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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

NEW ZEALAND

FROM 10 TO 20 SEPTEMBER 2012

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

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

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in New Zealand carried out from 10 to 20 September 2012 as part of the published programme of FVO audits on the monitoring of residues in live animals and animal products in European Union (EU) Member States and in third countries.

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, in order to assess whether these systems offer adequate assurance that the products and animals concerned are within the specified residue limits laid down in EU legislation. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit.

With regard to those commodities for which equivalence in residue monitoring has been concluded under the terms of the Veterinary Agreement between the EU and New Zealand (see section 3 of the report for more details), the evaluation was based on the standards laid down in said Agreement.

The audit assessed the performance of the competent authorities and other officially authorised entities involved in residues and veterinary medicinal product controls and the legal and administrative measures put in place to give effect to the relevant EU requirements. Attention was also paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues audit to New Zealand in 2006.

It is concluded that in terms of the number of samples taken and the range of substances covered in the commodities for which New Zealand is currently listed in the Annex to Commission Decision 2011/163/EU, both the National Chemical Residue Plan (NCRP) and National Chemical Comtaminants Plan (NCCP) provide guarantees which, with the exception of and absence of monitoring for one substance group in aquaculture fish, are largely equivalent to those foreseen by Council Directive 96/23/EC. The implementation of both of the plans and supervision of implementation is effective, being underpinned by a comprehensive staff training programme and verification system. Additional residue testing programmes in place provide further guarantees on the residues status of food exported to the EU and the prompt and thorough follow-up investigations of non-compliant results and verifiable actions taken on foot thereof, underpin the effectiveness of the residue control system.

With regard to the laboratory network, the fact that both laboratories are accredited to ISO 17025 and that the vast majority of methods are included in their respective scopes of accreditation should, in theory, give the competent authority confidence in the reliability of the results. In the case of the laboratory testing all of the NCRP samples, its performance is consistent with what would be expected from an accredited laboratory. However, notwithstanding its satisfactory performance in proficiency tests for beta-lactams and aflatoxins in milk, the – to a large degree - absence of validation data and a protocol for verifying the consistent performance of the screening tests used in the laboratory screening samples under the NCCP, means that the competent authority cannot guarantee that the detection limits reported by this laboratory and quoted in the NCCP for many antimicrobial substances, can be met, potentially undermining the effectiveness of this programme.

With regard to veterinary medicinal products, whilst the maintenance of medicines records is not mandatory across all species/commodities (as in the EU), on the basis of the evidence presented and standard of record keeping observed on-the-spot, the systems in place governing the authorisation, distribution and use of veterinary medicinal products give assurances equivalent to those required in EU legislation. Notwithstanding some issues identified on-the-spot with the maintenance of medicines records and on-farm verification of same, in general, the controls on the distribution and use give guarantees broadly equivalent to those described in Council Directive 2001/82/EC, a conclusion supported by the very low incidence of non-compliant findings of residues of authorised veterinary medicines in food. In relation to equidae, despite differences in the requirements regarding the identification of horses between New Zealand and the EU and the absence of analytical testing for one of the anabolic steroids currently on the market, all of the components of the scheme put in place by the industry together with the competent authority's on-farm verification programme, provide assurances on the residues status of horse meat intended for export to the EU.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
ACVM	Agricultural Compounds and Veterinary Medicines
AOZ and AMOZ, AHD and SEM	Marker residues of the nitrofuran drugs furazolidone, furaltadone, nitrofurantoin and nitrofurazone respectively
ASD	Animal Status Declaration
CC-alpha / CC-beta	Decision Limit / Detection Capability
DDE	Dichlorodiphenyldichloroethylene (metabolite of DDT)
DG(SANCO)	Health and Consumers Directorate-General
EC	European Community
ELISA	Enzyme-linked immuno-sorbent assay
EU	European Union
EURL	European Union Reference Laboratory
FVO	Food and Veterinary Office
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC:
HACCP	Hazard Analysis Critical Control Points
HGP	Hormonal Growth Promotant
HPLC/Fluor	High Performance Liquid Chromatography with Fluorescence Detector
HPTLC	High performance thin layer chromatography
IANZ	International Accreditation New Zealand
ISO	International Organisation for Standardisation
LAS	MPI Laboratory Approval Scheme
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
LOD	Limit of Detection
LOQ	Limit of Quantification
MPI	Ministry for Primary Industries
MPL	Maximum Permissible Level

MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NCCP	National Chemical Contaminants Programme (milk)
NCRP	National Chemical Residues Programme
NRL	National Reference Laboratory
OMAR	Overseas Market Access Requirements
RASFF	Rapid Alert System for Food and Feed
RVM	Restricted Veterinary Medicine
SOP	Standard Operating Procedure
TPIA	Third Party Inspection Agency (an independent body approved by the competent authority to perform certain functions. It may or may not be a crown entity).
VA Online	MPI Verification Services Database

1 Introduction

The audit took place in New Zealand from 10 to 20 September 2012. The audit team comprised two auditors from the Food and Veterinary Office (FVO). The audit was undertaken as part of the FVO's audit programme, evaluating control systems and operational standards in the residues sector. Representatives from the central competent authority responsible for Systems Audit of the control of residues in animals and animal products accompanied the audit team during the audit.

An opening meeting was held on 10 September 2012 with the central competent authority responsible for implementing residue monitoring in live animals and animal products and for the authorisation of veterinary medicinal products– the Ministry for Primary Industries (MPI). At this meeting, the objectives of, and itinerary for, the audit were confirmed and the control systems were described by the authority.

2 Objectives

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, in order to assess whether these systems offer adequate assurance that the products and animals concerned comply with specified residue limits laid down in European Union (EU) legislation. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit.

With regard to those commodities for which equivalence in residue monitoring has been concluded under the terms of the Veterinary Agreement between the EU and New Zealand (see section 3 for more details), the evaluation was based on the standards laid down in said agreement.

The audit focussed on the roles of the competent authorities at central and regional levels, the legal and administrative measures in place to give effect to the relevant EU requirements, controls with regard to residues and veterinary medicinal products and their operation, and the performance of residue laboratories. Attention was paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues audit to New Zealand (DG (SANCO)/8020/2006 MR Final) in November 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 MPI
	Regional	2	Meetings at the MPI Regional Offices in the South Island (Invercargill) and the North Island (Wanganui)
Laboratories		2	Private laboratories
Farms		4	One sheep farm, two dairy farms, one beef feedlot
Establishments		4	Three slaughterhouses (horse, cattle, sheep) and one honey packer
Other Sites		2	One wholesaler and one retailer (private veterinary practice) of veterinary medicinal products

3 Legal Basis

There is a Veterinary Agreement between the EU and New Zealand on sanitary measures applicable to trade in live animals and animal products (approved on behalf of the Union by Council Decision 97/132/EC). Annex V of the Veterinary Agreement – which has been updated and amended on several occasions, the most recent being in 2006 [1] - includes in Section 5 (General Horizontal Issues) residue monitoring in 'red meat species' for New Zealand exports to the EU with the status Yes (1) [2]. For other species/products the status Yes (3) [3] is agreed.

The term "red meat species" is not defined in Union law. In Chapter 8 ("Meat Products") of the 1999 version of Annex V to the Veterinary Agreement [4] ruminants and horses were summarised under "red meat", and farmed and wild game were listed separately. In the residues section (42 A "Horizontal Issues"), a Yes (1) mark was indicated for 'red meat species' only. The New Zealand authority has argued that it was not the intention to differentiate between ruminants, horses, farmed and wild game on the basis of residues – only on animal health – and, in fact in the most recent amendment of Annex V to the Veterinary Agreement, ruminants and horses are not specifically listed under 'red meat'.

Therefore the residue monitoring programmes for bovine, ovine/caprine, equine, farmed and wild game are classified as Yes (1) under the Veterinary Agreement. The other commodities for which New Zealand is listed in the Annex of Commission 2011/163/EU as having an approved residue monitoring plan (aquaculture, milk and honey) are classified as Yes (3) under the Veterinary Agreement and were evaluated under the general provisions of Union legislation and, in particular Council Directive 96/23/EC and 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.

The audit was performed according to the guidelines laid down in Annex VI to the Veterinary Agreement.

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

4 Background

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

Commission Decision 2011/163/EU indicates that New Zealand's residue monitoring plan is approved in accordance with Council Directive 96/23/EC for bovine, ovine, equine, aquaculture milk, farmed game, wild game and honey.

4.2 Summary of previous FVO audit reports

Residue monitoring was last audited by the FVO in 2006 (DG (SANCO)/8020/2006 MR Final) and the audit report (henceforth referred to as the 2006 FVO audit) has been published on the website of

1 *Official Journal L 338, 05/12/2006, pp. 3-44.*
2 *Equivalence agreed with Union law - Council Directives 96/22/EC and 96/23/EC - model health attestations to be used.*
3 *Equivalence in form of compliance with importing Party's requirements – existing certification to be used.*
4 *Official Journal L 332, 23/12/1999, p 10.*

the Directorate – General for Health and Consumers here http://ec.europa.eu/food/fvo/act_getPDF.cfm?PDF_id=6070. The report concluded that whilst residue monitoring was generally executed in accordance with national and/or EU standards, the effectiveness of the control system was undermined by shortcomings in the follow-up of non-compliant results and occasional long turnaround times from sample receipt to analysis. For some of the Yes (3) commodities, there was no testing for some relevant substance groups and, in relation to honey, the own-checks programme in place could not be considered as an official control programme. In relation to veterinary medicinal products, it was noted that the authorisation of substances which were either explicitly prohibited or not authorised for use in food producing animals in the EU, combined with the absence of a general requirement for maintenance of farm medicines records, had the potential to weaken guarantees on the residue status of exported consignments. In its response to the report, the New Zealand competent authority undertook to address the issues identified.

There were two subsequent FVO audits in 2011 in which residues and veterinary medicine issues were not the main focus, nevertheless touched on these issues to a greater or lesser extent: DG SANCO 2011-6135 MR Final (henceforth referred to as the 2011 FVO meat audit) covered public health and certification procedures for fresh meat and focused *inter alia* on the production of hormone-free beef and horse meat for the EU market. The report has been published here: http://ec.europa.eu/food/fvo/act_getPDF.cfm?PDF_ID=9292 DG(SANCO) 2011-6127-MR Final (henceforth referred to as the 2011 FVO milk audit) covered the production of raw milk and dairy products for human consumption destined for export to the European Union and certification. The report of that audit has been published here: http://ec.europa.eu/food/fvo/act_getPDF.cfm?PDF_ID=9492.

In relation to the scope of the current audit, the 2011 FVO meat audit recommended that animal status declarations (ASDs) should be backed up by appropriate documentation and that supplementary ASDs for *equidae* should be (properly) verified. The 2011 FVO milk audit recommended that the code of practice in place for the performance of farm dairy assessments to ensure the appropriate verification of compliance with the New Zealand requirements for *inter alia,* veterinary medicine prescriptions, should be updated. The competent authority undertook to revise the code by December 2012.

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

Since the 2006 audit there have been two RASFF notifications for residues of veterinary medicinal products in honey – both for semicarbazide (SEM) in honey. SEM is a marker residue for the nitrofuran, nitrofurazone. Both notifications were reported in 2012. (See section 5.1.5. for information on the follow-up of these cases).

4.4 Production and Trade Information

According to EUROSTAT data, in 2011 New Zealand was the first ranked exporter of sheep meat (~ 160,000 tonnes; 82% of total) and eels (228 tonnes; 45% of total) to the EU, the second ranked exporter of dairy products (~50,000 tonnes; 34% of total) and the 6th ranked exporter of bovine meat (~12,000 tonnes; 5% of total). Other commodities exported included honey (9th ranked; ~3,700 tonnes; 2% of total) and equine meat (8th ranked; ~ 64 tonnes; 0.2% of total).

The MPI has also published statistical information on agricultural production in the Situation and Outlook for Primary Industries (SOPI) 2012. During the audit the competent authority confirmed that eel production is not an aquaculture activity, the latter being restricted to farmed salmon and bivalve molluscs.

With regard to exports to the EU and elsewhere, the specific standards that are to be met for each importing country are laid down in a series of "Overseas Market Access Requirements (OMAR)" elaborated by the MPI under section 60 of the *Animal Products Act (1999)*.

As New Zealand authorises the use of hormonal growth promotants (HGPs) for the production of beef, there is a split system in place to guarantee that beef destined for the EU market has been produced without the use of HGPs or beta-agonists for growth promotion. The *Animal Products (Regulated Control Scheme – Hormonal Growth Promotants) Notice 2012* describes the HGP control measures in place to achieve this objective.

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

Further to the situation described in the 2006 FVO report, the MPI is now the competent authority responsible for the control of residues in live animals and animal products, having been formed from the former Ministry of Agriculture and Forestry, Ministry of Fisheries and the New Zealand Food Safety Authority.

5.1.2 Planning of residue monitoring plan

Legal Requirements

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

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

Article 11 of Regulation (EC) No 178/2002, laying down the general principles and requirements of food law, specifies that food and feed imported into the EU for placing on the market within the EU shall comply with the relevant requirements of food law or conditions recognised by the EU to be at least equivalent thereto. In relation to maximum levels of residues and contaminants in food, Regulation (EC) No 470/2009 of the European Parliament and of the Council lays down Maximum

Residue Limits (MRLs) for residues of pharmacologically active substances in food which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Regulation (EC) No 396/2005 lays down maximum residue levels of pesticides in or on food and feed of plant and animal origin. Commission Regulation (EC) No 1881/2006 lays down Maximum Levels (MLs) for contaminants in food. Minimum Required Performance Limits (MRPLs) are defined in Article 4 of Commission Decision 2002/657/EC.

In accordance with Article 29 of Council Directive 96/23/EC, Commission approval of every third country's residue monitoring plan is necessary if that country is to remain on the list of third countries from which EU Member States may import animals and animal products. The list of countries and commodities with approved residue monitoring plans is in the Annex to Commission Decision 2011/163/EU.

Section 3 of the current report details the applicability of the Veterinary Agreement between the EU and New Zealand as it relates to residue monitoring.

Findings

Residue monitoring in New Zealand is organised under two different programmes. The National Chemical Residues Programme (NCRP) is established under the *Animal Products Act (1999)* by the *Animal Products (Regulated Control Scheme—Contaminant Monitoring and Surveillance) Regulations 2004*. It covers cattle, sheep, goats, deer, horses, pigs, ostrich, wild animals, poultry and farmed salmon. Honey is also included in the NCRP and the legal basis for this part of the NCRP is the *Animal Products (Regulated Control Scheme ─ Verification of Contaminants in Bee Products for Export) Notice 2010*.

The National Chemical Contaminants Programme (NCCP) covers raw milk and dairy products and is established under the *Dairy Industry (National Residue Monitoring Programme) Regulations 2002*. The latter plan is publicly available whereas public access to the NCRP, specifically the detailed sampling plan identifying individual species, sampling matrix and test compounds, is restricted.

The sampling regime for the 2012/2013 NCRP is outlined in the *Animal Products (Contaminant Monitoring and Surveillance) Notice 2012*. In respect of honey the sampling regime is outlined in the *Animal Products (Regulated Control Scheme ─ Verification of Contaminants in Bee Products for Export) Notice 2010*.

The MPI Standards Branch is responsible for elaboration of the NCRP and NCCP. According to the competent authority, the results from other residues monitoring programmes carried out in food of animal origin under the *Food Act 1981* e.g. the Food Residues Surveillance Programme, the Imported Food Monitoring Programme, the New Zealand Total Diet Study and the Sulphonamide-on-site programme (under the *Animal Products (Sulphonamide–On–Site Monitoring and Surveillance and Non–Sulphonamide Antibiotic Monitoring (Bobby Calves) Specifications) Notice 2005,* are considered when the NCRP and NCCP are being drawn up.

According to the competent authority both the NCRP and the NCCP have been recently audited by the MPI Verification Services Systems Audit team. The report of that audit has not yet been finalised.

The audit team noted that in respect of the NCRP:

- the plan which runs from July to June was well documented and elaborated. Relevant bodies including the main testing laboratory and MPI's Agricultural Compounds and Veterinary Medicines Group (ACVM) were involved in the planning process and there was documentary evidence to this effect. (The lack of inclusion of bodies such as the ACVM was criticised in the 2006 FVO audit). The plan takes into account animal production patterns,

the veterinary medicines (newly) authorised and used in the country, the results of the previous years' plans and findings made in other residue programmes (such as the New Zealand Total Diet Study) and a rationale for including these substances (or not) is documented in the plan;

- in relation to the commodities covered in the NCRP for which a Yes (3) designation has been applied (aquaculture fish – farmed salmon - and honey), the number of samples taken are in line with Council Directive 96/23/EC - – which was not the case in the 2006 FVO audit. Indeed the number of samples exceeds minimum EU requirements;
- in relation to the 'red meat' species, full equivalence to Council Directive 96/23/EC has already been agreed under the Veterinary Agreement. In that respect the only issue of note is that the anabolic steroid, methandriol, which is authorised for use in *equidae* – albeit as a restricted veterinary medicine and not for use in horses intended for human consumption - is not currently included in the panel of steroids currently tested for in the plan. (The parent substance is the major urinary metabolite);
- in relation to other commodities included in the NCRP for which there is a Yes (3) classification under the Veterinary Agreement, heavy metals (B3c) are not included in the plan for aquaculture fish (salmon). (Group B2a – anthelmintics – were not included in the 2011-2012 NCRP but are foreseen to be tested in the 2012-2013 plan. There are no anthelmintics (parasiticides) authorised for the treatment of salmon in New Zealand). Regarding heavy metals, whilst there is historical data indicating a low incidence of heavy metals in wild caught fish from the same waters in which the salmon farms are located, this does not take account of the risks of exposure of the salmon via feed;
- for honey, whilst the number of samples to be taken is in line with Council Directive 96/23/EC, it is also the case that heavy metals (B3c) are not included in the 2012-2013 plan. However, previous monitoring results in the 2009 New Zealand Total Diet Survey have indicated that contamination is negligible;

The audit team noted that in respect of the NCCP:

- the plan is very comprehensive in scope and includes both (bovine) raw milk and colostrum. The rationale for the inclusion of analytes and substance groups is described in the plan. Although not specified in the plan, testing for goat milk (46 farms) is also included. Sheep milk was last included in the plan in 2010 (there are only four farms producing milk). Buffalo are not included as there are only two farms producing milk. It was subsequently clarified by the MPI that products derived from milk produced on those farms are only eligible for the domestic market and may not be exported to the EU;
- the number of samples planned is based on *Codex Alimentarius* guidelines and exceeds minimum EU requirements. Furthermore many of the samples taken under the NCCP are tested for the full range of substance groups laid down in Directive 96/23/EC, again exceeding EU requirements;
- for some of the antimicrobials listed in the plan (see laboratory section, 5.2.1.2.) there is no evidence that the detection limits quoted can be achieved or even if the substances can be detected at all with the screening method used.

Conclusions on planning of the residue monitoring plan

In terms of the number of samples taken and the range of substances covered in the commodities for which New Zealand is currently listed in the Annex to Commission Decision 2011/163/EU, both the NCRP and NCCP provide guarantees which, with the exception of an absence of monitoring for one

substance group in farmed fish, are largely equivalent to those foreseen by Council Directive 96/23/EC.

5.1.3 Implementation of the residue monitoring plan

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive and must, in particular, meet the requirements of Article 4 and specify the particulars laid down in Article 7. Article 4(2)(b) and (c) of Council Directive 96/23/EC lays down the requirements for central competent authorities in co-ordinating the activities of all bodies involved in residues controls. Articles 5 and 12 of Council Directive 96/23/EC deal with aspects pertaining to the implementation of the residue monitoring plan. Sampling requirements are specified in Annex IV to Council Directive 96/23/EC and Commission Decision 97/747/EC and Commission Decision 98/179/EC lays down the rules for official sampling under the residue monitoring plan. EU methods of sampling for the official control of a wide range of residues in products of animal origin are laid down in several pieces of EU legislation: Commission Directive 2002/63/EC (pesticides); Commission Regulation (EU) No 252/2012 (dioxins, dioxin-like PCBs and non-dioxin-like PCBs); Commission Regulation (EC) No 333/2007 (certain chemical elements); Commission Regulation (EC) No 401/2006 (mycotoxins). Section 3 of the current report details the applicability of the Veterinary Agreement between the EU and New Zealand as it relates to residue monitoring.

Findings

Dissemination of the NCRP and NCCP:

The NCRP for red meat species is rolled out to sampling staff on a bimonthly basis (six rounds per year) and takes account of the seasonal production patterns and throughput of the slaughterhouses. A specially designed computer programme randomises the matrix/analyte combination (the latter designated by an assay code number) and allocates samples to the slaughterhouses in operation during the sampling period.

For live animal (urine) sampling, the plan (50 samples) is rolled out annually and takes place in five saleyards (10 samples per saleyard). It predominantly targets non-hormonal growth promotant (HGP) treated steers, though up to three non-HGP-treated heifers may be sampled in any batch of 10 cattle.

The honey and aquaculture plans are also established on an annual basis. For the former, there are two separate plans – one for MPI and one for a third party inspection agency (TPIA)[5], which in this case is a commercial company, 100% owned by the New Zealand government i.e. is a crown entity. In both cases, the list of premises to be sampled is supplied and the assays (defined by code number) to be performed on the samples is decided in advance. For the aquaculture plan, the 17 sampling sites are decided in advance and the assays to be performed are also decided in advance.

The NCCP is rolled out in a number of sampling rounds over the entire year, with the bulk of sampling taking place in the peak milk production period. The temporal distribution of the plan throughout the year takes account of the differing seasonal production patterns between the North and South islands. The dissemination of the sampling plans by round is undertaken by a subsidiary company of the TPIA. There is a procedure in place for determining the sampling dates on a

5 *In its response to the draft report the competent authority noted that in the New Zealand context, a TPIA is independent from the competent authority and may or may not be a crown entity.*

random basis and selecting the farms to be sampled on a random basis – which is done by the MPI Principal Adviser. The assays to be performed are also decided in advance by MPI.

Personnel responsible for sampling and sample locations:

For the NCRP both the MPI Verification Services and the TPIA are involved. Typically in a slaughterhouse, the samples would either be taken by the MPI Verification Services supervising veterinarian (official veterinarian) or the TPIA meat inspector acting under his/her direction. The TPIA's role in sampling is provided for in Schedule 3 of the *Animal Products (Export Requirement: Company Ante-Mortem and Post-Mortem Inspection) Notice 2012.* According to the competent authority, the decision as to whether MPI Verification Services are involved in sampling or not is often determined on a cost effectiveness basis. All 'Red meat' is sampled at processing establishments (slaughterhouses). Aquaculture samples are collected from farms and in processing establishments by MPI Verification Services staff.

Live animal (cattle) sampling (in saleyards) is only carried out by MPI Verification Services staff – the supervising veterinarian from a slaughterhouse.

For honey, samplers are the verifiers for the premises where the samples are taken and include both MPI Verification Services and the TPIA staff. The definition and role of samplers for bee products is set out in the *Animal Products (Regulated Control Scheme ─ Verification of Contaminants in Bee Products) Notice 2010*. Honey is collected at the randomly selected premises listed in the *New Zealand Premises Approved for Honey and Apiculture Products to European Union*. These premises (of which there are 265 currently listed) are operating under a so-called risk management programme provided for under the *Animal Products Act 1999*. The randomly selected list of premises to be sampled is provided to each of the responsible sampling bodies – the MPI and the TPIA - and the list remains confidential to the sampling co-ordinator and the samplers. The samples are collected at a verification visit as set out in the *Animal Products (Regulated Control Scheme ─ Verification of Contaminants in Bee Products for Export) Notice 2010*.

All NCRP samples are sent directly to the specified laboratory carrying out testing under the programme.

For the NCCP all sampling is undertaken at farm level by the TPIA staff. Samples are sent to the co-ordinating body (the subsidiary company of the TPIA) who in turn submit the samples to the relevant laboratory.

Sampling instructions:

The *MPI Technical Procedures (Residues)* covers the collection of samples of animal products (excluding dairy products, instructions for sampling of which are laid down in the *Dairy National Chemical Contaminants Programme - Operational Criteria*). There is a separate *Bee Products Residue Sampling Procedure*. Sampling instructions for live cattle – the lack of which was criticised in the 2006 FVO audit – is covered in the *MPI Technical Procedures (Residues)*.

Section 5.3 of the *MPI Technical Procedures (Residues)* requires that sampling plans remain confidential to the sampler. For most commodities, there is no prior warning that a sample will be collected, however for farmed salmon, there has to be a prior arrangement with the farm due to the location of the farms. For honey, although samples are collected at the planned verification visits – the farmer is not informed in advance whether a residues sample will be taken or not.

Supervision of implementation of the NCRP and NCCP:

Overall there are three officials at central level (in the MPI Standards Division) responsible for the NCCP and NCRP. For the former programme, the Principal Adviser (Primary Production) directs the TPIA's co-ordination of the plan's operational implementation. For the latter programme the

Manager (Chemical & Microbiological Assurance Programmes) and Specialist Adviser (Residues) oversee its operational implementation (with the exception of honey sampling which is supervised by an employee from the TPIA and an official from MPI Verification & Systems - Verification Services).

Day-to-day supervision of implementation of the NCRP is carried out by Residue Programme Co-ordinators, of which there are six. These MPI officials carry out their programme co-ordination role on a weekly rota basis. Their tasks are clearly described in their letter of designation from MPI, one of which is to reconcile the number of samples taken with the total number expected for the sampling period in question (e.g at the end of each two month sampling window for the red meat species).

For the NCCP, the implementation of the plan (co-ordinated by the subsidiary company of the TPIA and executed by the TPIA) is monitored regularly by the MPI Principal Adviser (Primary Production).

The audit team noted that:

- there were clear sampling instructions in place for samplers under both the NCRP and NCCP. MPI officials and the TPIA staff interviewed were well aware of their obligations and how samples should be taken, identified, stored and transported. (On-line) training records for both MPI and the TPIA staff were available for inspection and in all cases examined were up to date and relevant for the task in hand;
- samples examined by the audit team on-the-spot were properly identified, sealed with tamper-evident tape, and stored. Both routine NCRP and suspect samples taken as a consequence of a finding in the NCRP or other intelligence, were uniquely identified;
- for the NCRP there was evidence of regular contact between the Residue Programme Co-ordinators, the Manager (Chemical and Microbiological Assurance Programmes) and the Special Adviser (Residues) (emails, minuted monthly teleconference meetings);
- the laboratory carrying out all of the NCRP (and most of the NCCP) testing also informs the MPI (via email to a virtual mailbox) if there are sampling problems and evidence of this was seen in the visit to Laboratory A. Furthermore, a monthly report of progress being made vs the number of samples received and expected was also seen in both the laboratory and in the MPI. Sampling progress was also tracked by the supervising veterinarian in each of the slaughterhouses visited and it was verified by the audit team that samples indicated as being taken, had been taken;
- in both of the MPI regional offices visited it was seen that the Residue Programme Co-ordinators kept track of sampling progress in the NCRP and logged this in a secure web-based access-restricted sample-tracking spreadsheet programme. Where problems had occurred (e.g. wrong matrix collected), there were records to show that this had been communicated to the MPI Special Adviser (Residues) and in turn to the on-duty Residue Programme Co-ordinator who had arranged alternative samples to be collected;
- for the NCCP there were minuted quarterly meetings between the MPI Principal Adviser (Primary Production) and the TPIA programme manager;
- a comprehensive system of verification is also in place whereby different levels within the MPI Verification Services audit whether tasks (such as residue sampling) have been implemented in accordance with planned arrangements. Documentary evidence of such verifications were sought and received in both of the MPI regional offices visited and in the slaughterhouses.

Conclusions on implementation of the residue monitoring plan

The implementation of both the NCRP and NCCP and supervision of same is effective, being underpinned by a comprehensive training programme and verification system.

5.1.4 Other residues monitoring programmes

Legal Requirements

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

Findings

5.1.4.1 Other official residue testing programmes

In addition to the NCRP and NCCP, the other MPI residues and contaminant monitoring programmes of relevance to the current audit are the Food Residues Surveillance Programme, the Imported Food Monitoring Programme and the New Zealand Total Diet Study, all of which are established under the *Food Act 1981*. Every 5 years, the Total Diet Study samples and tests the typical diet of New Zealand citizens to measure the presence of residues, contaminants and elements in food.

There is also a Sulphonamide-on-site programme operated by the TPIA under the *Animal Products (Sulphonamide–On–Site Monitoring and Surveillance and Non–Sulphonamide Antibiotic Monitoring (Bobby Calves) Specifications) Notice 2005*. The non-sulphonamide component of the programme referred to in part 12 of the above Notice no longer applies with bobby calves being randomly selected at slaughter for inclusion in the (NCRP) antibiotic testing for bovine animals. According to the MPI the Notice is under review and will be modified to reflect the change[6].

5.1.4.2 Establishment own-checks

With the exception of dairy products, there is no obligation for food business operators to include residue testing in their own-checks programme. Operators are however obliged to ensure that in respect of product to be exported to the EU, any residues contained therein, comply with EU limits (EU OMAR).

In respect of meat intended for export to the EU, the *Animal Products (European Union Export Requirements – Animal Material and Products) Notice 2009* obliges primary processors to source animals from farms complying with relevant provisions laid down in the *Animal Products (Regulated Control Scheme─On-Farm and Stock Saleyard Verification) Notice 2009* particularly in respect of statements on medicinal treatments declared on the ASD accompanying the animals to the slaughterhouse. Slaughterhouse operators are obliged to verify the accuracy of the information (on medicines) included in the ASD.

With regard to milk, section 9 of the document, *DPC 1: Animal Products (Dairy): Approved Criteria for General Dairy Processing* established under the *Animal Products (Dairy Processing*

6 *In its response to the draft report the competent authority noted that Sulphonamide–On–Site testing is being phased out and will cease by 1 March 2013.*

Specifications) Notice 2006 – now updated by a 2011 Notice - requires that dairy products must not contain residues exceeding limits applicable in New Zealand and, in respect of exports to the EU, applicable EU limits. Section 9 (3) of *DPC 1* specifies that risk management programmes must contain a suitable sampling and testing plan for chemical contaminants and residues identified through HACCP Identification and Analysis as presenting a risk. In doing so the risk management programme operator should refer to the MPI NCCP and may defer to the monitoring conducted under that programme for compounds shown to be managed effectively.

Section 7 (11) (b) and (e) of *DPC 1* requires dairies to inform their verifying agency (i.e. the TPIA) on farms' performance in residues testing and whether there have been any failures (i.e. putative non-compliant results). In turn section 7 (2) (l) of the *Animal Products (Dairy Recognised Agency and Recognised Persons Specifications) Notice 2011 Number 2*, (established under section 167(1) (m), (p) and (q) of the *Animal Products Act 1999*), requires the recognised agency (i.e. the TPIA) to inform the MPI of any critical non-compliance found.

The audit team noted that:

- in the honey packer visited own checks for nitrofuran residues had been carried out and, batches of honey in which traces of SEM were detected were rejected;
- in the cattle feedlot visited, monthly testing for antibiotic residues and hormones residues was carried out. Results were all compliant. (Results in samples collected from this feedlot under the NCRP were also all compliant);
- there is substantial testing of raw milk by the dairy industry. In the 2011-2012 NCCP it was stated that during the 2011/12 season the industry was expected to undertake some 1.15 million raw milk residue tests, made up of approximately 700,000 antimicrobial (inhibitory substance) tests on individual farm milk supplies and 450,000 tanker beta-lactam tests;
- the dairy company which the two farms visited supply, had a policy of testing every batch of milk from farmers for a period of one year if the farm sample had failed the inhibitory substance test taken under the dairy's own-check programme;
- in the dairy farm visited the dairy company, had identified a potential aflatoxin contamination problem with a feed source (biscuit meal) being used on the farm and, own-check milk testing had detected aflatoxin M1 at a level of 0.02 µg/kg (the EU maximum level is 0.05 µg/kg). The farmer was instructed to stop feeding this material and subsequent samples did not contain traces of aflatoxin M1.

Conclusions on other residues monitoring programmes

The additional residue testing programmes in place underpin guarantees on the residues status of food exported to the EU.

5.1.5 Follow-up of non-compliant results

Legal Requirements

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

Findings

Under the NCRP (excluding honey), the legal basis for applying sanctions and carrying out follow-up investigations is the *Animal Products (Regulated Control Scheme – Contaminated Monitoring and Surveillance) Regulations 2004*, in particular regulation 14 and 15.

For HGPs, the legal basis for sanctions and carrying out follow-up investigations is provided by the *Animal Products (Regulated Control Scheme – Hormonal Growth Promotants) Notice 2012.*

For honey, the legal basis for sanctions and carrying out follow-up investigations is provided by the *Animal Products (Regulated Control Scheme ─ Verification of Contaminants in Bee Products for Export) Notice 2010* – Part 3 - Contaminant Surveillance. The instructions for taking action are described in this Notice.

The *Animal Products Act 1999* provides powers for Animal Products Officers under clauses 87, 88, 89, 90, 91 and 92. Additional powers for the supply of animals and animal products, movement control, recall and disposal are under clauses 81A, 81 B, 82, & 85. The Act also provides for offences, penalties and proceedings under Part 10.

Samplers and Residues Programme Co-ordinators have a role in non-compliant sample investigations and follow up and detailed staff instructions are included in the *MPI Verification Services Residues Programme Coordinator Procedures & Technical Procedures (Residues)*.

Following a non-compliant residues result the typical sanction is provision of a surveillance notice describing the restraint provisions, and surveillance listing of the supplier. This ensures targeting of animals at slaughter for sampling and testing. Animal products may be retained until a trace back is done and test results are reported. Following this a decision on product eligibility can be made. For example, if the results of targeted testing on retained product are compliant and the trace back confirms that the cause was an isolated event, the product will be eligible for intended markets. Surveillance listing is revoked once there is evidence of compliance.

For the NCCP the *Animal Products (Risk Management Programme Specifications) Notice 2008* (clause 17) requires the operator to specify freedom of access and other rights of the official verifier of the risk management programme in place – in this case, the TPIA. The *Animal Products (Dairy) Regulations 2005*, regulation 5 provides for follow-up investigations and sanctions for non-conforming dairy product. This is supported by the *Animal Products (Disposal of Non-conforming Dairy Material or Dairy Product) Notice 2012* which ensures that non-conforming product is withdrawn from trade and certification blocked.

Investigations following a non-compliant result take place under the supervision of an Animal Products Officer and the NCCP Principal Adviser manages this process.

Following a non-compliant residues result there is a trace back to the farm to determine the cause of the non-compliance and the risk management programme operator (I.e. the dairy company) is required to ensure that the situation has been corrected. Typically farm suppliers will be heavily penalised financially for any residue non-conformances as well as being subject to extensive follow-up testing. Risk management programme operators are also required to trace forward and confirm eligibility of all products into which the milk may have been incorporated until test results are known and a decision on product eligibility is made. The guidelines for managing residues in milk and dairy product lay down the procedure for confirming eligibility of product.

The turnaround times for NCRP samples have been set at 16 business days and are laid down in the *MPI Assurance Programme Requirements for Contract Laboratories 2012 – 2015*. With regard to NCRP samples the turnaround times are reported to the MPI every month along with a detailed list of samples that have a reporting delay together with the reason. From January to June 2012 the proportion of samples analysed within the target have ranged from 70 to 96%.

In the case of the NCCP, turnaround times have been specified in Section 5.11 of the Dairy National

Chemical Contaminants Programme – Criteria (Updated June 2008). Unless otherwise specified, the confirmed results shall be reported to the NCCP administrator within (i) 10 working days of sample receipt for Inhibitory Substances results and (ii) 20 working days of the full sampling round batch being received by the laboratory for all other analyses. Data provided demonstrated that for the vast majority of cases, both of the laboratories involved processed all of the samples within either 10 days (in the laboratory screening for inhibitory substances and carrying out ELISA tests for tetracyclines and aflatoxin M1) or 20 days (for the laboratory carrying out the other analyses on milk - pesticides, heavy metals, anthelmintics etc).

5.1.5.1 Non-compliant results in the NCRP and NCCP

Findings

According to the competent authority, in the 2011-2012 NCRP, 15 samples[7] were non-compliant for a range of substances including pirimphos methyl (honey), SEM (honey), diphenylamine (bovine fat), trenbolone (bovine bile), levamisole (ovine liver), eprinomectin (cervine liver), sulphamethazine, sulphadiazine and sulphaguanidine (bovine kidney – bobby calves), dichlorodiphenyldichloroethylene (DDE) (cervine fat) and piperonyl butoxide (ovine and bovine fat). Not all of these exceeded the New Zealand Maximum Permissible Levels (MPLs), but were investigated nonetheless.

With regard to the 2011-2012 NCCP, two samples out of a total of 350 analysed contained residues of DDE in excess of the *Codex Alimentarius* maximum limit but at less than the EU maximum limit.

In the visits to both of the MPI regional offices, the audit team selected a number of these non-compliant results at random (sulphonamides in bobby calves, a putative finding of an aminoglycoside in a horse, the HGP trenbolone in a steer, and six cases of SEM in sheep and goat meat) and noted that:

- all of the individual cases were well documented (files were held in the 'VA Online' database) and had been followed up promptly. Where appropriate (e.g. the sulphonamide case and the trenbolone case), producers had been placed on a surveillance list and resampled in accordance with legislative requirements. Subsequent compliant results led to their removal from the list. The SEM cases – all results between 0.2 and 0.3 µg/kg, under the EU Minimum Required Performance Limit (MRPL) of 1 µg/kg – were thoroughly investigated. There was no evidence that nitrofurazone had been used in any of the farms implicated;
- investigation of the trenbolone case revealed a breakdown in sample traceability in the slaughterhouse in question (both HGP-free and HGP-treated animals had been slaughtered on the same day and it was likely that the viscera trays had lost their identification number to the carcase on the line since (a) this same problem had subsequently been observed by the supervising veterinarian in the establishment and (b) a subsequent analysis on the associated muscle sample was compliant). The certification status of the processing establishment was suspended pending a resolution to deficiencies identified in its operation during a subsequent technical audit by the MPI Verification Services Regional Technical Manager. All of the product produced on the day (from HGP-free animals) was made non-EU eligible and the processing establishment was instructed to recall exported product. The farmer was

7 *In its response to the draft report the competent authority noted that the information on non-compliant results provided to the audit team prior to the audit was interim. Subsequently the competent authority has confirmed that seven of these results were non-compliant with New Zealand statutory requirements.*

surveillance-listed and an on-farm verification was also carried out by MPI with satisfactory results (i.e. no problems found). The results of two follow-up samples were also compliant and the farm was removed from the surveillance list. Certification status was reinstated for the establishment once it was verified by MPI that the deficiencies in traceability had been rectified;

- in the case of the two DDE findings in colostrum, the risk management programme operators (the dairies) were advised by the MPI to review the collection information of both tanker loads. In both cases it was confirmed that the tanker loads conformed with *Codex Alimentarius* (and EU) maximum limits and no market restriction was applied.

5.1.5.2 Non-compliant results reported under the RASFF

Findings

See section 4.3. Two RASFF notifications were raised in January and May 2012 (SEM in 'Wild Forest Honey' at 1.1 and 1.2 µg/kg). The MPI Systems Audit Team conducted an investigation into both cases in May 2012 and a copy of the audit report was furnished to the audit team.

The audit team noted that:

- the report was very comprehensive in scope and trace back from the honey processor (packer) to the individual supplying farms had been carried out – 11 separate entities were included in the scope of the audit;
- there was no evidence that there had been any (illegal) use of nitrofurazone in any of the apiaries implicated. The competent authority noted that recent data generated by an EU National Reference Laboratory (NRL) indicated a possible natural source of SEM in certain types of honey produced in the EU.

Conclusions on follow-up investigations/actions

The prompt and thorough follow-up investigations of non-compliant results and verifiable actions taken on foot thereof, underpin the effectiveness of the residue control system in place.

5.2 LABORATORIES

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans submitted by third countries must have an effect at least equivalent to those provided for in the Directive. Article 15 of Council Directive 96/23/EC requires that official samples are examined in approved laboratories. Requirements for accreditation of laboratories are laid down in Point 1.2. of the Annex to Commission Decision 98/179/EC. The rules for analytical methods to be used in the testing of official samples taken pursuant to Article 15(1) of Council Directive 96/23/EC are laid down in Commission Decision 2002/657/EC – in particular Articles 3, 4, 5 and 6 which cover *inter alia*, validation requirements and quality control. More specific requirements for analytical methods for certain substances are laid down in the annexes to Commission Regulation (EU) No 252/2012 (dioxins, dioxin-like PCBs and non-dioxin-like PCBs in foodstuffs), Commission Regulation (EC) No 333/2007 (chemical elements in foodstuffs) and Commission Regulation (EC) No 401/2006 (mycotoxins).

Findings

All laboratories carrying out testing under the NCRP and NCCP are required to be accredited to ISO 17025 by International Accreditation New Zealand (IANZ). Residue testing laboratories are designated by MPI in two ways under the *Animal Products Act 1999* and these designations are stratified by the commodity to be tested i.e. dairy products and non-dairy products. Both groups of laboratories are recognised under the *Animal Products Act 1999* as Recognised Agencies and the list of all such recognised agencies is published on the MPI website. The laboratories are approved by the MPI under its Laboratory Approval Scheme (LAS) and the *Animal Products (Recognised Agencies and Persons Specifications) Notice 2011* provides for recognition of LAS laboratories for residue testing of non-dairy commodities. The LAS scheme sets out the requirements that must be met to become approved, not least of which is accreditation by IANZ to ISO 17025, while the Notice sets out the requirement for laboratories as recognised agencies. The LAS Approved laboratories list is here: http://www.foodsafety.govt.nz/registers-lists/laboratorysignatories/index.htm

Section 5.1 of the *Dairy National Chemical Contaminants Programme – Operational Criteria* requires that the laboratories providing analysis under the NCCP must be MPI recognised dairy laboratories and agreed by the NCCP Administrator. The agreement is formalised through contract arrangements with the laboratory. For laboratories testing milk and dairy products for general food safety purposes, including NCCP and industry residue monitoring, the laboratories are required to be recognised agencies under section 103 of the *Animal Products Act 1999* and the *Animal Products (Dairy Recognised Agency and Recognised Persons Specifications) Notice 2011* applies.

Two (semi-) private laboratories are contracted to provide testing services for the NCRP and NCCP from 2012 – 2015. In the case of the laboratory responsible for all of the NCRP (Laboratory A), the vast majority of analytical methods used are included in its scope of accreditation. For Laboratory B, the three methods it uses for the NCCP are all within the scope of accreditation.

The audit team visited both of the laboratories testing under the NCRP and NCCP, henceforth referred to as Laboratory A and B respectively. Both were also visited in the 2006 FVO audit.

5.2.1 Laboratory A

Findings

The laboratory carries out all of the testing under the NCRP and, with the exception of antibiotic and aflatoxin M1 screening in the NCCP, it carries out all of the remaining testing under that programme. The laboratory carries out approximately 2000 residues analyses per month under these programmes.

The audit team noted that:

- the laboratory was well equipped with several state-of-the-art tandem mass spectrometers coupled to either gas or liquid chromatographs;
- training record of staff randomly selected by the audit team for examination were in order – staff were trained for the methods they were performing;
- from 2010 to date the laboratory had participated in 90 proficiency tests for veterinary drug residues and contaminants with satisfactory performance in the majority of cases (77). Regarding the unsatisfactory results, three files were selected at random by the audit team. Corrective action requests had been raised and the issues had been dealt with satisfactorily, either within laboratory (e.g. utilisation of a more suitable ion for quantification of florfenicol amine) or in collaboration with the proficiency test provider (low recoveries of triclabendazole sulfoxide in one round);

- the most recent IANZ audit took place in June 2012. A number of deficiencies were identified in the IANZ report. In each case examined by the audit team, corrective action requests had been raised and the issues – many of which were of a relatively minor nature - had been dealt with satisfactorily;
- a comprehensive internal quality control system was in place in the laboratory including a blind check sample programme and maintenance of control charts for each method. The effectiveness of implementation of the blind check sample programme and the maintenance of control charts had also been subject to internal audit as part of the regular schedule of internal audits in the laboratory. An internal audit in June 2012 had focussed on the method for pesticides in fat (covering 284 substances) and a number of corrective action requests had been raised – including *inter alia*, acceptance criteria for analytical recovery not being met on some occasions. Action had been taken to address these deficiencies and had been documented. Furthermore, the quality controls in place for the method in question had revealed poor recoveries for 14 pesticides out of the suite tested. This had been notified in writing to the MPI – in accordance with MPI rules - and in the interim the laboratory was not including the results of these compounds in the data provided to the MPI and, with the agreement of MPI, was developing an alternative method for these problem pesticides;
- another internal audit in 2011 had focussed on several Liquid Chromatography-(Tandem) Mass Spectrometry (LC-MS/MS) methods including those for beta-agonists, steroids, cocidiostats and amphenicols. Minor shortcomings were identified and corrective actions were taken, documented and checked off by the internal auditor;
- in general, for the instrumental methods used, calibration curves are made up in matrix (i.e. spiked matrix which is then extracted) and absolute recoveries (for quality control charts) are determined by including an extracted matrix spike at the end of the run. Where possible deuterated internal standards are used for the MS/MS methods;
- a validation SOP for instrumental methods is in place which includes a specific reference to Commission Decision 2002/657/EC in respect of validation for veterinary drug residues.
- four analytical methods were selected at random by the audit team and examined – antimicrobials in milk by a four plate microbial growth inhibition assay with solvent extraction pre-treatment; avermectins in milk by HPLC-Fluorescence; steroids in urine by LC-MS/MS and beta-agonists in urine by LC-MS/MS;
- the four plate test which is run as a qualitative test was adapted from a published method for milk powder and covers 27 substances in the validation file – beta-lactams, cephalosporins, macrolides, tetracyclines, aminoglycosides and enrofloxacin – though only 18 were listed in the data provided to the audit team prior to the audit. The validation file listed limits of quantification (LOQ) based on single recovery spikes for all 27 substances and repeatability (5 replicate determinations) for nine substances. Quoted LOQs satisfied EU MRLs where established. In day-to-day operation, four substances are run at two different spiking levels for quality control. With few exceptions the performance of the quality control samples was satisfactory;
- the avermectin method had been validated over two days. The method covering six substances was capable of detecting concentrations at and below EU MRLs. The quality control data for the milk samples was satisfactory and problems were only seen when the method was applied to water and plasma (for which it is not validated). Repeatability data were as expected for such a method (~10%);
- the steroid method was developed by an EU NRL and transferred. (This method was not in place during the 2006 FVO audit). It covers 29 analytes – 15 run in positive chemical

ionisation mode and 14 in negative mode – with deuterated internal standards for 18 compounds. LOD, LOQ and both CCalpha and CC beta had been calculated and were consistent with the values recommended by the EURL. On one occasion when the blind check sample did not work, a corrective action request had been raised and the problem solved;

- the beta-agonist method covered six analytes, all of which had deuterated internal standards. The quality control charts and blind check samples demonstrated that the method was working consistently and the calculated values for LOD, LOQ, CC-alpha and CC-beta were consistent with those recommended by the EURL;
- with regard to analytical issues identified in this laboratory during the 2006 FVO audit, it is still the case that there is no method for sulphonamides in honey, though tylosin and streptomycin have been added. The LOQ for chloramphenicol in honey now satisfies the EU MRPL. Nitrofurans have been added to the suite of assays for farmed salmon;
- storage, identification and traceability of residues samples was also checked. The sample submissions and identification and packing were in accordance with instructions. Samples were anonymised (the analyst just had a laboratory number) and in the several examples selected at random by the audit team, traceability back to the farm of origin was possible in every case;
- in all of the examples selected at random by the audit team, samples had been processed within the agreed turnaround times with MPI.

5.2.2 Laboratory B

Findings

Within the NCCP the laboratory tests raw milk for antimicrobials (by a commercially available microbial growth inhibition test), tetracyclines and aflatoxin M1 (by commercially available enzyme-linked immuno-sorbent assay (ELISA) kits). All of the tests (and several others) are included in the scope of accreditation and are approved by the MPI.

The audit team noted that:

- the laboratory is highly automated and the NCCP samples make up a minute proportion of the analyses carried out;
- for the main assay employed - a commercially available microbial growth inhibition test for antimicrobials which is used to test approximately 2,500 samples daily – quality control samples are run in every assay (Penicillin G at the EU MRL and half the MRL) and the performance of the test for this analyte was satisfactory (as expected for an assay using Bacillus *stearothermophilus* as the indicator organism which is sensitive to beta-lactam antibiotics);
- there is no validation Standard Operating Procedure (SOP) in place or documented procedure for validating the performance of the purchased assays. This issue was also identified in the 2006 FVO audit;
- the 'validation file' for the above test for antimicrobials consisted of several published papers and conference presentations quoting the sensitivity of the assay for a range of antimicrobials, sometimes with conflicting results compared to the manufacturer's quoted data. The laboratory had carried out a comparison of this test with a previously used test on 1670 actual milk samples several years ago and the results from both assays were similar;

- for the 49 antimicrobials listed in the NCCP as being tested for using this method and for which levels of reporting have been specified in the NCCP, the plan states that for 27 of these, the method is not validated. For several of these substances selected at random by the audit team, it was not possible to verify that the laboratory could actually detect the substances in question at the quoted limits (e.g. bacitracin, colistin, enrofloxacin, marbofloxacin). Furthermore, some of the data on the validation file which had been generated in a Belgian study suggested that these substances could not be detected at all with the test in question;
- for some substances for which the method is specified as being validated, it is either not sufficiently sensitive to meet the EU MRL (e.g. for all of the tetracyclines, though these are also tested by a more sensitive ELISA test), or the validation file contained conflicting information from the different studies quoted (e.g. neomycin, tylosin, streptomycin, spectinomycin);
- in relation to the applicability of this test for the few samples of milk from other species which are, or have been included in the NCCP, there was no documentary evidence available to demonstrate that the method could be applied to the other species;
- the laboratory had performed 40 separate proficiency tests from 2010 to date (36 for antimicrobials – 31 for Penicillin G – in ultra-high temperature treated milk and four for aflatoxin M1 in milk powder). All of the results for aflatoxin M1 were satisfactory. With one exception (a transcription error) the performance in the Penicillin G tests was satisfactory. For the five rounds of a collaborative trial (three cephalosporins, one beta-lactam and one oxytetracycline), the results were all satisfactory with the exception of the oxytetracycline trial. The compound was not detected at either half of or at the EU MRL. The proficiency test provider had erroneously marked this performance as 'good' even though none of the laboratories participating in the trial were able to detect the analyte;
- in addition to the growth inhibition test mentioned, NCCP samples are also analysed for tetracyclines using a commercially available ELISA which, according to the manufacturer's data sheet, will detect oxytetracycline, chlortetracycline and tetracycline at or below the EU MRL of 100 µg/kg. The test is run as per the manufacturer's instructions with a positive control sample of oxytetracycline at 10 µg/kg. There was no validation file demonstrating the performance of the kit in this laboratory or evidence that it would detect the other tetracyclines as stated;
- for aflatoxin M1 analysis, two separate kits are used, one of which has been approved by MPI. The newer kit had been run once in 2010 back-to-back with the original kit, but apart from that there were no validation data available;
- in relation to internal audit activities, there is an annual schedule of six per year. Corrective action requests had been raised in three audit reports selected at random by the audit team. These had all been dealt with though the time frame for so doing (~100 days) exceeded the time frame listed in the quality manual (~30 days);
- sample traceability and identification could be ensured and, as for the NCRP, the ownership of the samples was anonymised;
- all of the ELISA kits and other assays pertinent for the NCCP were adequately stored and were in date. Some analytical standards were out of date, though, these are not used in the day to day running of any of the assays.

Conclusions on laboratories

The fact that both laboratories are accredited to ISO 17025 and that the vast majority of methods are included in their respective scopes of accreditation should, in theory, give the competent authority confidence in the reliability of the results. The performance of the laboratory testing all of the NCRP samples is consistent with what would be expected from an accredited laboratory. Notwithstanding its satisfactory performance in proficiency tests for beta-lactams and aflatoxins in milk, the - to a large degree - absence of validation data and a protocol for verifying the consistent performance of the screening tests used in the laboratory screening samples under the NCCP, means that the competent authority cannot guarantee that the detection limits reported by this laboratory and quoted in the NCCP for many antimicrobial substances, can be met, potentially undermining the effectiveness of this programme.

5.3 Veterinary medicinal products and medicated feedingstuffs

5.3.1 Authorisation, distribution and use of veterinary medicinal products

Legal Requirements

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

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

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

The relevant provisions in EU law governing the marketing authorisation of veterinary medicinal products are laid down in Articles 5-15, 21-30, 58-62 and 83 of Directive 2001/82/EC and for certain products authorised on an EU-wide basis, in Articles 30-40 of Regulation (EC) No 726/2004. Provisions governing the distribution and use of veterinary medicinal products are laid down in Articles 65-71 of Directive 2001/82/EC. Veterinary medicinal products which are authorised for use in food producing animals may only contain pharmacologically active substances which are listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010. Article 67(aa) of Directive 2001/82/EC requires that veterinary medicinal products for food producing animals are only dispensed to the public under a veterinary prescription unless exempted under the conditions laid down in Article 2 of Commission Directive 2006/130/EC.

In respect of medicated premixes conditions governing their 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

Legislation:

The *Agricultural Compounds and Veterinary Medicines Act 1997* and its Regulations (*ACVM (Exemption and Prohibited Substances) Regulations 2011*) form the legal framework for issuing marketing authorisations for veterinary medicinal products for use in food producing animals. The competent authority responsible is the MPI.

Classification of medicines:

The classification of veterinary medicinal products is described in the *ACVM Operational Interpretation 182 of October 2009* and products are grouped into either 'restricted veterinary medicines (RVM) or unrestricted veterinary medicines (over the counter). The registration requirements for veterinary medicines and the entire register of veterinary medicinal products is publicly available on the MPI website.

RVMs may only be sold by sellers operating under an MPI-approved operating plan, with the exception of practising veterinarians supplying RVMs only for their clients (under a so-called 'veterinary authorisation'), who do not need to have such an operating plan in place. The MPI has published guidance on the standards and procedures it expects RVM sellers to adhere to and the operating plan template which has to be completed by RVM sellers prior to MPI approval and public listing.

Veterinary medicinal products (or rather pharmacologically active substances) expressly prohibited from use in food producing animals in New Zealand are specified in Schedule 1 of the *ACVM (Exemption and Prohibited Substances) Regulations 2011*. In contrast to the EU where substances such as stilbenes and thyrostats are specifically prohibited, such substances are not listed in Schedule 1 of the Regulations, however, stilbenes and thyrostats are not authorised for use in food producing animals in New Zealand. Additionally, oestradiol 17-beta is prohibited for use in food producing animals under the *Animal Products (Control of Specified Substances) Notice 2007*. This is in line with the provisions of Council Directive 96/22/EC.

Withdrawal periods and MRLs:

The MPI has elaborated an ACVM registration standard and guideline for determination of a residue withholding period for veterinary medicines. In the event that no residue depletion data have been provided by the applicant, default withholding periods (published on the MPI website) are applied to those formulations (with the exception of sustained release formulations) and range from 10 days (eggs) to 91 days (ruminant meat).

No authorisation of a veterinary medicinal product is granted until an MRL has been established (if applicable). However, it should be noted that under the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Food Standards 2012* there is a default MRL of 0.1 mg/kg. In establishing a default withholding period a risk assessment is undertaken to ensure residues in animal commodities complies with the default MRL.

In order to meet market access requirements, a parallel list of substances and MPLs are laid down in the *Animal Products (Contaminant Specifications) Notice 2008*. Some MPLs are lower than the established or default MRL and, according to the competent authority, these MPLs may be the limiting residue when setting a withholding period for products registered for food producing animals in New Zealand. For contaminants listed in the *Animal Products (Contaminant Specifications) Notice 2008* but for which an animal product or animal material is not listed, the

default MPL is 0.01 mg/kg if the substance against which the contaminant is measured is the named active ingredient in a trade name product registered as an agricultural compound under the *Agricultural Compounds and Veterinary Medicines Act 1997*. For contaminants not listed in the *Animal Products (Contaminant Specifications) Notice 2008*, the default MPL is 0.001 mg/kg for animal material and animal products (unless the contaminant is one in which no MPL is required).

HGPs:

Specific controls and data recording requirements are in place over the supply and administration of HGPs – of which there is one preparation currently on the market - to cattle. These are laid down in the *Animal Products (Regulated Control Scheme - Hormonal Growth Promotants) Notice 2012*. HGPs are classified as RVMs and may only be implanted by a veterinarian or an adequately trained technician under his direct employ. In addition to their national animal identification and traceability radio frequency identification device tag, implanted cattle are tagged with an orange 'hormone' tag (supplied with the product by the manufacturer). Implanted cattle are entered by the veterinarian responsible into the HGP database. Only practising veterinarians registered as such by the Veterinary Council of New Zealand and who have been issued with a username and password to access the HGP database, are permitted to enter data.

Medicinal treatment records:

Farmers of bovine, ovine, caprine, cervine, equine and aquaculture animals and bees are not required by law to have a risk management programme in place and are therefore not legally obliged to maintain medicine treatment records. If cattle have received HGPs, farmers are required to keep records of this administration in accordance with the *Animal Products (Regulatory Control Scheme – Hormonal Growth Promotants) Notice 2012*.

Dairy farmers are required to keep medicines records under their dairy processor's risk management programme. *NZCP1: Code of Practice for the Design and Operation of Farm Dairies* requires that veterinary medicines are used according to label instructions.

For honey, secondary processors (i.e. at the extraction phase) have to have a risk management programme. Bee keepers supplying honey for export are required to complete the *Apiarist and Bee keeper Statement for the Harvest of Honey and Other Bee Products for Human Consumption* form which includes a declaration that only veterinary medicines or agricultural compounds permitted for use in beehives or beekeeping equipment have been used, and they have been used in accordance with any label or approval conditions.

Section 1 of the Animal Status Declaration (ASD) provided for by the *Animal Products Act 1999* requires farmers to make a declaration on the medicinal treatments received for the animal or animals (mob) referred to on the form when it/they are being moved from the farm to another farm or to slaughter. Slaughterhouse operators are obliged to verify the accuracy of the information (on medicines) included in the ASD.

The audit team noted that:

- in common with the situation in the EU, no antimicrobials are authorised for use in bee keeping;
- in the honey packer visited, the contract with its suppliers required them to declare *inter alia* that, the honey would satisfy the EU OMAR and that the honey shall contain no antibiotics;
- the range of authorised veterinary medicinal products is broadly similar to that in the EU with the exception of HGPs (which are authorised with a 'split system in place for EU production). The beta-agonist ractopamine is also authorised as a growth promoter for swine. (Pig meat is not exported to the EU);

- in the case of equidae (see 5.3.3.) several anabolic injectable preparations, containing *inter alia*, esters of stanozolol, methandriol and 19-nortestosterone, are on the market, albeit for use in *equidae* not intended for food production. They are only available on veterinary prescription (RVMs). By way of comparison, there are no such products authorised for equidae in the EU in line with the provisions of Council Directive 96/22/EC;
- with few exceptions, antimicrobials for use in food producing animals are only available on veterinary prescription and are classified as restricted veterinary medicines. The exceptions pertain to in-feed antimicrobials such as flavomycin (no longer authorised in the EU) and the polyether ionophore antibiotics which are classified (as in the EU) as coccidiostats;
- in the wholesaler and in the veterinary practice visited, the medicines observed by the audit team complied with legislative requirements;
- on each of the four farms visited, veterinary authorisations' were available for the RVMs prescribed and in storage. These were valid for one year and listed the conditions and medicines (and amounts) which could be supplied to the farm. Records of the veterinary authorisations were also held in the veterinary practice;
- all farms maintained medicines records – both dairy farms used a template for record keeping supplied by the dairy (risk management programme operator). On the beef feedlot (which kept the records electronically) and the sheep farm, it was possible to reconcile the medicines records with the ASDs for animals moved to slaughter. No animals had gone for slaughter within any drug withdrawal periods. On one of the dairy farms, the records were incomplete as some treatments had not been recorded (e.g. with temephos) and there were missing data for March 2011 (treatments had been applied but the medicine was not specified in the records). These points had not been remarked on in the TPIA's verification report of this farm on 5 April 2012. There was a remark that 'treatment records were good'. It was also recorded though that some out of date medicines were observed by the verifier and were dealt with satisfactorily on the day of the verification audit (see 5.3.2.);
- the veterinary practice visited (which supplied medicines to other practising veterinarians) had an up-to-date MPI certificate of compliance as a seller of RVMs, valid for three years;
- in both the veterinary practice and the wholesaler visited, a random check of the customer invoices confirmed that only practicing veterinarians registered as such by the Veterinary Council of New Zealand had been sold RVMs by both premises;
- in relation to the administration of HGPs, in the veterinary practice visited, HGPs had been administered to their clients by a trained technician in its employ. The technician's training record was available. He was trained for the purpose and had been checked annually and endorsed every 12 months by the supervising veterinarian as required by national legislation. It could be verified that HGP-treated cattle for which paper records had been retained in the veterinary practice, had been entered into the HGP database as required;
- the MPI Verification Services Systems Audit Team had also audited controls on HGPs in 2011 and the veterinary practice visited had been included in that exercise. No non-compliances were detected in this audit (which concurred with the findings during the current FVO audit).

Conclusions on authorisation, distribution and use of veterinary medicinal products

In spite of the fact that the maintenance of medicines records is not mandatory across all species/commodities (as in the EU), on the basis of the evidence presented and standard of record keeping observed on-the-spot, the systems in place governing the authorisation, distribution and use

of veterinary medicinal products give assurances equivalent to those required in EU legislation.

5.3.2 Controls on the distribution and use of veterinary medicinal products

Legal Requirements

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

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

Findings

Checking of treatment records on farms (excluding dairy and apiaries) is carried out as part of the MPI Verification Services on-farm verification programme pursuant to the *Animal Products (Regulated Control Scheme—On-Farm and Stock Saleyard Verification) Notice 2009*. MPI supervising veterinarians in slaughterhouses carry out these checks. In the context of verifying the accuracy of information contained on the ASDs, internal MPI guidelines from 11 September 2012 specify that follow-up action is required for *inter alia*, absence of an invoice or other information for treatments administered by the farmer's veterinarian, absence of details of medicines purchased from the veterinarian and absence of records for control of withdrawal periods. The total absence of any medicines records is seen as unacceptable and such cases would be referred to the MPI Systems Audit Team. According to the competent authority, this policy has been in place since the new round of on-farm verifications began in July 2012. A total of 900 such on-farm verifications are scheduled for the 2012-2013 period – this is an increase of 300 over previous years and these were added to cover geographically remote areas (far from slaughterhouses) not previously included in the programme. This action was taken in response to recommendation no 4 made in the 2011 FVO meat audit report.

Checks on apiaries (producing honey for export to the EU) are carried out as part of the verification process referred to in the *Animal Products (Regulated Control Scheme — Verification of Contaminants in Bee Products for Export) Notice 2010*. Verification is carried out by personnel of an MPI Recognised Agency (as defined in section 60A of the *Animal Products Act 1999*), in this case, the TPIA.

Every dairy farm is subject to a farm dairy assessment at least once per year by an independent farm dairy assessor recognised under the risk management programme. The assessment must meet the standard defined in *NZCP2: Assessment of Farm Dairies*, and as outlined in the dairy company's

risk management programme to confirm that the farm dairy meets the requirements of *NZCP1: Code of Practice for the Design and Operation of Farm Dairies.*

Currently in New Zealand, the assessment function is carried out by either the TPIA or by another independent third party. Farm dairy assessments are required under that part of the risk management programme covering activities at the farm (part 7 of *DPC2: Animal Products (Dairy) Approved Criteria for Farm Dairies*). Medicines records are one of the elements included in the annual farm dairy assessment.

Additionally, every (dairy) risk management programme is subject to verification by an MPI Recognised Agency. As for honey, the TPIA fulfils this role. When verifying a dairy processor's risk management programme, in addition to verification at the headquarters of the dairy processor, a selection of farms and farm dairy assessors will be included as part of exercise. The findings of the verification exercise are provided to the MPI.

According to the competent authority, the MPI Systems Audit Team (and its predecessor the Compliance and Enforcement Group) conducted in 2006 a number of allocated audits and special audits on the distribution and use of veterinary medicinal products at each of the relevant points in the distribution chain of veterinary medicines (e.g. wholesalers, retailers (pharmacies, veterinarians, farmers' co-operatives etc, feed mills producing medicated feeding stuffs and farms).

The audit team noted that:

- records of MPI on-farm verifications were held centrally in the VA Online database. In several examples selected at random by the audit team it was seen that ASDs were checked and elements such as residues, withdrawal periods and medicines records were included in each report. In cases where shortcomings were observed in the maintenance of treatment records, recommendations to the farmer were made. In the case of the sheep farm visited, the findings of the on-farm verification report from March 2012 concurred with the on-the-spot findings of the audit team;
- in both regional MPI offices visited, the programme for delivery of on-farm verifications was on schedule. Of the 219 verifications carried out in the South Island since July 2012, the results were acceptable in 91% of cases (200);
- several examples of verifications (by the TPIA) of dairy risk management programmes were sought and provided to the audit team. These had been submitted to the MPI as required and medicines record keeping and the use of veterinary medicines were covered in the reports, though, in the first dairy farm visited by the audit team, the verification report did not mention some shortcomings identified by the audit team, pre-dating the verification (see 5.3.1.);
- in the second dairy farm visited, another organisation (other than the TPIA) carried out the farm dairy assessments. In the annual assessments carried out in March 2011 and July 2012, no issues were identified with regard to medicines storage or records, which accorded with the findings of the audit team on the spot;
- a summary report on 'Prescription Animal Remedy (obsolete term for RVMs) Traders (veterinarians) from March 2007 was available. The audit had been carried out in 2006 and covered twelve randomly selected veterinary practices. Among the recommendations made in the report, one focussed on the training provided by veterinarians to clients who buy, hold and use RVMs and on farm verification to ensure that the dispensing and use legislative requirements are met.

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

Notwithstanding some issues identified on-the-spot with the maintenance of medicines records and, in one case, the fact that these were not remarked on in the report of the on-farm verification, in general, the controls on the distribution and use give guarantees broadly equivalent to those required by EU legislation (Council Directive 2001/82/EC), a conclusion supported by the very low incidence of non-compliant findings of residues of authorised veterinary medicines in food.

5.3.3 Identification of equidae and medicines records requirements

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.

Equidae which are eligible for human consumption, when treated with pharmacologically active substances listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010, must have this treatment recorded in a medicines record kept on the farm as required by Article 10 of Council Directive 96/23/EC.

There is also more specific EU legislation governing the administration of veterinary products to such animals. Commission Regulation (EC) No 1950/2006 lists certain pharmacologically active substances which are deemed to be essential for the treatment of *equidae* and even though they are not listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 these substances may also be used to treat *equidae* intended for human consumption. Such treatment must also be recorded in Part 3 of Section IX of the equine passport and a period of six months from the date of last treatment to time of slaughter must be observed. The format of the passport (identification document) is laid down in Commission Regulation (EC) No 504/2008 which requires that all *equidae* must be accompanied by an identification document.

If *equidae* are treated with a substance which is neither listed in Table 1 of the Annex to Commission Regulation (EU) No 37/2010 nor defined as an essential substance by Commission Regulation (EC) No 1950/2006, such a treatment permanently excludes the animal from the food chain. Exclusion from the food chain must be declared by the horse owner under Part 2 of Section IX of the equine passport.

Findings

There is only one slaughterhouse slaughtering horses in New Zealand. It currently processes approximately 1700 per year and the majority (~95%) of these animals come from five suppliers each of which applies his own unique numbered and coloured collar to each horse prior to transport to slaughter.

The control system put in place to give effect to EU requirements on horsemeat has been described in section 5.3. of the 2011 FVO meat audit report DG SANCO 2011-6135 MR Final. That report found that whilst the system of official controls allows (possibly treated) horses to be traced back during the previous 180 days prior to their slaughter, there were no procedures in place to verify the correctness of the information provided on the supplementary ASD which is submitted to the slaughterhouse by the supplier. The purpose of this supplementary ASD introduced in 2007 is to

record the mandatory 6 month withholding period for treatment with specified substances. It also contains a list of substances (e.g. anabolic steroids, phenylbutazone etc) which the supplier certifies as never having been administered to the horse in the six months prior to slaughter.

The audit team noted that:

- in the establishment, horses have been excluded for slaughter for the EU market because of discrepancies in animal identification and ASDs, the last such case being in May 2012;
- the establishment audits each supplier regularly – four desk top audits and one visit per annum. The aim of these audits is to verify that the information contained on the supplementary ASD is accurate – this information is supplied to the supplier by the original owner (in the form of a signed statement) and forms the basis of the supplementary ASD which the supplier signs and which accompanies the animal to the slaughterhouse. The procedure is described in the slaughterhouse operating profile;
- records of the establishment's own audits showed that for four of the suppliers, the traceability from supplementary ASDs to the group ASD accompanying the batch of horses to slaughter and to the original signed statements, were generally acceptable. In one case this had not happened and the establishment had imposed further documentary requirements on that supplier before accepting horses from him. The problem had been rectified;
- reports of supplier audits carried out by MPI Verification Services were available. The audit team selected the records for two suppliers. In one dated 5 June 2012, horses purchased by the supplier had been treated by the previous owner with a parasiticide and the supplier had (correctly) identified and marked them as non-EU eligible. However, one shortcoming related to trace back as some original owner declarations could not be located. The result of the audit was 'acceptable with follow-up' and a follow-up visit had been made to this supplier on 22 August 2012 with a satisfactory outcome. In the second case dated 21 August 2012, the result was 'acceptable with no follow-up required';
- according to the competent authority a new initiative for the 2012-2013 on-farm verification cycle is to go one step back to the original owner selling the horse to the supplier. Such audits have not taken place yet;
- one of the injectable anabolic steroids authorised for *equidae* (methandriol in combination with 19-nortestosterone), is not currently included in the panel of 23 anabolic steroids and their metabolites currently tested for in the NCRP (see 5.1.2.). According to the slaughterhouse operator, the percentage of ex-race horses and trotters slaughtered is high. In the opinion of the audit team this is the type of animal which would most likely have been treated with the anabolics in question, as per label indications, to aid recovery after injury;
- according to the competent authority 50 horses (~2.7% of slaughtered horses) are tested for anabolic agents annually. Whilst it is the case that methandriol is not included in the range of substances, the other authorised anabolic agents are (19-nortestosterone and stanozolol) and there have been no detections.

Conclusions on requirements for the identification of *equidae* and maintenance of medicines records

Despite differences in the requirements regarding the identification of horses between New Zealand and the EU and the absence of analytical testing for one of the anabolic steroids currently on the market, all of the components of the scheme put in place by the industry together with the MPI on-farm verification programme, provide assurances on the residues status of horse meat intended for export to the EU.

5.4 Follow-up of relevant recommendations made in previous FVO report on residues (DG SANCO 2006-8020 MR Final)

N	Recommendation	Findings
1	To amend the NRCP (with regard to inclusion of relevant substance groups and compulsory sample figures) for farmed and wild game, aquaculture products and honey in order to ensure that it will offer guarantees on the residue status of exported food commodities which are at least equivalent to the standards set out in Community legislation (Article 29 of Council Directive 96/23/EC).	See 5.1.2. Both the NCRP and NCCP provide guarantees which are largely equivalent to those foreseen by Council Directive 96/23/EC, though there are some substances which, for the Yes (3) commodities, are required to be included in the NCRP. See Recommendation nos 1, 2 and 3 of the current report.
2	To establish an official residue control programme for honey in accordance with Council Directive 96/23/EC.	Achieved. See 5.1.2: *Animal Products (Regulated Control Scheme – Verification of Contaminants in Bee Products for Export) Notice 2010*.
3	To ensure a timely residue analysis for all commodities, in particular for honey, in order to enable a timely and effective follow-up of non-compliant results	Achieved. See sections 5.1.3. and 5.1.5. In comparison to the 2006 FVO audit, the majority of samples are now analysed in a timely fashion and follow-up takes place promptly.
4	To strengthen the follow-up procedures of non-compliant NRCP results.	Achieved. See section 5.1.5. (follow-up). There is now a central register of all follow-up activities for the NCRP, which was not the case in 2006 and follow-up procedures have been developed.
5	To ensure an official follow-up of non-compliant milk results in the framework of the national milk residues programme in line with the provisions of Article 54 of Regulation (EC)	It is still the case that the risk management programme operator has primary responsibility for investigating non-compliant results found in the NCCP. Article 16 (2) of Council Directive 96/23/EC requires the 'appropriate' authority to carry out an investigation on the farm of origin. The New Zealand system is compatible with the objectives of the aforesaid Article and there is no evidence that the effectiveness of follow-up has been affected by

	No 882/2004.	the arrangements in place.
6	With regard to the residues laboratories, to ensure that all relevant procedures and data are available for the analytical methods listed in the NRCP.	See section 5.2.1. Improvements have been made in the performance of Laboratory A, though the lack of validation data in Laboratory B remains an issue and potentially undermines the effectiveness of the NCCP. See Recommendation no 4 of the current report
7	To ensure that residues of VMPs banned (Council Directive 96/22/EC) or not authorised (Council Regulation (EEC) No 2377/90) in the EU are not present in exported commodities, in accordance with EU import requirements.	On the basis of (a) the expanded testing carried out under the NCRP relative to 2006 and (b) the very low rate of non-compliant results reported annually in both the NCRP and NCCP, this objective would appear to have been largely met. One issue however remains the lack of testing in the NCRP of equine tissues for residues of the anabolic steroid methandriol. See Recommendation no 2 of the current report.
8	To ensure that horse meat exported to the EU provides guarantees equivalent to those laid down by Article 11 of Council Directive 96/22/EC.	See 5.3.3. Achieved though the methandriol issue remains. See Recommendation no 2 of the current report.
9	To ensure that commodities exported to the EU do not contain residue concentrations exceeding Community MRLs (Council Regulation (EEC) No. 2377/90), MLs (Council Directive 86/363/EEC), and MRPLs (Commission Decision 2002/657/EC).	See response to old Recommendation no 7 above.
10	To strengthen the official control system on the use of VMPs at all levels of distribution and use in order to offer guarantees which are at least equivalent to those provided for in Article 11	See 5.3.1. and 5.3.2. Although there is no legal obligation for farms to keep medicines records, there was no evidence that such records are not being kept and this is backed up by an expanded programme of on-farm verifications by the MPI and an emphasis on verifying the veracity of the information on treatments contained on the ASD.

	and 12 of Council Directive 96/23/EC.	
11	To ensure that with regard to the treatment of food producing animals, there will be sufficient farm medicines records in place to offer guarantees which are at least equivalent to those provided for in Article 10 of Council Directive 96/23/EC and Article 69 of Directive 2001/82/EC.	See response to old Recommendation no 10 above.

6 Overall Conclusions

In terms of the number of samples taken and the range of substances covered in the commodities for which New Zealand is currently listed in the Annex to Commission Decision 2011/163/EU, both the NCRP and NCCP provide guarantees which, with the exception of an absence of monitoring for one substance group in aquaculture fish, are largely equivalent to those foreseen by Council Directive 96/23/EC. The implementation of both of the plans and supervision of implementation is effective, being underpinned by a comprehensive staff training programme and verification system. Additional residue testing programmes in place underpin guarantees on the residues status of food exported to the EU and the prompt and thorough follow-up investigations of non-compliant results and verifiable actions taken on foot thereof, underpin the effectiveness of the residue control system.

With regard to the laboratory network, the fact that both laboratories are accredited to ISO 17025 and that the vast majority of methods are included in their respective scopes of accreditation should in theory give the competent authority confidence in the reliability of the results. In the case of the laboratory testing all of the NCRP samples, its performance is consistent with what would be expected from an accredited laboratory. However, notwithstanding its satisfactory performance in proficiency tests for beta-lactams and aflatoxins in milk, the - to a large degree - absence of validation data and a protocol for verifying the consistent performance of the screening tests used in the laboratory screening samples under the NCCP, means that the competent authority cannot guarantee that the detection limits reported by this laboratory and quoted in the NCCP for many antimicrobial substances, can be met, potentially undermining the effectiveness of this programme.

With regard to veterinary medicinal products, whilst the maintenance of medicines records is not mandatory across all species/commodities (as in the EU), on the basis of the evidence presented and standard of record keeping observed on-the-spot, the systems in place governing the authorisation, distribution and use of veterinary medicinal products give assurances equivalent to those required in EU legislation. Notwithstanding some issues identified on-the-spot with the maintenance of medicines records and on-farm verification of same, in general, the controls on the distribution and use give guarantees broadly equivalent to those described in Council Directive 2001/82/EC, a conclusion supported by the very low incidence of non-compliant findings of residues of authorised

veterinary medicines in food. In relation to *equidae*, despite differences in the requirements regarding the identification of horses between New Zealand and the EU and the absence of analytical testing for one of the anabolic steroids currently on the market, all of the components of the scheme put in place by the industry together with the competent authority's on-farm verification programme, provide assurances on the residues status of horse meat intended for export to the EU.

7 Closing Meeting

A closing meeting was held on 20 September 2012 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement with the findings of the report.

8 Recommendations

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

N°.	Recommendation
1.	To include testing for Groups B2a and B3c in the NCRP for farmed salmon in line with the provisions of Annex II to Council Directive 96/23/EC.
2.	To include testing for the anabolic steroid methandriol in equine urine in line with the provisions of Article 11(1)(c) of Council Directive 96/23/EC.
3.	To review the list of analytes (particularly antibiotics) in the NCCP and ensure that only those for which it can be verified that the screening method is fit for purpose, are included in the NCCP, as per the requirements of the fifth indent of Article 7 of Council Directive 96/23/EC.
4.	To ensure that all analytical methods used for either the NCRP or NCCP are validated to a standard equivalent to that required by Commission Decision 2002/657/EC.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2012-6533

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Veterinary Agreement		
Dec. 97/132/EC	OJ L 57, 26.2.1997, p. 4	97/132/EC: Council Decision of 17 December 1996 on the conclusion of the Agreement between the European Community and New Zealand on sanitary measures applicable to trade in live animals and animal products
Audits by the Commission Services		
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Food Law		
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Monitoring and sampling of residues in food of animal origin		

Legal Reference	Official Journal	Title
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dec. 97/747/EC	OJ L 303, 6.11.1997, p. 12-15	97/747/EC: Commission Decision of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
Approval of residue monitoring plans submitted by third countries		
Dec. 2011/163/EU	OJ L 70, 17.3.2011, p. 40-46	2011/163/EU: Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC
Validation of analytical methods for residues and Minimum Required Performance Limits		
Dec. 2002/657/EC	OJ L 221, 17.8.2002, p. 8-36	2002/657/EC: Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
Bans on the use of hormones and beta-agonists for growth promotion in food producing animals		
Dir. 96/22/EC	OJ L 125, 23.5.1996, p. 3-9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of ß-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Maximum Residue Limits for veterinary medicinal products in food of animal origin		

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

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

Legal Reference	Official Journal	Title
Reg. 252/2012	OJ L 84, 23.3.2012, p. 1-22	Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006
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
Horse identification (passport)		
Reg. 504/2008	OJ L 149, 7.6.2008, p. 3-32	Commission Regulation (EC) No 504/2008 of 6 June 2008 implementing Council Directives 90/426/EEC and 90/427/EEC as regards methods for the identification of equidae
Medicines essential for the treatment of equidae		
Reg. 1950/2006	OJ L 367, 22.12.2006, p. 33-45	Commission Regulation (EC) No 1950/2006 of 13 December 2006 establishing, in accordance with Directive 2001/82/EC of the European Parliament and of the Council on the Community code relating to veterinary medicinal products, a list of substances essential for the treatment of equidae