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FINAL REPORT OF A MISSION

CARRIED OUT IN

INDIA

FROM 16 TO 24 SEPTEMBER 2009

IN ORDER TO EVALUATE THE CONTROL 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 an endnote.

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) mission in India, carried out between 16 and 24 September 2009, as part of the published programme of FVO inspections on residue controls in third countries.

The objective of the mission was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, including the controls on the distribution and use of veterinary medicinal products and feed additives, the use of which may give rise to residues in such products. The evaluation was based on the standards set out in Council Directive 96/23/EC, and other relevant Community legislation in this field, including legislation on the control and distribution of veterinary medicinal products. The mission 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 Community requirements with regard to import of food of animal origin into the EU.

There is a system of residues control in India but the national residue control plan is inadequate in scope and sample numbers for several commodities and the sampling does not always cover the whole year. The undertakings made by the Indian competent authorities in response to recommendations 1, 3, 4, 6, 7, 8, 9, 10, 11 and 12 in the report of the previous FVO residue mission (DG SANCO 2006-8015) have not been met. Follow-up investigations of non-compliant results are not effective in identifying the actual source of detected residues and important investigations and corrective actions at the level of the primary producers (farms) are delegated by the competent authority to the exporting establishments. There is no effective control on the distribution and use of veterinary medicinal products, particularly in aquaculture farms, dairy farms and apiaries, as evidenced by the high frequencies of non-compliant results in the national residue control plan and the RASFF alerts for crustaceans. A system of pre-export testing of crustaceans for inter alia chloramphenicol and nitrofurans, which has been in place since August 2005, has not been effective. The effectiveness of the national residues control plan is further compromised by inconsistencies and sometimes serious weaknesses in laboratory performance and interpretation of laboratory results which undermine the reliability of guarantees given by the Indian competent authorities based on analytical results. These deficiencies are mitigated to a certain extent by food business operators' own-check residue programmes, by the pre-export testing being made official in 2009 and by an official pre-harvest testing for nitrofurans and chloramphenicol in crustaceans, which, whilst being implemented in Andhra Pradesh, is yet to be implemented in all aquaculture producing states. However, it is concluded that the residue controls in aquaculture products, honey, milk and poultry do not currently provide guarantees equivalent to those laid down in Council Directive 96/23/EC.

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

Table of Contents

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	**Explanation**
AOZ and AMOZ, AHD and SEM	Marker residues of the nitrofuran drugs furazolidone, furaltadone, nitrofurantoin and nitrofurazone respectively
CC-alpha / CC-beta	Decision limit/ Detection capability
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
EIA	Export Inspection Agency
EIC	Export Inspection Council
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
EU	European Union
FVO	Food and Veterinary Office
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC: A1 Stilbenes, stilbene derivatives, and their salts and esters A2 Antithyroid agents A3 Steroids A4 Resorcyclic acid lactones including zeranol A5 Beta-agonists A6 Compounds included in Annex IV to Regulation (EC) No 2377/90 B1 Antibacterial substances, including sulphonamides, quinolones B2a Anthelmintics

	B2b Anticoccidials B2c Carbamates and pyrethroids B2d Sedatives B2e Non-steroidal anti-inflammatory drugs (NSAIDs) B2f Other pharmacologically active substances (e.g. corticosteroids) B3a Organochlorine compounds including PCBs B3b Organophosphorus compounds B3c Chemical elements B3d Mycotoxins B3e Dyes B3f Others
HACCP	Hazard Analysis and Critical Control Points
HPLC	High Performance Liquid Chromatography
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
MPEDA	Marine Products Export Development Agency
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NABL	National Accreditation Board for Testing and Calibration Laboratories
NaCSA	National Centre for Sustainable Aquaculture
NRCP	National Residue Control Plan
NRL	National Reference Laboratory

RASFF	Rapid Alert System for Food and Feed
SOP	Standard Operating Procedure

1 Introduction

The mission took place in India from 16 to 24 September 2009. The mission team comprised 3 inspectors from the Food and Veterinary Office (FVO) and one observer from the Surveillance Authority of the European Free Trade Association. The mission was undertaken as part of the FVO's planned mission programme, evaluating control systems and operational standards in this sector.

Representatives from the central competent authority accompanied the inspection team during the whole mission. An opening meeting was held on 16 September 2009 with the central competent authority and representatives of the central competent authority responsible for the authorisation of veterinary medicinal products. At this meeting, the objectives of, and itinerary for, the mission were confirmed by the inspection team and the control systems were described by the authorities.

2 Objectives Of The Mission

The objective of the mission was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, including the controls on the distribution and use of veterinary medicinal products (VMPs) and feed additives, the use of which may give rise to residues in such products. The mission was based on the evaluation of the equivalence of India's standards to Council Directive 96/23/EC and other relevant Community legislation in this field, including legislation on the control and distribution of VMPs. The mission 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 VMPs 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 product mission to India (DG (SANCO)/8015/2006) in September 2006. The table below lists sites visited and meetings held in order to achieve that objective.

Meetings/Visits		**n**	**Comments**
Competent Authorities	**Central**	**2**	Opening and closing meetings with the Export Inspection Council (EIC) and other competent authorities
	Regional	**2**	Meetings with the export Inspection Agency (EIA) in Chennai and the Marine Products Export Development Agency (MPEDA) in Bhimavaram
Laboratories		**4**	Government laboratories EIA-Chennai, MPEDA Bhimavaram, ELISA-laboratory Bhimavaram and one EIC approved private laboratory
Farms		**2**	2 aquaculture farms (shrimp and scampi)
Establishments		**2**	2 EIC approved export establishments for poultry and aquaculture

		products, respectively.
Other sites	**3**	1 feed mill for aquaculture feed, 2 wholesalers/retailers of veterinary medicinal products

3 Legal Basis for the Mission

The mission was carried out under the general provisions of Community 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;

– 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.

A full list of the legal instruments referred to in this report is provided in the Annex. Legal acts quoted in this report refer, where applicable, to the last amended version.

4 Background

4.1 COUNTRY STATUS IN RELATION TO SUBMISSION OF RESIDUES CONTROL PLANS

Commission Decision 2004/432/EC as last amended by Commission Decision 2008/772/EC, indicates that India's residues monitoring plan is approved in accordance with Council Directive 96/23/EC for milk, aquaculture products, eggs and honey. India has also applied for approval of its residue monitoring plan for poultry meat.

4.2 SUMMARY OF PREVIOUS FVO MISSION RESULTS

The residues sector was inspected by the FVO in 2003 (DG(SANCO)/9208/2003 MR Final) and 2006 (DG(SANCO)/8015/2006 MR Final). The reports of both missions (henceforth referred to as the 2003 and 2006 FVO residue missions, 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 2006 FVO residue mission report stated that comprehensive residue control plans were implemented and additional pre-export testing programmes were in place for some commodities. However, this report identified shortcomings in laboratory performance, a lack of follow-up investigations on farm by competent authorities when non-compliant results had been detected, and ineffective controls on medicines used in the export sector.

4.3 RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS REGARDING RESIDUES FOR PRODUCTS OF ANIMAL ORIGIN FROM INDIA

Since the 2006 mission (i.e. 1 October 2006 – 27 August 2009) there were no RASFF notifications for residues of veterinary medicinal products in honey, eggs or farmed finfish. However, there have been 89 RASFF notifications concerning nitrofuran metabolites in farmed crustaceans. Details of these RASFF notifications are included under point 5.1.6.2.

4.4 PRODUCTION AND TRADE INFORMATION

India exports aquaculture products, eggs and honey to the EU. Production and export data supplied by the Export Inspection Council (EIC) are summarised in the table below.

Commodity	**National production (tonnes)**	**Number of EIC approved establishments** **(production in these establishments, tonnes)**	**Export to EU 07/08** **(tonnes)**
aquaculture products	3 200 000 133 427 of which were crustaceans.	218 (not available)	351 finfish 25 673 crust.
milk	10 480 000	6 (not available)	0
honey	65 000	6 (not available)	3456
eggs	2 670 000	3 (not available)	4508
poultry	2 312 800	4 (76 800)	0

Aquaculture farms mainly produce black tiger shrimp (*Penaeus monodon*) although there is also production of freshwater scampi (*Machrobrachium rosenbergii*), small quantities of white shrimp (*Penaeus indicus*) and of different carp species (*Catla catla* , *Labeo rohita* and *Cirrhus mrigala*). Shrimp are produced in brackish water while scampi and carp are produced in fresh water. Species specific commercial feedingstuffs are used.

Milk is collected by Dairy Cooperative Societies from their members, who typically have 2-10 cows each. The collected milk is then sent to the District Milk Union in the State where it is processed. No dairy establishments are approved for export to the EU.

5 Findings And Conclusions

5.1 RESIDUE CONTROL PROGRAMMES

5.1.1 Competent authorities involved

The central competent authority is the EIC (under Ministry of Commerce and Industry) which also implements the residue control programme for milk, eggs, honey and poultry through the Export Inspection Agencies (EIA). The Marine Products Export Development Authority (MPEDA), which is a statutory body under the same ministry, implements the residue control programme for aquaculture products in cooperation with its National Centre for Sustainable Aquaculture (NaCSA) and under the guidance of EIC.

The Coastal Aquaculture Authority is currently in the process of registering all aquaculture farms and hatcheries in salt and brackish waters in coastal areas (i.e. within 2 km of the high tide lines of the coast and rivers). Other aquaculture farms (e.g. inland freshwater farms) are to be registered by the State authorities. Clusters of farms (societies) are being registered by MPEDA and function as contact points for NaCSA. A procedure to register feed mills producing feed for the aquaculture sector is under development by MPEDA.

5.1.2 Planning of the national residue control plan (NRCP)

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. 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 Community for placing on the market

within the Community shall comply with the relevant requirements of food law or conditions recognised by the Community 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. 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 control 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 as last amended by Commission Decision 2008/772/EC.

Findings

The Indian NRCP is based on the requirements of Council Directive 96/23/EC. The NRCP for milk, eggs, poultry and honey is elaborated by the EIC, while MPEDA is responsible for elaborating the NRCP for aquaculture products. Once the finalised plans for milk, eggs, poultry and honey have been submitted to the Commission Services in March, the regional sampling plans are sent from the EIC to the four regional EIAs for implementation. The NRCP for aquaculture products is finalised by MPEDA in December and regional sampling plans are sent out to the implementing MPEDA offices.

The mission team noted that:

- in response to recommendation No 1 in the 2006 FVO residue mission report the EIC undertook to incorporate substances in the NRCP based on availability and use of veterinary medicinal products. However, the EIC and MPEDA do not have information about sales or usage patterns for veterinary medicinal products when elaborating the NRCP. The scope of testing within each substance group is determined mainly by laboratory capability, which has led to the omission of important pharmacologically active substances. For example, the poultry company visited used doxycycline, neomycin, amoxicillin as well as the anticoccidials salinomycin and diclazuril. None of these substances have been included in the egg NRCP and of these, only amoxicillin has been included in the poultry NRCP;
- certain risks have been taken into account in the planning procedure. For example, findings of chloramphenicol in milk in the 2008-09 NRCP had resulted in a 20% increase of samples analysed for chloramphenicol in 2009-10;
- a number of maximum residue limits (MRLs) listed in the NRCP exceed Community limits in the Annexes to Regulation (EC) 2377/90;
- sample numbers for honey and crustaceans are based on national production as foreseen in Council Directive 96/23/EC, while for aquaculture finfish, milk, eggs and poultry the sample numbers are based on export quantities. However, total throughput in the export approved establishments should be the basis for the calculations of sample numbers under the NRCP, if these are not based on national production, as all of the establishments throughput could potentially be exported to the EU;
- the EIC stated that it does not have access to data on the total throughput in export approved establishments. However, for poultry, the total throughput was known but it was not used as the basis for calculating the NRCP sample numbers;
- the NRCPs for crustaceans, milk, eggs and honey cover all substance groups specified in Annex II to Council Directive 96/23/EC;
- when NRCP samples are taken from processed products the processing itself may affect the

residue content in the sample and the result would not reflect the residue status of the raw material as intended in Council Directive 96/23/EC;

- regarding the NRCP for aquaculture:
  - the sampling plan for farmed finfish does not cover substance groups A1, A3, B3a, B3c, B3d or B3e;
  - the MRLs are mostly in line with Community requirements. However, the MRL for oxolinic acid exceeds the Community MRL and ivermectin has no Community MRL for aquaqulture products;
  - a proportion of samples are planned to be taken from finished product which, in the EIC export approved establishment visited, could be traced back to individual farm level;
- regarding the NRCP for milk:
  - the majority of the milk samples are analysed for all A, B1 and B2 substance groups;
  - the listed MRLs are mostly in line with Community requirements. However, for gentamicin and aflatoxin M1 Community MRLs are exceeded;
  - in addition to the 300 samples under the NRCP, 150 official samples of processed milk products are also analysed for residues;
  - a sample of raw milk is normally traceable back to the level of a Dairy Cooperative Society ("village") and comprises blended milk from all groups of cows owned by individual members of the society;
- regarding the NRCP for eggs:
  - quoted MRLs are mostly in line with Community requirements. However, the MRL for endrin exceeds the Community MRL and the combined MRL applied for tetracycline/chlortetracycline/oxytetracycline exceeds Community MRLs, which are set for each individual substance. In addition, sulphonamides have no Community MRL for eggs;
  - 55 (28%) of the 200 samples are planned to be collected from final product which cannot be traced back to farm level, which is a requirement in the EU under Council Directive 96/23/EC;
- regarding the NRCP for honey:
  - each sample is analysed for all substance groups included in the NRCP.
  - the honey plan refers in general to the national action levels as "EU MRLs" although EU MRLs only exist for coumafos and amitraz;
  - 188 (47%) of the 400 samples are collected from processed honey which cannot be traced back to farm level, which is a requirement in the EU under Council Directive 96/23/EC;
- regarding the NRCP for poultry:
  - the total sample number for 2009/10 is 220. However, total production in the EIC export approved establishments is 76800 metric tonnes, which should have resulted in 384 samples being taken according to Council Directive 96/23/EC, if export is to be approved for the EU market;
  - the NRCP for poultry does not include any coccidiostats (B2b);
  - MRLs are listed for moxidectin and several pyrethroids which have no EU MRLs for poultry;
  - 76 (35%) of the 220 samples are planned to be taken from processed products which can be linked to a slaughter date, but not to the individual farm as it is common for several farms to deliver birds on the same day. There are no establishments approved for export of poultry meat to the EU.

Conclusions on planning

The structure of the NRCP is mostly in line with Community requirements, with the exception of the NRCP for poultry and finfish which do not include several relevant substance groups. The sample numbers for finfish, milk, eggs and poultry are less than required under Council Directive 96/23/EC, which is the basis for the Indian NRCP. In addition, the effectiveness of the residue control is hampered by sampling of processed products which cannot be traced to farm level and by a lack of correlation between the scope of testing and the pharmacologically active substances used in the species concerned.

5.1.3 Implementation of the NRCP

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. Articles 4, 5 and 12 of Council Directive 96/23/EC deal with aspects pertaining to the implementation of the national residue control 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 national residue control plan. Community methods of sampling for the official control a wide range of residues in products of animal origin are laid down in several pieces of Community 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

The NRCP for all commodities is financed by the Government of India under five year budget plans for the EIC. All sampling for the NRCP is carried out by MPEDA/NaCSA officers (aquaculture) and EIA officers (milk, eggs, honey and poultry). Sampling instructions have been included in the NRCPs for milk, eggs, honey and poultry. Sampling instructions for aquaculture samples have been issued as a regulation by the Coastal Aquaculture Authority (S.O. 7 March 2008).

The mission team noted that:

- the regional sampling plans for aquaculture products had been sent out in January and the sampling covered the whole calendar year;
- the start of sampling for the NRCP for eggs, poultry, milk and honey had been delayed from April until September 2008 and May-July 2009, respectively, due to delays in distribution of the sampling plans from EIC. The sampling period ends in February;
- sampling officers in the sub-regional MPEDA office visited were not aware of the sampling instructions issued by the Coastal Aquaculture Authority;
- prior warning is normally given when samples are collected for the NRCP. In the EU, sampling should be unforeseen and unexpected in line with Article 15(1) of Council Directive 96/23/EC and the Annex to Commission Decision 98/179/EC;
- sampling of poultry and aquaculture was sometimes clustered, i.e. samples for many substance groups were collected during one farm. In the EU, efforts should be made to avoid multiple sampling from one producers as laid down in Article 15(1) of Council Directive 96/23/EC and the Annex to Commission Decision 98/179/EC;
- samples collected by EIA officers are brought to the analysing laboratory by these officials. However MPEDAs aquaculture samples for the NRCP are not adequately sealed, when sent to the laboratory by postal/courier services. In the EU, sample containers must be officially

sealed to maintain sample integrity as required by Article 15(1) of Council Directive 96/23/EC and the Annex to Commission Decision 98/179/EC;
- due to a lack of analytical methods, all 2009 NRCP samples for milk, poultry and eggs submitted to EIA-Chennai had been stored in this laboratory between three weeks and more than three months before being sent to subcontracted laboratories. One of these laboratories had notified the EIA at the end of August that they would close their operations. No other laboratory had been approached to analyse these poultry samples (for group A substances), which had been accumulating in EIA-Chennai since the end of June;
- the sampling instructions for milk sampling require that an unspecified amount of formaldehyde is added to all milk samples except those submitted for screening for beta-lactams. The EIC stated that in practice the final concentration of formaldehyde is 0.2%. No validation data were available to prove that this substance does not influence the results for any of the residue analyses.

Conclusions on implementation

Although sample numbers are in line with the plan sampling has not covered the whole production year due to delays in distribution of the plan from central level. The effectiveness of the residue controls is sometimes hampered by clustered sampling, prior warning regarding sampling, batching of samples before analysis and failure to ensure sample security during transport. In addition, the competent authority cannot guarantee that analytical results for milk are reliable following the addition of a preservative at sampling. These shortcomings in implementation undermine the effectiveness of residue controls in animal products.

5.1.4 Supervision of implementation of the NRCP

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 coordinating the activities of all bodies involved in residues controls.

Findings

EIC has the overall responsibility for supervision of the NRCP implementation in all commodities. The actual supervision during the sampling year is carried out by MPEDA (aquaculture) and the relevant regional EIAs. For aquaculture, monthly reports of collected samples, analyses and results are sent from MPEDA to the EIC as well as to the Ministry of Health and Family Welfare, which is responsible for controls on veterinary medicinal products. For milk, eggs, and poultry all laboratory results are sent to the relevant EIA. For honey, the testing laboratories report monthly to each relevant EIA as well as to the national reference laboratory for honey. Each EIA sends a consolidated monthly report to the EIC detailing samples taken, analysing laboratories, test results and additional information about any non-compliant results.

The mission team noted that:

- the number of samples analysed in 2008 were in line with the 2008 NRCP for all commodities;
- timely reports had been sent to the EIC from the regional EIA visited. Timely reports had

also been sent to the EIC and to the Ministry of Health and Family Welfare from the MPEDA office visited;
- substantial delays in laboratory analysis of certain samples for the 2009 NRCP (submitted to EIA-Chennai) had not led to any documented remedial action by the supervising regional EIA.

Conclusions on supervision

Clear reporting routines from samplers to regional and central authorities are in place and are adhered to. However, the actual supervision was not always effective, as long delays had not been acted upon by the regional EIA.

5.1.5 Other residues control 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 and Article 19 of Regulation (EC) No 178/2002 obliges food business operators to inform the relevant competent authorities when non-compliances are detected, which may pose a risk to the consumers.

5.1.5.1 Official pre-harvest testing of aquaculture crustaceans intended for the export market

Findings

An official pre-harvest testing programme for crustaceans, comprising compulsory testing for all four nitrofuran metabolites and for chloramphenicol by (enzyme-linked immuno-sorbent assay (ELISA), was introduced from 1 April 2009 in the State of Andhra Pradesh, where 39% of the tiger shrimp and 59% of the scampi are produced. Six dedicated laboratories for ELISA testing under the pre-harvesting programme have been established by MPEDA in Andhra Pradesh and another ten will operate in the other states. The screening analyses are paid for by the farmers who must provide additional payments for confirmatory analyses of screening positive samples. EIC approved export establishment should only procure crustaceans from registered farms and ponds from which screening negative test results have been obtained. The EIC stated that this programme will be extended to all crustaceans processed in EIC approved export establishments.

The mission team noted that:

- the official registration of all aquaculture farms is not completed, particularly concerning fresh water farms. In addition, unless the aquaculture farmer owns or leases the land for the farm it cannot be registered, leaving thousands of aquaculture farms outside the compulsory registration system;
- the official pre-harvest testing programme for crustaceans is currently operating based on a request from the EIC to the EIA and the establishments. It will not be compulsory until the official notification from the Government of India has been published which, according to the EIC, is expected to take place in December 2009;
- screening negative results of the pre-harvest analyses were issued by the ELISA-laboratories

to the farmers, who have to provide the test result to the establishment prior to harvest. Screening positive pre-harvest results were submitted to MPEDA for confirmatory analysis and non-compliant results were reported in the same way as non-compliant NRCP samples (see 5.1.6.1);

- one of the two aquaculture farms visited in Andhra Pradesh had sold scampi to an EIC export approved establishment in May 2009 without supplying pre-harvest test results. According to the producers society these scampi had subsequently been pre-export tested for the EU market in September 2009;
- in contrast, in the EIC approved export establishment (for fish and fisheries products) visited the requirement for pre-harvest test result was in operation and test results were available for procured consignments of crustaceans since 4 April 2009.
- in the ELISA-laboratory visited in Bhimavaram, samples were collected by staff contracted by the laboratory. Since 1 April 2009 this laboratory had processed 3480 samples. Screening positive samples were submitted to the nearby MPEDA laboratory for confirmation by Liquid Chromatography-(Tandem) Mass Spectrometry (LC-MS/MS);
- since 1 April 2009, 230 samples had been screened positive in the ELISA-laboratory visited. So far MPEDA in Bhimavaram had carried out confirmatory analyses on 57 of these samples. MPEDA head quarters stated that it had become too costly to perform confirmatory analyses on all screening positive samples exceeding the limits of detection for the ELISA tests (0.15 µg/kg for chloramphenicol and 0.5 µg/kg for nitrofuran marker substances). Based on the Community minimum required performance limit (MRPL), MPEDA had recently decided to deem as "compliant" all screening results up to 0.29 µg/kg for chloramphenicol and 0.99 µg/kg for nitrofuran metabolites and only submitting samples exceeding these levels for confirmatory analysis. As these screening results are not corrected for analytical recovery, there is a distinct possibility that samples containing chloramphenicol and nitrofurans at concentrations in excess of their respective MRPLs will be falsely deemed as "compliant", thus undermining the effectiveness of the pre-harvest testing programme.

5.1.5.2 Pre-export testing of consignments intended for the EU market

Findings

Under the EIC approval scheme (August 2005) each fish and fisheries product establishment must conduct pre-export testing for antibiotics (chloramphenicol, nitrofuran metabolites, tetracycline and sulphonamides) of each consignment of crustaceans (not finfish) intended for the EU market. The analyses must be performed by an EIA laboratory or by an EIC approved laboratory using HPLC-MS/MS or other appropriate equipment meeting Community limits.

The mission team noted that:

- in response to recommendation No 5 in the 2006 FVO residue mission report the EIC undertook to ensure that by 31 December 2006 ca 20% of the pre-export samples would be collected by official staff. This was never implemented. However, on 25 March 2009 the Directors of the four EIA regions were requested in writing by the EIC to ensure that the compulsory pre-export sampling would no longer be carried out by the establishment but by a representative from the analysing laboratory. Instructions were also provided on how to take a composite sample of a consignment and the EIC required that health certificates for the EU should be accompanied by the test results for nitrofurans. In the EIC approved export fish and fisheries product establishment visited, laboratory submission forms indicated that this change had been implemented;

- in the establishment visited traceability between each consignment, its analytical result and the export health certificate was assured;
- this pre-export testing programme already fulfils the requirements of Commission Decision 2009/727/EC which was published the week after this mission (30 September 2009).

5.1.5.3 Official monitoring in EIC export-approved establishments

Findings

EIC approved export establishments for fish and fishery products are inspected by the EIA once per month to once per 3 months depending on risk. During these inspections EIA officials take samples which are submitted to an EIA laboratory or an EIC approved laboratory for analysis of antibiotics (chloramphenicol, nitrofuran metabolites, tetracyclines and bacterial inhibitors). Such official samples are collected each month from 5% of the approved establishments.

The mission team noted that:

- in the EIC-approved fish and fishery product establishment visited, official EIA monitoring samples of crustaceans had been collected and analysed in accordance with the EIC approval scheme.

5.1.5.4 Establishment own-checks for residues

Findings

Under the EIC approval schemes for exporting establishments each approved establishment has the sole responsibility for maintaining the quality and safety of their products with the aid of a Hazard Analysis and Critical Control Points (HACCP) based own check system. Special requirements are included for residue testing within the compulsory HACCP programme. The establishments are responsible for complying with national requirements as well as the requirements of the importing country. Each EIC approved export establishment is obliged to keep a register of all supplying farms and the feed mills producing feed for these farms. EIA officials are to carry out periodic monitoring of the establishments verifying *inter alia* the own check system.

Under their HACCP programmes EIC-approved establishments for fish and fishery products are obliged to conduct residue tests for antibiotics and pesticides (crustaceans) every 2 months from one supplier. EIC-approved poultry establishments are obliged to carry out monthly tests from all supplying farms. EIC approved egg establishments are obliged to carry out residues tests once per year per supplier. EIC-approved milk processing plants are obliged to conduct residue testing in their internal laboratory or in an EIC-approved laboratory on procured raw milk from each holding (i.e. village) once per 1-3 months depending on the substance to be tested. EIC approved honey establishments are obliged to test honey from each supplier once or twice per month depending on the substance to be tested.

The mission team noted that:

- the requirements for self monitoring of residues, laid down in the EIC approval schemes, in export approved establishments for milk, eggs, honey and poultry cover all mandatory substance groups under Council Directive 96/23/EC;
- in the EIC-approved export fish and fishery product establishment visited every procured batch was tested for chloramphenicol and nitrofuran marker residues AOZ and AMOZ, using commercial ELISA-kits, in the in-house laboratory which applied limits of action in

line with EU MRPLs. These test were carried out both before and after processing;
- in the EIC-approved poultry establishment visited, the documented own-check programme did not include all required substance groups. Nine substance groups had been omitted. This had been pointed out by the EIA inspector during a monitoring visit but no corrective action had been taken by the company. In addition, substance groups B1 and B2a, which were listed in the own-check program, had never been analysed. The company stated during the visit by the FVO team that they did not intend to carry out these analyses until export to the EU was allowed;
- the poultry company stated that two samples per month were analysed from any two of the 24 supplying flocks. However, sample results were available only for the flocks directly owned by the company and not for any flocks on farms which were under contract.

Conclusions on other residues control programmes

The pre-export testing of all consignments of crustaceans for the EU market, which has been in place since 2005, has not been effective in preventing the export of crustaceans containing nitrofurans as seen by the numerous RASFF notifications. Establishments' own-check programmes for residues, the recently introduced official pre-harvest testing programme for crustaceans and amendments in the sampling procedures for the pre-export testing system may, when fully implemented, add to the guarantees given by the competent authority regarding the residue status of exported crustaceans. However, recent amendments made to interpretation of the screening results in the pre-harvest testing programme undermine the effectiveness of the pre-harvest testing programme and increase the risk that crustaceans containing residues of nitrofurans and chloramphenicol are falsely to be deemed compliant at harvest.

5.1.6 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

The EIC is responsible for coordinating follow-up investigations of RASFF notifications, while the EIA is responsible for most other follow-up investigations of non-compliant results under the NRCP and the other official sampling schemes. Follow up investigations of non-compliant NRCP samples taken on aquaculture farms are carried out by MPEDA, through its National Centre for Sustainable Aquaculture (NaCSA).

The mission team noted that:

- in response to recommendation No 3 in the 2006 FVO residue mission report the EIC undertook to make efforts to enhance controls at farm level. However, the EIA still delegated all follow-up investigations regarding NRCP samples from fish and fishery product establishments, poultry, eggs, milk and honey to the export approved establishments and did not carry out any follow-up investigations on farm, even when required to do so under the NRCP (MRL violations);
- in July 2009, MPEDA headquarters requested that the MPEDA laboratories should arrange for follow-up sampling on the farms where non-compliant NRCP samples had been detected

in 2008. This request referred to the recommendation given in the 2006 FVO residue mission report. Evidence was seen that this information had been forwarded via the MPEDA laboratory to the MPEDA sampling officers in the region visited;

- there have been no efforts by MPEDA, NaCSA or the EIA to identify for example the suppliers of nitrofurans to aquaculture farms, where non-compliances had been found;
- through the recently introduced registration system for aquaculture farms the Coastal Aquaculture Authority and the registering State authorities have been given the legal powers to issue fines or to de-register registered aquaculture farms. However, the Coastal Aquaculture Authority stated that to date non-compliant residues results had not been provided by MPEDA on the form stipulated under the rules of the Coastal Aquaculture Authority. Therefore no action had been taken by the Coastal Aquaculture Authority on these findings. In addition, the majority of fresh water farms are still not registered by the State authorities.
- in response to recommendation No 4 in the 2006 FVO residue mission report the EIC undertook to examine the possibility to implement sanction procedures as referred to in Articles 22-27 of Council Directive 96/23/EC. However, neither the EIC, MPEDA nor the EIA has the legal power to take action or issue sanctions against a farmer in case of residues violations. This was also the case at the times of the previous FVO residue missions in 2003 and 2006.

5.1.6.1 Non-compliant results in the 2008 and 2009 NRCP and in "other" residue control programmes

Findings

Non-compliant results from the aquaculture sampling are sent from the analysing MPEDA laboratory to the MPEDA field office. This office forwards the information to the EIC and to the relevant EIA regional office (establishment samples), the Coastal Aquaculture Authority/State authority (samples from registered farms), and NaCSA (samples from farms, hatcheries and feed). The EIA will perform follow-up investigations of samples from establishments, while MPEDA/NaCSA is responsible for follow-up of samples taken from farms, hatcheries or feed.

For milk, eggs, poultry and honey, the non-compliant laboratory results are sent to the relevant EIA office. For eggs, poultry and honey these non-compliant results are communicated from the EIA as an Internal Alert Information to the EIC and to the EIC-approved establishment / the farm/ feed mill, depending on where the sample was collected. Depending on the commodity this information is also sent to all approved honey laboratories (honey), egg product exporters' association or poultry meat exporters' association (eggs and poultry). Export-approved establishments so informed are obliged *inter alia* to identify the supplier, take additional samples from implicated suppliers and to submit a report of their investigations to the EIA, which may then revoke the Internal Alert. In addition, the NRCP for eggs and poultry contains instructions for the EIA officers to carry out follow-up investigations on farm for MRL violations.

The EIA is responsible for advising the exporters not to procure raw material from a supplier linked to a non-compliant sample and to ensure that no products are exported until corrective actions have been taken and the Internal Alert has been revoked. The exporter is also advised to conduct regular training for suppliers to minimise the risk of residues in the products.

For honey the analysing laboratory also sends all results to the National Reference Laboratory (NRL) for honey which is responsible for carrying out follow-up sampling in the establishment and for organising awareness programmes for honey suppliers. The NRL must also submit a report of such actions to the relevant EIA Office.

During the previous sampling year (1/4 2008 – 31/3/2009 for milk, honey, eggs, poultry; 2008 for

aquaculture) the following non-compliant results from the NRCP were reported to the Commission. The numbers in brackets refer to the total number of samples analysed for that residue.

Commodity	chloram-phenicol	nitrofurans	other antimicrobials	others
Crustaceans	15 (625)	16 (625)	21 (374) 20 tetracycline 1 sulphadiazine	1 (141) arsenic
Raw milk	2 (216)	-	-	-
Milk product	17 (133)	-	-	17 (133) aflatoxin M1
Hen eggs	-	-	2(140) sulphonamides oxytetracycline	-
Honey	5 (310)	-	36(274) sulphonamides 74(236) tetracyclines	52(258) lead 1(309) cadmium

The mission team noted that:

- although no non-compliant results for poultry had been reported to the Commission services for 2008/09, results in the EIA office and laboratory in Chennai showed that two NRCP samples from poultry had been non-compliant in this State during that sampling year. The EIC explained that additional samples are taken under the poultry NRCP but only the planned number of results are reported to the EU Commission;
- one follow-up investigation of a non-compliant finding in poultry had been requested by the EIA in Chennai five months after the sample was collected, due to a delay in obtaining the laboratory result. Although the result from sampling on farm showed an MRL violation the investigation had been carried out by the establishment, which identified the source of the residue. In the EU such follow-up investigations must be carried out by the competent authority in line with the requirements of Council Directive 96/23/EC;
- MPEDA/NaCSA has organised numerous awareness campaigns for aquaculture farmers regarding the proper use of antimicrobials;
- in the region visited timely follow-up investigations had been carried out by EIA in export-approved establishments for fish and fishery products. However, in none of these investigations was the source of the residue identified;
- shrimp feed was implicated as the probable source of nitrofurans in several meeting minutes provided by MPEDA. However, no actions had been taken to investigate this hypothesis;
- EIC approved export establishments are not obliged to immediately inform the EIA about non-compliant results in their own-check programmes. In the establishments visited own-check results were made available to the EIA during monitoring visits;
- regarding the non-compliant results for lead in honey the EIC has requested an investigation by the honey NRL. The report of this investigation is expected by January 2010.

5.1.6.2 Non-compliant results reported under the RASFF

Findings

Since the 2006 residues mission there have been 44 alerts for AOZ (marker substance for furazolidone) and 5 alerts for SEM (marker substance for nitrofurazone) in *Penaeus monodon* (black tiger shrimp) imported from India. For *Machrobrachium rosenbergii* (scampi) there have been 35 alerts for SEM and one for a combination of SEM and AOZ. One alert for AOZ and 3 alerts for SEM did not specify the crustacean species. The number of alerts for *Macrobrachium sp.* has been increasing in the past years while the annual number of alerts for *Penaeus sp*. has remained constant.

The mission team noted that:

- the 2008 results of the Indian NRCP showed a similar uneven distribution of AOZ and SEM between the two major species of crustaceans as has been seen in the RASFF alerts;
- crustacean muscle samples (without shell) are analysed under the Indian NRCP;
- follow-up investigations of RASFF alerts, including sampling of other consignments are carried out in the exporting establishment by an Inter-Departmental Panel comprising representatives from EIA and the Central Institute of Fisheries Technology;
- the identification of the farm(s) of origin for the rejected consignment is the responsibility of the establishment (following a request issued by the EIA), as is further action to prevent use of veterinary medicinal products which can lead to residues. No official investigations are carried out on farm[1];
- if rejected consignments are returned to India samples from the consignment are taken by the Inter-Departmental Panel and analysed in two laboratories, none of which should have performed the pre-export tests. If these results confirm the result from the EU the consignment needs to be destroyed. If the samples in India are compliant the consignment is released for other markets;
- the establishment is prohibited from exporting to the EU until the follow-up investigation carried out by the establishment has been reported to the EIA and a favourable assessment of all follow-up actions has been made by the Inter-Departmental Panel.

Conclusions on follow-up investigations/actions

The delegation of all responsibility for follow-up, corrective action and enforcement at primary producer level to the export-approved establishments has not been effective in preventing incorrect/illegal use of veterinary medicinal products, particularly in crustaceans, milk and honey and does not provide guarantees equivalent to those provided under Articles 16-18 and 22-27 of Council Directive 96/23/EC.

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

1 ***In their comments to the draft report the Indian competent authorities stated that follow up to farm level is now possible since the issuing of GOI Notification SO 2714 (E) dated 28 October 2009.***

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

In India official residues testing is coordinated by the EIC and carried out by a number of nominated laboratories – both governmental and private. The governmental laboratories are supervised by different competent authorities. The table below presents the overview of laboratories listed by the EIC in the 2009 NRCP for testing of residues in different commodities.

Laboratories listed in the 2009 NRCP in India		
Commodity	**Organisation responsible for laboratory**	**Number of laboratories involved in NRCP tests**
Aquaculture	MPEDA + EIC	3 EIC-approved MPEDA laboratories (Cochin, Nellore, Bhimavaram) + 16 MPEDA ELISA-screening laboratories
Poultry	EIA	4 EIA-laboratories (Mumbai, Chennai, Kolkata, Kochi) + 5 private laboratories approved by EIC
Eggs	EIA	3 EIA-laboratories (Mumbai, Chennai, Kolkata) + 5 private laboratories approved by EIC
Milk	EIA	4 EIA -laboratories (Mumbai, Chennai, Kolkata, Kochi) + 6 private laboratories approved by EIC
Honey	EIA	4 EIA-laboratories (Mumbai, Chennai, Kolkata, Kochi) 1 NRL (Jammu) + 5 private laboratories approved by EIC

There is an NRL designated for honey only. It organises proficiency tests for routine laboratories, confirms the results of non-compliant samples generated in the routine laboratories, compiles data

for the competent authority and assists in investigations of these non-compliant results. For all other commodities in question the functions and responsibilities similar to NRLs in the Member States, as described in Article 14 of Council Directive 96/23/EC, are borne by the EIC. The EIC operates a laboratory approval scheme based on the requirements similar to those set out in the ISO/IEC 17025 standard. A list of approved laboratories is published on the EIC website.

The mission team noted that:

- all laboratories involved in the NRCP testing are accredited to ISO 17025 by the National Accreditation Board for Testing and Calibration Laboratories (NABL) which is a member of the International Laboratory Accreditation Co-operation;
- there was no consistent policy for the selection of laboratories for testing of NRCP samples. The EIC approval scheme covers only private and some MPEDA laboratories but the same requirements are not applied to the EIA laboratories. This results in disparities in the levels of expertise of different laboratories testing NRCP samples;
- the only criterion for approval set out in the document on the EIC laboratory approval scheme is that laboratories shall comply with ISO/IEC 17025 standard – accreditation is not required. Moreover it provides that the compliance criteria may be relaxed at the discretion of the EIC and the approved laboratory;
- none of the laboratories approved for NRCP testing had validated methods for analysing residues of stilbenes (A1) and steroids (A3) in aquaculture and stilbenes (A1), steroids (A3), resorcylic acid lactones (A4), beta-agonists (A5) and anticoccidials (B2b) in poultry;
- five samples collected from a returned consignment positive for nitrofurans were submitted to EIA-Chennai and to an EIC approved laboratory. Presence of nitrofurans was confirmed in all five samples by the EIC laboratory while no nitrofuran residues were detected by EIA-Chennai.

5.2.2 On the spot visits in the laboratories

Findings

The mission team visited 4 laboratories. One was an EIC approved private laboratory whilst the other three were governmental (EIA-Chennai and two MPEDA laboratories in Bhimavaram) One of the MPEDA laboratories was an ELISA-screening laboratory testing aquaculture products only.

The mission team noted that:

- in response to recommendation No 6 in the 2006 FVO residue mission report the competent authority stated that validation of all methods relevant for the NRCP would be finalised during 2007. Although progress has been made, many methods are still not validated and therefore can not give guarantees equivalent to Commission Decision 2002/657/EC;
- in response to recommendation No 7 in the 2006 FVO residues mission report the competent authority undertook to ensure that internal standards would be used in all laboratories. However, internal standards were used only in the MPEDA laboratory visited, as had been the case during the previous residues mission;
- in response to recommendation No 8 in the 2006 FVO residue mission report the competent authority undertook to ensure a consistent policy for correcting for analytical recovery. However, results were not corrected for analytical recovery in any of the laboratories visited nor is there any guideline in place which specifies when results are to be corrected for recovery;
- in response to recommendation No 9 of the 2006 FVO residues mission report the competent authority undertook to harmonise the approach for effective quality controls. No

harmonised approach was in place. There were no measures in place to control the ongoing performance of the methods (e.g. quality control charts). Neither positive nor negative control samples were run in every laboratory or in every assay and there were no harmonised criteria for acceptance or rejection of analytical results;

- in response to recommendation no 10 in 2006 FVO residue mission report the competent authority stated that participation in proficiency tests would be a pre-condition for laboratory approval by the EIC. However, this was not the case in all laboratories visited.
- the facilities were adequate (space, ventilation, etc.) and all laboratories were well equipped with modern and appropriate instrumentation and had quality manuals and Standard Operating Procedures (SOP) in place. Service contracts for the maintenance of major items were generally in place;
- in none of the laboratories visited did the instructions for sample receipt and distribution specify sample acceptance/rejection criteria;
- the approach taken to validation of methods varied widely between laboratories. In some cases the validation was insufficient to guarantee that the methods for chloramphenicol and nitrofuran metabolites would reliably detect concentrations of these analytes at the MRPL;
- one of the laboratories visited did not have an SOP for method validation and staff could not demonstrate sufficient knowledge of method validation;
- none of the laboratories visited had performed an assessment of method reproducibility, a key performance parameter, which was also noted in the 2006 FVO residue mission report;
- none of the laboratories visited were aware or could provide evidence, that matrix samples used for method validation were free from the residues in question;
- spiking levels used to validate analytical recovery were frequently much higher than the Community limits and consequently the capability of these methods to detect residues at Community limits could not be demonstrated.

5.2.2.1 EIC approved private laboratory, New Delhi

Findings

This laboratory was established in 1990. The laboratory has a wide portfolio of activities in analytical chemistry, is accredited by NABL and bears other accreditations and certifications. It is analysing samples of milk and honey for the NRCP.

The mission team noted that:

- the scope of accreditation includes residues analysis of pesticides, heavy metals, polychlorinated biphenyles, dioxins and dibenzofurans. During the last visit of NABL in 2008, no non-compliances in the residue laboratory were detected;
- the laboratory is regularly audited by the EIC under its approval scheme. Fourteen different deficiencies had been found during the last EIC visit but only a few directly related to residues analysis. Corrective action had been taken to address these deficiencies;
- sample turnaround times were not monitored but it was seen by the mission team in reports issued that results were generated quickly and were reported promptly to the relevant bodies;
- all records were well maintained and traceable. A computerised laboratory information management system is under implementation;
- the laboratory has internal SOPs for method validation for residue analysis based on the harmonized guidelines from the International Union of Pure and Applied Chemists for single laboratory validation for analytical methods of analysis. These SOPs specifying acceptance criteria for the following parameters only: specificity, linearity, recovery, precision expressed as coefficient of variation and signal to noise ratios at which detection/quantification limits

can be determined. Neither repeatability nor reproducibility is required;

- the SOP for method validation for pesticide residues which was examined by mission team was inadequate. It outlined validation parameters but did not provide any technical instructions on how these parameters should be estimated;
- a 6-point external buffer standard calibration curve is most frequently used for calibration of instruments. Spiked matrix extracted curves and internal standards are not used for calibration. In the method for lead in honey (inductively-coupled plasma mass-spectrometry) a 3-point external buffer standard calibration curve was used. According to Community rules at least a 5-point standard calibration curve should be used;
- all working standard solutions were prepared from substances bearing appropriate certificates and the laboratory had an SOP for balance checking and calibration which met measurement traceability requirements. However there was no procedure in place to cross-check the performance of the prepared standard solutions;
- regarding chloramphenicol and nitrofurans, one precursor ion and two product ions are measured making both methods suitable for the confirmation of these compounds as per Commission Decision 2002/657/EC;
- the methods for determination of chloramphenicol in honey and milk and validation summary sheets for nitrofurans and tetracyclines in honey and milk were examined. All methods utilise LC-MS/MS. In line with the limited scope of the internal validation SOP, relevant validation data were missing from the validation file - no data on reproducibility were available for each of these methods;
- one positive control spiked sample is run in every assay which is not enough for reliable recovery assessment. Moreover spiking levels of 3 µg/kg (10x the MRPL) for nitrofuran metabolites in milk or for chloramphenicol - 1.5 µg/kg in honey or 1 µg/kg in milk are too hight to allow a realistic assessment of method performance at the MRPL;
- declarations contained in the laboratory Quality Manual of having procedures for monitoring the validity of test results had not been put into practice. The laboratory has no SOP in place describing how to apply quality control measures. Neither control charts for trend assessment nor Certified Reference Materials had been used, nor had retesting of retained items. The only measure applied was single spiked samples at the end of each run regardless of the length of that run;
- the laboratory had reportedly participated in one proficiency test for cadmium in honey organized by the NRL in January 2009 and an inter-laboratory comparison for fluoroqinolones and metronidazole in honey. Results of these tests were not provided to mission team.

5.2.2.2 EIA laboratory in Chennai

Findings

EIA-Chennai has been accredited to ISO/IEC 17025 by NABL since 2007 and it is located on the same premises as the local EIA office. EIA-Chennai is listed in the 2009/10 NRCP for testing of milk, eggs, honey and poultry.

The mission team noted that:

- the scope of accreditation covers the following residue groups in fish and fishery products, milk and milk products and eggs/eggs products: chloramphenicol, oxytetracycline, nitrofuran parent substances and metabolites, sulfametazine, carbamates and pyrethroids, organochlorine and organophosphorous compounds and heavy metals. The EIC informed the mission team directly before the mission that EIA-Chennai was currently analysing milk,

eggs and poultry for the 2009/10 NRCP. However, it was noted on the spot that all such samples had been subcontracted to other laboratories as, in spite of a number of the methods being included in the scope of accreditation, EIA-Chennai did not have the required analytical methods;

- the laboratory was carrying out analyses for chloramphenicol, nitrofurans, sulphonamides, tetracyclines and heavy metals in samples of aquaculture products taken by EIA staff during monitoring visits to establishments;
- when subcontracting the analyses of NRCP samples the EIA-Chennai could use any EIC-approved laboratory, not only those approved by EIC for carrying out residue analyses;
- the mission team was informed that numerous personnel changes had taken place recently. Staff interviewed lacked basic knowledge on method validation, quality control issues, standards and certified reference materials and were sometimes even reluctant to respond questions asked by mission team;
- for all methods, calibration was based on a standard calibration curve. Spiked matrix extracted curves were not used for calibration;
- for the ICP-MS method for heavy metals and the HPLC screening method for oxytetracycline, only single point calibrations were used and no acceptance/rejection criteria were specified for such calibration. However in case of a positive screening results a full calibration was done;
- for all nitrofurans metabolites respective calibration curves started from 1.5 µg/kg which is higher than MRPL;
- there was no SOP in place detailing how validation should be performed. Method SOPs included the necessary method description;
- the methods for chloramphenicol, nitrofurans and sulphamethazine were in the process of revalidation due to a change of operators and equipment. Previous validation files were not available for inspection by the mission team;
- the revalidation files for chloramphenicol and nitrofurans were examined. In these files the matrix used had not been specified and only CC-alpha and CC-beta values had been determined. Relevant validation data were missing from the validation files for each of these methods;
- methods for heavy metals, sulphamethazine and oxytetracycline had been validated for recovery based on standard spiking at different concentration levels but the residue/contaminant matrix content had not been taken into account and was not assessed beforehand;
- there were no proper measures in place to control ongoing method performance. Quality control charts started in 2008 for ICP-MS method for lead had not been maintained. When used, one positive control sample was added at the end of each run;
- the laboratory had successfully participated in a proficiency test and an inter-laboratory comparison for heavy metals testing in water and shrimps and for oxytetracycline in shrimps. It also took part in proficiency tests and inter-laboratory comparisons for the testing of chloramphenicol, nitrofurans, organophosphorous and organochlorine pesticides in shrimps but those results had not been evaluated.

5.2.2.3 MPEDA laboratory, Bhimavaram

Findings

This laboratory was set up in 2004 as one of three MPEDA quality control laboratories. It is accredited to ISO/IEC 17025 by the NABL and approved by EIC of India. In the NRCP it is listed for testing aquaculture products. The laboratory not only analyses samples under the NRCP – it also

analyses commercial samples.

The mission team noted that:

- methods suitable for screening and confirmation of chloramphenicol, nitrofuran metabolites, tetracycline, oxytetracycline, oxolinic acid, sulphadiazine, malachite green/leuco-malachite green, chemical elements and organochlorine pesticides in fish and fishery products are within the scope of accreditation;
- a Quality Manual was in place and during the most recent NABL audit only one minor non-compliance concerning result reporting had been identified;
- laboratory personnel had extensive experience in residues chemistry and a good knowledge of the requirements of Commission Decision 2002/657/EC. They had participated in extensive training courses and a national expert from a leading EU residues laboratory had conducted training on-the-spot;
- the registration of samples received follows a uniform laboratory sample identification system. However sample acceptance/rejection criteria were not identified and samples were not sealed;
- there was an SOP for method validation covering uncertainty assessment but reproducibility was not included. A very recently issued (07/2009) comprehensive instruction for calculating CC-alfa and CC-beta was presented to mission team;
- for all methods, matrix based external calibration curves (5 point) and internal standards were possible are used. Positive and negative control spiked samples were run in every assay but at the beginning of the run only. The 'positive' control spiked samples were at MRL or MRPL levels where applicable;
- regarding chloramphenicol and nitrofurans, one precursor ion and two product ions are measured making both LC-MS/MS methods suitable for the confirmation of these compounds as per Commission Decision 2002/657/EC. However, whilst validation had been carried out for each of the methods, and quoted limits of detection and limits of quantification as well as linearity ranges satisfy Community MRPLs, the spiking levels used to generate the performance criteria for such as accuracy, recovery, repeatability and uncertainty, were not adequate (3 and 5 µg/kg for all four nitrofuran metabolites and 0.75, 1.5 and 3.0 µg/kg for chloramphenicol). These can not guarantee that both methods will reliably determine concentrations of either chloramphenicol or nitrofuran metabolites around their respective Community MRPLs;
- the laboratory has an SOP for quality control checks but it does not specify when a result may be accepted or rejected. According to the explanation given by laboratory staff, assay results are accepted if the recoveries of the positive control spike(s) fall within the range of 70-120%. Results falling outside these ranges will be repeated at the discretion of the operator;
- results are not corrected for analytical recovery. Commission Decision 2002/657/EC states that depending on level of recovery obtained for batch of analysed samples – a fixed or specific recovery correction factor should be used;
- quality control charts (detailing the recoveries for the spiked positive control samples) are not maintained. Certified reference materials are used for the Atomic Absorption Spectroscopy methods;
- results were generated quickly and reported timely to the relevant bodies. In cases where non-compliant results were found, it is the laboratory policy to repeat the test on these samples before 'confirming' them as non-compliant;
- in 2009 the laboratory has participated in six inter-laboratory comparisons generally organised by other MPEDA laboratories. These were for nitrofuran metabolites, tetracycline, oxytetracycline, heavy metals and chloramphenicol in shrimps. Each participating laboratory

correctly quantified the residues in question however all distributed samples contained residue concentrations in excess of Community MRLs or MRPLs where applicable;
- the laboratory performance in internationally recognized proficiency testing scheme for testing of chloramphenicol, tetracyclines and dyes in prawns or fish muscle was satisfactory.

5.2.2.4 MPEDA ELISA screening laboratory, Bhimavaram

Findings

This MPEDA laboratory was designated to perform ELISA screening testing of pre-harvest aquaculture samples for content of chloramphenicol and nitrofuran metabolites. It became operational from 1 April 2009.

The mission team noted that:

- the laboratory had not been accredited but there was a Quality Manual and an SOP for screening of chloramphenicol and nitrofuran metabolites residues in shrimps;
- the laboratory had state of the art facilities and was operated by qualified personnel;
- validation data were available for limits of detection and limits of quantification in standard solutions, linearity of calibration curves, and for recovery;
- measuring instruments were calibrated daily but no positive control samples are included in each run;
- ELISA-kits were stored in a refrigerator but the storage temperature was not monitored;
- recovery assessment in the validation phase was done based on shrimp samples spiked with 0.3 µg/kg of chloramphenicol and 1.0 µg/kg of nitrofurans. These concentrations are equal to MRPLs required by EU legislation.

Conclusions on laboratories

Some improvements in the standards of laboratory service have been made but none of the five laboratory recommendations to previous residues mission (DG (SANCO) 8015/2006) had been satisfactory addressed. The inconsistent approach of the EIC regarding approval of laboratories for NRCP testing has resulted in unequal levels of their expertise and capabilities. The lack of supervision of laboratory performance, important shortcomings in method validation, incomparable test results due to lack of correction for analytical recovery and very limited quality control standards in place cumulatively undermine confidence in results generated for certain analytes. This is particularly the case for nitrofuran metabolites and chloramphenicol, which on the basis of the evidence presented, may not be reliably detected in some laboratories at concentrations close to the Community MRPLs and consequently can not provide guarantees on the residues status of commodities intended for export to the EU. Furthermore the laboratory deficiencies in quality control observed by the mission team in laboratories which had been accredited to ISO/IEC 17025 by NABL, raise doubts about the effectiveness of accreditation system.

5.3 VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

5.3.1 Authorisation 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.

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 Community 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 a Community-wide basis, in Articles 30-40 of Regulation (EC) No 726/2004. Veterinary medicinal products which are authorised for use in food producing animals may only contain pharmacologically active substances which are listed in Annexes I, II, or III to Council Regulation (EEC) No 2377/90. The use of one specific category of veterinary medicinal product – medicated premixes – is governed by Council Directive 90/167/EEC.

Findings

Manufacturing licences for drugs including veterinary medicinal products are granted by State Licensing Authorities. In accordance with the Drugs and Cosmetics Rules (under the Drugs and Cosmetics Act) the Office of the Drugs Controller General is responsible for evaluation of the safety and efficacy of new drugs for veterinary use, in consultation with the Ministry of Agriculture and veterinary experts.

The mission team noted that:

- in response to recommendation No 11 in the 2006 FVO residue mission report the Indian competent authority undertook to examine the aspect of product-specific or default withdrawal periods for implementation. No action was taken until August 2009 when the Drugs Controller General proposed to all State Drug Controllers that they may suggest to manufacturers of veterinary drugs to voluntarily include default withdrawal times (in line with those listed in Article 11(2) of Directive 2001/82/EC) on the labels;
- in response to recommendation No 12 in the 2006 FVO residue mission report the competent authority undertook to consider prohibition of certain substances across all exported commodities. With the exception of a prohibition in 2008 for diclofenac, which has MRLs in the EU for bovine and porcine tissues, no such action has been taken.
- as in 2006 national pharmaceutical legislation does not foresee the establishment of MRLs for any authorised substance and authorised products do not have to include any withdrawal periods on the labels. There is no specific legislation in place concerning the use of veterinary medicinal products in animal feedingstuffs;
- the Drugs and Cosmetics Rules require that drugs for veterinary use are labelled "not for human use; for animal use only" and a symbol of an animal head. Although veterinary medicinal products may be authorised for use in specific species, target species is not required on the label;

- in the national residue control plans for eggs and poultry, minimum withdrawal period for eggs (7 days) and for poultry (2 weeks) are indicated and expected to be communicated to farmers by the establishments. The residue control plans for milk, aquaculture and honey do not contain specified withdrawal periods. However, although withdrawal periods are not required on veterinary medicinal products, notification SO 2720 regarding milk requires that the retention time for a drug must be taken into account before milk is delivered;
- a number of veterinary medicinal products which are prohibited or illegal for use in food producing animals in the EU are authorised in India. Examples are chloramphenicol, furazolidone (marker residue AOZ), dimetridazole and ronidazole (all from substance group A6), as well as carbadox and virginiamycin;
- as described in the 2006 FVO residue mission report a number of notifications had been issued with the aim to restrict or ban the use of certain medicinal products in aquaculture farms, egg production or honey production producing for the export market.

Conclusions on authorisation of veterinary medicinal products

The situation with regard to authorisation, distribution and availability of veterinary medicinal products is identical to that described in the 2003 FVO mission report. Several substances (e.g. chloramphenicol and nitrofurans) which are prohibited in the EU are available and used in India, also in export sectors where they have been prohibited for several years. Due to the lack of legal requirements for withdrawal periods on medicines for food producing animals, veterinarians and farmers cannot take into account food safety aspects when such animals are treated.

5.3.2 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 establishes conditions for the administration of substances, referred to in its Annex II, List B and Annex III, to farm and aquaculture animals.

The relevant provisions in Community law governing the distribution and use of veterinary medicinal products are laid down in Articles 65-71 of Directive 2001/82/EC. 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

The general rule is that, with the exception of vitamins and minerals, a veterinary medicinal product must be sold as "prescription-only" and this should be stated on the label. Such products can only be sold on prescription by a registered medical practitioner (veterinarian).

The mission team noted that:

- medicines for fish, crustaceans and honey bees are not covered by the prescription system as these products cannot for legal reasons be prescribed by veterinarians[2]. No other profession is authorised to prescribe medicines for aquaculture animals or honey bees;
- several medicinal products containing anthelminthics intended for use in *inter alia* aquaculture animals were available in one wholesaler/retailer visited. Some were authorised veterinary medicinal products and others were additives which do not require authorisation. These, and other, veterinary medicinal products can legally be sold by retailers directly to aquaculture farmers;
- some additives which were labelled as probiotics contained different anthelminthic substances and some feed supplements for aquaculture (not for therapeutic use) contained ivermectin and undeclared "parasiticidal and protozoacidal agents" ;
- according to the EIA, EIC and other sources, medicines for crustaceans are normally sold to farmers, not by pharmacies but by aquashops, aqua consultants or by so called "shrimp doctors" who have no formal medical training. Such sale is illegal.

Conclusions on distribution and use of veterinary medicinal products

The prescription system should ensure that veterinary practitioners are involved when traditional food producing animals (mammals and birds) are treated with veterinary medicinal products. However, the free availability of veterinary medicinal products to other food producing species, including aquaculture animals and honey bees, increases the risk that treatments with veterinary medicinal products take place without concern for residues in foodstuffs.

5.3.3 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 Community 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 Community 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.

2 ***In their comments to the draft report the Indian competent authorities stated that the prescription system will soon apply also to veterinary medicines used in aquaculture. In addition, the sales of veterinary medicinal products without prescription has been raised with the Drugs Controller of India as outlined in the action plan in response to recommendation 13 of this report.***

As third countries' national residue control plans must provide guarantees with an effect equivalent to those established in Directive 96/23/EC, it is necessary that third countries' systems governing the distribution, placing on the market and administration of veterinary medicinal products (as laid down in Article 7 of the Directive) also provide guarantees in line with those offered by EC legislation, particularly in relation to the use and control of the substances included in Annex I to Directive 96/23/EC in animals and animal products intended for export to the EU.

Findings

The Ministry of Health and Family Welfare is responsible for controls on the manufacture and distribution of medicinal products for animal and human use. A minimum inspection frequency of not less than once per year for all establishments for the sale of medicinal products is laid down in national legislation. Each State Drug Control Department is responsible for implementing these controls and for training the inspectors. These inspections can be made without prior warning if the inspector has reason to believe activities are in breach of national legislation.

The mission team noted that:

- it was not possible for the mission team to assess if the stipulated inspection frequencies had been adhered to in general as the Ministry of Health and Family Welfare did not provide the requested inspection data. However, one of the wholesalers visited had not been inspected between 1999 and 2008;
- medicines authorised by the State Drug Controller in one State may be sold in any State. However there is no national database or list which comprises all authorised veterinary medicinal products and their authorisation numbers. Thus, it is not possible for an inspector to assess whether all drugs placed on the market are legal;
- there is no requirement for pharmacies or farmers to keep or register prescriptions from veterinary practitioners. This is a requirement in the EU;
- in the pharmacy visited only the surname of the prescribing veterinarian was registered when products were sold, which is not in line with national legislation, which requires that the veterinarian's full name and registration number should be recorded. This had been noted in an inspection report by the State Drug Controller but a subsequent inspection by the same body had not made note of the fact that this deficiency remained;
- manufacture of medicated feedingstuffs is not covered under the Drugs and Cosmetics Act or any other national legislation. However, MPEDA is currently drafting a system for registration of feed mills producing feed for the aquaculture sector;
- no authority is responsible for controlling the use of veterinary medicinal products by veterinary practices or for controlling the production and distribution of medicated feedingstuffs or zootechnical additives;
- each export approved establishment must keep information about treatments used in the supplying farms and the establishment is responsible for ensuring proper use of medicines. In the poultry establishment such information was available only for the farm owned by the company. This poultry company had established their own default withdrawal periods for medicines;
- the EIA inspectors interviewed had not received training for inspections on the use of veterinary medicinal products;
- controls on medicine use on farms had been carried out by EIA for poultry, eggs and milk and inspection reports on standardised forms were available in the region visited. In some reports it had been noted that treatment records were not available on farm as they had been submitted to the export approved establishment. Files studied in the poultry establishment visited showed that deficiencies in flock and shed treatment records had not been noted during the EIA inspection;
- since 1 April 2009 MPEDA (through NaCSA) and the State fisheries department had carried

out regular visits to aquaculture farms/ societies in Andhra Pradesh. NaCSA had 40 staff to carry out controls of each registered farm/society twice per week. NaCSA visits were documented, but did not clearly indicate if any controls on veterinary medicinal products had been carried out. According to MPEDA there are 17,000 aquaculture farms in Andhra Pradesh alone;

- no records were available for State fisheries department visits to aquaculture farms (said to be carried out every two weeks) with the exception of signatures entered in farm records. One farm visited had been inspected once in June 2009 and in the other farm the record book had been signed from August although inspections were said to have been carried out since April;
- MPEDA and aquaculture farmers interviewed stated that aquaculture medicines and feed would normally be kept at home and not on the farm itself.

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

Most controls on the use of veterinary medicinal products in the export sector are delegated to the export approved establishments, including the control and enforcement of prohibitions of certain veterinary medicinal products. Certain official controls on treatment records on farm are carried out by EIA. There are no official controls on medicated feedingstuffs and no controls targeting the known illegal distribution of medicines in the aquaculture sector. This system of controls has not been effective in preventing incorrect use of veterinary medicinal products, as evidenced by the continuing findings of residues in honey, milk and aquaculture products.

6 Overall Conclusions

There is a system of residues control in India but the national residue control plan is inadequate in scope and sample numbers for several commodities and the sampling does not always cover the whole year. The undertakings made by the Indian competent authorities in response to recommendations 1, 3, 4, 6, 7, 8, 9, 10, 11 and 12 in the report of the previous FVO residue mission (DG SANCO 2006-8015) have not been met. Follow-up investigations of non-compliant results are not effective in identifying the actual source of detected residues and important investigations and corrective actions at the level of the primary producers (farms) are delegated by the competent authority to the exporting establishments. There is no effective control on the distribution and use of veterinary medicinal products, particularly in aquaculture farms, dairy farms and apiaries, as evidenced by the high frequencies of non-compliant results in the national residue control plan and the RASFF alerts for crustaceans. A system of pre-export testing of crustaceans for inter alia chloramphenicol and nitrofurans, which has been in place since August 2005, has not been effective. The effectiveness of the national residues control plan is further compromised by inconsistencies and sometimes serious weaknesses in laboratory performance and interpretation of laboratory results which undermine the reliability of guarantees given by the Indian competent authorities based on analytical results. These deficiencies are mitigated to a certain extent by food business operators' own-check residue programmes, by the pre-export testing being made official in 2009 and by an official pre-harvest testing for nitrofurans and chloramphenicol in crustaceans, which, whilst being implemented in Andhra Pradesh, is yet to be implemented in all aquaculture producing states. However, it is concluded that the residue controls in aquaculture products, honey, milk and poultry do not currently provide guarantees equivalent to those laid down in Council Directive

7 Closing Meeting

7 Closing Meeting
A closing meeting was held on 24 September 2009 with representatives of the central competent authority. At this meeting, the inspection team presented the main findings and preliminary conclusions of the mission. The authorities did not express disagreement and stated that they would take what ever actions were necessary in order address the observed deficiencies.

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 one month of receipt of this mission report.

N°.	Recommendation
1.	To ensure that the residue control plans for poultry and aquaculture finfish include all relevant substance groups listed in Annex II to Council Directive 96/23/EC, in line with the requirements of Article 29 of this Directive.
2.	To ensure that sample numbers for each commodity are based either on the total national production or the total throughput in export approved establishments in order to provide guarantees in line with the requirements of Chapters 2 and 3 of Annex IV to Council Directive 96/23/EC and Commission Decision 97/747/EC.
3.	To ensure that the sampling is unforeseen and unexpected and that the implementation covers the whole production year for each commodity in order to ensure that the guarantees provided about the residue status of commodities exported to the EU is at least equivalent to those provided under Article 15(1) of Council Directive 96/23/EC and point 2.1 of the Annex to Commission Decision 98/179/EC.
4.	To ensure effective official follow-up of investigations back to primary producer level when non-compliant test results are obtained. These investigations should have an effect at least equivalent to Art 16-18 of Council Directive 96/23/EC.
5.	When non-compliant residue levels are detected (of authorised or prohibited substances) to implement measures with an effect at least equivalent to those provided under Articles 22-27 of Council Directive 96/23/EC.
6.	To ensure that sampling procedures and analytical methods used in the existing supplementary pre-harvest and pre-export testing programmes are adequate to prevent that commodities with residues exceeding Community limits are exported to the EU in order to provide guarantees with an effect at least equivalent to those foreseen in

N°.	Recommendation
	Article 9 of Council Directive 96/23/EC.
7.	In line with the general requirements for analytical methods as specified in part 2.1. of the Annex to Commission Decision 2002/657/EC, to ensure that formaldehyde is not added to milk samples until it has been demonstrated that this measure does not affect the analytical result.
8.	To consider the application of consistent approval criteria for all laboratories designated for testing of residues of veterinary medicinal products in foods of animal origin within the NRCP to provide guarantees at least equivalent to those described in recital 3 and laid down in Article 5 of Commission Decision 2002/657/EC.
9.	To ensure that all methods used within the NRCP and also for the purposes of pre-export testing, are properly monitored and validated to a standard equivalent to Articles 3, 4 and 5 of Commission Decision 2002/657/EC and are demonstrably 'fit for purpose' in accordance with ISO 17025.
10.	To consider the use of quality control samples, internal standards and Certified Reference Materials, where available, in order to improve the reliability of assay performance to provide guarantees at least equivalent to those under Article 5 of Commission Decision 2002/657/EC.
11.	To ensure that a consistent policy of correcting for analytical recovery for residues of veterinary medicinal products is implemented in all of the laboratories in order to assure comparability of results and increase confidence in laboratory performance in line with Commission Decision 2002/657/EC.
12.	Ensure that for authorised veterinary medicinal products, all veterinarians have adequate information about withdrawal periods to ensure that prescribed medicines do not give rise to unauthorised levels of residues in animals or animal products processed for the European market. This is to ensure that the guarantees provided about the residue status of commodities exported to the EU is at least equivalent to those provided under Council Directive 96/23/EC, in particular Article 10 of this Directive.
13.	Ensure that the distribution of veterinary medicinal products is effectively controlled in order to provide guarantees about the residue status of commodities exported to the EU which are at least equivalent to those provided under Council Directive 96/23/EC, in particular Article 10 of this Directive.
14.	Ensure that official controls on the use of veterinary medicines on farms are effective in controlling which medicines are used and in detecting and preventing any use of substances which have been prohibited in the export sector. This is to ensure that the guarantees provided about the residue status of commodities exported to the EU is at least equivalent to those provided under Council Directive 96/23/EC, in particular

N°.	Recommendation
	Article 10 of this Directive.

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

http://ec.europa.eu/food/fvo/ap/ap_in_2009-8190.pdf

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
Dec. 98/140/EC	OJ L 38, 12.2.1998, p. 14-16	98/140/EC: Commission Decision 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
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
Monitoring and sampling for residues in food of animal origin		
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

Legal Reference	Official Journal	Title
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
Approval of residue monitiring plans submitted by third countries		
Dec. 2004/432/EC	OJ L 154, 30.4.2004, p. 44-50, corrected and re-published in OJ L 189, 27.5.2004, p. 33	2004/432/EC: Commission Decision of 29 April 2004 on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC
Validation of analytical methods for residues, and Minimum Required Perfromance 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		
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

Legal Reference	Official Journal	Title
		(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
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
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		

Legal Reference	Official Journal	Title
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
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