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Directorate F - Food and Veterinary Office

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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

VIET NAM

FROM 11 TO 20 SEPTEMBER 2012

IN ORDER TO EVALUATE THE MONITORING OF RESIDUES AND CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS, INCLUDING CONTROLS ON VETERINARY MEDICINAL PRODUCTS

In response to information provided by the Competent Authority, any factual error noted in the draft report has been corrected; any clarification appears in the form of a footnote.

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in Viet Nam, carried out from 11 to 20 September 2012, as part of the published programme of FVO audits on the monitoring of residues in live animals and animal products in European Union (EU) Member States and in third countries.

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, in order to assess whether these systems offer adequate assurance that the products and animals concerned are within the specified residue limits laid down in EU legislation. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit. The audit assessed the performance of the competent authorities and other officially authorised entities involved in residues and veterinary medicinal product controls and the legal and administrative measures put in place to give effect to the relevant EU requirements. Attention was also paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues audit to Viet Nam (DG (SANCO) 2009/8188) in October 2009.

Overall it is concluded that, in general, the systems of residues controls in Viet Nam for honey and aquaculture offer guarantees with an effect equivalent to those provided for by EU rules. The aquaculture and honey residue monitoring plans comply with the minimum requirements of Council Directive 96/23/EC and are generally implemented as planned, although sampling of honey could be more evenly distributed during the year and across a larger number of establishments. Laboratories performing analyses are operating at a very high level of performance, thus providing assurances on the reliability of analytical results. Follow-up measures for non-compliant results are generally equivalent to those provided for by EU rules. Notwithstanding several detections of residues in aquaculture consignments imported into the EU, the implementation of a system of official controls on the distribution and use of veterinary medicinal products, allied with official pre-export testing and own-checks performed by processing plants increase confidence in the residues status of both aquaculture products and honey.

The report makes a number of recommendations to the competent authorities of Viet Nam, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AAS	Atomic Absorption Spectroscopy
AOZ and AMOZ, AHD and SEM	Marker residues of the nitrofuran drugs furazolidone, furaltadone, nitrofurantoin and nitrofurazone respectively
CCα / Ccβ	Decision Limit / Detection Capability
CI-GC-MS	Chemical Ionisation - Gas Chromatography- Mass Spectrometry
CRM	Certified Reference Material
DAH	Department of Animal Health
DES	Diethylstilbestrol
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
EI-GC-MS	Electron Ionisation - Gas Chromatography- Mass Spectrometry
ELISA	Enzyme-Linked Immuno-Sorbent Assay
EU	European Union
FVO	Food and Veterinary Office
GC	Gas Chromatography
GC – ECD	Gas Chromatography – Electron Capture Detection
GC-MS	Gas Chromatography- Mass Spectrometry
GC-MS/MS	Gas Chromatography- Tandem Mass Spectrometry
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC
HPLC	High Performance Liquid Chromatography
ICP-MS	Inductive Coupled Plasma Mass Spectrometry
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography - Tandem Mass Spectrometry
LMG	Leucomalachite Green
LOD	Limit of Detection
LOQ	Limit of Quantification
MARD	Ministry for Agriculture and Rural Development
MG	Malachite Green
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
MS/MS	Tandem Mass Spectrometry
NAFIQAD	National Agro- Forestry- Fisheries Quality Assurance Department

NAFIQAD-SRA	National Agro- Forestry- Fisheries Quality Assurance Department Southern Region Authority
NCVHI 1	National Centre for Veterinary Hygiene Inspection No. 1
PCB	Polychlorinated Biphenyl
RASFF	Rapid Alert System for Food and Feed
RMP	Residue Monitoring Plan
SOP	Standard Operating Procedure
UPLC	Ultra Performance Liquid Chromatography
UPLC-MS/MS	Ultra Performance Liquid Chromatography Tandem Mass Spectrometry
UV	Ultra-Violet

1 Introduction

The audit took place in Viet Nam from 11 to 20 September 2012. The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one expert from a European Union (EU) Member State. The audit was undertaken as part of the FVO's audit programme, evaluating control systems and operational standards in the residues sector.

Representatives from the central competent authority responsible for the control of residues in animals and animal products accompanied the audit team during the audit. Two separate opening meetings were held on 11 September 2012, one with NAFIQAD (National Agro- Forestry- Fisheries Quality Assurance Department), the central competent authority responsible for implementing residue monitoring in aquaculture, and the second with DAH (Department of Animal Health) responsible for implementing residue monitoring in honey and the authorisation of veterinary medicinal products. At these meetings, the objectives of, and itinerary for, the audit were confirmed and the control systems were described by the authorities.

2 Objectives

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, in order to assess whether these systems offer adequate assurance that the products and animals concerned are within the specified residue limits laid down in EU legislation. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit. The audit focussed on the roles of the competent authorities at central and regional levels, the legal and administrative measures in place to give effect to the relevant EU requirements, controls with regard to residues and veterinary medicinal products and their operation, and the performance of residue laboratories. Attention was paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues audit to Viet Nam (DG (SANCO)/2009-8188 MR Final) in October 2009. The table below lists sites visited and meetings held in order to achieve that objective.

Meetings/Visits		**No.**	**Comments**
Competent Authorities	**Central**	**4**	Opening and closing meetings with MARD, NAFIQAD and DAH
	Regional	**3**	Meetings at the regional competent authority in: Regional competent authority aquaculture NAFIQAD-SRA Regional animal health office DAH No. 6 Local competent authority sub-department of NAFIQAD
Laboratories		**4**	Governmental laboratories: National Veterinary Hygiene Inspection Centre No. 1 Laboratory of NAFIQAD Branch 4 Laboratory of NAFIQAD Branch 6 Laboratory of Regional Animal Health Office DAH No. 6
Farms		**7**	Three shrimp aquaculture farms and four *Pangasius spp.* aquaculture farms
Establishments		**5**	Two honey processing plants Two shrimp processing establishments and one *Pangasius spp.* aquaculture processing plant
Other Sites		**4**	One retailer of veterinary medicinal products for all species, including bees. Three wholesalers/ retailers of veterinary medicinal products and feed premixes for aquaculture

3 Legal Basis

The audit was carried out under the general provisions of EU legislation, and in particular:

- Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products, and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC;
- Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

A full list of the legal instruments referred to in this audit report is provided in the Annex and refers, where applicable, to the last amended version.

4 Background

4.1 Country status in relation to EU-approval of residue monitoring plans

Commission Decision 2011/163/EU indicates that Viet Nam's residue monitoring plan (RMP) is approved in accordance with Council Directive 96/23/EC for aquaculture. Viet Nam has sought to be re-listed for honey following its removal from this list for honey in 2007.

4.2 Summary of previous FVO audit reports

The residues sector was inspected by the FVO in 2007 (DG(SANCO)/2007-7322 MR Final) and 2009 (DG(SANCO)/2009-8188 MR Final). The reports of both audits (henceforth referred to as the 2007 and 2009 FVO audits respectively) have been published on the website of the Directorate–General for Health and Consumers here: http://ec.europa.eu/food/fvo/ir_search_en.cfm. The most recent report concluded that for aquaculture products, the national residue control plan complied with minimum EU requirements and the laboratory network was adequate and sufficient for the purpose of residue controls. However, the effectiveness of residue controls was undermined by the limited scope of official testing for some groups of substances and non-dissuasive enforcement measures when non-compliant results were detected. For honey, the effectiveness of the official residues control plan was undermined by insufficient laboratory capacity, pre-announced sampling, lack of traceability of part of the samples and the lack of enforcement actions when non-compliances were detected. Results of the national residues plan and companies' own checks demonstrated the illegal use of unauthorised veterinary medicinal products and EU forbidden substances in bee keeping in Viet Nam. Overall controls on the distribution and use of veterinary medicinal products were weak and, although official controls on aquaculture products intended for export to the EU provided sufficient guarantees in relation to their residues status, the essential elements of an effective residues control system which would guarantee compliance with EU requirements were not in place for honey and other bee products.

4.3 Rapid Alert System for Food and Feed (RASFF) notification for products of animal origin from Viet Nam concerning residues

Since the 2009 FVO audit there were 20 RASFF notifications for residues of veterinary medicinal products in aquaculture products imported from Viet Nam in the period to August 2012. Seven

notifications involved the detection of nitrofuran metabolites (six SEM, one AOZ), four notifications concerning chloramphenicol detection, two for neomycin, one for ivermectin and six involving the detection of dyes (variously malachite green, leuco-malachite green and victoria pure blue). There were also 12 notifications for trifluralin in *Pangasius spp.* products, three of which also contained chlorpyriphos.

4.4 Production and Trade Information

Detailed production data for 2011 were supplied by NAFIQAD and are summarised in the table below. In 2011 total shrimp production was 495,657 tonnes and total *Pangasius spp.* production was 1,150,737 tonnes.

Production areas	Total aquaculture production in 2011 (tonnes)	Total freshwater production in 2011 (tonnes)	Total other aquaculture production in 2011 (tonnes)
Production in all 63 provinces in Viet Nam	3051887	2074005	977882
Production in 35 provinces covered by RMP	2728465	1750583	977882

NAFIQAD provided the following data on exports of fishery products to the EU in 2010 and 2011.

Type of product	Exports to EU in 2010 (tonnes)	Exports to EU in 2011 (tonnes)
Frozen shrimp	40591	42490
Frozen fish (including *Pangasius spp.*)	276639	230267
Frozen squid/octopus	25007	26846
Dried products	1743	2058
Others	41727	36422

DAH provided the following data on exports of honey to non-EU markets.

Country honey exported to	Exports in 2011 (tonnes)	Exports from January to August 2012 (tonnes)
USA	27125	12752
Malaysia	76	68
Indonesia	58	126
Mongolia	29	-
Japan	252	158
Thailand	-	175
Canada	98	-
Taiwan	-	46

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

Within the Ministry for Agriculture and Rural Development (MARD), NAFIQAD is responsible for the planning and implementation of the aquaculture RMP, including the follow-up of any non-compliant results. DAH, also within MARD, is responsible for developing the RMP for honey and submitting it to MARD for approval. The National Centre for Veterinary Hygiene Inspection No 1 laboratory (NCVHI 1) is responsible for taking and analysing honey RMP samples and coordinating follow-up actions in the case of any non-compliant results. DAH is also responsible for controls on the production, distribution and use of veterinary medicinal products.

5.1.2 Planning of residue monitoring plan

Legal Requirements

Third countries which export live animals or animal products to the European Union are obliged to submit to the European Commission a specific plan setting out the guarantees which it offers as regards the monitoring of the groups of residues and substances referred to in Annex I to Council Directive 96/23/EC on measures to monitor certain substances and residues thereof in live animals and animal products.

The residue plan should take account of the results of monitoring from the previous year and should be revised annually and updated at the request of the Commission, particularly when checks carried out by the Commission render it necessary. Article 29 of said Directive states that guarantees must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 and meet the requirements of Article 11(2) of Directive 96/22/EC. Articles 3 to 7 of Council Directive 96/23/EC deal with the requirements for residue monitoring plans. The levels and frequencies of sampling for residues are specified in Annex IV to Council Directive 96/23/EC and Commission Decision 97/747/EC.

Article 11 of Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, specifies that food and feed imported into the EU for placing on the market within the EU shall comply with the relevant requirements of food law or conditions recognised by the EU to be at least equivalent thereto. In relation to maximum levels of residues and contaminants in food, Regulation (EC) No 470/2009 of the European Parliament and of the Council lays down Maximum Residue Limits (MRLs) for residues of pharmacologically active substances in food which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Regulation (EC) No 396/2005 lays down maximum residue levels of pesticides in or on food and feed of plant and animal origin. Commission Regulation (EC) No 1881/2006 lays down Maximum Levels (MLs) for contaminants in food. Minimum Required Performance Limits (MRPLs) are defined in Article 4 of Commission Decision 2002/657/EC.

In accordance with Article 29 of Council Directive 96/23/EC, Commission approval of every third country's residue monitoring plan is necessary if that country is to remain on the list of third countries from which EU Member States may import animals and animal products. The list of countries and commodities with approved residue monitoring plans is in the Annex to Commission

Decision 2004/432/EC.

Findings

(a) Aquaculture

Decision No 130/2008/QD-BNN dated 31 December 2008 of MARD provides the main legal basis for the aquaculture RMP. The audit team noted that:

- planning for the 2012 RMP began in the fourth quarter of 2011, when NAFIQAD wrote to local and branch authorities requesting updated information on aquaculture production (area, species and volume of production). Previous non-compliant results were also taken into account in planning the RMP for the following year;
- each month local competent authorities submit information to the regional competent authorities on the types of diseases occurring in aquaculture in their areas and the chemicals and veterinary medicinal products being used by farmers. This information is processed and forwarded to NAFIQAD and is taken into account in RMP planning;
- although a detailed RMP for 2012 and results of implementation of the 2011 plan were sent to the Commission by 31 March 2012, these did not mention all laboratories involved in testing RMP samples. During the audit and upon a request for further clarification, the audit team received documentation showing that an additional three laboratories were involved in analysing RMP samples in 2011;
- the 2010 and 2011 RMPs covered 154 areas in 35 provinces, while the 2012 plan was extended to 163 areas in the same 35 provinces. These 163 areas cover the great majority of aquaculture production (see production data in section 4.4) and the areas from which exported products are sourced. NAFIQAD explained that, although they plan to extend the RMP to other areas over time, those areas currently not covered comprise mainly remote and mountainous areas without local staff and from which products to be exported are unlikely to be sourced;
- 4,206 samples were planned to be taken in 2011, covering production of 1,322,758 tonnes. The sampling rate, below the one sample per 100 tonnes of aquaculture production foreseen in EU legislation, has been justified based on the super-intensive methods of production for *Pangasius spp.* (Tra catfish) with productivity of 300-500 tonnes/hectare;
- MRLs are in accordance with EU limits and samples are collected at the various different stages of aquaculture production and cover the main substance group risks identified;
- the scope of substances tested for has been increased compared to the situation at the time of the 2009 FVO audit. For example praziquantel is now tested for. However substances such as doxycycline (contained in numerous products authorised for use in aquaculture in Viet Nam), neomycin and ivermectin (both detected in consigments of *Pangasius spp.* exported to the EU but not authorised for use in aquaculture in Viet Nam) and nitroimidazoles are currently not included in the scope of RMP testing. In this respect **recommendation No. 1** of the 2009 FVO audit report has only been partially addressed. Although there are no products containing neomycin authorised for use in aquaculture, the audit team found that products containing this substance intended for use in pigs and poultry were freely available on the market both in feed and as powders (see also section 5.3);
- the scope of substances tested for also includes trifluralin, aldrin, dieldrin, endrin, heptachlor, DDT, chlordane, hexachlorobenzene and lindane. In this respect **recommendation No. 2** of the 2009 FVO audit report has been addressed;
- the regional competent authority NAFIQAD Southern Region Authority (NAFIQAD-SRA)

visited by the audit team sends its RMP to processing plants and publishes it on the internet before all samples for the year have been taken. This document specifies the province/city, area and district where sampling will take place as well as the species to be sampled (for example *Penaeus vannamei, Penaeus monodon, Pangasius hypophtalmus* etc.). Such public availability of the RMP in advance of samples being taken means that sampling is not totally unforeseen or unexpected and undermines the ability of the competent authorities to detect the possible misuse of veterinary medicinal products in aquaculture.

(b) Honey

Circular No 23/2009/TT-BNN dated 29 April 2009 of MARD provides the legal basis for the RMP. The audit team noted that:

- although a detailed RMP for 2012 was given to the audit team at the opening meeting, this plan had not been sent to the Commission. In respect of the honey RMP, in 2010, 2011 and 2012 the Commission merely received two tables listing totals of samples planned per substance group for the current year and results of samples taken in the previous year, with no other details provided including of the laboratories testing the samples;
- the 2012 honey RMP was finalised in March 2012, with a draft plan being prepared by NCVHI 1 and sent to DAH at the end of February 2012. A scientific and technical committee then met to endorse the plan and it was sent to MARD for final approval;
- the 2012 RMP took account of the sampling and surveillance activities performed in 2011, and sampling was planned to be carried out during two main periods: February to April and October to December since most honey is collected from producers during those periods;
- the 2012 RMP foresees the taking of 189 samples, which is in line with the EU minimum requirement of 187 samples based on national production data;
- the scope of substances tested for now includes carbamates (carbaryl, aldricarb, methiocarb and pirimicarb), pyrethroids (alpha-cypermethrine and flumethrin) and amitraz. In this respect **recommendations No. 1 and 2** of the 2009 FVO audit report have been addressed.

Conclusions on planning of the residue monitoring plan

The aquaculture and honey RMPs basically comply with the requirements of Council Directive 96/23/EC. However the RMPs submitted to the Commission each year were found to be incomplete in some respects and some relevant veterinary medicinal products are also not yet included in the scope of testing of the aquaculture RMP. Publication of the aquaculture RMP in the southern region before all samples have been taken, indicating the areas and farmed species to be sampled, does not comply with the requirements of Council Directive 96/23/EC that sampling must be unforeseen and unexpected and compromises the effectiveness of the RMP in detecting potential misuse of veterinary medicinal products.

5.1.3 Implementation of the residue monitoring plan

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7. Article 4(2)(b) and (c) of Council Directive 96/23/EC lays down the requirements for central competent authorities in co-ordinating the activities of all bodies involved in residues controls. Articles 5 and 12 of Council Directive 96/23/EC deal with aspects pertaining

to the implementation of the residue monitoring plan. Sampling requirements are specified in Annex IV to Council Directive 96/23/EC and Commission Decision 97/747/EC and Commission Decision 98/179/EC lays down the rules for official sampling under the residue monitoring plan. EU methods of sampling for the official control a wide range of residues in products of animal origin are laid down in several pieces of EU legislation: Commission Directive 2002/63/EC (pesticides); Commission Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs); Commission Regulation (EC) No 333/2007 (certain chemical elements); Commission Regulation (EC) No 401/2006 (mycotoxins).

Findings

(a) Aquaculture

The audit team noted that:

- once the RMP is finalised it is sent from NAFIQAD to the regional competent authorities, who then allocate the samples to be taken among their districts depending on the volume and type of production;
- staff in local competent authorities choose the farms to be sampled on a random basis. Sampling is well-distributed throughout the year and across a large number of farms;
- based on the monthly progress of sampling implemented compared to planned, NAFIQAD reallocates sampling to other provinces where necessary to take account of any under-implementation detected;
- sampling is carried out without prior warning. Staff are well-trained and clear work instructions exist on the taking of samples. Samples are promptly delivered for testing to laboratories and, in the cases seen by the audit team, target turnaround times had been complied with (i.e. samples to be sent to the laboratory within two days, to be analysed and results reported within five days);
- some targeting of samples occurs: for example a farm which reported a non-compliant result for an A6 substance was re-sampled for A6 substances during the following year's RMP;
- results are received by the central competent authority NAFIQAD and are published on a monthly basis, with details of any farms reporting non-compliant results. In addition to the standard follow-up of non-compliant results (see section 5.1.5), this is another means of informing processing plants that they should not source product from these farms.

(b) Honey

The audit team noted that:

- since the last audit, detailed guidance notes have been developed by DAH on the implementation of the RMP: *inter alia* Guidance No 169/TY-VS1 of 31 January 2010 on sampling for inspection and surveillance of veterinary hygiene for bee honey manufacturers and traders, and Guidance No 170/TY-VS1 of 31 January 2010 on implementing inspections and the surveillance programme for veterinary hygiene of bee honey manufacturers and traders;
- sampling is carried out by staff from NCVHI 1 without prior warning to the establishment involved. Clear work instructions exist on the taking of samples, staff had received relevant training and samples were promptly delivered for testing to the laboratory;
- at the same time as taking RMP samples, staff from NCVHI 1 perform hygiene inspections of the honey producers or processing plants where sampling is being performed;

- although sampling is planned to be carried over two main periods (February to April and October to December), the audit team saw that in 2011 of the 177 samples planned for the whole year 174 had been taken over 11 days: 15-21 November and 1-14 December. In 2012 of the 187 samples planned for the whole year 136 had been taken over the nine days from 29 March to 6 April. Sampling is thus not carried out at variable intervals spread out over the relevant honey harvesting periods during the year;
- in the 2011 honey RMP samples were taken from 23 establishments, with some establishments being sampled more than once. DAH informed the audit team that there were 2,071 bee farms in Viet Nam and that one in every 30-50 farms was planned to be sampled under the RMP.

Conclusions on implementation of the residue monitoring plan

The aquaculture and honey RMPs are generally implemented as planned, although the effectiveness of the honey RMP is compromised by the uneven distribution of honey sampling during the year and the small number of establishments sampled.

5.1.4 Other residues monitoring programmes

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive. Article 11 of Council Directive 96/23/EC gives the option of conducting other residues testing, particularly in relation to detection of illegal treatment of food producing animals. Article 9 of Council Directive 96/23/EC foresees the application of own-checks by food business operators.

5.1.4.1 Official pre-export testing for aquaculture

Findings

An official Decision No 1471/QD-BNN-QLCL of 20 June 2012 lays down the scope of pre-export tests for aquaculture products before export health certificates are issued. The audit team noted that:

- for the EU market these requirements include *inter alia* testing for chloramphenicol, nitrofurans (AOZ and AMOZ), malachite green and leucomalachite green (MG/LMG), enrofloxacin, mercury, lead, cadmium and trifluralin;
- as part of the process of applying for an export health certificate, processing plants supply regional offices with details of the consignment including the identity of the product and traceability and labelling information;
- NAFIQAD informed that of 26,667 pre-export tests performed in 2011 there were 103 non-compliant results: 52 for chloramphenicol, 20 for MG/LMG, 19 for trifluralin and 12 for nitrofurans;
- the audit team examined the follow-up files for cases where MG/LMG had been detected in a pre-export test for a consignment of carp and where cadmium, mercury and trifluralin had been detected in consignments of fishery products. Non-compliant pre-export test results were subject to the same official follow-up as for non-compliant RMP samples (see also section 5.1.5).

5.1.4.2 Official pre-export testing for honey

Findings

Honey (exported to non-EU destinations) is subject to official pre-export testing for chloramphenicol before export health certificates are issued. The audit team noted that:

- as part of the process of applying for an export health certificate, processing plants supply regional DAH offices with details of their own checks already performed, which may include testing for residues depending on the customer's requirements;
- detailed instructions exist on the taking of pre-export samples and staff had received training on how to perform these tasks. Testing is performed in the laboratory of Regional Animal Health Office No 6 and non-compliant results are handled under the same DAH Guidance No 168/TY-VS1 which applies to RMP samples on dealing with bee honey that does not ensure food safety;
- the audit team saw the follow-up file for one case dating from 2010 when chloramphenicol had been detected in a pre-export test. The standard follow-up actions were taken, as would be applied for a non-compliant RMP test result (see also section 5.1.5).

5.1.4.3 Establishment own-checks

Findings

(a) Aquaculture

The audit team visited two shrimp processing plants and one *Pangasius spp.* processing plant. The audit team noted that:

- processing plants perform a variety of controls on their suppliers including *inter alia* the use and storage of chemicals and veterinary medicinal products. The *Pangasius spp.* processing plant visited by the audit team also required its supplier farms to be tested *inter alia* for dioxins, polychlorinated biphenyls (PCBs) and pesticides every 6 months and applied 100% pre-harvest checks for residues to incoming consignments of fish;
- extensive company own-checks for residues, based on customer requirements, were carried out as standard in the processing plants visited. These included testing for chloramphenicol, AOZ, AMOZ, MG/LMG, enrofloxacin, trifluralin, flumequin and chlorpyriphos. The results of these own-checks were provided to DAH when the companies applied for export health certificates.

(b) Honey

The audit team visited two honey processing plants and in Regional Animal Health Office No 6 also examined documentation submitted when processors applied for export health certificates for honey. The audit team noted that:

- processing plants generally have a fixed list of registered honey farm suppliers who supply the processing plants with honey under contract, thus facilitating traceability. Examples of these contracts seen by the audit team specify *inter alia* that the honey supplied is Vietnamese honey collected from the farmer's own beehives, shall be free of residues and that the producer will bear the financial loss if any residues contamination is detected in the

honey;

- company own-checks for residues were carried out as standard based on customer requirements and the results of these own checks were provided to DAH as part of applying for export health certificates. Such own-checks testing included testing for fluoroquinolones, streptomycin, chloramphenicol, carbendazim and C4-sugar adulteration. The processing plant operators stated that they would inform the regional DAH office of any non-compliant results detected in their own checks.

Conclusions on other residues monitoring programmes

Official pre-export testing of aquaculture and honey for residues, combined with good traceability and extensive testing for residues included in the own-checks programme of processing plants increase confidence in the residues status of aquaculture products and honey.

5.1.5 Follow-up of non-compliant results

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive. Measures to be taken by competent authorities in response to the finding of non-compliant residues results are described in Articles 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Council Directive 96/23/EC.

Findings

(a) Aquaculture

The audit team noted that:

- local supervisory authorities are responsible for the follow-up of any non-compliant results, including the taking of follow-up samples, ordering the suspension of harvesting, performing inspections to investigate the reasons for the contamination and the application of fines in some cases;
- in all of the cases seen by the audit team prompt and effective follow-up actions were taken following the reporting of non-compliant results. These included correspondence from the NAFIQAD SRA to the local authority informing them of the non-compliant result and asking them to inform the producer and perform a follow-up investigation as to the possible cause of the contamination;
- follow-up samples were taken routinely as part of the investigation and were analysed promptly. Detailed files were available for all cases examined by the audit team with written records documenting each stage of the investigation until the case was finally closed;
- detailed follow-up files were also available concerning the follow-up of RASFF alerts in consignments of fishery products exported to the EU or of non-compliant results detected in official pre-export tests. Traceability back to the farm of origin was possible in all cases seen by the audit team.

(b) Honey

The audit team noted that:

- NCVHI 1 is responsible for coordinating the follow-up of any non-compliant results. The last non-compliant RMP results date from 2010 and involved the detection of enrofloxacin, streptomycin and sulphadiazine. DAH Guidance No 168/TY-VS1 of 31 January 2010 on dealing with bee honey that does not ensure food safety sets out the procedures to be followed in such cases, including sending staff to seal the batch of honey in question, follow-up sampling and ordering the transformation or destruction of the implicated honey;
- in the cases seen by the audit team NCVHI 1 promptly informed the processing plant involved of the non-compliant result and instructed them to take specific actions such as prohibiting the further use of the honey involved, suspending further purchases from the apiary of origin, investigating the possible source or reasons for the contamination and transforming the honey so that it would not go for human consumption. Following receipt of the company's reply DAH performed an official inspection to confirm the actions taken;
- traceability of the honey back to the farm or farms of origin was possible in all cases of non-compliant results seen by the audit team and in the processing plants visited. In this respect **recommendation No. 4** of the 2009 FVO audit report concerning traceability back to the farm of origin has been addressed.

Conclusions on follow-up investigations/actions

Follow-up measures for non-compliant results detected under the RMPs for aquaculture and honey are effective and generally equivalent to the requirements of Council Directive 96/23/EC. Official follow-up also takes place in the case of RASFF alerts or non-compliant results detected in official pre-export tests.

5.2 LABORATORIES

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive. Article 15 of Council Directive 96/23/EC requires that official samples are examined in approved laboratories. Requirements for accreditation of laboratories are laid down in Point 1.2. of the Annex to Commission Decision 98/179/EC. The rules for analytical methods to be used in the testing of official samples taken pursuant to Article 15(1) of Council Directive 96/23/EC are laid down in Commission Decision 2002/657/EC – in particular Articles 3, 4, 5 and 6 which cover, *inter alia*, validation requirements and quality control. More specific requirements for analytical methods for certain substances are laid down in the annexes to Commission Regulation (EC) No 1883/2006 (dioxins and dioxin-like PCBs in foodstuffs), Commission Regulation (EC) No 333/2007 (chemical elements in foodstuffs) and Commission Regulation (EC) No 401/2006 (mycotoxins).

5.2.1 General description

Findings

(a) Aquaculture

In 2011 aquaculture RMP samples were analysed in nine laboratories: NAFIQAD branches 1-6 and three additional private laboratories which were used to test a small number of samples depending

on the number of samples taken and the capacity of NAFIQAD branches 1-6. These private laboratories were not mentioned in the 2012 RMP and 2011 results submitted to the Commission by 31 March 2012 (see also section 5.1.2).

(b) Honey

Circular 23/2009/TT-BNN of MARD appointed NCVHI 1 to take RMP samples and carry out residue analysis in honey. In 2012 another pesticides laboratory (Northern Pesticide Control and Testing Centre) has been analysing RMP samples for carbamates, pyrethroids, amitraz, organochlorine compounds, organophosphorous compounds and arsenic. The 2012 RMP and 2011 results submitted to the Commission by 31 March 2012 did not specify which laboratories were performing RMP analyses (see also section 5.1.2).

5.2.2 On the spot visits in the laboratories

The audit team visited four laboratories. The audit team noted that:

- state-of-the-art equipment was available, including GC and HPLC systems with various detectors, UPLC, LC-MS/MS and UPLC-MS/MS systems, GC-ECD, GC-MS and GC-MS/MS systems, ICP-MS apparatus;
- sufficient staff resources were available in all cases. Staff were highly trained, good training records were available and many analysts had participated in international training courses;
- standard operating procedures (SOPs) for validation were available including all the requirements of Commission Decision 2002/657/EC;
- the management of standards was satisfactory and instruments were properly identified and calibrated, including pipettes and pH meters. Maintenance of equipment was performed routinely and logbooks were up-to-date. Monitoring of the temperature of freezers and refrigerators was performed daily by means of calibrated thermometers;
- there was regular participation in proficiency tests with generally satisfactory results. In case of questionable or unsatisfactory results, cause analysis and corrective actions were always immediately initiated. For some methods when the laboratories could not participate in proficiency tests (for example no proficiency tests were available), no use was made of alternatives mentioned in the ISO/IEC 17025:2005 standard.

5.2.2.1 NAFIQAD Branch No. 4

Findings

This laboratory is one of the six NAFIQAD laboratories involved in the analysis of RMP samples for aquaculture and also analyses pre-export test samples. The audit team noted that:

- all methods applied for the RMP are in the scope of accreditation. In the last accreditation body audit by VILAS in July 2012 concerning technical requirements related to residue analysis one minor non-compliance was noted;
- validation files for fluoroquinolones with LC-MS/MS were examined in detail during the audit and found to be very complete. A large variety of samples, representative of routine analyses, were used in these validations. The performance characteristics include CCα and CCβ and the measurement uncertainty was calculated with the validation of every method being repeated each year. In this respect **recommendation No. 5** of the 2009 FVO audit report concerning the validation of analytical methods has been addressed;

- Cd, Hg, Pb and As are measured by means of ICP-MS. In order to prevent contamination, samples for these elements are prepared and analysed separately from other samples. Each measurement series contained next to the standard curve, with a criterion for the regression coefficient of at least 0.99, the reagent blank, control standards and a certified reference material (CRM), which is analysed in duplicate. Control charts for the four elements are kept for this CRM;
- registrations for the analysis of chloramphenicol (screening with ELISA) and fluoroquinolones, sulphonamides and trimethoprim by means of LC-MS/MS were also examined. All registrations were very complete and demonstrated that criteria for the calibration curves, blank sample and positive control sample were controlled. In addition, for LC-MS/MS control standards were used after ten injections and at the end of the series. The criteria applied for identification are those required by Commission Decision 2002/657/EC;
- the laboratory participates in proficiency tests organised by FAPAS, KFDA (Korea Food and Drug Administration) and NAFIQAD. Performance is generally very good and when questionable ($2 \leq |z| \leq 3$) or unsatisfactory results ($|z|>3$) are obtained, analysis and corrective actions are immediately initiated.

5.2.2.2 NAFIQAD Branch No. 6

Findings

In this laboratory most of the analyses are samples of *Pangasius spp.*. The audit team noted that:

- all methods applied for the RMP are in the scope of accreditation;
- the methods and registrations for the analysis for trifluralin (GC-MS), MG and LMG (UPLC-MS/MS), diethylstilbestrol (DES) and methyltestosterone (UPLC-MS/MS) and tetracyclines (HPLC) were examined. Isotopically labelled internal standards are used in all mass spectrometric methods examined. The regression coefficient (r2) for the calibration curves, comprising at least six points (including zero) and obtained as extracted standards to compensate for the matrix effect, must be at least 0.99. A blank sample and a positive control are always included. The criteria applied for identification with mass spectrometry are those required in Commission Decision 2002/657/EC;
- a detailed examination of the validation files for trifluralin (GC-MS), MG and LMG (UPLC-MS/MS), DES and methyltestosterone (UPLC-MS/MS) and tetracyclines (HPLC) was made. Validation was performed on at least three days at a minimum of three concentrations around the level of interest each in seven-fold. Comprehensive validation files were available, which included calculations of the decision limit (CCα), detection capability (CCβ) and measurement uncertainty. Only for DES and methyltestosterone, for which the validation was done in 2008, was the validation done on one day and CCα and CCβ had been determined. However the ongoing internal quality assurance demonstrated that this method is also fit-for-purpose (criteria for identification are always met for the control samples spiked at 1 µg/kg). In this respect **recommendation No. 5** of the 2009 FVO audit report concerning the validation of analytical methods has been addressed;
- Cd, Hg, Pb and As are measured by means of ICP-MS and in every series a CRM is analysed as positive control sample;
- the laboratory participates regularly in proficiency tests. Performance is generally excellent. In a few cases in 2010 and 2011 questionable ($2 \leq |z| \leq 3$) or unsatisfactory results ($|z|>3$) were obtained. In one case the reason for this was that the sample received was in a state of

decomposition (prawn for chloramphenicol in 2010) and in another case the matrix was unfamiliar to the laboratory (bovine matrix instead of fish matrix for avermectins in 2011).

5.2.2.3 National Centre for Veterinary Hygiene Inspection No. 1

Findings

This laboratory analyses all of the samples for the honey RMP for all substance groups, with the exception of carbamates, pyrethroids, organochlorine compounds, organophosphorous compounds and arsenic, which are analysed in another laboratory (Northern Pesticide Control and Testing Centre). The audit team noted that:

- the laboratory is ISO-17025 accredited by VILAS. Currently three methods concerning determination of residues in honey are in the scope of accreditation: streptomycin, furazolidone (AOZ) and fluoroquinolones. All methods are ELISA-methods;
- during the last accreditation body VILAS audit however on 5-6 September 2012, no less than 13 new methods for residues in honey were presented for accreditation. There were a number of non-compliances, but the laboratory said that these will have been addressed within one month. These methods for the matrix honey include the analysis of: enrofloxacin, AMOZ, AHD, SEM, flumequine, sulfadiazine, sulfamethazine and sulfaquinoxaline with ELISA; chloramphenicol and four tetracyclines (oxytetracycline, tetracycline, chlortetracycline and doxycycline) with LC-MS/MS; lead, cadmium and mercury with AAS;
- validation for AOZ by means of ELISA was performed on different days at four different concentrations (0.3, 0.6, 0.9 and 1.0 µg/kg). Linearity, precision, recovery, LOD, LOQ, CCα, CCβ and measurement uncertainty were calculated. The calculation of LOD, LOQ and CCα were based on the analysis of 20 blank samples. CCα and CCβ were calculated to be 0.19 and 0.37 µg/kg respectively, which is fit-for-purpose. The validation of AMOZ and enrofloxacin was performed in a similar way at three concentrations (0.5, 1.0 and 1.5 µg/kg for AMOZ; 5, 10 and 15 µg/kg for enrofloxacin). The CCβ obtained demonstrated that the methods allowed to detect these substances at 1 µg/kg and 10 µg/kg respectively as specified in the RMP;
- the validation file for chloramphenicol by means of LC-MS/MS was very complete. Linearity was done with a calibration curve of seven points on two occasions. Repeatability, within-laboratory reproducibility and recovery were determined at three levels around the MRPL by analysing samples at these concentrations on three days in six fold ; LOD, LOQ and CCα were calculated starting from 20 blank samples also demonstrating the specificity, while CCβ was calculated starting from 20 samples spiked at CCα. The measurement uncertainty was also determined;
- the validation of the HPLC method with UV-detection for four tetracyclines (oxytetracycline, tetracycline, chlortetracycline and doxycycline), done in August 2011, included LOD, LOQ, linearity, recovery and precision. Repeatability, within-laboratory reproducibility and recovery were determined on three levels (35, 62.5 and 125 µg/kg) by analysing spiked samples on two days in six-fold. The LOQ obtained was 20 µg/kg. In the later validation in 2012 for these tetracyclines by means of LC-MS/MS the CCα values obtained ranged from 3.4 to 6.5 µg/kg. The validation was done on three days with three concentrations each in six-fold. The parameters determined are CCα, CCβ, LOD, LOQ, repeatability and within-lab reproducibility, linearity (r2>0.98), the range, recovery and measurement uncertainty. In this respect **recommendation No. 5** of the 2009 FVO audit report concerning the validation of analytical methods has been addressed;

- records with chromatograms for the analysis of tetracyclines by HPLC, used up to now, were examined. Criteria for the calibration curves, blank sample and recoveries for the tetracyclines of the positive control sample at 125 µg/kg were demonstrably controlled. Although the levels in the control sample are high in relation to the levels specified in the RMP (ranging from 25 to 35 µg/kg depending on the substance), based on the chromatograms of the negative samples and validation at 35 µg/kg the method is fit-for-purpose. In the near future this method will be replaced by the LC-MS/MS method;
- validation is underway but not yet fully completed for some ELISA methods for antibacterial substances (tylosin, norfloxacin, amoxicillin, penicillin V and ampicillin);
- registrations for the analysis of AOZ (screening with ELISA) and of chloramphenicol by means of LC-MS/MS were also examined. The registrations were very complete and demonstrated that criteria for the calibration curves, blank sample and recovery of the positive control sample were controlled. For LC-MS/MS in addition a control was made on the level of the internal standard chloramphenicol-d5 and criteria applied for identification based on two transitions for MS/MS are those required in Commission Decision 2002/657/EC. In this respect **recommendation No. 6** of the 2009 FVO audit report concerning appropriate quality control measures has been addressed;
- temperature of refrigerators was controlled and recorded daily, with the exception of the one used for the preservation of honey samples for which no records were available;
- the laboratory participates regularly in proficiency tests for Pb, Cd and As in water and meat (five proficiency tests in 2010 and 2011) with good results. Only in one case a questionable result ($2 \leq |z| \leq 3$) was obtained for lead. A cause analysis was performed and corrective actions were taken. For the other substances however there was only very recently a proficiency test for chloramphenicol in honey (August 2012) and for sulphonamides in honey (September 2012). Results for these latest proficiency tests were not yet available.

5.2.2.4 Regional Animal Health Office No. 6

Findings

This laboratory is performing pre-export testing for honey (to non-EU destinations such as the USA and Japan). For the moment the only residue tested is chloramphenicol by means of screening with ELISA. The audit team noted that:

- the laboratory is ISO-17025 accredited. Concerning residues in honey for the moment only the ELISA method for chloramphenicol is in the scope of accreditation. In 2011 more than 600 samples of honey were analysed for chloramphenicol;
- each measurement series for chloramphenicol contained a standard curve with six points, a blank and a spiked sample at the MRPL of 0.3 µg/kg. Together with the samples, these standards and controls are applied in duplicate on the plates. Samples containing an apparent concentration of ≥ 0.2 µg/kg of chloramphenicol are sent for confirmation with LC-MS/MS. Records are very complete and a control chart is kept for the positive control sample. In this respect **recommendation No. 6** of the 2009 FVO audit report concerning appropriate quality control measures has been addressed;
- staff are well-trained and there is regular contact with NCVHI 1 who use the same kit for chloramphenicol;
- the validation of the ELISA method for chloramphenicol was performed on different days by different operators with light coloured and dark coloured honey in concentrations around

the MRPL. The validation demonstrated that the method was capable of detecting chloramphenicol below the applied level for confirmation of 0.2 µg/kg. The laboratory is preparing validation for other residues in honey, such as ELISA-methods for the screening of streptomycin and nitrofurans. The validation plan for streptomycin in honey was already approved and completed in June 2012. In this respect **recommendation No. 5** of the 2009 FVO audit report concerning the validation of analytical methods has been addressed;

- the samples are stored at room temperature and avoiding incoming daylight. Samples are normally analysed within 3 to 4 working days;
- the laboratory participated recently in a proficiency test for chloramphenicol in honey. Honey test material was obtained from FAPAS in August 2012 and results are not yet available.

Conclusions on laboratories

Considerable progress has been made since the 2009 audit, with laboratories now operating at a very high level of performance, thus providing assurances on the reliability of analytical results and facilitating effective implementation of both the honey and aquaculture RMPs.

5.3 Veterinary medicinal products and medicated feedingstuffs

5.3.1 Authorisation, distribution and use of veterinary medicinal products

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 and meet the requirements of Article 11(2) of Directive 96/22/EC.

Article 7 of Council Directive 96/23/EC provides for legislation on the use of (pharmacologically active) substances listed in Annex I to the Directive and, in particular, provisions on their prohibition or authorisation, distribution and placing on the market and the rules governing their administration. Articles 4, 5 and 7 of Council Directive 96/22/EC establish conditions for the administration of substances, referred to in its Annex II, List B and Annex III, to farm and aquaculture animals.

According to Article 11(2) of Council Directive 96/22/EC, Member States may not import live animals or animal products from third countries which authorise the use of stilbenes or thyrostats in food producing animals. Member States are also prohibited from importing products of animal origin for human consumption if the animals from which such products have been derived have been treated at any time with either thyrostatic substances, stilbenes, stilbene derivatives, their salts and esters, oestradiol 17β and its ester-like derivatives, and beta-agonists if administered for the purposes of growth promotion.

The relevant provisions in EU law governing the marketing authorisation of veterinary medicinal products are laid down in Articles 5-15, 21-30, 58-62 and 83 of Directive 2001/82/EC and for certain products authorised on an EU-wide basis, in Articles 30-40 of Regulation (EC) No 726/2004. Provisions governing the distribution and use of veterinary medicinal products are laid down in Articles 65-71 of Directive 2001/82/EC. Veterinary medicinal products which are authorised for use in food producing animals may only contain pharmacologically active substances which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Article

67(aa) of Directive 2001/82/EC requires that veterinary medicinal products for food producing animals are only dispensed to the public under a veterinary prescription unless exempted under the conditions laid down in Article 2 of Commission Directive 2006/130/EC.

In respect of medicated premixes conditions governing the distribution and use are laid down in Articles 2, 8 and 9 of Council Directive 90/167/EEC. Production of medicated feedingstuffs can only take place in establishments which have been authorised for the production of feedingstuffs containing additives in accordance with Articles 9, 10, 11 and 13 of Regulation (EC) No 183/2005 and the production process must satisfy the conditions laid down in Annexes I and II to that Regulation.

Findings

As described in the 2009 FVO report, DAH is responsible for issuing market authorisations for all veterinary medicinal products for food-producing animals and controlling imports of such products into Viet Nam. Lists of authorised veterinary medicinal products, and those which are specifically permitted or prohibited to be used in aquaculture or for bees, are maintained by DAH. Off-label use of veterinary medicinal products in food-producing animals is not permitted. According to DAH, MRLs are established in line with those set down in EU legislation or on the basis of scientific studies.

(a) Aquaculture

The four appendices to Circular 15/2009/TT-BNN together set down those chemicals, drugs and antibiotics which are either prohibited or authorised for veterinary uses or for manufacturing and trading in aquaculture. Since the 2009 FVO audit, trifluralin (Circular 20/2010/TT-BNNPTNT of 2 April 2010) and cypermethrin, deltamethrin and enrofloxacin (Circular 03/2012/TT-BNNPTNT of 16 January 2012) have been added to the list of substances prohibited for use in aquaculture. The commercial production of medicated feed is prohibited, although farmers may add veterinary medicinal products to feed using their own mixers.

(b) Honey

The veterinary medicinal products which may be used in bee-keeping are set down in Circular Letter No. 52/2009/TT of 21 August 2009. Article 17 of Circular Letter No: 23/2009/TT-BNN (stipulations on veterinary hygiene monitoring and surveillance for bee honey manufacture and trade) specifically bans the importation, production, trade or use of antibiotics and toxic chemicals for prevention and treatment of bee diseases. Article 18 of this Circular further stipulates that it is prohibited to mix antibiotics or hormones into feeds used in bee-keeping. According to DAH and representatives of the Vietnamese National Apiculture Association, efforts have been made since the 2009 FVO audit to raise awareness amongst bee-keepers of the restrictions regarding the use of veterinary medicinal products and to provide relevant guidance to encourage responsible use of medicines. Guideline Number 115/TY-DT of 19 January 2010 provides information for the prevention and control of *Varroa destructor* and *Tropilaelaps mercedesae* based on good agricultural and hygiene practices. Details are provided of biological control techniques and the use of formic or lactic acid where necessary.

Farmers may buy veterinary medicinal products from retailers and in the case of larger producers who have their own technical staff, from wholesalers or directly from the manufacturers. According to Article 15 of Circular Letter No: 23/2009/TT-BNN veterinary practitioners must diagnose conditions and prescribe the use of veterinary medicinal products for bee-keeping and, as described in the 2009 FVO report, similar requirements are in place for veterinary medicinal products intended for use in aquaculture. According to the DAH, all veterinary pharmacies are required to have a veterinarian present who may prescribe treatments based on a description of symptoms, or a clinical examination. Records are required to be kept of the incoming and outgoing sales of

veterinary medicinal products and farmers are required to maintain treatment records which specify the condition for which treatment was required, the medicine used and any applicable withdrawal period.

The audit team noted that:

- the list of chemicals and antibiotics banned from manufacturing or trading in aquaculture set down in appendix 1 to Circular No. 15/2009/TT-BNN includes those substances listed in Table 2 of Regulation (EU) No 37/2010 (MG and gentian violet). The list of substances approved for use in aquaculture is generally in line with those listed in Table 1 of Regulation (EU) No 37/2010;
- similarly, the list of substances authorised for use in bee-keeping includes only those which are currently listed for this purpose in Table 1 of Regulation (EU) No 37/2010;
- the aquaculture farmers, food business operators and retailers and wholesalers of veterinary medicinal products involved in this sector which were visited by the audit team had been made aware of the changes to the list of banned substances by various means including direct e-mails and the provision of leaflets and posters which clearly explain which substances cannot be used;
- product information inserts or the labels of veterinary medicinal products checked by the audit team conformed with the national requirements, which are generally as set down in Directive 2001/82/EC. This included details of the species, dosage and any relevant withdrawal periods. The national authorisation code and batch number was also given;
- prescriptions for the sale of veterinary medicinal products were available in some cases seen by the audit team. These had often been issued by the veterinarian present in the pharmacy. Records for the incoming purchases and outgoing sales of veterinary medicinal products were provided when requested by the audit team and these indicated the date of sale, the products sold and the name of the purchaser. These showed that in some cases, aquaculture farmers had also purchased veterinary medicines not authorised for use in aquaculture. It was explained that veterinary medicinal products for species of animals other than fish or bees, may be bought by farmers without a prescription. It was acknowledged that veterinary medicinal products obtained in this way could potentially be misused and that this may be reflected in the non-compliant results detected in the RMP, in pre-export checks and in RASFF alerts for aquaculture products (see sections 4.3, 5.1.4 and 5.1.5);
- in the aquaculture farms visited, standard pond books were used to record daily information such as mortality rates, the use of feed, chemicals, minerals and veterinary medicinal products and the date when the pond was finally harvested. In each case seen by the audit team, it was possible to verify that for veterinary medicinal products used the applicable withdrawal periods had been respected;
- according to representatives of the Vietnamese National Apiculture Association, standard diaries have been distributed to registered bee-keepers to be used to record relevant production information, including the presence of any disease and the use of veterinary medicinal products. In one such diary seen by the audit team, information relating to a prescribed treatment regime for control of Varroa destructor (with formic acid) was recorded. No other veterinary medicinal products were used.

Conclusions on authorisation, distribution and use of veterinary medicinal products

The system in place for the authorisation, distribution and use of veterinary medicinal products is similar to that provided for in EU legislation.

5.3.2 Controls on the distribution and use of veterinary medicinal products

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7 which provides for legislation on the use of (pharmacologically active) substances listed in Annex I to the Directive and, in particular, provisions on their prohibition or authorisation, distribution and placing on the market and the rules governing their administration. Article 10 of Council Directive 96/23/EC lays down the veterinary medicines record keeping requirements for stockowners.

The relevant provisions in EU law governing competent authorities' obligations to carry out inspections throughout the distribution chain of veterinary medicinal products in order to verify compliance with the provisions of the EU code relating to veterinary medicinal products (Directive 2001/82/EC) are laid down in Articles 65, 66, 68, 69 of that Directive. With regard to ensuring that the production of medicated feedingstuffs is in accordance with Council Directive 90/167/EEC, the rules governing control functions by the competent authorities are laid down in Articles 4, 9 and 13 of said Directive.

Findings

The control of wholesalers and retailers of veterinary medicinal products is carried out by the sub-departments of animal health based on an inspection programme which has been strengthened in the last year in accordance with Circular 14 of 23 March 2011. According to this Circular, wholesalers and retailers of veterinary medicinal products should be inspected once or twice a year based on two risk-based categories. A more comprehensive checklist than that used at the time of the 2009 FVO audit is included in the annex to this Circular and it includes specific points regarding records, checks on labelling requirements and that all veterinary medicinal products on sale are authorised in Viet Nam.

The local management authorities are responsible for the inspection of aquaculture farms and the Department of Fisheries is responsible for control of the production, distribution and use of feedingstuffs for aquaculture. The roles of the competent authorities and the Vietnamese National Apiculture Association in implementing the inspection and surveillance programme for veterinary hygiene of bee honey manufacturers and traders is set down in guidance No. 170/TY-VS1 of 31 January 2010. According to this document, the Vietnamese National Apiculture Association is responsible for preparing and updating a list of honey producers and traders and for organising training aimed at encouraging the adoption of HACCP and good manufacturing and production practices in order to enhance food safety. NCVHI 1, the sub-departments of animal health and the regional animal health offices may all carry out inspections of bee-keepers and traders regarding the use of veterinary medicinal products, namely related to RMP sampling, follow-up of non-compliances and the issuing of export certificates respectively. The audit team noted that:

- data provided by the DAH showed that, in 2011, approximately 60% of wholesalers and 46% of pharmacies selling veterinary medicinal products were inspected. Non-compliances were detected in approximately 11% of inspections. According to the DAH, the most common problems detected related to labelling issues and the sale of expired or non-authorised products;
- significant deficiencies detected in the pharmacies and wholesalers were notified to the Provincial Inspector who carried out follow-up inspections or imposed sanctions to deter further non-compliance. Examples seen by the audit team included fines and the seizure and

destruction of non-compliant products. According to the competent authorities, it is planned to strengthen sanctions further in 2013;

- one wholesaler of veterinary medicinal products visited had been inspected regularly by the sub-department of animal health, but had also been checked by the Department of Fisheries in relation to the sale of feed and by the provincial inspector owing to a history of non-compliances. In addition, the wholesaler had been subject to a market control inspection which included checks on the labelling and authorisation of veterinary medicinal products being sold. Sanctions had been imposed in relation to shortcomings in the labelling of one product;
- all pharmacies visited by the audit team had been inspected regularly by the sub-department of animal health and corrective actions had been required to address any deficiencies identified;
- data provided by the competent authorities showed that in 2011, inspections concerning the use of veterinary medicinal products were carried out in approximately 200 hatcheries, 1,700 shrimp farms and 1,630 fish farms. Non-compliances were detected in less than 1% of these inspections. The aquaculture farms visited had been inspected regularly by the sub-department of animal health to check compliance with the veterinary hygiene conditions and the sub-department of fisheries to inspect compliance with feed and environmental requirements. The results of these inspections were generally well-documented and points checked related to the accuracy and completeness of the pond record books, including the use of veterinary medicinal products;
- during 2010, a special programme of controls was conducted by the Department of Fisheries in which the wholesaler and one of the pharmacies and two farms visited had been checked to verify that no products or feeds containing trifluralin were sold or being used in aquaculture farms;
- according to data provided by DAH, in 2011 NCVHI 1 carried out approximately 40 inspections among of a total of 2,071 registered apiaries. In practice, the inspections were carried out at the same time that samples for the RMP were collected and apiaries to be visited were selected by the processing establishment. The results of inspections were recorded using standard checklists which included checks that the production diary had been completed properly and that the use of veterinary medicinal products was recorded and that this was in-line with the prescribed treatment regime. In these respects **recommendation No. 7** of the 2009 FVO audit concerning implementing a system of controls over the distribution and use of veterinary medicinal products together with dissuasive enforcement measures has been addressed;
- according to data provided by the Department of Fisheries, 199 samples of commercially produced feed were analysed in 2011 to check for a number of quality and safety parameters, including two nitrofuran metabolites and chloramphenicol. No non-compliances were detected. In 2010, an additional inspection and sampling programme was implemented in order to verify if the ban on the use of trifluralin in aquaculture introduced in April 2010 was being respected. In these respects **recommendation No. 3** of the 2009 FVO audit concerning the national feed sampling policy has been addressed. All aquaculture farms visited by the audit team used commercially produced feed although veterinary medicinal products were mixed into this feed on-farm when required. The use of these veterinary medicinal products was recorded in the pond books.

Conclusions on official controls on the distribution and use of veterinary medicinal products

Steps have been taken since the previous FVO audit to strengthen the official controls on the

distribution and use of veterinary medicinal products and the sanctions that may be imposed when non-compliances are detected. These controls now provide additional reassurances regarding the usage of veterinary medicinal products in commodities which may be exported.

5.4 Follow-up of relevant recommendations made in previous FVO report on residues (DG SANCO 2009-8188 MR Final)

No.	Recommendation	Findings
1	To ensure that all appropriate veterinary medicinal products are included in the scope of testing in the national residues plans, taking account of the availability of medicines on the domestic market and the likelihood of their use in each of the production sectors, to the extent that guarantees provided should be at least equivalent to the requirements of Council Directive 96/23/EC.	This recommendation has been fully addressed in respect of honey and partially addressed as regards aquaculture where substances such as doxycycline, neomycin, ivermectin and nitroimidazoles are still not tested for (see section 5.1.2 and recommendation No. 2 of this report).
2	To broaden the scope of the testing for pesticides, taking account of their availability and the likelihood of their residues, to the extent that guarantees provided should be at least equivalent to the requirements of Council Directive 96/23/EC.	This recommendation has been addressed (see section 5.1.2).
3	To review the feed sampling policy under the national residues plan, aiming at the detection of illegal or unauthorised use of medicines, as required by Council Directive 96/23/EC.	This recommendation has been addressed (see section 5.3.2).
4	To ensure that when non-compliant results are found in honey, traceability back to the farm of origin is possible in order to facilitate timely investigations and actions which are at least equivalent to the requirements of Council Directive 96/23/EC.	This recommendation has been addressed in that traceability back to the farm of origin was possible in all cases seen by the audit team.
5	To ensure that all analytical methods are properly validated to a standard at least equivalent to that required by Article 3 of Commission Decision 2002/657/EC.	This recommendation has been addressed for both honey and aquaculture, with all analytical methods being either fully validated or in the process of being so (see section 5.2.2).
6	In addition to the general requirement for validation, in respect of honey analysis, ensure that appropriate quality control measures are put in place to demonstrate that the analytical methods used are fit for purpose and satisfy the requirements laid down in Article 5 of Commission Decision 2002/657/EC.	This recommendation has been addressed (see sections 5.2.2.3 and 5.2.2.4).
7	To implement a system of effective official controls over the distribution and use of veterinary	This recommendation has been addressed (see section 5.3).

	medicinal products together with dissuasive enforcement measures to avoid illegal or unauthorised use (off-label) of veterinary medicinal products as required in national legislation, with an effect at least equivalent to the requirements laid down in Directive 2001/82/EC.	

6 Overall Conclusions

In general the systems of residues controls in Viet Nam for honey and aquaculture offer guarantees with an effect equivalent to those provided for by EU rules. The aquaculture and honey residue monitoring plans comply with the minimum requirements of Council Directive 96/23/EC and are generally implemented as planned, although sampling of honey could be more evenly distributed during the year and across a larger number of establishments. Laboratories performing analyses are operating at a very high level of performance, thus providing assurances on the reliability of analytical results. Follow-up measures for non-compliant results are generally equivalent to those provided for by EU rules. Notwithstanding several detections of residues in aquaculture consignments imported into the EU, the implementation of a system of official controls on the distribution and use of veterinary medicinal products, allied with official pre-export testing and own-checks performed by processing plants increase confidence in the residues status of both aquaculture products and honey.

7 Closing Meeting

A closing meeting was held on 20 September 2012 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement and stated that they would take what ever actions were necessary in order to address the recommendations of the audit report.

8 Recommendations

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within twenty five working days of receipt of this audit report.

N°.	Recommendation
1.	Ensure that the information included in the honey and aquaculture residue monitoring plans provided to the Commission services is complete and accurate, taking into account the requirements of Council Directive 96/23/EC.
2.	Ensure that all appropriate veterinary medicinal products are included in the scope of testing in the aquaculture residue monitoring plan, taking account of the availability of medicines on the domestic market, the likelihood of their use in the relevant production sector and residues detected in exported consignments, to the extent that guarantees provided should be at least equivalent to the requirements of Council

N°.	Recommendation
	Directive 96/23/EC.
3.	Ensure that the aquaculture residue monitoring plan, including details of districts, areas and species to be sampled, is not published before samples are taken, in order to ensure that residue surveillance is in line with the objectives laid down in Annex III to Council Directive 96/23/EC.
4.	Ensure that sampling of honey is carried out at variable intervals spread out over the whole year, across a representative number of establishments and avoiding multiple sampling from the same sites in order to provide guarantees at least equivalent to the requirements of the Annex to Commission Decision 98/179/EC.

The competent authority's response to the recommendations can be found at:

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6535

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Audits by the Commission Services		
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in 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
Food Law		
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in 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
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in 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
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ 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
Monitoring and sampling of residues in food of animal origin		

Legal Reference	Official Journal	Title
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dec. 97/747/EC	OJ L 303, 6.11.1997, p. 12-15	97/747/EC: Commission Decision of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
Validation of analytical methods for residues and Minimum Required Performance Limits		
Dec. 2002/657/EC	OJ L 221, 17.8.2002, p. 8-36	2002/657/EC: Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
Bans on the use of hormones and beta-agonists for growth promotion in food producing animals		
Dir. 96/22/EC	OJ L 125, 23.5.1996, p. 3-9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Maximum Residue Limits for veterinary medicinal products in food of animal origin		

Legal Reference	Official Journal	Title
Reg. 470/2009	OJ L 152, 16.6.2009, p. 11-22	Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council
Reg. 37/2010	OJ L 15, 20.1.2010, p. 1-72	Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin
Maximum Residue Levels for pesticide residues in food of animal origin		
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Maximum Levels for contaminants in food		
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Authorisation of veterinary medicinal products		
Dir. 2001/82/EC	OJ L 311, 28.11.2001, p. 1-66	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products

Legal Reference	Official Journal	Title
Dir. 2006/130/EC	OJ L 349, 12.12.2006, p. 15-16	Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription
Reg. 726/2004	OJ L 136, 30.4.2004, p. 1-33	Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
Medicated feedingstuffs and additives		
Dir. 90/167/EEC	OJ L 92, 7.4.1990, p. 42-48	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
Reg. 1831/2003	OJ L 268, 18.10.2003, p. 29-43	Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition
Reg. 183/2005	OJ L 35, 8.2.2005, p. 1-22	Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene
Sampling methods and methods of analysis for contaminants in foodstuffs		
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Reg. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs

Legal Reference	Official Journal	Title
Reg. 1883/2006	OJ L 364, 20.12.2006, p. 32-43	Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs
Sampling methods for pesticides in foodstuffs		
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC
Approval of residue monitoring plans submitted by third countries		
Dec. 2011/163/EU	OJ L 70, 17.3.2011, p. 40-46	2011/163/EU: Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC