintain high professional technical standards.

- Consider a more merit-based and open nomination and selection process for the Veterinary Affairs Council and sub-committee membership;
- Explore options for the Veterinary Affairs Council to become more independent of government, such as through annual re-registration fees that fund Council activities and the election of Council membership by fee paying registrants;
- Consider developing a points system for continuing education linked to re-registration, as per other developed country Veterinary Statutory Body systems.

B. VSB capacity	Levels of advancement
The capacity of the VSB to implement its functions and	1. The VSB has no capacity to implement its functions and objectives.
	2. The VSB has the functional capacity to implement its main objectives.
objectives in conformity	3. The VSB is an independent representative organisation with the
with OIE standards.	functional capacity to implement all of its objectives.
man one standards.	4. The VSB has a transparent process of decision making and conforms
	to OIE standards.
	5. The financial and institutional management of the VSB is submitted to
	external auditing.

*Evidence* (see Appendix 6): E54, 55, 64, 65, 76, 77, 81, 137, 179,208,

## <u>Findings:</u>

The Veterinary Affairs Council is adequately funded and resourced by government to perform its function in developing and administering the national veterinary examination. It has good capacity with its planning functions to address the demand for veterinary skills across different sectors and geographically and to utilise scholarships or other incentives to respond to national needs and identified gaps.

The system of one-off, lifetime registration of veterinarians presents some risks relating to maintaining veterinary standards in the context of continuing education and ongoing employment.

At present a newly registered veterinarian could have a complete career change to one outside veterinary science, remain registered and after years be able to return immediately to full veterinary practice. Most developed countries have adopted regular, annual re-registration linked in some way to the continuation of active practice, and increasingly, also to continuing education requirements, to mitigate risks associated with lack of current veterinary knowledge and practice.

It was reported that the Veterinary Affairs Council did require reporting by registered veterinarians of location and employment every two years but that compliance with this requirement was low, and that this lack of reporting did not influence registration or capacity to practice.

From evidence provided, it seems that the Veterinary Affairs Council could also do more to safeguard the professional and technical standards of veterinarians in the country, including through the implementation of disciplinary measures. Eleven cases of disciplinary action involving private and government veterinarians were reported in 2014 and five in 2015. However, these were reported as not being related to veterinary practice but due to unrelated criminal convictions e.g. licence suspension due to traffic or other criminal offences unrelated to veterinary practice.

It was not clear that if a client or member of the public has a legitimate issue with practices undertaken or services received from a veterinarian, that there exists a clear avenue to contact the Veterinary Affairs Council and report the matter and for the matter to be duly investigated, with the possibility of disciplinary action. The Veterinary Affairs Council did not report receiving any complaints from members of the public.

## Strengths:

A strong and competent Veterinary Affairs Council with good levels of resourcing, and three sub-committees.

## Weaknesses:

- Veterinary Affairs Council not truly independent or autonomous as dependent on MAFF resources
- The one-off, lifetime registration of veterinarians particularly limits options for maintaining veterinary standards.

- Review options for managing client complaints relating to veterinary professional standards using international models or models from other professions, and with legal advice:
- Review the present system of one-off, lifetime registration of veterinarians particularly in relation to maintaining veterinary standards in the context of continuing education and ongoing employment;
- Conduct a review to assess possible unreported breaches of professional standards or misconduct in veterinary practice, and not just those based on unrelated criminal activity.

III-6 Participation of producers	Levels of advancement
and other interested parties in	1. Producers and other interested parties only comply and do
joint programmes	not actively participate in programmes.
The capability of the VS and producers and interested parties to formulate and implement joint programmes in regard to animal health and food safety. This competency includes collaboration with relevant authorities, including other ministries and Competent Authorities, national agencies and decentralised institutions that share authority or have mutual interest in relevant areas	2. Producers and other interested parties are informed of programmes and assist the VS to deliver the programme in the field.
	3. Producers and other interested parties are trained to participate in programmes and advise of needed improvements, and participate in early detection of diseases.
	4. Representatives of producers and other interested parties negotiate with the VS on the organisation and delivery of programmes.
	5. Producers and other interested parties are formally organised to participate in developing programmes in close collaboration with the VS.

## Evidence (see Appendix 6): E87

## Findings:

The Veterinary Services have developed joint programmes with non-government or semigovernment groupings and associations; these programmes involve joint contributions (financial or in-kind) from producers as well as government. A wide array of joint activities is in place.

A pilot, voluntary live pig traceability programme has been developed in partnership with the pig industry. The programme, including maintaining the database, is managed by the pig industry with some MAFF financial and technical support. At present, there are approximately 2,000 pig farmers utilising the programme, with the intention of further expansion.

MAFF has also developed an on-farm HACCP program for interested producers who work to meet set standards on their farms (beyond the mandatory biosecurity standards) and pay a fee to be certified via government inspection. At present there are only 200 farms certified. The major impediment to further uptake was the significant payment that was required for certification of 300,000 JPY.

There are no mandatory, official animal vaccination programmes in Japan other than for rabies, as prescribed in the Rabies Control Act. Vaccination against livestock diseases is voluntary and can be accessed by producers through a joint programme managed and co-financed by the prefectural Livestock Industry Federations and Associations, themselves funded centrally by MAFF, ALIC and the Japan Horse Racing Industry. Interest from farmers in vaccination is sought via their local associations. These numbers are passed onto the Livestock Industry Associations and then Federations (at prefectural level) who purchase the required number of vaccine doses, and then contract NOSAI veterinarians to deliver the vaccine on farms. Although the Livestock Industry Associations typically will cover the labour costs (through NOSAI contracts), farmers are required to contribute payment towards the cost of the vaccine.

Clinical, reproductive, and nutritional veterinary services provision through the Mutual Aid Scheme, as delivered by local NOSAI and private veterinary clinics, can also be considered as a joint programme, involving both government and industry contributions. Livestock farmers can voluntarily pay insurance premiums to access these services on demand, though there is also a level of government subsidisation, particularly relating to capital costs.

An emergency diseases insurance scheme managed by the Livestock Industry Association allows farmers to pay a subscription fee that provides them with access to compensation for indirect costs including loss of income and restocking resulting from an animal health emergency.

Abattoirs also pay fees for inspection activity by Meat Inspection Centres and to a third party agency for poultry meat inspection.

# Strengths:

> Numerous functional joint programmes involving farmer or other stakeholder contributions.

# **Recommendations:**

> None.

# **III.4** Fundamental component IV: Access to markets

This component of the evaluation concerns the authority and capability of the VS to provide support in order to access, expand and retain regional and international markets for animals and animal products. It comprises eight critical competencies.

## Critical competencies:

Section IV-1	Preparation of legislation and regulations
Section IV-2	Implementation of legislation and regulations and compliance thereof
Section IV-3	International harmonisation
Section IV-4	International certification
Section IV-5	Equivalence and other types of sanitary agreements
Section IV-6	Transparency
Section IV-7	Zoning
Section IV-8	Compartmentalisation

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*Terrestrial Code* References:

Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.

Points 1 and 2 of Article 3.2.7. on Legislation and functional capabilities: Animal health, animal welfare and veterinary public health / Export/import inspection.

Points 1 and 3 of Article 3.2.8. on Animal health controls: Animal health status / National animal disease reporting systems.

Sub-point g) of Point 4 of Article 3.2.10. on Veterinary Services administration: Trade performance history.

Article 3.2.11. on Participation in OIE activities.

Points 6 and 10 of Article 3.2.14. on Veterinary legislation, regulations and functional capabilities / Membership of the OIE.

Chapter 3.4. on Veterinary legislation.

Chapter 4.3. on Zoning and compartmentalisation.

Chapter 4.4. on Application of compartmentalisation.

Chapter 5.1. on General obligations related to certification.

Chapter 5.2. on Certification procedures.

Chapter 5.3. on OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.

Chapters 5.10. to 5.12. on Model international veterinary certificates.

IV-1 Preparation of legislation	Levels of advancement
and regulations	1. The VS have neither the authority nor the capability to
The authority and capability of the VS to actively participate in the preparation of national legislation and regulations in domains that are under their mandate, in order to guarantee its quality with respect to principles of legal drafting and legal issues (internal quality) and its accessibility, acceptability, and technical, social and economical applicability (external quality). This competency includes collaboration with relevant authorities, including other ministries and Competent Authorities, national agencies and decentralised institutions that share authority or have mutual interest in relevant areas	<ul> <li>participate in the preparation of national legislation and regulations, which result in legislation that is lacking or is out-dated or of poor quality in most fields of VS activity.</li> <li>2. The VS have the authority and the capability to participate in</li> </ul>
	the preparation of national legislation and regulations and can largely ensure their internal quality, but the legislation and regulations are often lacking in external quality.
	3. The VS have the authority and the capability to participate in the preparation of national legislation and regulations, with adequate internal and external quality in some fields of activity, but lack formal methodology to develop adequate national legislation and regulations regularly in all domains.
	4. The VS have the authority and the capability to participate in the preparation of national legislation and regulations, with a relevant formal methodology to ensure adequate internal and external quality, involving participation of interested parties in most fields of activity.
	5. The VS regularly evaluate and update their legislation and regulations to maintain relevance to evolving national and international contexts.

*Evidence* (see Appendix 6): E49, 50, 51, 52, 53,54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70,71, 72,73, 79, 100, 121, 138

## <u>Findings</u>

The Veterinary Services have updated and comprehensive legislation and regulations developed according to the standard Government of Japan format. Legislation has good internal and external quality and is prepared in partnership with stakeholders. The Animal Health Division of MAFF has two staff who work on legislative issues as permanent members of staff responsible for drafting new legislation and regulations.

The structure of legislation is laws (acts) with subordinate regulations – Government Ordinance and Ministerial Ordinance. This legislation is further supported by 'Ministerial announcements', 'Ministerial Notices' and Guidelines including Standards. The VS make full use of these legislative instruments.

When required, new legislation is drafted by MAFF Animal Health Division, or other divisions and agencies. Government and Ministerial Ordnances can be issued rapidly – within one week in cases of an emergency.

MAFF has a number of Councils that may be contacted in the drafting and review process. These include the Council of Food, Agriculture and Rural Area Policies and its sub-committee, Veterinary Affairs Council, Pharmaceutical Affairs and Food Sanitation Council and its sub-councils, Agricultural Affairs Council with its Feed Affairs sub-council and the Health Science Council and its sub-committee on infectious diseases.

Following drafting of new legislation, discussions are held with the relevant industry associations providing an opportunity to modify the draft material; legislation is also provided for public comment.

Some key items of legislation for the VS include:

## Act on domestic animal infectious disease control (1951)

This Act promotes the livestock industry by preventing and controlling infectious diseases (including parasitic diseases) of domestic animals. The Act is comprehensive and well-structured with seven chapters and 69 articles covering general provisions, the prevention of outbreaks of infectious disease in domestic animals, the prevention of spread of infectious disease in domestic

animals, export and import quarantine, measures concerning the management pathogens, miscellaneous provisions and penalties. This act was most recently amended in 2012.

## Rabies prevention act (1950)

This Act established the obligation to vaccinate and register dogs in Japan and to conduct quarantine inspections upon departure from and entry into Japan. There have been no cases of rabies in Japan since 1957.

Act on the prevention of infectious diseases and medical care for patients suffering from infectious diseases (1998)

This public health act provides the authority to promote human health by preventing the incursion and spread of infectious diseases by taking measures to prevent their entry and control disease outbreaks through appropriate medical care. The VS are responsible for controlling zoonotic diseases that threaten human health.

## Livestock Hygiene Service Centres Act (1950, amended 1999)

This Act established the Livestock Hygiene Service Centres in order to improve the local animal health situation and so to promote the livestock industry. The location, name and jurisdictional district of the centres was then provided under Prefectural Ordnance.

A number of other acts are in place to provide the necessary mandate for the VS. These acts cover feed safety, poultry meat inspection, abattoirs, food sanitation, beef traceability and pharmaceutical affairs.

VS work closely with the relevant competent authorities such as other ministries, particularly MHLW and MoE, Customs, specific agencies such NIAH, NVAL and FAMIC and the independent Food Safety Commission of Japan. Legislation is in place requiring collaboration and cooperation of the respective ministries and the support of the independent institutes and the Food Safety Commission of Japan.

National Acts, supported by subordinate regulations (eg Government and Ministerial Ordinances) that provide the implementation details and are updated as needed. Following updates a process of dissemination and awareness is undertaken first with staff and then to the public.

Prefecture governors are responsible for the delivery of animal health operations in their jurisdiction. This mandate is provided by national legislation. Specific prefectural ordinances are developed by the individual prefectures to cover their specific needs in areas such as land use, local registration and licensing.

No legislation exists covering veterinary para-professionals. Veterinary para-professionals are generally not used by the VS – with technical tasks undertaken by registered veterinarians except for poultry meat inspection. The private sector is developing a veterinary nurse qualification and registration programme; this programme is not yet finalised but is expected to be endorsed in legislation.

Veterinary legislation and regulations are generally updated as the national context changes and with reference to international standards. The management of BSE in Japan has evolved with the reduction in risk in Japan and the improved understanding of the condition internationally. This has resulted in changes to the Ministerial Ordinance for BSE. In contrast the rabies legislation has remained largely unchanged for more than 50 years and may be considered to be out of date in the context of current risks.

# <u>Strengths:</u>

- > Comprehensive, well-structured legislation with the necessary subordinate 'Ordinances';
- > Legislation is generally up to date and in alignment with the international context;
- Legislation has good internal and external quality.

- > Develop/amend legislation to require the registration of veterinary para-professionals
- Review and revise the Rabies Prevention Act considering the current risks of rabies incursion and its management;
- Review older legislation to ensure its up to date;
- > In the longer term, consider absorbing the Acts relating to rabies and BSE into related generic animal health and public health acts, given declining risks.

IV-2 Implementation	Levels of advancement
of legislation and	1. The VS have no or very limited programmes or activities to ensure
regulations and	compliance with relevant legislation and regulations.
compliance thereof	2. The VS implement a programme or activities comprising inspection and
The authority and	verification of compliance with legislation and regulations and recording
capability of the VS to	instances of non-compliance, but generally cannot or do not take further
ensure compliance with legislation and regulations under the VS mandate.	action in most relevant fields of activity.
	3. Veterinary legislation is generally implemented. As required, the VS have
	a power to take legal action / initiate prosecution in instances of non-
	compliance in most relevant fields of activity.
	4. Veterinary legislation is implemented in all domains of veterinary
	competence and the VS work to minimise instances of non-compliance.
	5. The compliance programme is regularly subjected to audit by the VS or
	external agencies.

*Evidence* (see *Appendix 6*): E12, 13, 14, 15

## <u>Findings:</u>

The Veterinary Services have strong programmes of communication at national and local levels to increase awareness and compliance with legislation. Compliance rates are exceptional with very few cases of failure.

The local Prefecture Animal Health Divisions and the Livestock Hygiene Service Centres sometimes receive notifications of problems in businesses trading companion animals. These notifications are investigated and typically result in a warning of the need to improve and a revisit.

Prefecture and health divisions also manage the local supply and distribution of veterinary drugs and biologicals. To ensure the proper distribution and effective use of veterinary medicines, sites are visited and guidance provided on their storage, sale and use through veterinary clinics and drug stores for both livestock and companion animals. These distributors are inspected and their facilities licensed. Minor failings to comply are sometimes identified and corrected by providing advice; the typical non-compliance is a minor problem with the accuracy of record keeping of the storage and supply of veterinary medicines.

The Veterinary Council has the disciplinary powers to investigate and to suspend or prohibit the practice of veterinary medicine by veterinarians. Records available showed that eleven veterinarians were subjected to 'administrative disposition' in 2014 and five in 2015. Administrative disposition typically results in removal of the licence to practice veterinary medicine. One case was cited in which a veterinarian had committed a criminal act of dangerous driving and was therefore no longer allowed to practice veterinary medicine. Cases did not involve professional negligence or misconduct in the treatment of animals.

AQS records show that there is only a very low level of non-compliance – only three cases were recorded in 2015 based on the Act on Domestic Animal Infectious Diseases Control.

## Strengths:

- Strong extension programme of the requirements as laid down in legislation;
- High levels of awareness and compliance with all government programmes;
- > Evidence of non-compliance and how these cases were handled.

## Weaknesses:

> Few reports of compliance activities, penalties imposed or audit programmes.

- Continue enforcement activities and consolidate compliance/non-compliance data at prefecture and national levels;
- Ensure the compliance programme is regularly subjected to audit by the VS or external agencies;
- > Develop a stronger animal welfare compliance programme with producers, transporters and industry.

IV-3 International	Levels of advancement
harmonisation	1. National legislation, regulations and sanitary measures under the mandate of the VS do not take account of international standards.
The authority and capability of the VS to be active in the international harmonisation of	<ol> <li>The VS are aware of gaps, inconsistencies or non-conformities in national legislation, regulations and sanitary measures as compared to international standards, but do not have the capability or authority to rectify the problems.</li> </ol>
regulations and sanitary measures and to ensure that the national legislation and regulations under their mandate take account of relevant international standards, as appropriate.	3. The VS monitor the establishment of new and revised international standards, and periodically review national legislation, regulations and sanitary measures with the aim of harmonising them, as appropriate, with international standards, but do not actively comment on the draft standards of relevant intergovernmental organisations.
	4. The VS are active in reviewing and commenting on the draft standards of relevant intergovernmental organisations.
	5. The VS actively and regularly participate at the international level in the formulation, negotiation and adoption of international standards <sup>11</sup> , and use the standards to harmonise national legislation, regulations and sanitary
	measures.

## *Evidence* (see Appendix 6): E39, 40, 79

## <u>Findings:</u>

The Veterinary Services very actively and regularly participate at international forums and conferences monitoring the changing international environment and the increasing demands of trade liberalisation – most recently with the signing of the Trans Pacific Partnership. Strong support is provided for the development of regional and international standards and activities.

The VS lead and support the formulation, negotiation and adoption of international standards, commenting on draft standards of relevant intergovernmental organisations such is OIE and *Codex Alimentarius*. Changes in international standards are monitored and inconsistencies or non-conformities identified; legislation and standards may then be revised according to national policies with consideration to the changes in international standards, but maintaining Japan's low levels of acceptable risk, particularly in the field of consumer food safety.

National legislation, regulations and sanitary measures are very rigorous compared with international standards and no gaps or inconsistencies were identified to the mission. If limitations were identified in the current legislation then the system is in place to quickly draft new legislative instruments or amendment of existing ones to harmonise national legislation, regulations and sanitary measures.

As an example, NVAL takes a lead role in the VICH (International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products) approach to the registration and management of veterinary medicines and biologicals along with the USA and EU. Guidelines are being developed for the standardised approval of veterinary products and VICH members are obligated to adopt these guidelines – so far more than 50 guidelines have been prepared. NVAL implements training and extension activities in support of the VICH approach internationally.

## Strengths:

- The VS plays a leading role internationally in the development of standards;
- Legislation and standards are generally updated to align with international standards, and scientific justification (e.g. Food Safety Commission of Japan risk assessments) are provided in the cases where international standards are exceeded.

<sup>&</sup>lt;sup>11</sup> A country could be active in international standard setting without actively pursuing national changes. The importance of this element is to promote national change.

## Weakness:

Overly rigorous policies, legislation and programmes in comparison with international norms.

## Recommendations:

Some standards in Japan are overly rigorous by international norms and these would benefit from review considering acceptable risk and cost-effectiveness – consider particularly the BSE and rabies prevention and surveillance programmes, Johne's disease eradication and feed safety monitoring.

IV-4 International	Levels of advancement
certification <sup>12</sup>	1. The VS have neither the authority nor the capability to certify animals,
The authority and capability of the VS to	animal products, services or processes.
	2. The VS have the authority to certify certain animals, animal products,
certify animals, animal	services and processes, but are not always in compliance with the national
products, services and	legislation and regulations and international standards.
processes under their	3. The VS develop and carry out certification programmes for certain animals,
mandate, in accordance	animal products, services and processes under their mandate in compliance
with the national	with international standards.
legislation and	4. The VS develop and carry out all relevant certification programmes for any
regulations, and	animals, animal products, services and processes under their mandate in
international standards.	compliance with international standards.
	5. The VS carry out audits of their certification programmes, in order to
To more this I Os als not former	maintain national and international confidence in their system.

*Evidence* (see Appendix 6): E42 - 48, 184, 209

## <u>Findings:</u>

International certification is carried out by MAFF with policy set by the Animal Health Division's International Affairs Office and implemented by AQS.

Japan has a robust vigorous programme for animal disease surveillance with a list of notifiable diseases and the requirement for early reporting. This programme is supported by ample resources to complete the necessary verification, examination and laboratory testing needed to support the certification of animals and products for international trade.

Import and export inspections of animals and livestock products are implemented based on the Act on Domestic Animal Infectious Diseases Control, Rabies Prevention Act, and the Act on Prevention of Infectious Diseases and Medical Care for Patients Suffering Infectious Diseases.

In the case of animal import/export, document checks and detailed laboratory tests are implemented during the quarantine periods based on the law. The inspection certificate will be issued when it can be confirmed the tested animal is not likely to spread any of the animal diseases defined by the law. In addition, in the case of import, clinical examination will be implemented on the plane /ship at the arrival port.

MHLW authorise abattoir and poultry slaughtering facilities and meat processors which meet the hygiene requirements of the importing country. MHLW guidelines require that the health certificate should be prepared for the animal product, using a unique identifier, when the product is processed in an authorised facility. Animal health certificates are signed by the Director of the local Meat Inspection Centre, a veterinarian.

Import/export inspections of live animals, genetics and livestock products are implemented in accordance with the guidelines established by AQS. These guidelines regulate the procedures of import/export inspections, dealings after tests according to the results, designation of the place for the tests, the measurements the disease detected, and the managements of the facilities for the tests. Laboratory tests are applied in accordance with the SOP established by AQS. This SOP regulates products and maintenance of the equipment, samples and reagents, procedures of tests, and method of evaluation and recording. An internal audit monitors compliance based on the guidelines of AQS.

Currently Japan exports beef, pork and poultry products to 18 countries.

<sup>&</sup>lt;sup>12</sup> Certification procedures should be based on relevant OIE and Codex Alimentarius standards.

# Strengths:

- > Well established documented process for international certification with ample resources and good animal health data;
- > Ongoing auditing and review programme.

# **Recommendations:**

> Consider the development and introduction of e-certification.

IV-5 Equivalence	Levels of advancement
and other types of	1. The VS have neither the authority nor the capability to negotiate or approve
sanitary agreements	equivalence or other types of sanitary agreements with other countries.
The authority and capability of the VS to negotiate, implement and maintain equivalence and other types of sanitary agreements with trading partners.	2. The VS have the authority to negotiate and approve equivalence and other types of sanitary agreements with trading partners, but no such agreements have been implemented.
	3. The VS have implemented equivalence and other types of sanitary agreements with trading partners on selected animals, animal products and processes.
	4. The VS actively pursue the development, implementation and maintenance of equivalence and other types of sanitary agreements with trading partners on all matters relevant to animals, animal products and processes under their mandate.
	5. The VS actively work with interested parties and take account of developments in international standards, in pursuing equivalence and other types of sanitary agreements with trading partners.

## *Evidence* (see Appendix 6): none specific

## <u>Findings:</u>

Equivalence agreements have not been negotiated with regional trading partners because Japan has a higher animal health status than most of its neighbours and many of its trading partners. Many endemic diseases are subject to national disease control programmes and therefore trade restrictive measures can be theoretically applied according to the principles of the OIE Code. As such there is little incentive for Japan to develop equivalence agreements.

Japan imports large quantities of agricultural products and foods of animal origin and has in place risk mitigation measures. Control is based on agreements requiring appropriate standards and strict management of the import of live animals and animal products by AQS.

Japan has developed sanitary agreements with a number of countries for a range of products including HPAI regionalisation from US and LPAI regionalisation from a range of countries including many EU countries, US & Canada. Japan accepts meat products from FMD free zones in Brazil.

## Strengths:

- Strong policy protecting high animal health status;
- Established programme of international sanitary agreements.

## **Recommendations:**

The low levels of risk accepted by the VS of Japan should be reviewed considering international standards and norms

IV-6 Transparency	Levels of advancement
The authority and capability of the VS to notify the OIE of its sanitary status and other relevant matters (and to notify the WTO SPS Committee where applicable), in accordance with established procedures.	1. The VS do not notify.
	2. The VS occasionally notify.
	3. The VS notify in compliance with the procedures established by
	these organisations.
	4. The VS regularly inform interested parties of changes in their
	regulations and decisions on the control of relevant diseases and of
	the country's sanitary status, and of changes in the regulations and
	sanitary status of other countries.
	5. The VS, in cooperation with their interested parties, carries out
	audits of their transparency procedures.

# *Evidence* (see Appendix 6): E221

# <u>Findings:</u>

Japan is transparent in communicating its animal health status and reports both immediately and routinely as required to the OIE World Animal Health Information System and to other international bodies.

With such a strong field network of registered veterinarians having close regular contact with all livestock farmers, as well as a very comprehensive active surveillance programme, MAFF has an excellent and constantly updated knowledge of its animal disease status for the purposes of international reporting. It reports with full transparency. As described in CC II.5A, it could consider modernising its national animal health information system in line with current information technologies.

# <u>Strengths:</u>

> Excellent animal health surveillance system.

# **Recommendations:**

> Develop an integrated national animal health information system.

IV-7 Zoning	Levels of advancement
The authority and capability of the VS to establish and maintain disease free zones, as necessary and in accordance with the criteria established by the OIE (and by the WTO SPS Agreement where applicable).	1. The VS cannot establish disease free zones.13
	2. As necessary, the VS can identify animal sub-populations with distinct health status suitable for zoning.
	3. The VS have implemented biosecurity measures that enable it to establish and maintain disease free zones for selected animals and animal products, as necessary.
	4. The VS collaborate with producers and other interested parties to define responsibilities and execute actions that enable it to establish and maintain disease free zones for selected animals and animal products, as necessary.
	5. The VS can demonstrate the scientific basis for any disease free zones and can gain recognition by trading partners that they meet the criteria established by the OIE (and by the WTO SPS Agreement where applicable).

# Evidence (see Appendix 6): none

# <u>Findings:</u>

The policy of the Veterinary Services do not to endorse zoning and so no legislation or programme exists. This Critical Competency is therefore not assessed however Japan has the objective of increasing its export markets in livestock and livestock products

## **Recommendations:**

Consideration should be given to developing a policy for zoning to protect export markets in case of an emergency disease outbreak.

<sup>&</sup>lt;sup>13</sup> If the VS has the authority and capability but chooses not to implement zoning, this CC should be recorded as "not applicable at this stage"

<b>IV-8</b> Compartmentalisation	Levels of advancement
The authority and capability of the VS to establish and maintain disease free	1. The VS cannot establish disease free compartments.14
	2. As necessary, the VS can identify animal sub-populations with a distinct health status suitable for compartmentalisation.
compartments as necessary	3. The VS ensure that biosecurity measures to be implemented enable it
and in accordance with the	to establish and maintain disease free compartments for selected
criteria established by the	animals and animal products, as necessary.
OIE (and by the WTO SPS	4. The VS collaborate with producers and other interested parties to
Agreement where	define responsibilities and execute actions that enable it to establish and
applicable).	maintain disease free compartments for selected animals and animal
	products, as necessary.
	5. The VS can demonstrate the scientific basis for any disease free
	compartments and can gain recognition by other countries that they meet
	the criteria established by the OIE (and by the WTO SPS Agreement
	where applicable).

Terrestrial Code reference(s): Appendix 1

Evidence (see Appendix 6): none

#### Findings:

The policy of the Veterinary Services does not currently support compartmentalisation and so no legislation or programme exists. This Critical Competency is therefore not assessed however Japan has the objective of increasing its export markets in livestock and livestock products.

#### **Recommendations:**

Consideration should be given to developing a policy for compartmentalisation to protect export markets in case of an emergency disease outbreak.

<sup>&</sup>lt;sup>14</sup> If the VS has the authority and capability but chooses not to implement compartmentalization, this CC should be recorded as "not applicable at this stage"

# **PART IV: CONCLUSIONS**

The PVS Evaluation mission was conducted with excellent support from the Animal Health Division of MAFF. A comprehensive programme of meetings and interviews allowed a sound understanding of the very well developed, diverse and sometimes complex systems of the Veterinary Services in Japan. Key agencies and places visited included particularly the MHLW, MoE, AQS, and several prefectures, universities, primary producers and processors. The team were provided with translators and translations of all key documents. It can be concluded that the PVS Evaluation mission completed a valid assessment of the VS.

Japan has a history of a high animal health status for its intensive livestock industries, horse racing sector and companion animals and a very strong focus on veterinary public health and food safety.

Japan is a net importer of live animals and animal products but adopts a very rigorous approach to identifying and mitigating possible risks. Despite the low levels of accepted risk Japan has faced a number of major disease challenges in recent years including BSE, FMD and HPAI; all these outbreaks of TADs have been effectively managed and the diseases eliminated. Japan has also implemented a number of effective disease control and eradication programmes including against CSF, TB, brucellosis and Aujeszky's disease.

There is a recognised opportunity to increase livestock production and exports to high value markets. This is challenged by a tightly regulated market and generally low production with small farms, ageing, part time farmers and often low production rates. The desire to increase livestock exports and to manage imports requires the development of bilateral or multilateral trading agreements. Japan's philosophy of minimising risk and supporting its farmers tends to limit imports with the resulting increase in local prices and the potential to breach the principles of the WTO SPS agreement.

The VS would benefit from a longer term 5 year strategic plan to identify how it can best support the broader strategic direction of livestock farming in Japan. Japan's unique products and world's best practice animal and veterinary public health measures should continue to assist Japan in marketing its high cost/high value production to high value, premium markets overseas, such as the high end restaurant trade of its Asian neighbours.

It was observed that the VS manage effective programmes with excellent levels of commitment and resources – including quarantine, animal disease surveillance, disease control (both animal diseases and zoonoses), emergency response and food safety.

Overall the assessment of the VS is that they operate at the highest level internationally with no major weaknesses.

Notwithstanding the excellence achieved, some weaknesses and therefore opportunities for further strengthening were identified. These areas include particularly:

- The lack of structured continuing education programmes;
- The lack of an autonomous VSB and the one-time registration of veterinarians;
- The review of existing programmes to assess their objectives, efficiency and costeffectiveness; periodic audits of activities are recommended;
- Overly rigorous risk analysis and risk mitigation as compared with international standard and norms; increased use of risk analysis and cost-benefit analysis is recommended e.g. swill feeding, rabies;
- The limited number of laboratories with quality assurance accreditation or of quality management programmes;
- The increased use of differential diagnostic testing for priority exotic diseases such as FMD is recommended;

- The benefit of working more closely with producers and industry to identify and address their priorities and support; there is strong collaboration with the industry but only limited forums for representative discussions;
- The specific review of programmes that have been successfully completed but remain active and a considerable cost to the VS and/or owners/producers such as the continuing monitoring of CSF, the ongoing mandatory vaccination against rabies, very high levels of feed safety testing, and the continuing requirement to test some animals for BSE;
- Animal welfare guidelines and/or the necessary legislation are established in most areas but robust compliance programmes are lacking in certain key areas such as livestock transport and slaughter and the use of animals in experiments;
- Increased review and reporting of compliance programmes for legislation such as professional standards and the use of veterinary medicines.

This PVS Evaluation mission is an important step in assessing the level of advancement of a national VS against internationally endorsed OIE standards. Japan's assessment is one of the highest achieved internationally.

# **PART V: APPENDICES**

### **Appendix 1: Terrestrial Code references for critical competencies**

Critical Competences	Terrestrial Code references
I.1.A I.1.B I.2.A I.2.B	<ul> <li>Points 1-5 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / Independence / Impartiality / Integrity / Objectivity.</li> <li>Points 7 and 14 of Article 3.1.2. on Fundamental principles of quality: General organisation / Human and financial resources.</li> <li>Article 3.2.5. on Evaluation criteria for human resources.</li> <li>Article 3.2.12. on Evaluation of the veterinary statutory body.</li> <li>Points 1-2 and 5 of Article 3.2.14. on Organisation and structure of Veterinary Services / National information on human resources / Laboratory services.</li> </ul>
1.3	<ul> <li>Points 1, 7 and 14 of Article 3.1.2. on Fundamental principles of quality: Professional judgement / General organisation / Human and financial resources.</li> <li>Article 3.2.5. on Evaluation criteria for human resources.</li> <li>Sub-point d) of Point 4 of Article 3.2.10. on Veterinary Services administration: In-service training and development programme for staff.</li> <li>Point 9 of Article 3.2.14. on Performance assessment and audit programmes.</li> </ul>
1.4	Point 2 of Article 3.1.2. on Fundamental principles of quality: Independence.
1.5	<ul> <li>Point 1 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.</li> <li>Point 9 of Article 3.2.14. on Performance assessment and audit programmes.</li> </ul>
I.6.A I.6.B	<ul> <li>Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.</li> <li>Article 3.2.2. on Scope.</li> <li>Points 1 and 2 of Article 3.2.3. on Evaluation criteria for the organisational structure of the Veterinary Services.</li> <li>Point 4 of Article 3.2.10. on Performance assessment and audit programmes: Veterinary Services administration.</li> </ul>
1.7	<ul> <li>Point 2 of Article 3.2.4. on Evaluation criteria for quality system: "Where the Veterinary Services undergoing evaluation than on the resource and infrastructural components of the services".</li> <li>Points 2 and 3 of Article 3.2.6. on Evaluation criteria for material resources: Administrative / Technical.</li> <li>Point 3 of Article 3.2.10. on Performance assessment and audit programmes: Compliance.</li> <li>Point 4 of Article 3.2.14. on Administration details.</li> </ul>
I.8 I.9	<ul> <li>Points 6 and 14 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / Human and financial resources.</li> <li>Point 1 of Article 3.2.6. on Evaluation criteria for material resources: Financial.</li> </ul>
I.10 I.11	<ul> <li>Point 3 of Article 3.2.14. on Financial management information.</li> <li>Points 7, 11 and 14 of Article 3.1.2. on Fundamental principles of quality: General organisation / Documentation / Human and financial resources.</li> <li>Point 4 of Article 3.2.1. on General considerations.</li> <li>Point 1 of Article 3.2.2. on Scope.</li> <li>Article 3.2.6. on Evaluation criteria for material resources.</li> <li>Article 3.2.10. on Performance assessment and audit programmes.</li> </ul>
II.1A II.1B II.2	<ul> <li>Point 9 of Article 3.1.2. on Fundamental principles of quality: Procedures and standards.</li> <li>Point 1 of Article 3.2.4. on Evaluation criteria for quality systems.</li> <li>Point 3 of Article 3.2.6. on Evaluation criteria for material resources: Technical.</li> <li>Point 5 of Article 3.2.14. on Laboratory services.</li> </ul>
II.3	Chapter 2.1. on Import risk analysis
11.4	<ul> <li>Points 6 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / Procedures and standards.</li> <li>Point 2 of Article 3.2.7. on Legislation and functional capabilities: Export/import inspection.</li> <li>Points 6 and 7 of Article 3.2.14. on Veterinary legislation, regulations and functional capabilities / Animal health and veterinary public health controls.</li> </ul>



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II.5.A II.5.B II.6	<ul> <li>Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.</li> <li>Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.</li> <li>Sub-points a) i), ii) and iii) of Point 7 of Article 3.2.14. on Animal health: Description of and sample data from any national animal disease reporting system controlled and operated or coordinated by the Veterinary Services / Description of and sample reference data from other national animal disease reporting systems controlled and operated by other organisations which make data and results available to Veterinary Services / Description and relevant data of current official control programmes including: or eradication programmes for specific diseases.</li> <li>Chapter 1.4. on Animal health surveillance.</li> <li>Chapter 1.5. on Surveillance for arthropod vectors of animal diseases.</li> <li>Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.</li> <li>Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.</li> </ul>		
	Sub-point a) of Point 7 of Article 3.2.14. on Animal health and veterinary public health controls: Animal health.		
11.7	<ul> <li>Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.</li> <li>Points 1-3 of Article 3.2.8. on Animal health controls: Animal health status / Animal health control / National animal disease reporting systems.</li> <li>Sub-point a) of Point 7 of Article 3.2.14. on Animal health and veterinary public health controls: Animal health.</li> <li>Chapter 4.12. on Disposal of dead animal.</li> </ul>		
II.8.A II.8.B II.8.C	<ul> <li>Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.</li> <li>Article 3.4.12. on Human food production chain.</li> <li>Points 1-5 of Article 3.2.9. on Veterinary public health controls: Food hygiene / Zoonoses / Chemical residue testing programmes / Veterinary medicines/ Integration between animal health controls and veterinary public health.</li> <li>Points 2, 6 and 7 of Article 3.2.14. on National information on human resources / Veterinary legislation, regulations and functional capabilities / Animal health and veterinary public health controls.</li> <li>Chapter 6.2. on Control of biological hazards of animal health and public health importance through ante- and post-mortem meat inspection.</li> </ul>		
	<ul> <li>References to Codex Alimentarius Commission standards:</li> <li>Code of Hygienic practice for meat (CAC/RCP 58-2005).</li> <li>Code of Hygienic practice for milk and milk products (CAC/RCP/ 57-2004).</li> <li>General Principles of Food Hygiene (CAC/RCP 1-1969; amended 1999. Revisions 1997 and 2003).</li> </ul>		
II.9	<ul> <li>Points 6 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / Procedures and standards.</li> <li>Points 3 and 4 of Article 3.2.9. on Veterinary public health controls: Chemical residue testing programmes / Veterinary medicines.</li> <li>Sub-point a) ii) of Point 6 of Article 3.2.14. on Animal health and veterinary public health: Assessment of ability of Veterinary Services to enforce legislation.</li> <li>Chapters 6.6. to 6.10. on Antimicrobial resistance.</li> </ul>		
II.10	<ul> <li>Points 3 and 4 of Article 3.2.9. on Veterinary public health controls: Chemical residue testing programmes / Veterinary medicines.</li> <li>Sub-points b) iii) and iv) of Point 7 of Article 3.2.14. on Veterinary public health: Chemical residue testing programmes / Veterinary medicines.</li> </ul>		
II.11	Chapter 6.3. on Control of hazards of animal health and public health importance in animal feed.		
II.12.A II.12.B	<ul> <li>Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.</li> <li>Chapter 4.1. on General principles on identification and traceability of live animals.</li> <li>Chapter 4.2. on Design and implementation of identification systems to achieve animal traceability.</li> </ul>		
II.13	Section7 on Animal Welfare		

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	<ul> <li>Sub-point b) of Point 2 of Article 3.2.6. on Administrative resources: Communications.</li> <li>Point 4 of Article 3.2.14. on Administration details.</li> </ul>
	<ul> <li>Chapter 3.3. on Communication.</li> </ul>
	<ul> <li>Point 13 of Article 3.1.2. on Fundamental principles of quality: Communication.</li> </ul>
	<ul> <li>Point 2 of Article 3.2.3. on Evaluation criteria for the organisational structure of the</li> </ul>
III.2	Veterinary Services.
111.2	> Point 4 and Sub-point g) of Point 9 of Article 3.2.14. on Administration details and on
	Sources of independent scientific expertise.
	Chapter 3.3. on Communication.
III.3	Article 3.2.11. on Participation on OIE activities.
	Point 4 of Article 3.2.14. on Administration details. Deinte C. Z and O of Article 2.4.2. on Fundamental principles of quality Veterinery.
	Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation / General organisation / Procedures and standards.
111.4	<ul> <li>Point 7 of Article 3.2.3. on Evaluation criteria for the organisational structure of the</li> </ul>
	Veterinary Services.
	Article 3.4.5. on Competent Authorities.
	Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.
III.5.A	Point 9 of Article 3.2.1. on General considerations.
III.5.B	Article 3.2.12. on Evaluation of the veterinary statutory body.
	Article 3.4.6. on Veterinarians and veterinary para-professionals.
	Points 6 and 13 of Article 3.1.2. Fundamental principles of quality: Veterinary legislation / Communication.
	<ul> <li>Points 2 and 7 of Article 3.2.3. on Evaluation criteria for the organisational structure of the</li> </ul>
III.6	Veterinary Services.
	> Point 7 of Article 3.2.14. on Animal health and veterinary public health controls.
	Point 4 of Article 3.4.3. on General principles: Consultation.
	Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary
	legislation / General organisation / Procedures and standards.
IV.1	Points 1 and 2 of Article 3.2.7. on Legislation and functional capabilities: Animal health, animal welfare and veterinary public health / Export/import inspection.
	<ul> <li>Point 6 of Article 3.2.14. on Veterinary legislation, regulations and functional capabilities.</li> </ul>
	<ul> <li>Chapter 3.4. on Veterinary legislation.</li> </ul>
	Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary
	legislation / General organisation / Procedures and standards.
IV.2	> Points 1 and 2 of Article 3.2.7. on Legislation and functional capabilities: Animal health,
	<ul> <li>animal welfare and veterinary public health / Export/import inspection.</li> <li>Point 6 of Article 3.2.14. on Veterinary legislation, regulations and functional capabilities.</li> </ul>
	<ul> <li>Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.</li> </ul>
	<ul> <li>Article 3.2.11. on Participation in OIE activities.</li> </ul>
IV.3	Points 6 and 10 of Article 3.2.14. on Veterinary legislation, regulations and functional
	capabilities / Membership of the OIE.
	Points 6, 7 and 9 of Article 3.1.2. on Fundamental principles of quality: Veterinary
	legislation / General organisation / Procedures and standards.
IV.4	<ul> <li>Point 2 of Article 3.2.7. on Legislation and functional capabilities: Export/import inspection.</li> <li>Sub-point b) of Point 6 of Article 3.2.14. on Veterinary legislation, regulations and</li> </ul>
10.4	functional capabilities: Export/import inspection.
	<ul> <li>Chapter 5.2. on Certification procedures.</li> </ul>
	Chapters 5.10. to 5.12. on Model international veterinary certificates.
	> Points 6 and 7 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation /
	General organisation.
IV.5	Sub-point g) of Point 4 of Article 3.2.10. on Veterinary Services administration: Trade
	performance history.
	Chapter 5.3. on OIE procedures relevant to the Agreement on the Application of Sanitary and Phytosanitary Measures of the World Trade Organization.
	<ul> <li>Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.</li> </ul>
IV.6	<ul> <li>Points 1 and 3 of Article 3.2.8. on Animal health controls: Animal health status / National</li> </ul>
0.71	animal disease reporting systems.
	Chapter 5.1. on General obligations related to certification.
IV.7	Point 6 of Article 3.1.2. on Fundamental principles of quality: Veterinary legislation.
IV.8	Chapter 4.3. on Zoning and compartmentalisation.
	Chapter 4.4. on Application of compartmentalisation.

### **Appendix 2: Glossary of terms**

Terms defined in the Terrestrial Code that are used in this publication are reprinted here for ease of reference.

### <u>Animal</u>

A mammal, bird or bee.

#### Animal identification

The combination of the identification and registration of an animal individually, with a unique identifier, or collectively by its epidemiological unit or group, with a unique group identifier.

#### Animal identification system

The inclusion and linking of components such as identification of establishments/owners, the person(s) responsible for the animal(s), movements and other records with animal identification.

#### Animal welfare

How an animal is coping with the conditions in which it lives. An animal is in a good state of welfare if (as indicated by scientific evidence) it is healthy, comfortable, well nourished, safe, able to express innate behaviour, and if it is not suffering from unpleasant states such as pain, fear and distress. Good animal welfare requires disease prevention and veterinary treatment, appropriate shelter, management, nutrition, humane handling and humane slaughter/killing. Animal welfare refers to the state of the animal; the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

#### Border post

Any airport, or any port, railway station or road check-point open to international trade of commodities, where import veterinary inspections can be performed.

#### **Compartment**

An animal subpopulation contained in one or more establishments under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases for which required surveillance, control and biosecurity measures have been applied for the purposes of international trade.

#### Competent Authority

The Veterinary Authority or other Governmental Authority of a Member, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the Terrestrial Code and the OIE Aquatic Animal Health Code in the whole territory.

#### <u>Disease</u>

The clinical and/or pathological manifestation of infection.

#### Emerging disease

A new infection or infestation resulting from the evolution or change of an existing pathogenic agent, a known infection or infestation spreading to a new geographic area or population, or a previously unrecognised pathogenic agent or disease diagnosed for the first time and which has a significant impact on animal or public health.

#### Equivalence of sanitary measures

The state wherein the sanitary measure(s) proposed by the exporting country as an alternative to those of the importing country, achieve(s) the same level of protection.

#### International veterinary certificate

A certificate, issued in conformity with the provisions of Chapter 5.2., describing the animal health and/or public health requirements which are fulfilled by the exported commodities.

#### Laboratory

A properly equipped institution staffed by technically competent personnel under the control of a specialist in veterinary diagnostic methods, who is responsible for the validity of the results. The Veterinary Authority approves and monitors such laboratories with regard to the diagnostic tests required for international trade.

#### <u>Meat</u>

All edible parts of an animal.

#### Notifiable disease

A disease listed by the Veterinary Authority, and that, as soon as detected or suspected, must be brought to the attention of this Authority, in accordance with national regulations.

#### Official control programme

A programme which is approved, and managed or supervised by the Veterinary Authority of a country for the purpose of controlling a vector, pathogen or disease by specific measures applied throughout that country, or within a zone or compartment of that country.

#### Official Veterinarian

A veterinarian authorised by the Veterinary Authority of the country to perform certain designated official tasks associated with animal health and/or public health and inspections of commodities and, when appropriate, to certify in conformity with the provisions of Chapters 5.1. and 5.2. of the Terrestrial Code.

#### Official veterinary control

The operations whereby the Veterinary Services, knowing the location of the animals and after taking appropriate actions to identify their owner or responsible keeper, are able to apply appropriate animal health measures, as required. This does not exclude other responsibilities of the Veterinary Services eg food safety.

#### <u>Risk analysis</u>

The process composed of hazard identification, risk assessment, risk management and risk communication.

#### <u>Risk assessment</u>

The evaluation of the likelihood and the biological and economic consequences of entry, establishment and spread of a hazard within the territory of an importing country.

#### Risk management

The process of identifying, selecting and implementing measures that can be applied to reduce the level of risk.

#### Sanitary measure

A measure, such as those described in various Chapters of the Terrestrial Code, destined to protect animal or human health or life within the territory of the OIE Member from risks arising from the entry, establishment and/or spread of a hazard.

#### **Surveillance**

The systematic ongoing collection, collation, and analysis of information related to animal health and the timely dissemination of information so that action can be taken.

#### **Terrestrial Code**

The OIE Terrestrial Animal Health Code.

#### <u>Veterinarian</u>

A person with appropriate education, registered or licensed by the relevant veterinary statutory body of a country to practice veterinary medicine/science in that country.

#### Veterinary Authority

The Governmental Authority of an OIE Member, comprising veterinarians, other professionals and para-professionals, having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the Terrestrial Code in the whole territory.

#### (Veterinary) legislation

The collection of specific legal instruments (primary and secondary legislation) required for the governance of the veterinary domain.

#### Veterinary para-professional

A person who, for the purposes of the Terrestrial Code, is authorised by the veterinary statutory body to carry out certain designated tasks (dependent upon the category of veterinary para-professional) in a territory, and delegated to them under the responsibility and direction of a veterinarian. The tasks for each category of veterinary para-professional should be defined by the veterinary statutory body depending on qualifications and training, and according to need.

#### Veterinary Services

The governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the Terrestrial Code and the OIE Aquatic Animal Health Code in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. Private sector organisations, veterinarians, veterinary paraprofessionals or aquatic animal health professionals are normally accredited or approved by the Veterinary Authority to deliver the delegated functions.

#### Veterinary statutory body

An autonomous regulatory body for veterinarians and veterinary para-professionals.

#### <u>Wildlife</u>

Feral animals, captive wild animals and wild animals.

#### <u>Zoonosis</u>

Any disease or infection which is naturally transmissible from animals to humans.

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Name	Position Vice minister for	Institution	Location Tokyo
Mr Hiromichi	International Affairs,	MAFF	IUNYU
Matsushima	MAFF		
	Opening Meeting	g MAFF Headquar	rters 11 October
Dr John Weaver	OIE Team Leader	5	Tokyo
Dr John Stratton	OIE Team		Tokyo
Dr Julie	OIE Team		Tokyo
Punderson			-
	Chief Veterinary Officer		Токуо
	and Director Animal Health Division,		
Dr Norio Kumagai	Food Safety and	MAFF	
	Consumer Affairs		
	Bureau		
	OIE Delegate, and		Токуо
	Director		
	International Animal Health Affairs Office,		
Dr Kazuo Ito	Animal Health Division,	MAFF	
	Food Safety and		
	Consumer Affairs		
	Bureau		
	Deputy Director International Animal	MAFF	Токуо
	Health Affairs Office,		
Dr Tatsumi Okura	Animal Health Division,		
	Food Safety and		
	Consumer Affairs		
	Bureau Deputy Director		<b>T</b> .1
	Deputy Director International Animal	MAFF	Токуо
Dr Yosuke	Health Affairs Office,		
Yamaki	Animal Health Division,		
	Food Safety and		
	Consumer Affairs Bureau		
	Deputy Director	MAFF	Tokyo
	International Animal		Tokyo
Dr Kiyoko	Health Affairs Office,		
Kotsubo	Animal Health Division,		
	Food Safety and Consumer Affairs		
	Bureau		
	Deputy Director	MAFF	Токуо
,	International Animal		
Dr Yoshihiro	Health Affairs Office,		
Kawada	Animal Health Division, Food Safety and		
	Consumer Affairs		
	Bureau		
	Deputy Director	MAFF	Токуо
	Animal Disease Control		
Dr Yuichi Kishita	and Prevention Office Animal Health Division		
	Food Safety and		
	Consumer Affairs		
	Bureau		
Dr Masahiko	Director for AMR	MAFF	Токуо
Hayashi	Animal Products Safety Division,		
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	Food Safety and		
	Consumer Affairs		
	Bureau		
Dr Satoshi Maema	Deputy Director Animal Products Safety Division, Food Safety and Consumer Affairs	MAFF	Токуо
	Bureau		
Dr Yoshiyuki Sunaga	Deputy Director Animal Products Safety Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr Akiko Oishi	Deputy Director Animal Products Safety Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr Shoko Iwamoto	Deputy Director Animal Products Safety Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr Tatsuro Sekiya	Deputy Director Animal Products Safety Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr Takashi Morigaki	Deputy Director Animal Products Safety Division, Food Safety and Consumer Affairs Bureau	MAFF	Токуо
Dr Masatsugu Okita	Deputy Director Animal Products Safety Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr Sonoko Kondo	Deputy Director Animal Products Safety Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr Yuka Watanabe	Deputy Director Animal Products Safety Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr Hiroko Io	Section Chief Animal Products Safety Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo



	March and March	Niener Mat	Taluar
Prf. Fukiko Ueda	Member of Veterinary Council, Professor	Nippon Veterinary and Life Science	Токуо
	Assistant Director	University	Telue
	Assistant Director, Office of Wild life	MoE	Tokyo
Dr. Yasuko	Management,		
Neagari	Wildlife Division,		
neagan	Nature Conservation		
	Bureau		
	Deputy Director	MAFF	Tokyo
	International Animal		lonyo
Dr. Tomoyuki	Health Affairs Office,		
Takehisa	Animal Health Division,		
	Food Safety and		
	Consumer Affairs		
	Bureau		
	Assistant Director	MAFF	Токуо
Dukinghing	International Animal		
Dr Kiyohisa	Health Affairs Office,		
Kamomae	Animal Health Division, Food Safety and		
	Consumer Affairs		
	Bureau		
	Section Chief	MAFF	Токуо
	Animal Health Division,		
Dr Mari	Food Safety and		
Kamogawa	Consumer Affairs		
	Bureau, MAFF		
	Chaff		
	Staff Animal Health Division,		
Dr Saki Segami	Food Safety and	MAFF	Toluro
Di Saki Segami	Consumer Affairs	MAFF	Tokyo
	Bureau, MAFF		
Dr. Akemi	Principal Officer, AQS	MAFF	Tokyo
Kamakawa	•		
NA	Animal Quarantine	MAFF	Токуо
Mr. Takashi	Officer		
Okazaki	Planning and Coordination Division		
	AQS		
	Regional Veterinary		Токуо
Dr Caitlin Holley	Officer, OIE RRAP		TORYO
Dr. Fania Dwi	Regional Veterinary		Tokyo
	Officer, OIE RRAP		
		15, MAFF Headqua	
Dr John Weaver	OIE Team Leader		Tokyo
Dr John Stratton	OIE Team		Tokyo
Dr Punderson	OIE Team		Tokyo
	Deputy Director	MAFF	Tokyo
	International Animal		
Dr Tatsumi Okura	Health Affairs Office, Animal Health Division,		
	Food Safety and		
	Consumer Affairs		
	Bureau		
	Deputy Director	MAFF	Tokyo
Dr Yosuke	International Animal		
Yamaki	Health Affairs Office,		
	Animal Health Division,		
	Food Safety and		
	Consumer Affairs		



	Duroou		
	Bureau Section Chief		Talva
Dr Mari Kamogawa	Section Chief Animal Health Division, Food Safety and Consumer Affairs	MAFF	Токуо
Dr Nobuyuki Takahashi	Bureau Section Chief Animal Health Division, Food Safety and Consumer Affairs Bureau,	MAFF	Токуо
Dr Saki Segami	Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF	Токуо
Dr Shiro Inukai	Director, Livestock Production Technology Office, Livestock Production Promotion Division, Livestock Industry Department, Agricultural Production Bureau	MAFF	Токуо
Ms Ritsuko Yoneda	Deputy Director, Livestock Production Promotion Division, Livestock Industry Department, Agricultural Production Bureau	MAFF	Токуо
Dr Toshitaka Higashira	Deputy Director Inspection and Safety Division, Department of Environmental Health and Food Safety, Pharmaceutical safety and Environmental Health Bureau	MHLW	Токуо
Dr Tadahiro Kawagoe	Section Chief Inspection and Safety Division, Department of Environmental Health and Food Safety, Pharmaceutical safety and Environmental Health Bureau	MHLW	Токуо
Dr Kazuko Otsuka	Deputy Director Tuberculosis and Infectious Diseases Control Division, Health Service Bureau	MHLW	Токуо
Dr Motomitsu Taguchi	Deputy Director Animal Welfare and Management Office, Policy and Coordination Division, Nature Conservation Bureau	МоЕ	Tokyo



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	Deputy Director,			Tokyo	
	General Affairs				
Mr Yasuyuki	Division, Food Safety				
Hanawa	Commission	FSCJ			
	Secretariat, Cabinet				
	Office, Government of				
	Japan				
	Associate Director	FSCJ		Tokyo	
	General Affairs				
	Division,				
Dr Emi Takagi	Food Safety				
	Commission				
	Secretariat, Cabinet				
	Office, Government of				
	Japan				
	Section Chief	FSCJ		Tokyo	
	General Affairs				
	Division,				
Ms Kayako lida	Food Safety				
	Commission				
	Secretariat, Cabinet				
	Office, Government of				
	Japan Dagutu Director	5001		<b>T</b> . I	
	Deputy Director	FSCJ		Tokyo	
	Second Risk				
Dr. Hissie Okura	Assessment Division,				
Dr Hisako Okura	Food Safety				
	Commission Secretariat, Cabinet				
	Office, Government of				
	Japan				
	Risk Assessment	FSCJ		Tokyo	
	Senior Expert Officer	F3C3		ТОКУО	
	Second Risk				
	Assessment Division,				
Dr Yoko Aoyama	Food Safety				
	Commission				
	Secretariat, Cabinet				
	Office, Government of				
	Japan				
	Risk Assessment			Tokyo	
	Senior Expert Officer			. en je	
	Second Risk				
	Assessment Division,				
Ms Akane	Food Safety	FSCJ			
Matsushita	Commission				
	Secretariat, Cabinet				
	Office, Government of				
	Japan				
		ts, meeting	s and int	terviews	
Thursday 13 October					
Dr John Weaver	OIE Team Leader				
Dr John Stratton	OIE Team				
Dr Julia	OIE Team				
Punderson					
Mr Shaii Takayahi	Head of Tsukuba, Produc	ction	Kyorits	u Seiyaku	Ibaraki
Mr Shoji Takeuchi	Division		Corpor	ation	
Mr Tomobiro Oca	Dep Head of Plant, Produ	uction		u Seiyaku	Ibaraki
Mr Tomohiro Seo	Division		Corpor		
Dr Kazuo				u Seiyaku	Ibaraki
Kawakami	Management Dept.		Corpor		
Dr Yoshiko		ant Desit		u Seiyaku	Ibaraki
Eguchi	Development Manageme	ent Dept.	Corpor		
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Dr Kenichi Sakamoto	Director-General NIAH	NIAH	Ibaraki
Dr Takashi Yokoyama	Director, Department of Planning and General Administration	NIAH	Ibaraki
Dr Kazuhiro Yoshihara	Director, Department of Animal Disease Control and Prevention	NIAH	Ibaraki
Dr Toshiyuki Tsutsui	Director, Division of Viral Disease and Epidemiology	NIAH	Ibaraki
Dr Takehiko Saito	Director, Division of Transboundary Animal Disease	NIAH	Ibaraki
Dr Ikuo Uchida	Director, Division of Bacterial and Parasitic Disease	NIAH	Ibaraki
Dr Masumi Sato	Director, Division of Pathology and Pathophysiology	NIAH	Ibaraki
Dr Takayuki Kubota	Planning and General Administration	NIAH	Ibaraki
Dr Aikito Saito	Head Coordinator of Animal Health Governmental Affairs	NIAH	Ibaraki
Ikuho Tomita	Director, Food Safety and consumer Affairs Dept.	Kanto Regional Agricultural Administration Office	Saitama
Mr Makoto Kimura	President	FAMIC	Saitama
Mr Kunugi Yutaka	Dir, Feed Control Division	FAMIC	Saitama
Mr Ishibashi Takayuki	Dir, Feed Analysis I Division	FAMIC	Saitama
Ms Sayaka Hashimoto	Dir, Feed Analysis II Division	FAMIC	Saitama
	Friday 14 C	October	
Dr John Weaver	OIE Team Leader		Tokyo
Dr John Stratton	OIE Team		Tokyo
Dr Punderson	OIE Team		Tokyo
Dr Tetsya Nakamoto	Deputy Supervisor for Agricultural Insurance, Management Improvement Bureau	MAFF	Tokyo
Dr Akira Yokoo	Manager of Livestock Insurance Section, Division for Planning, Research and Training, National Agricultural Insurance Association	NOSAI	Tokyo
Mr Takashi Himeda	Vice Executive Director	Japan Livestock Industry Association	Токуо
Mr Junichi Sekiya	Staff	Japan Livestock Industry Association	Tokyo
Dr Hiroyuki Nakayama	President of JSVS, Lab.of Vet. Pathol	Univ of Tokyo Vet School	Tokyo
Dr Takeshi Haga	Div. of Infection Control and Disease Prevention	Univ of Tokyo Vet School	Tokyo
Dr. Hirofumi Kugita	Regional Representative	OIE RRAP	Tokyo
Dr Caitlin Holley	Regional Veterinary Officer, OIE RRAP	OIE RRAP	
Dr. Fania Dwi	Regional Veterinary Officer, OIE RRAP	OIE RRAP	
<b>D</b> 1 1 111	Monday 17 0	Uctober	
Dr John Weaver	OIE Team Leader		Osaka
Dr Yosuke Yamaki	Deputy Director, International Animal Health Affairs Office, Animal Health Division, Food Safety and	MAFF	Osaka



[	Consumer Affairs Bureau	1	
	Professor, Head of Veterinary		Osaka
	Department		USaka
Dr. Kazumi Sasai	Graduate school of Life and	Osaka prefecture University	
	Environmental Sciences		
	Advisor to the President, Vice	Osaka prefecture University	Osaka
	Director, Vice-Dean Professor		
Dr. Jyoji Yamate	Graduate School of Life and		
	Environmental Sciences		
Dr. Maaami	Professor	Osaka prefecture University	Osaka
Dr. Masami	Graduate School of Life and		
Miyake	Environmental Sciences		
Dr. Tadayoshi	Professor	Osaka prefecture University	Osaka
Takeuchi	Graduate School of Life and		
	Environmental Sciences		
Dr. Terumasa	Professor, Director of the	Osaka prefecture University	Osaka
Shimada	Veterinary Medical Center,		
	Graduate School of Life and		
D. M. C. J	Environmental Sciences		
Dr. Masafumi	Professor, Graduate School of Life	Osaka prefecture University	Osaka
Mukamoto	and Environmental Sciences		Ocalia
Dr. Tomomi	Director, AQS Kansai Airport	AQS	Osaka
Sugizaki	Branch		Oaalka
Dr. Hiroyuki	Vice Director, AQS Kansai Airport	AQS	Osaka
Otomo	Branch Chief, 1st Animal Quarantine		Osaka
Dr.Yoshito Tani	Division, AQS Kansai Airport	AQS	USaka
DI. TOSTILO TATI	Branch	AQS	
Dr. Akemi			Osaka
Kamakawa	Principal Officer, AQS	AQS	Osaka
Dr John Stratton	OIE Team		Miyazaki
	Deputy Director, Animal Health		Miyazaki
Dr Yuichi Kishita	Division	MAFF	wiyazaki
Dr Kazuhiro			Miyazaki
Kubota	Director, Animal Health Division	Miyazaki Prefecture	,
Dr Hiroyuki Miura	Deputy Director, Animal Health	Miyazaki Prefecture	Miyazaki
-	Division	Miyazaki Flelecidle	
Dr Nobuyuki	Assistant Director, Animal Health	Miyazaki Prefecture	Miyazaki
Marumoto	Division	Miyazaki i Torootaro	
Dr Takuya	Assistant Director, Animal Health	Miyazaki Prefecture	Miyazaki
Nishimura	Division		
Dr Kazuhiko Iki	Deputy Director, Hygiene	Miyazaki Prefecture	Miyazaki
	Management Division		
Dr Takashi	Assistant Director, Hygiene	Miyazaki Prefecture	Miyazaki
Shimomura	Management Division		Mixozoki
Dr Hiroyuki Miyamoto	Executive Director	Miyazaki Prefectural Livestock Association	Miyazaki
wiyamoto	Director for Veterinary Service	Miyazaki Prefectural	Miyazaki
Dr Hiroshi Ohta	Director for Veterinary Service Division	Livestock Association	wiiyazani
Dr Julia			Hokkaido
Punderson	OIE Team		
-	Assistant Director		Hokkaido
Dr Kiyobioo	International Animal Health Affairs		
Dr Kiyohisa Kamomae	Office,	MAFF	
Ramonae	Animal Health Division,		
	Food Safety and Consumer Affairs		
Dellatered	Bureau, MAFF		
Dr Hidenori Takaku	Chief (livestock hygiene)	Hokkaido prefecture	Hokkaido
Takaku Dr Satoshi			Hokkaida
Tachibana	Dir, Tokachi LHSC	Hokkaido Tokachi LHSC	Hokkaido
racilidaria			



Dr Seiji Fujii	Rick Managar, Takashi LHSC	Hokkaido Tokachi LHSC	Hokkaido
Dr Yoshio	Risk Manager, Tokachi LHSC Head of Livestock Diagnostic		Hokkaido
Kusabuka	Center	Tokachi NOSAI	FIUKKAIUU
Dr Osamu			Hokkaido
Hayashiguchi	Livestock Section Manager	Tokachi NOSAI	
Mr Kazufumi	Section Chief, Environmental		
Hiratsuka	Health Division, Obihiro, HC		
Dr Shinich Tamaoki	Head, Food Sanitation, Obihiro HC	Hokkaido Obihiro HC	Hokkaido
Dr Massahiko Watanabe	Environmental Health and Sanitation, Obihiro HC	Hokkaido Obihiro HC	Hokkaido
Dr Ayuko Saitou	Specialist	Hokkaido Prefecture	Hokkaido
Mr Hamana Kouj	Dep Director General	Tokachi Subprefect	Hokkaido
	Tuesday 18		
Dr John Weaver	OIE Team Leader	OIE	Osaka
Dr Yosuke Yamaki	Deputy Director, International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs Bureau, MAFF	MAFF	Osaka
Mr. Haruhisa Ishikawa	Director General, Department of Environment, Agriculture, Forestry and Fisheries	Osaka Prefecture	Osaka
Ms. Hisako Mori	Deputy Director General Department of Environment, Agriculture, Forestry and Fisheries	Osaka Prefecture	Osaka
Dr. Shoji Yamamoto	Director Animal Protection and Livestock Division	Osaka Prefecture	Osaka
Dr. Yukiko Hino	Deputy Director, Head of Livestock Hygiene group, Animal Protection and Livestock Division	Osaka Prefecture	Osaka
Dr. Masatoshi Hashimoto	Chief Senior Staff Animal Protection and Livestock Division	Osaka Prefecture	Osaka
Dr. Michiyo Haoka	Senior Staff Animal Protection and Livestock Division	Osaka Prefecture	Osaka
Mr. Takashi Tsutsumigawa	Deputy Director, Head of Wildlife group Animal Protection and Livestock Division	Osaka Prefecture	Osaka
Dr. Atsuo Mayanagi	Deputy Director, Head of animal Welfare group, Animal Protection and Livestock Division	Osaka Prefecture	Osaka
Dr. Masato Takeda	Chief Senior Staff, Animal Protection and Livestock Division	Osaka Prefecture	Osaka
Dr. Hiroki Murayama	Director, Osaka prefecture Livestock Hygiene Service Centre	Osaka Prefecture	Osaka
Dr. Shigeru Morino	Director, AQS Kobe Branch	AQS	Нуодо
Mr. Shinichi Fujisawa	Chief, Osaka Sub-Branch, AQS Kobe Branch	AQS	Нуодо
Mr. Hitoshi Hamana	Senior Quarantine Officer Osaka Sub-Branch, AQS Kobe Branch	AQS	Нуодо
Mr. Ryuichi Sato	Senior Quarantine Officer Osaka Sub-Branch, AQS Kobe Branch	AQS	Нуодо
Dr. Reiko	Senior Quarantine Officer	AQS	Нуодо



Fukutomi	Osaka Sub-Branch, AQS Kobe Branch		
Ms. Sachiko Umemura	AQS Officer, Osaka Sub-Branch, AQS Kobe Branch	AQS	Нуодо
Ms. Mai Fujiwara	AQS Officer, Osaka Sub-Branch, AQS Kobe Branch	AQS	Нуодо
Mr. Kenji Yamamoto	AQS Officer, Osaka Sub-Branch, AQS Kobe Branch	AQS	Нуодо
Dr. Akemi Kamakawa, DVM	Principal Officer, AQS	AQS	Нуодо
Dr John Stratton	OIE Team		Miyazaki
Dr Yuichi Kishita	Deputy Director, Animal Health Division	MAFF	Miyazaki
Dr Takuya Nishimura	Assistant Director, Animal Health Division	Miyazaki Prefecture	Miyazaki
Dr Takashi Katayama	Veterinary Official, Animal Health Division	Miyazaki Prefecture	Miyazaki
Dr Yoichi Takamure	Director, Animal Health Division	Miyazaki Central LHSC	Miyazaki
Dr Akinobu Arikawa	Director, Production and Veterinary Medical Centre	NOSAI Miyazaki Association	Miyazaki
Dr Kohsei Usui	Director, Livestock Division	NOSAI Miyazaki Association	Miyazaki
Dr Atsushi Hayashi	Director, Livestock Medical Division	NOSAI Miyazaki	Miyazaki
Dr Hiroshi Kawano	Director, North Clinic Centre	NOSAI Miyazaki	Miyazaki
Mr Kazuhiro Sakobun	Director, Livestock Administrative Division	Miyazaki Central Agricultural Cooperative	Miyazaki
Dr Julie Punderson	OIE Team		Hokkaido
Dr Kiyohisa Kamomae	Assistant Director, International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF	
Dr Hidenori Takaku	Chief (livestock hygiene)	Hokkaido Prefecture	Hokkaido
Ms Chiharu Kobayashi	Chief, Livestock Promotion	Tokachi Sub-prefecture	Hokkaido
Mr Tadashi Nishiyama	General Manager	Yotsuba Milk Products	Hokkaido
Mr Fumio Imai	General Manager, Quality Control	Yotsuba Milk Products	Hokkaido
Mr Osamu Nitta	General Manager	Yotsuba Milk Products	Hokkaido
Mr Tukasa Sato	Hokuren Livestock Market Manager	Hokuren	Hokkaido
	Wednesday 19	9 October	
Dr John Weaver	OIE Team Leader		Aichi
Dr Yosuke Yamaki	Deputy Director, International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs Bureau, MAFF	MAFF	Aichi
Dr. Hiroyuki Okachi	Director, Livestock Industry Division, Department of Agriculture, Forestry and Fisheries	Aichi Prefecture	Aichi
Mr. Tatsuya Fukanuma	Assistant Director, Livestock Administration/ Environment/ Feed Group, Livestock Industry Division	Aichi Prefecture	Aichi
Dr. Junichi Matsui,	Assistant Director, Livestock Hygiene Group, Livestock Industry	Aichi Prefecture	Aichi



	Division		
Dr. Akemi Kaneko	Assistant Director, Livestock Hygiene Group, Livestock Industry Division	Aichi Prefecture	Aichi
Dr. Masahito Inaba	Assistant Director, Livestock Hygiene Group, Livestock Industry Division	Aichi Prefecture	Aichi
Dr. Moe Nakayama	Assistant Director, Livestock Hygiene Group, Livestock Industry Division	Aichi Prefecture	Aichi
Dr. Kouhei Inagaki	Assistant Director, Livestock Hygiene Group, Livestock Industry Division	Aichi Prefecture	Aichi
Dr Julie Punderson	OIE Team		Hokkaido
Dr Kiyohisa Kamomae	Assistant Director, International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF	Hokkaido
Mr Shunsuke Tsuchiya	Director General	Hokkaido Prefecture	Hokkaido
Mr Ryouji Morita	Dir General for Food Safety Promotion	Hokkaido Prefecture	Hokkaido
Mr Terukazu Odawara	Dep Dir General	Hokkaido Prefecture	Hokkaido
Mr Terumi Tada	Asst Dir General for Technical Affairs & Production Promotion	Hokkaido Prefecture	Hokkaido
Dr Hideki Nishi	Section Manager for Livestock Hygiene	Hokkaido Prefecture	Hokkaido
Mr Hidenori Takaku	Chief, Livestock Hygiene	Hokkaido Prefecture	Hokkaido
Dr Miyuko Hiramatsu	Dir of Livestock Hygiene	Hokkaido Prefecture	Hokkaido
Dr Yasuhiro Konno	Chief Examiner (animal pharmaceutical affairs and safety measures)	Hokkaido Prefecture	Hokkaido
Dr Fumiaki Eguchi	Hokkaido Livestock Industry Assoc	Public Interest Incorporated Association, Hokkaido Association of Hygiene Guidance for Livestock and its Products	Hokkaido
Dr Yasuhiro Igarashi		Public Interest Incorporated Association, Hokkaido Association of Hygiene Guidance for Livestock and its Products	Hokkaido
Dr Takeo Hongou	Chief	MoE	Hokkaido
Dr Nobuo Ozaki	Chief Examiner	Hokkaido Prefecture	Hokkaido
Dr John Stratton	OIE Team		Miyazaki
Dr Yuichi Kishita	Deputy Director, Animal Health Division	MAFF	Miyazaki
Dr Masuo Suovoshi	Professor	Miyazaki University	Miyazaki
Sueyoshi Dr Junzo Norimine	Professor	Miyazaki University	Miyazaki
Dr Masahiro Yasuda	Professor	Miyazaki University	Miyazaki
Dr Takeshi			Miyazaki
Osawa	Professor	Miyazaki University	5

Dr. John Manuer			Aich:
Dr John Weaver	OIE Team Leader		Aichi
Dr Yosuke Yamaki	Deputy Director International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs		Aichi
	Bureau, MAFF		
Mr. Mitsuhiro Shiraishi	Executive Director	JA Higashinihon Cooperative Feed Mills	Aichi
Mr. Syunichiro Nakayama	Director Quality Control Department	JA Higashinihon Cooperative Feed Mills	Aichi
Mr. Susumu	Manager	JA Higashinihon	Aichi
Teshigawara	Chita Plant	Cooperative Feed Mills	
Ms. Hiromi Yamaguchi	Director Operation Department, Chita Plant	JA Higashinihon Cooperative Feed Mills	Aichi
Mr. Kazuyoshi Matsubara	General Manager, Quality Assurance Section, Feed & Livestock Production Division	JA/ZEN-NOH	Aichi
Dr. Seiya Otsuka	Director, AQS Chubu Airport Branch	AQS	Aichi
Mr. Tomio Ogawa	Vice Director, AQS Chubu Airport Branch	AQS	Aichi
Dr. Sachiko Fuchinoue	Principal Officer (Technical Coordination) AQS Chubu Airport Branch	AQS	Aichi
Ms. Hideko Hiraga	Chief, Animal Quarantine Division, AQS Chubu Airport Branch	AQS	Aichi
Mr. Yoshinori Wagatsuma	Director, General Affairs Division, AQS Chubu Airport Branch	AQS	Aichi
Dr. Hiroyuki Osaka	Chief, Exotic Disease Inspection Division, Laboratory Department, AQS	AQS	Aichi
Dr. Akemi Kamakawa	Principal Officer, AQS	AQS	Aichi
Dr Julie Punderson	OIE Team		Iwate
Dr. Tomoyuki Takehisa	Deputy Director, International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs Bureau, MAFF	MAFF	Iwate
Dr Mika Honnami	Advisor, Livestock Div	Iwate Prefecture	Iwate
Dr Maki Takahashi	Chief Advisor, Livestock Div	Iwate Prefecture	Iwate
Mr Shinya Kikuchi	Director, Livestock Div	Iwate Prefecture	Iwate
Mr Katsuhiko Fujishiro	Executive Director, Livestock Div	Iwate Prefecture	Iwate
Dr Atsushi Sato	Dep Director, Iwate MIC	Iwate Prefecture	Iwate
Dr Nobuko Hisamatsu	Chief Advisor, Iwate MIC	Iwate Prefecture	lwate
Dr Nobuaki Saito	Chief Advisor, Food Safety Division	Iwate Prefecture	Iwate
Dr Takashi Takahashi	Director, Food Safety Division	Iwate Prefecture	Iwate
Mr Ryouichi Makino	General Manager, Manufacturing Dept	Iwate Chikusan Ryutsu Center Co, LTD	Shiwa
Mr Masaki Ohtsu	Manager, Quality Control	Iwate Chikusan Ryutsu Center Co, LTD	Shiwa
Mr Masahiro Hatakeyama	Beef Farmer		Iwate

Mr Syunichiro Minato	JA representative	JA Iwate chuoh	Iwate			
Mr Takehiro Yoshida	JA representative	JA Iwate chuoh	Iwate			
Mr Syuuji Tano	JA representative	JA/ZEN-NOH Iwate	Iwate			
Dr John Stratton	OIE Team		Miyazaki			
Dr Yuichi Kishita	Deputy Director, Animal Health Division	MAFF	Miyazaki			
Dr Masahiro Furukawa	Deputy Director, Livestock Division	Kagoshima Prefecture	Kagoshima			
Dr Toshirou Yonemaru	Section Chief for Animal Health, Livestock Division	Kagoshima Prefecture	Kagoshima			
Mr Kouji Nishida	Section Chief for Wildlife, Conservation Division	Kagoshima Prefecture	Kagoshima			
Mr Hiro Koganezono	Officer, Conservation Division	Kagoshima Prefecture	Kagoshima			
Dr Manabu Yamaguchi	Deputy Director, Hygiene Management Division	Kagoshima Prefecture	Kagoshima			
Dr Atsushi Kabeyama	Assistant Director, Hygiene Management Division	Kagoshima Prefecture	Kagoshima			
Ms Eiko Shimodouzono	Officer, Hygiene Management Division	Kagoshima Prefecture	Kagoshima			
Mr Sasahira	Farmers	Sasahira Pig farm	Kagoshima			
Dr Shoichirou Fujisono	Director-General, Kagoshima Central LHSC	Kagoshima Prefecture	Kagoshima			
Ms Tomoko Tsutsumi	Deputy Director-General, Kagoshima Central LHSC	Kagoshima Prefecture	Kagoshima			
Dr Hiroyuki Ohzono	Director, Control Measures Division, Kagoshima Central LHSC	Kagoshima Prefecture	Kagoshima			
Dr Masayuki Tamotsu	Director, Laboratory Test Division, Kagoshima Central LHSC	Kagoshima Prefecture	Kagoshima			
Dr Tadatsune Okuno	Veterinary Officer, Kagoshima Central LHSC	Kagoshima Prefecture	Kagoshima			
	Friday 21 O	ctober				
Dr John Weaver	OIE Team Leader		Aichi			
Dr Yosuke Yamaki	Deputy Director, International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF				
Toshiki Kamiya	Head, Central livestock hygiene centre	Aichi LHSC	Aichi			
Dr Shigeru Matsuo	Deputy Director (Disease prevention group) Hygiene and sanitary division	Aichi LHSC	Aichi			
Dr Sumie Arai	Assistant Director, Hygiene and sanitary division	Aichi LHSC	Aichi			
Dr Masao Yamamoto	Instruction group, High-level diagnosis division	Aichi LHSC	Aichi			
Dr Norie Sugie	Director, High-level diagnosis division	Aichi LHSC	Aichi			
Dr Atsunori Sugimoto	Deputy Director, High-level diagnosis division	Aichi LHSC	Aichi			
Mr. Masahito Nomura	Manager	Nukata Farm	Aichi			
Mr. Seiji Kimura Vice President, Head Office Sun Egg Corp Aichi						



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Mr. Seiichiro Kito	Director, Head Office	Sun Egg Corp	Aichi
Dr. Satoko Sukigara	Veterinarian Sukigara Farm Assist	Sun Egg Corp	Aichi
Dr. Sumie Arai	Assistant Director, Health and Hygiene Division, Aichi Central Livestock Hygiene Service Centre	Sun Egg Corp	Aichi
Dr. Atsunori Sugimoto	Assistant Director, Advanced Disease Diagnosis Division, Aichi Central Livestock Hygiene Service Centre	Sun Egg Corp	Aichi
Dr. Toshikatsu Ito	Head, Institute of Sanitary Affairs	Aichi Federation of Economic Organizations	Aichi
Dr. Osamu Eguchi	Veterinarian, Institute of Sanitary Affairs	Aichi Federation of Economic Organizations	Aichi
Dr. Mitsuaki Gohda	Head Gohda Poultry Clinic	Aichi Federation of Economic Organizations	Aichi
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			Aichi
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Dr. Sumie Arai	Assistant Director, Consulting Group Health and Hygiene Division	Central Livestock Hygiene Service Centre	Aichi
Dr. Masao Yamamoto	Director, Advanced Disease Diagnosis Division	Central Livestock Hygiene Service Centre	Aichi
Dr. Norie Sugie	Assistant Disease Diagnosis Group Advanced Disease Diagnosis Division	Central Livestock Hygiene Service Centre	Aichi
Dr. Atsunori Sugimoto	Assistant Director, Planning and Coordination/ Special Infectious diseases Group, Advanced Disease Diagnosis Div	Central Livestock Hygiene Service Centre	Aichi
Dr. Masaya Matsuda	Assistant Director, Livestock Hygiene Group Toyota-Kamo Branch Office	Central Livestock Hygiene Service Centre	Aichi
Dr. Junichi Matsui	Assistant Director, Livestock Hygiene Group Livestock Industry Division, Aichi prefectural government	Central Livestock Hygiene Service Centre	Aichi
Dr. Akemi Kaneko	Assistant Director, Livestock Hygiene Group Livestock Industry Division, Aichi prefectural government	Central Livestock Hygiene Service Centre	Aichi
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Dr. Tomoyuki Takehisa	Deputy Director, International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF	Fukushima
Eimei Sato (PhD)	President	NLBC	Fukushima
Shizuo Sekimura	Director, Planning and Coordination Dept	NLBC	Fukushima
Ms Hiroko Takashima	NLBC	NLBC	Fukushima
Dr HirooShimamori	Director, Cattle ID Dept	NLBC	Fukushima



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YamaguchiManagement DivisionKagoshima PrefectureCDr AtsushiAssistant Director, HygieneKagoshima PrefectureKagoshimaMa EikoOfficer, Hygiene ManagementKagoshima PrefectureKagoshimaDr YoshihiroDirector, Hygiene and EnvironmentAira Public Health CentreKagoshimaMr TomoyukiAssistant Director, Hygiene and Environment DivisionAira Public Health CentreKagoshimaDr ShinichiDirector-GeneralSueyoshi Meat InspectionKagoshimaDr HitoshiDeputy Director-GeneralSueyoshi Meat InspectionKagoshimaDr Kouji KuriwakiDirector, First Inspection DivisionSueyoshi Meat InspectionKagoshimaDr Kouji KuriwakiDirector, Second InspectionSueyoshi Meat InspectionKagoshimaDr HitoshiDirector, Laboratory test DivisionSueyoshi Meat InspectionKagoshimaDr TakayaVeterinary OfficerSueyoshi Meat InspectionKagoshimaDr YoshihaaDirector, Laboratory test DivisionSueyoshi Meat InspectionKagoshimaDr YashinoiVeterinary OfficerSueyoshi Meat InspectionKagoshimaDr YashinoiVeterinary OfficerSueyoshi Meat InspectionKagoshimaDr YashinoiVeterinary OfficerSueyoshi Meat InspectionKagoshimaDr YashinoiVeterinary OfficerSueyoshi Meat InspectionKagoshimaDr YashinoiVeterinary OfficerNanchiku Co., Ltd.KagoshimaMr TayoshiManaging DirectorNanchiku Co., Ltd.KagoshimaM			Kagoshima Prefecture	Kagoshima
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Ms Eiko Shimodouzono         Officer, Hygiene Management Division         Kagoshima Prefecture         Kagoshima           Shimodouzono         Director, Hygiene and Environment Division         Aira Public Health Centre         Kagoshima           Mr Tomoyuki         Assistant Director, Hygiene and Environment Division         Aira Public Health Centre         Kagoshima           Dr Shinichi Haruguchi         Director-General         Sueyoshi Meat Inspection Centre         Kagoshima           Dr Hioshi Uchiohkubo         Deputy Director-General         Sueyoshi Meat Inspection Centre         Kagoshima           Dr Kouji Kuriwaki         Director, First Inspection Division         Sueyoshi Meat Inspection Centre         Kagoshima           Dr Hioshi Mawabata         Division         Sueyoshi Meat Inspection Centre         Kagoshima           Dr Takaya Yoshioka         Director, Laboratory test Division         Sueyoshi Meat Inspection Centre         Kagoshima           Dr Yoshihisa Hayashi         Veterinary Officer         Sueyoshi Meat Inspection Centre         Kagoshima           Dr Yoshiokia         Veterinary Officer         Sueyoshi Meat Inspection Centre         Kagoshima           Dr Yoshio Kitano         Senior Managing Director         Nanchiku Co., Ltd.         Kagoshima           Mr Tsuyoshi Yaekura         Managing Director         Nanchiku Co., Ltd.         Kagoshima	Dr Atsushi	Assistant Director, Hygiene	Kagoshima Prefecture	Kagoshima
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Dr Hitoshi KawabataDirector, Second Inspection DivisionSueyoshi Meat Inspection CentreKagoshimaDr Takaya YoshiokaDirector, Laboratory test DivisionSueyoshi Meat Inspection CentreKagoshimaDr Rie HayataVeterinary OfficerSueyoshi Meat Inspection CentreKagoshimaDr Yoshihisa HayashiVeterinary OfficerSueyoshi Meat Inspection CentreKagoshimaDr Takeshi YoshinoVeterinary OfficerSueyoshi Meat Inspection CentreKagoshimaDr Yoshihisa HayashiVeterinary OfficerSueyoshi Meat Inspection CentreKagoshimaDr Takeshi YoshinoVeterinary OfficerSueyoshi Meat Inspection CentreKagoshimaDr Yoshio KitanoSenior Managing DirectorNanchiku Co., Ltd. (Meat processing company with slaughter house)KagoshimaMr Tsuyoshi YaekuraDirector, Quality Control DivisionNanchiku Co., Ltd. (Meat processing company with slaughter house)KagoshimaMr Shinya FuruchiDeputy Director, Quality Control DivisionNanchiku Co., Ltd. (Meat processing company with slaughter house)KagoshimaMr Shinya FuruchiDeputy Director, Quality Control DivisionNanchiku Co., Ltd. (Meat processing company with slaughter house)KagoshimaDr Mitsuaki Goda Toshikatsu ItoHead Veterinarian Head, Aichi federation of economic organizationsGoda poultry clinicAichiDr Osamu EguchiVeterinarian, Aichi federation of economic organizationsInstitute of sanitary affairs of agricultural productsAichi <td></td> <td>Director, First Inspection Division</td> <td>Sueyoshi Meat Inspection</td> <td>Kagoshima</td>		Director, First Inspection Division	Sueyoshi Meat Inspection	Kagoshima
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HayashiVeterinary OfficerCentreDr Takeshi YoshinoVeterinary OfficerSueyoshi Meat Inspection CentreKagoshimaDr Yoshio KitanoSenior Managing DirectorNanchiku Co., Ltd. (Meat processing company with slaughter house)KagoshimaMr Tsuyoshi YaekuraManaging DirectorNanchiku Co., Ltd. (Meat processing company with slaughter house)KagoshimaMr Mitsunori TsurudaDirector, Quality Control DivisionNanchiku Co., Ltd. (Meat processing company with slaughter house)KagoshimaMr Shinya FuruichiDeputy Director, Quality Control DivisionNanchiku Co., Ltd. (Meat processing company with slaughter house)KagoshimaDr Mitsuaki GodaHead VeterinarianGoda poultry clinicAichiToshikatsu ItoHead, Aichi federation of economic organizationsInstitute of sanitary affairs of agricultural productsAichiDr Osamu EguchiVeterinarian, Aichi federation of economic organizationsInstitute of sanitary affairs of agricultural productsAichi	Dr Rie Hayata	Veterinary Officer		Kagoshima
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Dr Osamu Eguchi         Veterinarian, Aichi federation of economic organizations         Institute of sanitary affairs of agricultural products         Aichi           Masabito Nomura         Aichi         Aichi         Aichi         Aichi		Head, Aichi federation of economic	Institute of sanitary affairs of	Aichi
Masabito Nomura Aichi	Dr Osamu Eguchi	Veterinarian, Aichi federation of	Institute of sanitary affairs of	Aichi
	Masahito Nomura			Aichi

	Monday 24 0	October	
Dr John Stratton	OIE Team		Tokyo
Dr Julie Punderson	OIE Team		Tokyo
Dr John Weaver	OIE Team Leader		Tokyo
Dr Minoru Yamamoto	Director General	NVAL	Tokyo
Dr Koji Oishi	Director	NVAL	Tokyo
Dr Yasuaki Ogikubo	Director, Planning and Coordination	NVAL	Tokyo
Dr Mayumi Kijima	JVARM Section leader	NVAL	Tokyo
Dr Kinya Yamomoto	Planning and Coordination	NVAL	Tokyo
Sr Satoshi Inoue	Chief, Laboratory of Transmission Control of Zoonosis	NIID	Tokyo
Dr Keigo Shibayama	Director, Dept of Bacteriology	NIID	Tokyo
Dr Kazushi Yamauchi	Director, Planning and Coordination	NIID	Токуо
Dr Yuko Kumagai	Director, Division of International Cooperation	NIID	Токуо
	Tuesday 25 (	October	
Dr John Stratton	OIE Team		Tokyo
Dr Julie Punderson	OIE Team		Tokyo
Dr Toshinobu Koga	Manager of Secretariat	JVMA	Tokyo
Dr Atsushi Fukuda	Veterinary Affairs	JVMA	Tokyo
Dr Masato Sakai	Executive Director	JVMA	Tokyo
Mr Yoshiki Saitou	President, Feed & Livestock Products	JA / ZEN-NOH	Tokyo
Dr Gorou Suzuki	Attaché to General Manager	JA / ZEN-NOH	Tokyo
Hiroshi Yonekura	General Manager, Feed & Livestock Products	JA / ZEN-NOH	Tokyo
Dr Narutoshi Ochiai	General Manager, Institute of Animal Health	JA / ZEN-NOH	Tokyo
Dr Takanori Namimatsu	Chief Manager, R&D, Institute of Animal Health	JA / ZEN-NOH	Tokyo
Dr Katsuyoshi Uruno	Chief Manager, Diagnostic Centre, Institute of Animal Health	JA / ZEN-NOH	Tokyo
	Wednesday 26 October	r. Closina Meetina	
Dr John Weaver	OIE Team Leader	,	
Dr Julia Punderson	OIE Team		Токуо
Dr Norio Kumagai	Chief Veterinary Officer Director, Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF	Токуо
Dr Kazuo Ito	OIE Delegate & Director of International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr Tatsumi Okura	Deputy Director, International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo

Dr Yosuke Yamaki	Deputy Director, International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF	Токуо
Dr Yuichi Kishita	Deputy Director, Animal Disease Control and Prevention Office, Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr. Tomoyuki Takehisa	Deputy Director, International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr Kiyohisa Kamomae	Assistant Director, International Animal Health Affairs Office, Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr Saki Segami	Animal Health Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr. Akemi Kamakawa	Principal Officer, AQS	MAFF	Tokyo
Dr Satoshi Maema	Deputy Director Animal Products Safety Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr Akiko Oishi	Deputy Director, Animal Products Safety Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo
Dr Takashi Morigaki	Deputy Director, Animal Products Safety Division, Food Safety and Consumer Affairs Bureau	MAFF	Tokyo

### Appendix 4a: Timetable of the mission and sites/ facilities visited

Date	Assessor	Time	Location	Activities
11/10	All	AM	Tokyo	Opening meeting; Outline of the OIE PVS process; itinerary
			-	confirmation
			Tokyo	Courtesy visit to Vice Minister for International Affairs
			Tokyo	Overview of Japan VS
			Tokyo	Explanation of Ministries; Ministry of Agriculture, Forestry
				and Fisheries(MAFF)
		PM	Tokyo	Animal disease control, Animal Products Safety, Animal
				Quarantine Service, Veterinary Affairs, VMP, feed safety
			Tokyo	Ministry of Environment (Wild Life)
12/10	All	AM	Tokyo	MAFF (excluding Animal Health Division and Animal
				Products Safety Division)
			Tokyo	Food Safety- Ministry of Health, Labour and Welfare
		<b>D</b> 14		(MHLW)- zoonosis; meat inspection
		PM	Tokyo	Ministry of the Environment – AI surveillance in wild birds
			Taluxa	Livestock Production Promotion Division
			Tokyo	Cattle ID and traceability system
13/10	All	AM	Tokyo Ibaraki	Food Safety Commission KSC Pharmaceuticals
13/10	All	Alvi	Ibaraki	NIAH / NARO
		PM	Saitama	FAMIC
14/10	JP/JS	AM	Tokyo	NOSAI, MAFF
14/10	JF/JO		Tokyo	JLIC
	JW	AM	Tokyo	Meetings with Animal Health Division
	All	PM	Tokyo	
			Tokyo	University of Tokyo School of Veterinary Medicine
			Tokyo	JSVS
			Tokyo	OIE Regional Office
15/10	All		Tokyo	Information review
16/10	All		Tokyo	Begin drafting report
	JP	PM	Tokachi	Transfer Tokyo to Tokachi
	JS	PM	Miyazaki	Transfer Tokyo to Miyazaki
17/10	JP	AM	Tokachi	LHSC
		PM	Tokachi	NOSAI veterinary clinic
			Obihiro	Public Health Centre
	JW	AM	Osaka	Osaka Prefecture University Veterinary School
		PM	Osaka	Osaka LHSC
			Kansai	Kansia Airport AQS
	JS	AM	Miyazaki	Miyazaki prefecture- animal health
			Miyazaki	Miyazaki food safety
		PM	Miyazaki	Miyazaki Livestock Industry Association
18/10	JP	AM	Tokachi	Yotsuba Milk Processing Centre
		PM	Hokuren	Hokkaido Ag Cooperative livestock market
	JW	AM	Osaka	Osaka prefecture- AH
		<b>D</b> 14	Osaka	Osaka prefecture wildlife and animal welfare
		PM	Osaka	Osaka sub-branch AQS
	JS	AM	Miyazaki	Miyazaki NOSAI veterinary clinic and laboratory
		PM	Miyazaki	Miyazaki FMD memorial centre
10/10		A N A	Miyazaki	Miyazaki central agricultural cooperative livestock market
19/10	JP	AM	Sapporo	Courtesy visit prefectural agricultural offices
			Sapporo	Hokkaido prefecture government- AH
		PM	Sapporo	Hokkaido prefecture wildlife (MoE)
		Iwate	Flight from Sapporo to Iwate	

	JW	AM	Osaka	Transfer Osaka to Aichi	
		PM	Aichi	Aichi prefecture AH	
	JS	AM	Miyazaki	Miyazaki Uviversity Veterinary School	
		PM	Kagoshima	Transfer to Kagoshima	
20/10	:0/10 JP		Iwate	Iwate prefecture Livestock Division/Public Health Division	
			Iwate	Iwate Meat Inspection Centre	
		PM	Iwate	Slaughterhouse, processing and retail facility	
			Iwate	Beef feedlot/farm	
	JW	AM	Aichi	Feed manufacturing	
		PM	Chubu	Chubu AQS airport branch	
	JS	AM	Kagoshima	Kagoshima prefecture government offices- AH	
			Kagoshima	Kagoshima wildlife management	
		PM	Kagoshima	Pig farm	
			Kagoshima	Kagoshima Central LHSC	
21/10	/10 JP AM		Iwate	Transfer by train to Fukushima	
	JW	PM Fukushima		NLBC, national cattle ID and traceability centre	
			Fukushima	NLBC experimental farm beef feedlot	
		AM	Aichi	Aichi Central LHSC	
		PM	Aichi	Private veterinarian	
			Aichi	Private laboratory	
	JS	AM	Kagoshima	Kagoshima public health cenre	
		PM	Kagoshima	Kagoshima MIC	
			Kagoshima	Slaughterhouse and processing facility	
22/10	All		Tokyo	Information synthesis	
23/10	All		Tokyo	Draft report	
24/10	JW	AM	Tokyo	NVAL	
			Tokyo	NIAH	
	JS/JP	AM	Tokyo	Meetings with Animal Health Division	
25/10	JS/JP	PM	Tokyo	JVMA	
	JS/JP	PM	Tokyo	National Federation of Agricultural Cooperative Associations	
	JW		Tokyo	Meetings with Animal Health Division	
26/10	JP/JW	AM	Tokyo	Closing meeting	

### Appendix 4b: Timetable of the mission and sites/ facilities visited

				*Please be advised this schedule may be	e subject to change.	
Date Organisations						
Sun	9	*Dr Julia Punderson arrives in Tokyo			Tokyo	
Mon	10	*Dr John Weaver and Dr John Stratton arriv	es in Tokyo		Tokyo	
Tue	11	Courtesy call Animal Health Division, Animal Quarantine Service, Animal Products Safety Division, Ministry of Agriculture, Forestry and Fisheries Office of Wildlife Management, Ministry of the Environment			Tokyo	
Wed	12	Tuberculosis and Infectious Disease Control Division, Inspection and Safety Division, Ministry of Health, Labour and Welfare Office of Animal Companionship, MoE Livestock Production Promotion Division, MAFF Food Safety Commission				
Thu	13	Pharmaceutical company, National Institute of Animal Health, Food and Agricultural Materials Inspection Center				
Fri	14	Agricultural Insurance Supervisor, MAFF and NOSAI Japan Livestock Industry Association, Tokyo University (OIE Regional Representation for Asia and the Pacific)			Tokyo	
Sat	15					
Sun	16	(Dr Julia Punderson)		(Dr John Stratton)		
Mon	17	<northern area=""></northern>	(Dr John Weaver)	<sothern area=""> Miyazaki Prefecture</sothern>		
Tue	18	Hokkaido Prefecture	<central area=""></central>			
Wed	19	Iwate Prefecture National Livestock Breeding Center in	Osaka Prefecture	Kagoshima Prefecture	-	
Thu	20	Fukushima	Aichi Prefecture Animal Quarantine Service			
Fri	21		Feed manufacturing company			
Sat Sun	22 23					
Mon	24	National Veterinary Assay Laboratory, MAFF National Institute of Infectious Diseases, MHLW			Tokyo	
Tue	25	Japan Veterinary Medical Association National Federation of Agricultural Cooperative Associations *Dr John Stratton leaves Japan			Tokyo	
Wed	26	Closing meeting *Dr John Weaver leaves Japan				
Thu 27 *Dr Julia Punderson leaves Japan					Tokyo	
*Details in next pages						

Schedule of OIE PVS Team in Japan (as of 5 October 2016)

#### Tokyo area (for Dr John Weaver, Dr John Stratton and Dr Julia Punderson)

	Organisation	Location				
Tuesday, 11 October						
9:30am	(Leave the hotel) (Transfer by car)					
10:00am – 11:30am	10:00am – 11:30am Courtesy call on Vice-Minister for International Affairs Animal Health Division, MAFF					
	(Lunch provided by MAFF)	(MAFF)				
0:30pm – 2:30pm	Animal Health Division & Animal Quarantine Service, MAFF	MAFF				
	(Break)					
2:40pm – 4:40pm	Animal Products Safety Division, MAFF (veterinary affairs, veterinary medicines and biologicals, animal feed safety)	MAFF				
	(Break)					
4:50pm – 6:00pm	Office of Wildlife Management, Ministry of the Environment (surveillance for Avian Influenza in wild birds)	MAFF				
	(Transfer by car)					
7:00pm – 9:00pm	Official dinner	(near the hotel)				
Wednesday, 12 Octob	er					
9:30am	(Leave the hotel) (Transfer by car)					
10:00am – 11:00am	Tuberculosis and Infectious Disease Control Division, Ministry of Health, Labour and Welfare (zoonosis)	MAFF				
11:00am – 12:00am	Inspection and Safety Division, MHLW (food safety administration including meat inspection)	MAFF				
	(Lunch provided by MAFF)	(MAFF)				
1:30pm – 4:00pm	Office of Animal Companionship, MoE Livestock Production Promotion Division, MAFF (Animal Welfare)	MAFF				
	(Transfer by car)					
5:00pm – 6:00pm	Food Safety Commission (risk assessment of food safety)	FSC (Tokyo)				
6:30pm	(Transfer by car) Arrival at the hotel					





Tokyo area (for <u>Dr</u> John Weaver, <u>Dr</u> John Stratton and <u>Dr</u> Julia <u>Punderson</u> )				
	Organisation	Location		
Thursday, 13 October				
6:45am	(Leave the hotel) (Transfer by public transportation (train))			
9:00am – 10:50am	Kyoritsu Seiyaku Corporation (pharmaceutical company)	KSC (Ibaraki)		
	(Transfer by car)			
11:20am – 2:40pm	National Institute of Animal Health (national reference laboratory) with lunch provided by MAFF	NIAH (Ibaraki)		
	(Transfer by car)			
4:30pm – 5:50pm	Food and Agricultural Materials Inspection Center (inspection of feed and feed additive manufacturers and importers)	FAMIC (Saitama)		
	(Transfer by public transportation (train))			
7:00pm	Arrival at the hotel			
Friday, 14 October				
9:30am	(Leave the hotel) (Transfer by car)			
10:00am – 11:30am	Agricultural Insurance Supervisor, MAFF NOSAI (livestock insurance and nation-wide veterinary clinics)	MAFF		
11:00am – 12:00am	(Lunch provided by MAFF)	(MAFF)		
1:00pm	(Leave MAFF) (Transfer by car)			
1:30pm – 3:00pm	Japan Livestock Industry Association	JLIA (Tokyo)		
	(Transfer by car)			
3:30pm – 4:30pm	University of Tokyo	UT (Tokyo)		
4:30pm –	OIE Regional Representation for Asia and the Pacific	OIE RR (Tokyo)		
	(Transfer by public transportation (train) to the hotel)			





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Japan
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#### Tokyo area (for Dr John Weaver, Dr John Stratton and Dr Julia Punderson)

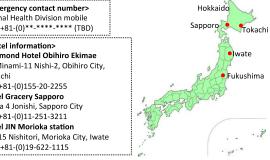
	Organisation	Location
Monday, 24 October		
8:30am	(Leave the hotel) (Transfer by public transportation (train))	
10:00am – 12:00am	National Veterinary Assay Laboratory, MAFF (approval and inspection of animal medicines and biologicals)	NVAL (Tokyo)
	(Transfer by public transportation (train) and Lunch)	
2:30pm – 4:30pm	National Institute of Infectious Diseases, MHLW (laboratory for human infectious diseases including zoonosis)	NIID (Tokyo)
	(Transfer by car)	
5:00pm	Arrival at the hotel	
Tuesday, 25 October		
9:30am	(Leave the hotel) (Transfer by car)	
10:00am – 12:00am	Japan Veterinary Medical Association	JVMA (Tokyo)
	(Transfer by car)	
0:30pm – 1:30pm	(Lunch provided by MAFF)	(MAFF)
3:00pm	(Transfer by car)	
3:30pm – 4:30pm	National Federation of Agricultural Cooperative Associations	ZEN-NOH (Tokyo)
4:45pm	(Transfer by car) Arrival at the hotel	
	Dr John Stratton leaves for Haneda Airport	
Wednesday, 26 Octob	er	
9:30am	(Leave the hotel) (Transfer by car)	
10:00am – 12:00am	Closing meeting	MAFF
	(Lunch provided by MAFF)	(MAFF)
	Dr John Weaver leaves for Narita Airport	
Thursday, 27 October		
	Dr Julia Punderson leaves for Narita Airport	



Note – On Tuesday 25 October the team ended up having further discussions with MAFF in the morning and travelling to the Japan Veterinary Medical Association in the afternoon.

Sunday, 16 October		Thursday, 20 Octo
3:10pm	(Leave the hotel) (Transfer by public transportation (train) to the airport)	8:00
4:55pm – 6:30pm	(Flight from Haneda Airport to Tokachi-Obihiro Airport (ANA4767))	8:30am – 10:10
7:20pm	(Transfer by public transportation (bus)) Arrival at the hotel in Tokachi	11:20am – 12:00
Monday,17 October		
8:30am	(Leave the hotel) (Transfer by car)	1:20pm – 3:00
9:00am – 11:00pm	Tokachi Livestock Hygiene Service Center	
	(Lunch) (Transfer by car)	3:30pm – 4:00
1:00 pm – 3:00pm	NOSAI veterinary clinic	5:00
	(Transfer by car)	Friday, 21 October
3:30pm – 5:30pm	Public health center	9:30
5:40pm	(Transfer by car) Arrival at the hotel in Tokachi	
Tuesday,18 October		
8:30am	(Leave the hotel) (Transfer by car)	1:30pm – 4:00
9:00pm – 11:00pm	Milk processing factory	6:50
	(Lunch) (Transfer by car)	
1:00pm – 3:00pm	Hokkaido Agricultural Cooperative livestock market	
7:20pm	(Transfer by car and public transportation (bus)) Arrival at the hotel in Sapporo	<b>Emergency conta</b> Animal Health Divi TEL: +81-(0)**-***
Wednesday, 19 Octobe	er	<hotel information<="" td=""></hotel>
9:10am	(Leave the hotel)	Richmond Hotel O
9:30am- 14:00pm	Hokkaido prefectural government (Animal health related division, Wildlife related division), Hokkaido Livestock Industry Association (with lunch break)	17 Minami-11 Nish Tokachi Tel: +81-(0)155-20
	(Lunch) (Transfer by public transportation (train and flight)) Shin-Chitose Airport (4:25pm) to Iwate-Hanamaki Airport (5:10pm) (JAL2839).	Hotel Gracery Sap 4 Kita 4 Jonishi, Sa Tel: +81-(0)11-251 Hotel JIN Morioka
6:20pm	(Transfer by public transportation (bus)) Arrival at the hotel in Iwate	1-6-15 Nishitori, M TEL: +81-(0)19-622

Thursday, 20 October				
8:00am	(Leave the hotel) (Transfer by car)			
8:30am – 10:10am	lwate prefectural government (Animal health related division, Food safety related division)			
	(Transfer by car)			
11:20am – 12:00am	Meat inspection center			
	(Lunch) (Transfer by car)			
1:20pm – 3:00pm	Slaughter house including meat processing factory			
	(Transfer by car)			
3:30pm – 4:00pm	Cattle farm			
5:00pm	(Transfer by car) Arrival at the hotel in Iwate			
Friday, 21 October				
9:30am	(Leave the hotel) (Transfer by public transportation (train			
	(Lunch)			
1:30pm – 4:00pm	National Livestock Breeding Center in Fukushima (animal identification and traceability)			
6:50pm	(Transfer by public transportation (train)) Arrival at the hotel in Tokyo			





#### Central area (for Dr John Weaver)

Monday,17 October				
5:30pm	(Leave the hotel) (Transfer by public transportation (train) to the airport)			
7:15am – 8:35am	(Flight from Haneda Airport to Kansai Airport (JAL221))			
	(Transfer by car)			
9:30am – 2:30pm	Osaka Prefectural University, Osaka Livestock Hygiene Service Center (with lunch break)			
	(Transfer by car)			
3:00pm – 5:00pm	Kansai Airport Branch, Animal Quarantine Service			
6:30pm	(Transfer by public transportation (train)) Arrival at the hotel in Osaka			
Tuesday,18 October				
9:00am	(Leave the hotel) (Transfer by car)			
10:00am – 12:00am	Osaka prefectural government (Animal health related division, Wildlife and Animal welfare related division)			
	(Lunch) (Transfer by car)			
1:30pm – 5:00pm	Osaka Sub-branch, Animal Quarantine Service			
5:40pm	(transfer by car) Arrival at the hotel in Osaka			
Wednesday, 19 October				
10:00am	(Leave the hotel) (Transfer by public transportation (train))			
	(Lunch)			
1:30pm – 3:30pm	Aichi prefectural government (Animal health related division)			
4:00pm	(Transfer by public transportation (train)) Arrival at the hotel in Aichi			

Thursday, 20 October				
8:30am	(Leave the hotel) (Transfer by car)			
9:30am – 12:00am	Feed manufacturing company			
	(Lunch) (Transfer by car)			
1:30pm – 4:30pm	Chubu Airport Branch, Animal Quarantine Service			
6:00pm	(Transfer by car) Arrival at the hotel in Aichi			
Friday, 21 October				
8:30am	(Leave the hotel) (Transfer by car)			
9:30am – 11:30am	Aichi Central Livestock Hygiene Service Center			
	(Lunch) (Transfer by car)			
0:30pm – 2:30pm	Private veterinarian, Private laboratory			
	(Transfer by car)			
3:00 pm – 4:00pm	Chicken farm			
8:00pm	(Transfer by public transportation (train)) Arrival at the hotel in Tokyo			



<Hotel information>
KEIHAN TENMANBASHI, 1-2-10 Tanimachi, Osaka City, TEL: +81-(0)6-6945-0321
Dai-ni Fuji Hotel, 2-10-24 Higashisakura, Nagoya City TEL: +81-(0)5-2931-1111

<Emergency contact number>

Animal Health Division mobile TEL: +81-(0)\*\*\_\*\*\*\*\_\*\*\*\* (TBD)

#### Southern area (for Dr John Stratton)

Sunday, 16 October (Leave the hotel) (Transfer by public transportation (train) 2:20pm to the airport) (Flight from Haneda Airport to Miyazaki Airport (ANA613)) 4:25pm – 6:10pm (Transfer by public transportation (bus)) 7:20pm Arrival at the hotel in Miyazaki Monday,17 October 8:40am (Leave the hotel) (Transfer by car) Mivazaki prefectural government (Animal health related division, Food safety related 9:00am – 12:00am division) (Lunch) (Transfer by car) 1:30pm – 3:30pm Miyazaki Livestock Industry Association 3:50pm (Transfer by car) Arrival at the hotel in Miyazaki Tuesday,18 October (Leave the hotel) (Transfer by car) 8:30am NOSAI related facilities (NOSAI laboratory center, NOSAI 9:30pm - 11:30pm veterinary clinic, etc.) (Lunch) (Transfer by car) 1:00pm - 2:00pm FMD's Memorial Center (Transfer by car) 3:00pm – 5:00pm Miyazaki Central Agricultural Cooperative livestock market (Transfer by car) Arrival at the hotel in Miyazaki 5:30pm Wednesday, 19 October 9:30am (Leave the hotel) (Transfer by car) 10:00am- 12:00am Miyazaki University (Lunch) (Transfer by car) 3:30pm Arrival at the hotel in Kagoshima

Thursday, 20 October					
8:30am	(Leave the hotel) (Transfer by car)				
9:00am – 11:00am	Kagoshima prefectural government (Animal health related division, Wildlife related division)				
	(Lunch) (Transfer by car)				
1:00pm – 2:30pm	Pig farm				
	(Transfer by car)				
3:30pm – 5:00pm	Kagoshima Central Livestock Hygiene Service Center				
	(Transfer by car)				
6:10pm	6:10pm (Transfer by car) Arrival at the hotel in Kagoshima				
Friday, 21 October					
9:00am	(Leave the hotel) (Transfer by car)				
10:00am – 11:00am Public health center					
	(Lunch) (Transfer by car)				
1:00pm – 4:00pm	Meat inspection center and slaughterhouse including meat processing factory				
	(Transfer by car)				
7:30 pm – 9:25pm (Flight from Kagoshima Airport to Haneda Airport (ANA630))					
10:30pm	10:30pm (Transfer by public transportation (train)) Arrival at the hotel in Tokyo				
<emergency contact="" number=""></emergency>					

<**Emergency contact number>** Animal Health Division mobile TEL: +81-(0)\*\*\_\*\*\*\*\_\*\*\*\* (TBD)



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ASSESSOR	DATE	From	То	Flight No.	Departure	Arrival
J Weaver	10 Oct	Jakarta	Tokyo	JL720	0645	1625
	17 Oct	Tokyo	Kansai	JL221	0715	0835
	30 Oct	Tokyo	Jakarta	JL729	1800	0010
						+1D
J Stratton	9 Oct	Paris	Tokyo	AF276	1355	0830 +
						1D
	16 Oct	Tokyo	Miyazaki	AN613	0625	1810
	21 Oct	Kagoshima	Tokyo	AN630	1930	2125
	25 Oct	Tokyo	Paris	AF293	2255	0455
J Punderson	8 Oct	Baltimore	Chicago	JL7321	0800	0917
		Chicago	Tokyo	JL009	1235	1535+1D
	16 Oct	Tokyo	Tokacki	ABA4767	1655	1830
	19 Oct	Sapporo	Iwate	JA2839	1625	1710
	27 OCT	Tokyo	Chicago	JL010	1110	0855
		Chicago	Baltimore	JL7686	1145	1442

## Appendix 5: Air travel itinerary

### Appendix 6: List of documents used in the PVS evaluation

E = Electronic version

H = Hard copy version

P = Digital picture

Ref	Title	Author / Date / ISBN / Web	Related critical competences
	PRE-MISSION DOCUMENTS		•
E1	Baseline information	MAFF, 2016	~ all
E2	Data on animal hygiene	MAFF, 2016	II-7
E3	Apx. 1-2 (Data on animal hygiene)	MAFF, 2016	II-1B
E4	Apx. 2-1_Rinderpest_Holding _Facilities_letter	OIE, 2015	II-1B
E5	Apx. 2-2_Japan report Tsukuba final_A_NVAL&AHDmod&NIAH	OIE, 2015	II-1B
E6	Apx. 2-3_Japan report Kodaira Final_B_AHDmod&NIAH	OIE, 2015	II-1B
E7	Apx 1_a_1_Guideline_for_Control_of_FMD	MAFF, 2016	II-6, II-7
E8	Apx _a_4_Guideline_for_Control_of_ASF	MAFF, 2016	II-6, II-7
E9	Apx _a_4_Guideline_for_Control_of_CSF	MAFF, 2016	II-6, II-7
E10	Apx _a_4_Guideline_for_Control_of_BSE	MAFF, 2016	II-6, II-7
E11	Apx 1_a_5_Guideline_for_Control_of_NAI	MAFF, 2016	II-6, II-7
	MISSION DOCUMENTS		
E12	Enforcement of Domestic Animal Infectious Disease Control Law (Ordinance No. 35 of 1951) Chapter	GoJ, 1952 as amended	IV-2
E13	Act on Domestic Animal Infectious Diseases Control No. 166, (Amendment: May 8, 2012 Act No. 30)	GoJ, 1951 & 2012	II-6, II-7, IV-2
E14	Government Ordinance for Enforcement of the Act on Domestic Animal Infectious Diseases Control; Ordinance No. 235, 1953	GoJ, 1953	II-6, II-7, IV-2
E15	Ministerial Ordinance for Enforcement of the Act on Domestic Animal Infectious Diseases Control; General Provisions No. 35, 1953	MAFF, 1953	II-6, II-7, IV-2
E16	compensatory funding arrangements_1_b_4	Japanese only	I-9, II-6
E17	compensatory funding arrangements	Japanese only	I-9, II-6
E18	Activity reports (last 2 years) of epidemiological surveillance programme	MAFF 2016	II-5B
E19	Nationwide Surveillance (FY 2015) Domestic Animal Infectious Disease Prevention Program	MAFF 2016	II-5B
E20	Surveillance testing FY 2015 Domestic Animal Infectious Disease Prevention Program 2_a_3	MAFF 2016	II-5B
E21	Surveillance testing by prefecture FY 2015 2_a_4	MAFF 2016	II-5B
E22	Surveillance testing by prefecture FY 2014 2_a_5	MAFF 2016	II-5B
E23	Report of the domestic animal infectious diseases by Prefecture • 2015	MAFF 2016	II-5B
E24	FMD passive surveillance activities 2014- 2015	MAFF 2016	II-5A
E25	Outline of Domestic Animal Health Control Measures, 1999	MAFF 1999	II-6, II-7
E26	Abattoir Inspection Guidelines, 1972 as updated 2004	MHLW 2004	II-8
E27	Poultry Meat Inspection Implementation Guidelines, 1992	MHLW 1992	II-8
E28	BSE guidelines (Japanese only)	MAFF	II-7

E29	Food hygiene guidelines 2_b_4 (Japanese only)	MHLW	II-8
E30	Tri-ministerial cooperation 2_b_5_aa12	MAFF, MHLW, MoE	I-6A&B, II-6
E31	HPAI 2014-2015 2_b_6	MAFF, MHLW 2015	II-5, II-6, II-7
E32	2014 HPAI species (Japanese only)2_b_7	MAFF, MHLW 2015	11-6, 11-7
E33	Veterinary medicines and veterinary biologicals 2_b_8_ah13	MAFF	II-9
E34	Ranking of the Importance of Antimicrobials against Bacteria which affect Human Health through Food Commodities, 2006 updated 2014	FSCJ, 2014	II-3, II-9
E35	Report on the Japanese Veterinary Antimicrobial Resistance Monitoring System -2012 to 2013	NVAL, 2016	II-3, II-9
E36	Vaccination details (Japanese only)	MAFF	II-7
E37	AQS organisation chart 2_d_1_ad010_8- 2	AQS, 2016	11-4
E38	animal indeintification2_e_1_ah06	MAFF	II-12A
E39	Animal Welfare-oriented Beef Cattle Management Standards	JLTA, 2011	II-13, IV-3
E40	Animal Welfare-oriented Swine Management Standards	JLTA, 2011	II-13, IV-3
E41	Animal Welfare-oriented Egg-laying Hen Management Standards	JLTA, 2011	II-13, IV-3
E42	International certification (Japanese only)	MAFF	IV-4
E43	International certification (Japanese only)	MAFF	IV-4
E44	List of animal health requirements $3_2_1$	MAFF	II-4, IV-4
E45	Access to markets; certification and verification	MAFF	IV-4
E46	Act for Establishment of the Ministry of Agriculture, Forestry and Fisheries (Act No. 98, July 16, 1999, as amended 2016)	MAFF, 2016	IV-1
E47	MAFF Organizational Regulations; No. 139 March 31, 2016	MAFF, 2016	IV-1
E48	Act on the National Agriculture and Food Research Organization (Act No. 192, December 22, 1999, Last amended: Act No. 70, September 18, 2015)	NARO, 2015	IV-1
E49	Act on the Independent Administrative Corporation Food and Agricultural Material Inspection Centre; Act No. 183, December 22, 1999	FAMIC, 1999	I-6B, IV-1
E50	Community Health Law; Act No. 84 of 1994	GoJ 1947	IV-1
E51	Livestock Hygiene Service Centres; Act No. 160, as amended 1999	GoJ 1999	IV-1
E52	Outline of the Law for Partial Revision of the Pharmaceutical Affairs Law (Act No.84 of 2013)	GoJ 2013	II-9, IV-1
E53	Pharmaceutical affairs law, 2009	GoJ 2009	II-9, IV-1
E54	Veterinary License Act (Act No. 186, June 1, 1949) as amended: December 13, 2013 Act No. 103	GoJ 2013	III-5 / IV-1
E55	Veterinary Practice Act (Act No. 46, May 20, 1992) Last amended: Act No. 105, August 30, 2011	GoJ 2011	III-5 / IV-1
E56	Beef Traceability Law	GoJ	II-12 / IV-1
E57	Rabies Prevention Act (August 26, 1950) (LawNo.247, 1956, as amended 1998)	GoJ 1998	II-7 / IV-1
E58	Food Sanitation Act No. 233 of December 24, 1947	GoJ 1947	II-8 / IV-1
E59	Abattoir Law, No. 114, August 1, 1953	GoJ 1953	II-8 / IV-1



		0 10007	
E60	Poultry Slaughtering Business Control	GoJ 2007	II-8 / IV-1
	and Poultry Inspection Law No. 70, June		
	29, 1990 as amended December 27,		
	2007	0 1 4070	
E61	Act on Welfare and Management of Anim	GoJ 1973	II-13 / IV-1
500	als, No. 105 of October 1, 1973		
E62	Outline of the Act for Partial Amendment	GoJ	II-13 / IV-1
	to the Act on Welfare and Management of		
<b>F</b> 00	Animals		
E63	Ministerial Ordinance on the Veterinary	MAFF 2005	III-5 / IV-1
	Affairs Council (Cabinet Order No. 330, September 12,		
	(Cabinet Order No. 330, September 12, 1949)		
	Last amended: Cabinet Order No. 300,		
	September 22, 2005		
E64	Veterinary License Act Implementing	GoJ 2004	III-5 / IV-1
204	Order	000 200 1	
	(Cabinet Order No. 273, August 7, 1992);		
	Last amended: Cabinet Order 37, March		
	17, 2004		
E65	Veterinary License Act Implementing	MAFF 2014	III-5 / IV-1
-	Ordinance; No. 93, September 14, 1949;		
	Last amended as Ordinance No. 58,		
	November 18, 2014		
E66	Act for Establishment of the Ministry of	GoJ	IV-1
	Health, Labour and Welfare (Japanese		
	only)		
E67	Organizational Regulations of the Ministry	GoJ	IV-1
	of Health, Labour and Welfare (Japanese		
	only)		
E68	Act for Establishment of the Ministry of	GoJ	IV-1
	the Environment (Japanese only)		
E69	Organizational Regulations of the Ministry	GoJ	IV-1
	of the Environment (Japanese only)		
E70	Food safety basic act (Japanese only)	GoJ	II-8, IV-1
E71	Livestock Hygiene Service Centres Act	GoJ	II-8, IV-1
E72	(Japanese only)	GoJ	II-9, IV-1
E/2	Law on Securing Quality, Efficacy and	GOJ	11-9, 1V-1
	Safety of Products Including		
	Pharmaceuticals and Medical devices		
	(Japanese only)		
<b>F7</b> 0	Begulations Conving Quality Efficiency	Cal	
E73	Regulations Securing Quality, Efficacy and Safety of Products Including	GoJ	II-9, IV-1
	Pharmaceuticals and Medical devices		
	(Japanese only)		
E74	Outline of VS Japan (PVS evaluation)	MAFF 2016	I-6
E75	Outline of Animal Quarantine Service	AQS 2016	II-4
E76	Outline of veterinary affairs council	MAFF 2016	III-5
E77	Veterinary Affairs Council	MAFF 2016	III-5
E78	Feed Safety and Quality Assurance	FAMIC 2016	II-5 II-11
E79	Summary of the Law for Ensuring the	MAFF 2015	II-9, IV-1, IV-3
	Quality, Efficacy, and Safety of Drugs and		-,
	Medical Devices (Law No. 145 of 1960)		
E80	Outline of Regulation System of	APSD/MAFF 2015	II-9
	Veterinary Medicinal Products		
	(VMPs) in Japan		
E81	Overview of Animal Products Safety	FSC 2016	II-9
	Division, Food Safety and Consumer		
	Affairs Bureau		
	FAMIC brochure	FAMIC 2016	II-11
E82			
E82 E83	Feeds and Feed Additives in Japan -	FAMIC 2016	II-5B, II-9, II-11
E83	Feeds and Feed Additives in Japan - Safety Assurance by FAMIC		
	Feeds and Feed Additives in Japan - Safety Assurance by FAMIC Kyoritsu Seiyaku Corporation	FAMIC 2016 KSC 2016	II-5B, II-9, II-11 II-9
E83	Feeds and Feed Additives in Japan - Safety Assurance by FAMIC		



E86	Food Safety Commission of Japan	FSC presentation	II-3, II-8
E87	Agricultural mutual aid organizations' policies on livestock veterinarians	NAIA, 2016	I-6B, III-6
E88	National Agricultural Insurance Association	NOSAI, 2016	I-6B, II-6, II-7
E89	NOSAI presentation	NOSAI, 2016	I-6B, II-6, II-7
E90	Nosai staff and clinic numbers	NOSAI, 2016	I-1A, II-6, II-7
E91	NOSAI flowchart	NOSAI, 2016	I-1A, II-6, II-7
E92	Act on Authorization of Public Interest	GoJ, 2006	I-6B, IV-1
	Incorporated Associations and Public Interest Incorporated Foundations (Act No. 49 of 2006)		
E93	Cattle Identification and Traceability System in Japan	MAFF 2016	II-12
E94	Guidelines on animal welfare, Notification 85, 2013	MoE 2013	II-13
E95	leaflet of notification to import animal		11-4
E96	pamphlet_animal_welfare	MoE 2007	II-13, III-1
E97	Japan Livestock Industry Association	JLIA	I-6B
E98	Japanese Society for Veterinary Science	JSVS 2016	I-2A
E99	University of Tokyo catalogue	University of Tokyo 2016	I-2A
E100	Law Concerning Standardization, etc. of Agricultural and Forestry Products	GoJ 1950	IV-1
E101	Veterinary school curriculum	University of Tokyo, 2016	I-2A
E102	List of FSC veterinary risk assessments	FSC 2016	II-3, II-9, II-10, II- 11
E103	Methylprednisolone risk assessment	FSC 2016	II-3, II-9, II.10
E103	FSC Food Safety Journal	FSC 2016	II-3, III-1
E104 E105	MHLW brochure on measures to ensure food safety	MHLW 2014	III-1
E106	Hokkaido livestock hygiene 16	MAFF 2016	I-1A
E100	Hokkaido catalogue of hygiene guidance	MAFF 2016	I-6B
E107	Hokuren livestock market	NOSAI 2015	II-7, II-12A
E100	Hokkaido NOSAI	Hokkaido NOSAI 2016	I-6B
E103	NOSAI framework of Japan's agricultural insurance scheme	NOSAI 2016	II-5A, II-6, II-7
E111	Outline of Obihiro Health Centre's Activities (23)	MAFF 2016	I-6A, II-7
E112	Division of Duties at Environmental Health Division, Obihiro Health Centre	MHLW 2016	I-6A
E113	Outline of duties of Hokkaido Tokachi Livestock Hygiene Service Centre	MAFF 2016	II-5A&B, II-7, II-9
E114	Structure and Division of Duties in Hokkaido's Animal Protection and Welfare Management	MHLW 2016	II-13, III-1
E115	Sick and Injured Animal Protection Guidelines- Hokkaido wildlife	MoE	I-6B, II-13
E116	Flow Chart of Wounded Birds and Mammals Rescue Network System	MoE	I-6B, II-13
E117	Manual for Highly Pathogenic Avian Influenza in Wild Birds in Hokkaido	MoE	I-6B, II-6, II-7
E118	Dead Wild Bird Surveillance in Hokkaido	MoE	I-6B, II-6, II-7
E119	National Action Plan on Antimicrobial Resistance (AMR) 2016-2020	GoJ 2016	I-6B, II-9, II-10
E120	National surveillance FY20152_a_2_aa	FSC 2015	I-6A, II-3, II-5B
E121	Outline of relevant laws VS Japan rev4		IV-1
E122	FMD I AI passive surveillance 2_a_7	MAFF 2016	II-5B
E123	Biosecurity standards for cattle, buffalo, deer Annex 23-1	MAFF 2016	II-7
E124	Biosecurity standards for pigs and wild boar Annex 23-2	MAFF 2015	II-7
E125	Guideline for Assessment of the Effect of Food Additives 2010	FSC 2010	II-10



	1		
E126	Brief summary of Activity reports (last 2	MAFF 2016	II-5B
	years) of epidemiological surveillance		
	programme No9_2_a_1		
E127	No9_2_a_2_aa Notification of survey	MAFF 2015	II-5B, II-7
	(National infection disease)		
E128	No9_2_a_3_Active survey results(2014)	MAFF 2014	II-5B, II-7
E129	No9_2_a_4_Active survey results(2015)	MAFF 2015	II-5B, II-7
E130	No9_2_a_8_aa13Surveyü@guidline	MAFF 1999	II-5B, II-7
E131	Guidelines of control measures for	MAFF 2013	II-5B, II-7
	Johne`s/Aujeszky/PED/BVD disease		,
E132	No14_List of livestock industry related	MAFF 2016	I-6B
	associations		
E133	No24 List of conferences with	MAFF 2016	I-3
	prefectures and organizations across		
	Japan		
E134	National Institute of Infectious Diseases	NIID 2014	I-6B, II-7
E135	National Veterinary Assay Laboratory	NVAL 2015	II-9
E136	National Veterinary Assay Laboratory	NVAL 2016	II-9
L130	Laboratory161018	NVAL 2010	11-3
E137		JVMA 2016	I-2A, III-5
E13/	Overview of Japan Veterinary Medical Association		1-2A, III-3
E138	Japanese Agricultural Standards Law of	GoJ 1950	IV-1
E130		G01 1900	14-1
F400	1950	F80 2014	
E139	Risk Assessment for use of enanomycin	FSC 2014	II-3, II-9, II-10
<b>F4 46</b>	in food producing animals		
E140	Food Safety System in Japan	MHLW, 2016	I-2A, II-4, II-
			8A&B&C,
E141	FSC organisation chart	FSC 2016	II-3, II-9
E142	Kagoshima Meat Inspection	MHLW 2016	I-1A, II-8
E143	International Conference on Prevention	NIID, 2013	I-6B, II-7
	and Control of Rabies		
E144	Rabies Control guidelines 2013	MHLW 2013	II-7
	(Japanese only)		
E145	Laboratories permitted for handling the	MAFF 2016	II-1A&B,
	pathogens of the domestic animal		
	infectious diseases and notifiable		
	infectious diseases 2_c		
E146	Hokkaido data 16 outline	MAFF 2016	II-5B, II-7
E147	ZEN-NOH Report 2015	MAFF 2015	II-11
E148	Hokuren livestock requirements 74	MAFF 2016	II-7, II-12A
E149	Obihiro organization (22)	MHLW 2016	I-1A, I-6A,
E150	Environmental Health Division, Obihiro	MOE 2016	II-7
	Health Center		
E151	JA Aichi economic and agricultural and	JA 2016	I-6B
	meat products research institute (41)		
E152	Chuou Livestock Hygiene Service Centre,	Aichi LHSC	I-1A, I-7
	Achi		
E153	Domestic Animal Infectious Disease	Aichi LHSC, 2016	II-7
	Control Initiative	, -	
E154	Guidance for the activities of the Aichi	MAFF 2016	II-7
	Prefectural Livestock Association		-
E155	Aichi Livestock hygiene technical	MAFF 2016	II-7
	guidance initiative		_
E156	Aichi Diagnoses of diseases (57)	MAFF 2016	II-7
E157	Aichi Livestock industry promotion	MAFF 2016	III-1, III-2
	activities (56)		
E158		MAFF 2016	I-3, II-6, II-7
2.50	Aichi Results of Advanced Diagnostic		,,
	Department Operations (58)		
F456			
E159	Aichi Pathological Appraisal Group (59)	MAFF 2016	II-1B, II-7
E160	Aichi Livestock Industry Division	MAFF 2016	II-7, II-9, II-11
	Department of Agriculture, Forestry, and		
	Fisheries		
	Aichi Prefecture		
	I Custing of Livestal Liveiana Comise	MAFF 2016	II-7
E161	Outline of Livestock Hygiene Service Centre in Aichi Prefecture (38)		11-7



E162	Location and Control Area of Aichi	MAFF 2016	I-7
	Prefecture Livestock Hygiene Service		
	Centre (39)		
E163	AQS Division of Exotic Disease	MAFF 2016	II-4, II-7
	Inspection		
E164	AQS Outline of Centre and Laboratory	MAFF 2016	I-7, II-1B, II-4
	Department		
E165	AQS Outline of Chubu Airport Branch	MAFF 2016	I-7, II-4
E166	AQS Quality management system in	MAFF 2016	I-1A, I-7, II-1B,
E407	Animal Quarantine Service Chubu Airport		II-2, II-4
E167	AQS Kansai Airport Branch	MAFF 2016	II-2, II-4
E168	Animal Quarantine Service, Kobe Branch,	MAFF 2016	I-1A, I-7,
E169	Osaka and Ittotsu Designated ports and Designated	MAFF 2016	I-1A, I-7, II-1B,
E109	facilities for import-export inspection	MAFF 2010	II-2, II-4
	Kobe		11-2, 11-4
E170	Heat-processed meat and its products	MAFF 2016	ll-4
	derived from cloven-hoofed animals [ISO	MAIT 2010	11-4
	cert]		
E171	JA Higashi-Nihon Cooperative Feed Mills	JA	II-11
E172	Outline of Chita Feed Plant	JA Cooperative	II-11
E172	Animal Welfare and Livestock Section:	MOE 2016	I-1A, II-13
2.70	Organization and work distribution		
E174	Osaka LHSC (33)	MAFF 2016	I-1A, I-6B, I-7
E175	livestock status in Osaka Prefecture (36)	MAFF 2016	
	(2016)		
E176	Osaka Animal Welfare (34)	MOE 2016	II-7, II-13, III-1
E177	Osaka Prefecture University Graduate	Osaka Prefecture University	I-2A
	School		
E178	Osaka University	Osaka Prefecture University	I-2A
E179	council for the certification of registered	· · · · · · · · · · · · · · · · · · ·	I-2B, III-5
	vet nurse (Japanese)		
E180	Kagoshima Sasahira Pig Farm	MAFF 2016	
E181	Nanchiku pork products	Nanchiku, Inc 2016	
E182	Kagoshima LHSC	MAFF 2016	I-1A,II-7
E183	Kagoshima administration	MAFF 2016	I-1A,II-7
E184	Kagoshima Work of the Life & Sanitation	MHLW	II-8B, IV-4
	Division		
E185	Kagoshima Central Livestock	MAFF 2016	I-1A, I-7, II-1B, II-
	Hygiene Service Centre Catalogue		7, II-11
E186	LHSC resources	MAFF 2016	II-7, II-9
E187	Organizational Diagram of Kagoshima	MAFF 2016	I-1A, II-7
	Prefectural Administration		
E188	Kagoshima Meat Inspection (51)	MHLW 2016	II-8A&B
E189	Kagoshima Outline of Surveillance	MOE 2016	II-5B, II-7
E400	system for Wild Birds	U TA 2015	
E190	Japan Livestock Technology Assoc	JLTA 2015	I-6B, II-13
E191	Annual stakeholders meeting attendees list 2016	MHLW, 2016	II-2
E192	PED Outbreaks and Control in Japan	MAFF 2015	II-6, II-7
E192 E193	requirements for inseminators	MAFF 2015 MAFF	I-0, II-7
E193 E194	swill feeding guidelines 2006	MAFF 2013	II-7, II-11
E194 E195	Specifications and Standards of Feeds	MAFF 2013 MAFF 2015	II-11
2100	and Feed Additives (Ministerial		
	Ordinances 2015).		
E196	FAMIC sample testing 2015	FAMIC 2016	II-11
E197	FAMIC audit vs internal auditor	FAMIC 2016	I-11
E198	CE offerings by NIAH 2015	NIAH 2015	I-3
E199	laboratory CE offerings by NIAH 2015	NIAH 2015	I-3
E200	Summary of NIAH diagnostics	NIAH 2013	II-1A
E201	Status report pathology	NIAH 2015	II-1A
		NIAH 2012	II-13
E202	summary of animal use committees for		
E202	summary of animal use committees for NARO and NIAH		
E202 E203		MAFF	I-2A, I-11



E205	Ministerial Ord.33 on VMP post-marketing	MAFF 2005	II-9
	surv		
E206	VMP requiring monitoring	MAFF	II-9
E207	measures to increase livestock veterinarians	MAFF	I-1A, I-2A
E208	veterinary council actions	GoJ 1999	III-5
E209	Import risk analysis	MAFF	II-3, II-4, IV-4
E210	cost sharing for diseases	MAFF 2016	I-8, I-9, II-7
E211	JA outline of resources	JA 2016	II-1B, II-9, II-11
E212	Miyazaki Public Health Division	MHLW 2016	II-8
E213	MAFF organisation	MAFF 2016	I-6A
E214	Relationship between national and local governments-food safety	MHLW	I-6A
E215	Food Safety Risk Analysis	MAFF, MHLW, FSC	I-6A, II-3,
E216	Overview of Administration of Food Safety	MHLW	I-6A
E217	imported food safety leaflet	MHLW 2014	II-4, III-1
E218		USDA FSIS 2015	II-1B, II-8B,II-
-	FSIS Final report of audit Japan		8C,II-10, II-13
E219	measures for other diseases	MAFF	II-7
E220	disease control measures (reference (2))	MAFF	II-7
E221	OIE WAHIS	http://www.oie.int/wahis_2/public/ wahid.php/Wahidhome/Home	IV-6
E222		MoE	II-13
	Standards relating to the care and	https://www.env.go.jp/nature/dobu	
	keeping of industrial animals	tsu/aigo/2_data/rule.html	
	(Enactment in 1987, the last amendment	ENGLISH	
	in 2013)	http://www.env.go.jp/nature/dobut	
	/	su/aigo/2_data/laws/nt_h25_85_e	
<b>F000</b>		<u>n.pdf</u>	
E223		MoE (provided subsequent to the	II-13
	Guidelines relating to the methods of	mission) https://www.env.go.jp/nature/dobu	
	destruction of animals	tsu/aigo/2_data/rule.html	
	(Enactment in 2000, the last amendment	ENGLISH	
	in 2007)	http://www.env.go.jp/nature/dobut	
	,	su/aigo/2_data/laws/shobun_en.p	
E224	Standards relating to the care and	MoE (provided subsequent to the	II-13
	keeping of animals at home	mission)	
	(Enactment in 2002, the last amendment	https://www.env.go.jp/nature/dobu	
	in 2013)	tsu/aigo/2_data/rule.html	
E225	Standards relating to the care and	MoE (provided subsequent to the	II-13
	keeping of animals for exhibition	mission)	
	(Enactment in 2004, the last amendment	https://www.env.go.jp/nature/dobu	
<b>E</b> 000	in 2013)	tsu/aigo/2_data/rule.html	11.4.2
E226		MoE (provided subsequent to the mission)	II-13
	Standards relating to the care, keeping	https://www.env.go.jp/nature/dobu	
	and reducing pain of	tsu/aigo/2_data/rule.html	
	laboratory animals.	ENGLISH	
	(Enactment in 2006, the last amendment	http://www.env.go.jp/nature/dobut	
	in 2013)	su/aigo/2_data/laws/nt_h25_84_e	
		<u>n.pdf</u>	
E227	A basic plan for general prosecution of	MoE (provided subsequent to the	II-13
	actions for welfare and management	mission)	
	of animals	https://www.env.go.jp/nature/dobu	
	(Enactment in 2006, the last amendment in 2013)	tsu/aigo/2_data/rule.html	
E228	A Basic Plan for Modernization of Dairy	MAFF (provided subsequent to	II-13
	and Beef Cattle Production	the mission)	
	(Enactment in 2015)	http://www.maff.go.jp/j/chikusan/ki	
		kaku/lin/rakuniku_kihon_houshin.h	
		tml	

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### Appendix 7: Organisation of the OIE PVS Evaluation

#### Assessors Team:

- Team leader: Dr John Weaver
- Technical experts: Dr Julie Punderson & Dr John Stratton

#### **References and Guidelines:**

- o Terrestrial Animal Health Code (especially Chapters 3.1. and 3.2.)
  - OIE PVS Tool for the Evaluation of Performance of VS
    - → Human, financial and physical resources
    - → Technical capability and authority
    - → Interaction with stakeholders
    - → Access to markets

#### *Dates:* 11 – 26 October 2016

#### Language of the report: English

#### **Subject of the evaluation:** VS as defined in the Terrestrial Animal Health Code

- Not Inclusive of aquatic animals
- o Inclusive of other institutions / ministries responsible for activities of VS

#### Activities to be analysed: All activities related to animal and veterinary public health:

- Field activities:
  - → Animal health (epidemiological surveillance, early detection, disease control, etc)
  - $\rightarrow$  quarantine (all country borders),
  - → veterinary public health (food safety, veterinary medicines and biological, residues, etc)
  - $\rightarrow$  control and inspection,
  - → others
- o Data and communication
- Diagnostic laboratories
- Research
- o Initial and continuous training
- Organisation and finance
- Others as determined

#### Persons participating: See Appendix 3

#### Sites visited: See Appendix 4

#### Procedures:

- Assessment of data and documents
- o Representative field trips
- o Interviews and meetings with VS staff and stakeholders
- Review of organisation and programmes

#### Provision of assistance by the evaluated country

- o Background data
- o Translation of relevant documents, as required
- o Authorisation to visit designated sites
- o Logistical support

#### Reports:

- $\circ~$  A fact sheet or powerpoint will be presented at the closing session
- o A report will be sent to the OIE for peer-review no later than one month after the mission
- The assessed levels of advancement with strengths, weaknesses and references and recommendations for each critical competence will be provided

#### Confidentiality and publishing of results

The results of the PVS Evaluation are confidential between the country and the OIE and may only be published with the written agreement of Japan