EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO)/2007 - 7506 – MR Final

FINAL REPORT OF A MISSION

CARRIED OUT IN

MALAYSIA

FROM 27 JUNE TO 3 JULY 2007

IN ORDER TO EVALUATE THE CONTROL SYSTEMS IN PLACE
(INCLUDING ANIMAL HEALTH AND PUBLIC HEALTH ASPECTS)
GOVERNING THE PRODUCTION OF POULTRY MEAT PRODUCTS
INTENDED FOR EXPORT TO THE EUROPEAN UNION

Please note that factual errors in the draft report have been corrected.
Clarifications/observations made by the Malaysian Competent Authority in their response to the draft report are given as footnotes in bold, italic type, to the relevant part of the report.

TABLE OF CONTENTS

1. INTRODUCTION

The mission took place in Malaysia from 27 June to 3 July 2007 and was undertaken as part of the Food and Veterinary Office's (FVO)[1] planned mission programme.

The mission team (MT) comprised three inspectors from the FVO and one Member State expert.

1.1. Background to the mission

Malaysia is listed in Commission Decision 2005/432/EC[2] as a country from where imports of poultry meat products that have undergone heat treatment are authorised only from the Western Peninsular (MY-1) part. A previous mission was carried out in 1993; mission reference VI/3460/93.

At the time of the mission one meat products establishment was on the list of establishments approved to export to the European Union (EU). This establishment produces meat products from poultry meat imported from EU based approved establishments (mainly from The Netherlands).

The Competent Authority (CA) is considering proposing eight establishments, including slaughterhouses (SHs), for inclusion on the list of establishments approved either to export meat products to the EU or to provide poultry meat to meat product establishments in Malaysia to export to the EU as is established in Article 12 to Regulation (EC) No 854/2004.

Malaysia has a residue programme for poultry, which is approved by Commission Decision 2004/432/EC.

EUROSTAT sources indicate that Malaysia exported 31.5 tonnes of poultry meat products into the EU in 2006. During the visit to the sole establishment approved to export to the EU, the Food Business Operator (FBO) stated that 40 tonnes have been exported to the EU so far during 2007.

1.2. Mission objectives and proceeding

The objective of the mission was to assess whether the Malaysian CA is capable of delivering the animal health and public health guarantees required by the export health certificate as established in Commission Decision 2005/432/EC[3] with regard to export of poultry meat products to the EU, either derived from poultry meat imported from EU Member States or from domestic poultry meat.

In pursuit of this objective, the MT proceeded as follows:

- an opening meeting was held on 27 June 2007 with representatives from the CA. At this meeting the inspection team confirmed the objective of, and itinerary for the mission, and requested additional information required for the satisfactory completion of the mission.
- the following sites were visited:

---

1 List of abbreviations and special terms is drawn up in Part 1 of the Annex to this report.

2 Legal acts quoted in this report refer, where applicable, to the last amended version. Full references to the acts quoted in this report and legal basis for the mission are given in the Annex.

3 Commission Decision 2006/801/EC amend the model of the export health certificate for meat products intended for consignment to the EC from third countries.

COMPETENT AUTHORITY VISITS			Comments
Competent authority	Central	1	
	Regional	1	
LABORATORY VISITS			
Central/reference		1	
Regional		1	
LIVE ANIMAL CONTROL SITES			
Poultry farms		4	Three broiler, one duck
POULTRY PROCESSING ESTABLISHMENTS			
Slaughterhouses		3	One for ducks, two for broilers
Cutting plants		3	Attached to the visited slaughterhouses
Meat product plants		4	Three attached to slaughterhouses

- representatives from the CA accompanied the inspection team during the whole mission.

2. MAIN FINDINGS

2.1. Public health

2.1.1. Legislation

The animal and public health requirements in the poultry meat sector are

covered by national acts and regulations as follows:

- Animals Act 1953 (revised 2006)
- Food Act 1983 (Act 281) and Regulations
- The Meat Inspection Rules, 1985
- Code of veterinary practice for poultry slaughterhouse plant

The MT carried out a limited review, within the scope of this mission, of the main texts of the Malaysian legislation relevant to export in the poultry sector. From this limited review it was noted that the Malaysian legislation cannot be considered fully equivalent to Community requirements, in particular to Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 of the European Parliament and of the Council. In particular as:

- Requirements for chilled poultry meat are not in line with Community requirements established in Chapter V, Section II and in Chapter III, Section V of Annex III to Regulation (EC) No 853/2004.
- Official control in SH is neither carried out nor supervised by veterinarians, in contravention of Article 4 point 7 and to Chapter V, Section IV of Annex I to Regulation (EC) No 854/2004.

2.1.2. Competent authority performance

2.1.2.1. Structure

The CA is the Department of Veterinary Services (DVS) under the Ministry of Agriculture and Agro Based Industry. The DVS is organised at federal, state and district levels. However, the DVS at federal (central) level has all

the responsibilities in relation to poultry meat for export to the EU, as is in charge of certification, monitoring and control of the export chain.

Poultry establishments like SHs, cutting plants (CPs) and processing plants (PPs) which are part of the EU export chain are under the supervision of the federal level of the DVS.

However, the DVS state and districts officials have some roles in farms supervision as they issue transport permits and health certificates for live poultry transported from the holding to the SH. In addition, the effectiveness of the criteria set by the Federal Certification Programme as being implemented by poultry farms is being verified by DVS officials at state level.

2.1.2.2. Human resources

The CA stated that the numbers of staff performing official controls at federal, state and district levels were 48, 263 and 551 respectively.

The supervision and official control in poultry establishments is carried out by either a veterinary officer (VO), an assistant veterinary officer (AVO) or a veterinary assistant (VA) at federal level. In particular, supervision of establishments is carried out by federal VO. The routine official control of SH, CP and PP is carried out by federal AVO or by VA.

AVOs have to follow a three year course at the Veterinary University to obtain a diploma as AVO before they can be appointed. The VAs are officials trained in the DVS Veterinary Institute for three years before they can perform their official tasks.

The MT noted evidence of training provided to the AVOs. However, there was no evidence of training on Community requirements being provided to either the VOs, AVOs, or to the VAs.

2.1.2.3. Official control

<u>Import of raw material</u>

The DVS is in charge of the import and export control and certificates. Border inspection posts are located throughout the country to control the import of products. For EU export of poultry meat products, raw material is imported from an EU approved establishment. A VO from the DVS at federal level is present in the establishment approved to export to the EU to verify the processing hygienic conditions and that poultrymeat comes from an EU approved establishment.

<u>Approval for export</u>

Currently there is one meat products establishment approved to export to the EU. In addition, the CA consider proposing to the Commission services eight establishments to be included on the list of establishments approved to export meat products to the EU or to provide poultry meat to EU-approved meat product establishments.

The approval procedure for exporting poultry meat establishments is under the Veterinary Health Mark (VHM) certification scheme of the DVS. It signifies that establishments are in compliance with minimum standards of good manufacturing practices, good hygiene and sanitary practices based on

Hazard Analyses and Critical Control Points (HACCP) plans. It is verified by DVS inspections and: surveillance audits, followed up by compliance checks and review audits when renewal of approval is required.

However, the VHM certification procedure[4] does not take into account the legislation of the destination country of meat products exports, such as the EU.

Moreover, the MT has evidence that even HACCP plans which are part of the above-mentioned VHM certification procedure are not in complete accordance with Malaysian legal requirements.

The MT noted that HACCP plans are in place in all establishments visited. The plans are evaluated by the CA. However, HACCP deficiencies are not always identified by the CA. In addition, plans are not fully implemented by the FBO and sometimes do not reflect the reality of the operations. Finally some HACCP plans presented limits that were at variance with both Community and national requirements, e.g. temperature of 18º C for poultry meat when processing.

Official checks

Establishments approved to export have to have VHM certification.

The MT has evidence that surveillance audits are carried out by VO several times per year. Review audits are also carried out by the VO yearly to renew VHM certification. However, the MT identified serious deficiencies in the establishments visited which had not been reported by the DVS officials during the audit to the establishments (see Chapter 2.1.4).

When the approved establishment processes product for EU export, a VO from the DVS carries out a full inspection to verify the hygiene condition of the process and to verify that the poultry meat supplied is from an EU approved establishment.

However, SH proposed to be included on the list of approved establishments, are not all under daily DVS inspection as is required by Chapter II, Section III of Annex II and Chapter V, Section IV of Annex I to Regulation (EC) No 854/2004. When a daily DVS official inspection is carried out, it is not done by a VO in accordance with Chapter II, Section III of Annex II and Chapter V, Section IV of Annex I to Regulation (EC) No 854/2004, but by an AVO, VA or by FBO staff.

DVS officials take poultry meat samples when visiting establishments. These samples are sent to the DVS public health laboratory for microbiological analyses such as total plate counts, *E. Coli, Coliforms, Salmonella, Listeria Monocytogenes, Staphylococcus Aureus, and Campylobacter.*

When analyses results are not in compliance with the values set, the CA requests the FBO by letter to take actions to remedy the non-compliance.

Official control of potable water at establishment level is not carried out by DVS officials.

---

[4] ***In their comments of 4 September 2007 to the draft report, the CA stated that the VHM certification programme is voluntary.***

Ante-mortem inspection (AMI)

AMI is not carried out at farm level in Malaysia.

AMI is carried out in the SH by AVO, VA or by FBO staff under VA supervision. On arrival to the slaughterhouse the birds are assessed by DVS officials in those SH under DVS supervision. The CA stated that one SH proposed for inclusion on the approved list is not under daily DVS supervision.

When the farm and the SH are situated in the same state birds are transported to the SH without health certificate. Food chain information is not available to the FBO and to the DVS officials in the SH in advance prior to slaughter. In the case of the SH visited by the MT, the FBO is aware of the food chain information because the farms and the SH belong to the same company. However, if birds originate from other farms neither the DVS officials nor the FBO are able to check the food chain information as is required in Chapter II, Section I of Annex I to Regulation (EC) No 854/2004.

Post-mortem inspection (PMI)

Regarding post-mortem inspection, there is no continuous presence of a VO during slaughter. Post-mortem inspection is normally carried out by an AVO, VA or FBO staff not under VO supervision as is required in Chapter V; Section IV; Annex I Regulation (EC) No 854/2004.

In one SH visited, the VA was not able to inspect all the viscera of all birds as not all the birds were eviscerated before the PMI. In addition, daily inspection of the viscera and body cavities of a representative sample of birds is not carried out personally by a VO as is required in Chapter V, Section IV of Annex I to Regulation (EC) No 854/2004.

In one SH visited a large percentage of carcases showed faecal contamination and no corrective action was taken, in this case evisceration was considered a critical control point (CCP).

The CA stated that in one SH not visited by the MT no daily DVS inspection is carried out because of the absence of veterinary services. As a result official PMI is not carried out in this SH on a daily basis.

2.1.3. Laboratory service

The DVS public health laboratory was not visited by the MT. However, the MT received documented evidence that this laboratory is accredited to ISO standards 17025. Methods for microbiological test including *salmonella* and *listeria* were within the scope of the accreditation. The scope of accreditation includes also methods analysis for residues and contaminants.

2.1.4. Establishments visited

The MT visited four establishments.

Two establishments can be considered partially in compliance with Community requirements regarding layout, structure and hygiene conditions.

Two establishments can be considered as not in compliance with requirements set out in Regulations (EC) No 852/2004 and (EC) No 853/2004, regarding layout, structure and hygiene conditions as significant

deficiencies were identified by the MT. One of these establishments is the one currently approved to export poultry meat products to the EU.

In all establishments visited official supervision is unsatisfactory.

The MT identified a number of shortcomings (not all present in every establishment), of which the more relevant were the following:

- Use of hyperchlorinated water to remove surface contamination from poultry carcases in contravention of Article 3 of Regulation (EC) No 853/2004;
- No facilities available for disinfecting tools with hot water at no less than 82º C, or an alternative system having an equivalent effect, in contravention of paragraph 3, Chapter II, Section II of Annex III to Regulation (EC) No 853/2004;
- Lack of wash-hand basins in processing rooms, and wash-hand basins without hot water (paragraph 4, Chapter I of Annex II to Regulation (EC) No 852/2004);
- Temperature of poultry meat during processing or during storage above the limits established in paragraph 1 (b), Chapter V; Section II and in paragraph 1 and 2, Chapter III, Section V of Annex III to Regulation (EC) No 853/2004 respectively;
- Premises are not kept clean and maintained in good repair and condition in contravention of paragraph 1, Chapter I of Annex II to Regulation (EC) No 852/2004;
- Premises are not protected against the formation of condensation in contravention of paragraph 2 (b), Chapter I of Annex II to Regulation (EC) No 852/2004;
- Cleaning of live bird crates in SH not properly carried out in contravention of paragraph 6, Chapter II; Section II of Annex III to Regulation (EC) No 853/2004;
- Evisceration is not carried out properly to avoid contamination of the meat in contravention of paragraph 5, Chapter IV; Section II of Annex III to Regulation (EC) No 853/2004;
- Slaughter lines are not designed to avoid cross-contamination of poultry carcases, in particular, when poultry carcases are washed (paragraph 2 (e), Chapter II; Section II of Annex III to Regulation (EC) No 853/2004);
- HACCP plans are not properly implemented by FBO as is required by Article 5 of Regulation (EC) No 852/2004. Own-check records show critical limits which conflict with those set in Community or national legislation. No corrective actions are taken when monitoring indicates that a critical control point is not under control;
- AMI and PMI not properly carried out (see Chapter 2.1.2.3);
- Traceability system in place does not give enough information to trace back the products.

Poultry meat intended for export to the EU undergoes a heat treatment to reach a minimum temperature of 70º C as is determined in point D in Part 4 of Annex II to Decision 2005/432/EC. In the establishments visited this step

was considered a CCP. The monitoring of this CCP was carried out properly and records were in order.

Microbiological and physical-chemical analyses of potable water were regularly carried out by FBOs in establishments visited to determine the quality of the water.

Microbiological analyses of products were also carried out by the FBOs in the establishments visited.

2.2. Animal health

2.2.1. Farm supervision

At present, in Malaysia there are 4539 commercial poultry farms raising a total of about 125 million birds per year (mainly chickens and ducks). In addition, 158 hatcheries, 16 poultry slaughterhouses and 42 cutting plants are present. At a central level only the list of poultry meat exporting farms (333 in total) is kept. These farms are certified under a government accreditation scheme (SALT). This scheme includes the implementation of a programme for eradication of *salmonella*. The farms visited were free of *salmonella*.

A full list of all commercial poultry farms is kept and updated only at state level, this information was not always verifiable in all the states visited. It was also noted that when farms are registered the exact geographical coordinates are taken and recorded at the veterinary service. In addition, free range poultry are largely present in both rural and semi-urban areas, with a total population of about 3.6 million birds. Many poultry species are kept in this type of poultry holdings: chickens, layers, turkeys, quails, ducks, pigeons and fighting cocks. Poultry are sold and slaughtered at the wet market.

Regarding fighting cocks the CA stated that cock fighting is illegal in Malaysia but the keeping of fighting cocks is not prohibited. It is useful to mention the figure of 700 fighting cock being registered in the sole 1 km zone around the 2007 AI outbreak in Selangor. This gives an idea of their potential of spreading the disease, taking into account the fact that they are liable to move frequently between villages.

Farms under the SALT scheme are supervised by DVS officials. Each batch of birds before slaughtering is sampled for *salmonella*.

No all records were available in all farms.

Biosecurity measures were found to be satisfactory in two broiler farms visited. The MT also visited a free range duck farm. Although the birds were kept in the open and thus in theory in contact with wild birds, the MT noted that measures to minimise the contact had been taken.

2.2.2. Laboratory service

The laboratory network in Malaysia is constituted by seven regional laboratories. The MT visited the Veterinary Research Institute (VRI) at Ipoh, where all the samples concerning AI and the Newcastle Disease (ND) collected in suspected outbreaks are submitted for confirmation. The MT also visited the Regional Diagnostic Veterinary Laboratory (RDVL) at Petalin Jaya, which carries out laboratory tests in case of AI outbreaks and in the framework of the AI surveillance programme in the State of Selangor. Both laboratories were found to have in general well-trained and motivated staff.

VRI

Adequate equipment for virus isolation, Polymerase Chain Reaction (PCR) and Real Time-PCR (RT-PCR) is available, but sequencing equipment is lacking. The VRI is obliged to have sequencing carried out by an external laboratory and can take up to four days or more to have the virus sequenced. Serological investigations are performed by using commercial Enzyme Linked Inmuno-Sorbent Assay (ELISA) kits and Haemagglutination Inhibition (HI).

The VRI has not been officially designated as National Reference Laboratory (NRL) for AI and ND. In spite of that the laboratory guarantees:

- the confirmation of any outbreaks of infection
- the organisation of training course for RDVLs' scientists and technicians with regard to AI and ND diagnosis
- the definition of AI and ND diagnostic procedures
- the performance of proficiency tests on AI and ND diagnosis

However, the VRI is not able to guarantee that:

- a standard protocol for AI diagnosis is applied in all RDVLs;
- the application of diagnostic methods officially validated in all RDVLs. Certain RDVLs apply diagnostic methods not officially validated (Nucleic Acid Sequence Base Amplification (NASBA) and rapid methods) and with a poor sensitivity (rapid methods)
- the possible application of PCR and/or virus isolation methods for the testing of all the samples collected for AI diagnosis and surveillance

Petaling Jaya RDVL

With the current limitations, particularly for the execution of rapid molecular tests (Real Time-PCR), in case of an expected increasing number of samples to be processed, this will likely lead to laboratory overloading and delayed turn around time. In the current situation, the high number of samples which are collected and delivered to the laboratory in case of major epidemics can only be tested only by using commercial methods. These methods have not been validated and/or have limited or poor sensitivity which is a major drawback.

Serological investigations are performed by using commercial ELISA kits and HI.

Accreditation

Neither of the two laboratories visited are yet accredited. However documents were shown to the MT showing that the RDVL has started the accreditation process. The MT also verified in the same laboratory the existence of a Quality Manual and of a Standard Operating Procedure Manual. In February this year, the VRI organised a ring test to evaluate the reliability of RT-PCR methods applied for AI diagnosis in all RDVLs. At the time of the MT visit, no results had been sent back to VRI from the different RDVLs included in the trial.

2.2.3. Overview of the animal health situation

Since 2004, 18 outbreaks of H5N1 High Pathogenic AI (HPAI) have been reported. In particular, in 2004 a cluster of 12 infected villages were identified in Kelantan State, which is located in the North east part of Malaysia bordering Thailand. The CA suspect as a source of infection a spill-over of H5N1 HPAI from Thailand. No outbreaks were registered in 2005. In 2006 5 HPAI affected villages were detected in three states: Perak (3 outbreaks), Wilayah (1) and Penang (1). It should be pointed out, that a certain number of HPAI outbreaks were detected, but not reported to the international community because they were identified in restricted zones of previous outbreaks, and as such were considered as secondary outbreaks. Finally, in June 2007 an outbreak was reported in Selangor. All H5N1 HPAI outbreaks affected rural poultry, a part from two outbreaks of infection in the State of Perak: one in a chicken flock located in an agriculture institute, and the second in an eco-park situated in Bukit Merah. These two outbreaks were detected during the routine active surveillance carried out in affected areas.

With regard to ND, outbreaks of infection are regularly detected in backyard flocks and vaccination in commercial farms is currently practiced.

2.2.4. Avian influenza

AI is a compulsory notifiable disease as provided for in the Malaysian Animal health act of 1953 Article 2. However the definition of a case (field suspect and\or laboratory case) is found only in a Technical Protocol (Protocol for National Animal Disease Control) used by the veterinarians in the field. No cross reference between the legal base and the technical protocol exists. Therefore, paragraph 2 (b) of Article 2 of Commission Decision 94/438/EC is not adhered to.

Contingency plan

A disease contingency plan (DCP) is established at central level in 2004. It is constituted of two parts: (a) the plan itself and (b) the Manual of Standard Operation Procedures (Manual). The Manual has been distributed to the individual Malaysian states. States have the power to adapt the Manual to their particular situation. At the moment of the MT visit no translated copy of the Manual was available so it was not possible for the team to be acquainted with all the provisions in the DCP.

A specific dedicated room exists at central level to direct the operations in the field and to coordinate the surveillance in case of an outbreak. The room is provided with some technical material, some maps and communication equipment. A list of personnel of the different operational teams was found but was not up-to-date[5]. Reports of daily activities carried out during the control of outbreaks were available. Also at state level an especially dedicated room was found equipped with a list of personnel and phone numbers, communication materials and maps. Vaccination to combat AI

[5] ***In their comments of 4 September 2007 to the draft report, the CA clarified that a list of personnel that was involved in the operational team was prepared during the disease outbreak. The list that was referred to during the inspection was prepared during the 2006 outbreak and would be different from the list of personnel that was involved in the operational team of the 2007 outbreaks.***

infections is prohibited. However, guidelines on the possible application of emergency vaccination in the event of a HPAI epidemic are available.

The following further observations are relevant:

- The last update of the Manual was done in 2005, but no standardised basic manual was found at state level; some states still having the 2004 manual[6].
- Eradication measures applied in the field were not always consistent with the provisions of the Manual. While the Manual provides for three zones to be defined in case of an outbreak, in practise these three zones applied, in case of outbreak, to all exporting farms (mainly in Perak), while only two zones applied for the not exporting farms.
- Some discrepancies have been found between the Manual and the Technical Protocol concerning the threshold level to declare a suspect case of AI. Discrepancies were also found in the application of provisions during outbreak control activities at state level.

Field implementation of AI control measures

In case of a suspect outbreak an Alert Management Team will be informed at central level and the Rapid Action Team will be immediately mobilised for suspect case investigation. After the confirmation of HPAI stamping out of all birds is enforced in the affected village and in a radius of 1 KM around the outbreak site. During the depopulation samples are collected for virus identification. Virological surveillance activities are implemented in a 10 km radius area around the outbreak as proved by records seen in Perak and Selangor.

The following was also noted by the MT:

- Restrictions on the suspect farm and on the all area at risk of infection are not always imposed while awaiting for confirmation. In fact, in one state (Perak) restriction measures were adopted before confirmation, whilst in Selangor control and eradication interventions were only implemented at the time of laboratory confirmation of HPAI.
- Surveillance around the outbreaks is not always carried out in a systematic way. In fact in some cases only a part of the villages located in the surveillance area were tested both in Perak and Selangor[7]. Furthermore, different AI diagnostic tests were applied in the two laboratories (VRI at Ipoh and RDVL at Petalin Jaya). At VRI, all samples collected in the 10 Km area for virological examination were tested by RT-PCR, while at the RDVL rapid tests such as NASBA and a commercial ELISA antigen detection method were applied.

---

6 ***In their comments of 4 September 2007 to the draft report, the CA stated that the Manual of Standard Operation Procedures (Manual) was distributed to all the states in 2004 during the first AI outbreaks in Kelantan (2004 Manual). The manual was updated in 2005 with very minor changes in the procedures. Therefore, the 2004 manual is still valid for the states to use as an operation procedure.***

7 ***In their comments of 4 September 2007 to the draft report, the CA stipulated that surveillance around the outbreaks was carried out in a systematic way where villages within 1-10 km radius were randomly selected based on 10% prevalence and 95% confidence level. Within the selected villages poultry were randomly selected based on the same prevalence and confidence level.***

- The rapid tests applied are not specifically validated at federal level. Furthermore the known low sensitivity ELISA kit, may rule out the possible presence of AI, particularly in healthy flocks, when used in surveillance activities.
- From the examination of the files of the AI outbreaks, no epidemiological data on the possible origin and on the further spread of infection were available. It has been found that a well-structured epidemiological investigation is not systematically carried out in each AI outbreak. The Manual, in fact, does not include a standardised form to be used for the collection of epidemiological information in AI affected poultry premises.
- Cases of AI identified in the 10 km radius around an AI outbreak are considered as secondary foci of infection and are not notified to the Office International des Epizooties (OIE). No additional measures, other than the stamping out at affected premises, are enforced in such secondary outbreaks (paragraph 1 (h) of Council Directive 2002/99/EC).
- A flow-chart of all the activities to be implemented in case of AI has been produced by DVS, but proof of its actual application during an epidemic was not always available.
- The MT was told that no training was carried out for the operational teams in the field.
- The Government compensates farmers for birds stamped out in the affected and at risk premises. Cleansing and disinfection operations on affected premises were carried out under official control.

AI routine surveillance

Routine surveillance consists of:

- passive surveillance, which is based on the collection and examination of cloacal swabs from poultry flocks with a mortality rate equal to or exceeding 3%;
- active surveillance, which is carried out with the collection of samples for laboratory diagnosis of AI in healthy poultry flocks.

Routine surveillance activities are not based on standardised comprehensive provisions and instructions, which should define at least the sampling methodology (target number of samples to be collected, pooling of samples for laboratory testing, etc.) and laboratory methods (Commission Decision 2005/464/EC).

2.2.5. Newcastle disease

ND is a compulsory notifiable disease as provided for in the Malaysian Animal Act, 1953 Article 2. However the definition of a case (field suspect and\or laboratory case) is found only in a Technical Protocol (Protocol for National Animal Disease Control). No cross reference between the legal basis and the technical protocol exists (see 2.2.4).

Furthermore, no veterinary control measures are applied in case of a ND outbreak. It is important to note that commercial poultry are routinely vaccinated. ND vaccines must be authorised by the DVS, and the large majority of them is imported. However, their distribution within the country is not under official control.

2.3. Animal welfare

Animal welfare rules are followed when slaughter of poultry in the SH visited. Poultry were not completely stunned as in the SH visited a particular method of slaughter required by religious rites was carried out by the FBO (Article 5.2 of Council Directive 93/119/EC).

3. CONCLUSION

Public health

Based on the review of national legislation performed by the MT, significant Community requirements for poultry meat product exports are not included in Malaysian rules.

CA supervision of establishments cannot be considered satisfactory as the Community requirements are not sufficiently and evenly enforced. Furthermore DVS officials and FBOs show limited knowledge of Community requirements. Approval of establishments for export under the VHM scheme gives no guarantee that these establishments fulfil Community requirements.

AMI and PMI are not carried out in all SHs on a daily basis. When AMI and PMI are carried out the CA do not follow the requirements established in Chapter V, Section IV of Annex I to Regulation (EC) No 854/2004.

The meat products establishment approved to export to the EU and other establishments proposed for listing as approved establishment to export to the EU do not meet the requirements established in Regulations (EC) No 852/2004 and (EC) No 853/2004. Furthermore HACCP plans are not properly implemented. In particular, significant problems with the maintenance of cold chain have been identified in the above-mentioned establishments.

In the establishment approved to export to the EU, meat products have undergone the specific treatment referred to in point D in Part 4 of Annex II to Decision 2005/432/EC.

Animal Health

Concerning animal health, the system in place for farm checks and existing conditions at farm level potentially could deliver the necessary guarantees required for export to the EU. However at laboratory level the system is weakened by the lack of definition of the roles and responsibilities of the laboratories and by the use of non-validated diagnostic methods.

In the context of the recent outbreaks of AI, the CA has applied a procedure, which allowed them to contain the outbreaks. The CA has a clear policy of stamping out AI outbreaks, with a rapid response, although no proper outbreak investigations were carried out in line with the measures to be taken when "sanitary slaughter policy" is applied in accordance with Annex C to Commission Decision 93/342/EEC.

Concerning ND, at present, the situation does not meet the Community requirements set out in Council Directive 92/66/EEC and Decisions 93/342/EEC and 94/438/EC taking into account shortcomings in legislation and insufficient implementation i.e. a policy of non-intervention in case of outbreak. However, adequate biosecurity measures and the extensive use of vaccination in commercial flocks may have contributed to the fact that the overall animal health situation in such flocks remains favourable.

Overall conclusion

As regards the establishment currently approved to export poultry meat products to the EU, due the significant shortcomings identified in the establishment and the overall deficiencies regarding the official supervision of establishments, the CA is not currently in a position to certify that products originating from this establishment meet the public health requirements of the export health certificate as is established in Commission Decision 2005/432/EC.

Concerning authorisation to include in the list of approved establishment to export to the EU, SHs and CPs, supplying poultry meat to EU-export meat products establishments, given the shortcomings identified in the establishments visited, the overall deficiencies regarding the official supervision of establishments together with the shortcomings identified regarding the AI and ND situation, the CA cannot guarantee that meat products originating from these establishments meet the public and animal health standards established in Commission Decision 2005/432/EC and Commission Decision 2006/696/EC respectively.

4. CLOSING MEETING

A closing meeting was held on the 3 July 2007 with the CCA. At this meeting, the main findings and preliminary conclusions of the mission were presented by the inspection team. The representatives of the CA did not express any major disagreements with the main findings and preliminary conclusions and indicated their willingness to correct the deficiencies noted.

5. RECOMMENDATIONS

The CA should provide Commission Services with guarantees and an action plan, including a timetable for its completion, within 25 working days of receipt of the report in order to address the following recommendations concerning the production of poultry meat products (from EU sourced poultry meat) and destined for the EU market:

- The CA should provide appropriate guarantees that the Malaysian standards applicable to poultry meat product exports to the EU cover all Community requirements laid down in the export health certificate as established in Commission Decision 2005/432/EC. In particular the CA should guarantee that:
  a) Chilled and frozen temperature requirements of poultry meat and meat products to be in accordance with those established in Chapter V, Section II and in Chapter III, Section V of Annex III to Regulation (EC) No 853/2004;
  b) Shortcomings regarding structure, maintenance and layout identified by the MT are corrected;
  c) HACCP plans are properly implemented and that FBOs maintain a permanent procedure based on the HACCP principles as is established in Article 5 of Regulation (EC) No 852/2004;
  d) Official supervision of poultry meat product establishments is carried out in accordance with requirements providing guarantees at least equivalent to those established in Regulation (EC) No 854/2004.

In addition to the above-mentioned recommendations, should the CA maintain the application for export of poultry meat products derived from poultry meat produced in domestic SHs and CPs, the CA should provide Commission Services with an

action plan, including a timetable for its completion, in order to address the following recommendations:

- The CA should guarantee that official supervision of poultry meat and meat product establishments is carried out in accordance with requirements established in Regulation (EC) No 854/2004. In particular, AMI and PMI are to be carried out in all SH approved to supply poultry meat to EU-approved poultry meat products establishments. AMI and PMI are also to be carried out in accordance with the requirements established in Regulation (EC) No 854/2004.
- The CA should guarantee that poultry meat products intended for export to the EU have been prepared from fresh domestic poultry that satisfies the animal health requirements laid down in Decision 2006/696/EC. In particular the following points need to be addressed:
  a) The CA should establish a proper legal definition of a positive case for AI and ND in conformity with Article 2 (b) of Decision 93/342/EC;
  b) If sanitary slaughter measures are used to control outbreaks of AI and ND according to its definition in Article 1 of Decision 93/342/EC, all measures applied in this context should comply with the criteria set out in the Annex of that Decision;
  c) In order to improve efficacy and transparency of diagnostic work for AI and ND, the role and responsibilities of the laboratories participating in the diagnostic network for AI and ND should be clarified.

6. CA RESPONSE TO RECOMMENDATIONS

The Competent Authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/ap/ap_malaysia_7506_2007.pdf

ANNEX

1. List of Abbreviations and Special Terms Used

AI	Avian Influenza
AMI	Ante-Mortem Inspection
AVO	Assistant Veterinary Officer
CA/s	Competent Authority/ies
CCP	Critical control Point
CP/s	Cutting Plant/s
CRL	Community Reference Laboratory
DCP	Disease Contingency Plan
DVS	Department of Veterinary Services of the Ministry of Agriculture
EC	European Commission
ELISA	Enzyme Linked Immuno-Sorbent Assay
EU	European Union
FBO/s	Food Business Operator/s
FVO	Food and Veterinary Office
HACCP	Hazard Analyses and Critical Control Points
HI	Haemagglutination inhibition
HPAI	Highly Pathogenic Avian Influenza
ISO	International Standard Organisation
MT	Mission Team
ND	Newcastle disease
NRL	National Reference Laboratory
OIE	Office International des Epizooties (International Animal Health Bureau)
PCR	Polymerase Chain Reaction
PMI	Post-Mortem Inspection
PP	Processing Plant
RDVL/s	Regional Diagnostic Veterinary Laboratory/ies
RT-PCR	Real Time Polymerase Chain Reaction
SALT	Livestock Farm Certification Scheme`
SH/s	Slaughterhouse/s
VA	Veterinary Assistant
VHM	Veterinary Health Mark
VO	Veterinary Officer
VRI	Veterinary Research Institute

2. References to relevant community

Council Directive 92/66/EEC	L 260, 5.9.1992, p. 1	Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease
Commission Decision 93/342/EEC	L 137, 8.6.1993, p. 24	Commission Decision 93/342/EEC of 12 May 1993 laying down the criteria for classifying third countries with regard to avian influenza and Newcastle disease
Council Directive 93/119/EC	L 340, 31.12.1993, p 21	Council Directive 93/119/EC of 22 December 1993 on the protection of animals at the time of slaughter or killing
Commission Decision 98/140/EC	L 38, 12.2.1998, p 14	Commission Decision 98/140/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in third countries
Council Directive 2002/99/EC	L 18, 23.1.1993, p 11	Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption
Commission Decision 2004/432	L 183, 27.05.2004, p 33	Commission Decision of 29 April 2004 on the approval of residues monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC.
Commission Decision 94/438/EC	L 181, 15.07.1994, p. 35	Commission Decision 94/438/EC of 7 June 1994 laying down the criteria for classifying third countries and parts thereof with regard to avian influenza and Newcastle disease in relation to imports of fresh poultrymeat and amending Decision 93/342/EEC.
Regulation (EC) No 852/2004 of the European Parliament and of the Council	L 139, 30.4.2004, p. 1 Corrigendum OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs.
Regulation (EC) No 853/2004 of the European Parliament and of the Council	L 139, 30.4.2004, p. 55 Corrigendum OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin.
Regulation (EC) No 854/2004 of the European Parliament and of the Council	L 139, 30.4.2004, p. 206 Corrigendum L 226, 25.6.2004, p 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption.
Regulation (EC) No 882/2004 of the European Parliament and of the Council	L 165, 30.4.2004, p. 1 Corrigendum OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
Council Directive 2005/94/EC	L 10, 14.1.2006, p.16	Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC
Commission Decision 2005/432/EC	L 151, 14.6.2005, p. 3	Commission Decision 2005/432/EC of 3 June 2005 laying down the animal and public health conditions and model certificates for imports of meat products for human consumption from third countries and repealing Decisions 97/41/EC, 97/221/EC and 97/222/EC.
Commission Decision 2005/464/EC	L 164, 24.6.2005, p. 52	Commission Decision 2005/464/EC of on the implementation of survey programmes for avian influenza in poultry and wild birds to be carried out in the Member States
Commission Decision 2006/696/EC	L 295, 25.10.2006, p 1	Commission Decision of 28 August 2006 laying down a list of third countries from which poultry, hatching eggs, day-old chicks, meat of poultry, ratites and wild game-birds, eggs and eggs products and specified pathogen-free eggs may be imported in to and transit through the Community and the applicable veterinary certification conditions, and amending decision 93/342/EEC, 2000/585/EC and 2003/812/EC

3. Legal basis for the mission

The mission will be carried out under the general provisions of Community legislation and, in particular:

- Council Directive 2002/99/EC, in particular Article 10;
- Regulation (EC) No 882/2004 , in particular Article 46;
- Commission Decision 98/140/EC.