ANNEXURE E

ANNEXURE E

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Acting Deputy Director-General

SANCO

17. 07. 2007

Brussels,
F5/JMcE/dht D (2007) 651020

SUBJECT: **WITHDRAWAL OF APPROVAL FOR SOUTH AFRICA'S RESIDUE CONTROL PLAN FOR LIVE ANIMALS AND ANIMAL PRODUCTS FOR 2007:**

Your Excellency,

South Africa is currently included in the list of those third countries with approved residue monitoring plans for live animals and animal products which are specified in the Annex to Commission Decision 2004/432/EC (as last amended by Commission Decision 2007/362/EC). The commodities listed are bovine, ovine/caprine, swine, poultry, milk, wild game, farmed game and honey products.

I wrote to you on 28 March 2007 (ref. JMcE/dht D (2007) 650446), concerning the potential delisting of South Africa from the above list as certain information had not been submitted to the Commission services despite repeated requests.

This information has now been received by the Commission's Food and Veterinary Office (FVO) which is responsible for the technical evaluation of all third country residues control plans. In addition, the FVO has recently completed an inspection mission on residues controls in South Africa – Mission DG SANCO 2007-7585. The report of this mission is currently being prepared and will be issued to the South African competent authorities in due course.

I regret to inform you that the FVO mission team found many substantial deficiencies in the implementation of residues controls in South Africa. These have been communicated to the competent authorities during the course of the mission and will be described in detail in the forthcoming report.

However, in advance of the report I would wish to draw your attention to the fact that no official residues testing was performed in either 2006 or 2007 to date. Furthermore the results from 2005 have not yet been finalised. This means that successive residues plans submitted to the Commissions services had not actually been implemented.

H.E.M. Anil Sooklal
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DEPARTMENT OF AGRICULTURE

RECEIVED BY: SecSMAH
2007 -07- 23
DATE.....

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Given this unacceptable state of affairs, it is concluded that the current residues plan and guarantees offered can not be considered equivalent to those provided for by Community legislation. Consequently, I have no option but to recommend the delisting of South Africa for all of the commodities listed in the Annex to Commission Decision 2004/432/EC when this Decision is next amended. Future re-listing could be considered provided that the Commission has received substantiated guarantees that the deficiencies have been addressed satisfactorily.

I have the honour to be, Sir,

Yours faithfully,

Paola TESTORI COGGI
Acting Deputy Director-General

CC: Mr Lodewijk A.E. Briët, Head of Delegation of the EC to South Africa
Mr Paul van Geldorp, Head of Unit, SANCO D4
Mr Michael Scannell, Head of Unit, SANCO D3
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15/10/5-8

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL

Director General

SANCO

22. 01. 2008

DEPARTEMENT VAN LANDBOU
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2008 -01- 25
DIRECTORATE: VETERINARY SERVICES
DEPARTMENT OF AGRICULTURE

Brussels,
SANCO D4/DV/ga D(2008) 440018

Dear Dr Mogajane,

Subject: Residue Monitoring Plan, South Africa

Following the residue mission carried out by the Commission's Food and Veterinary Office (FVO), based in Grange, Ireland, DG SANCO's initial intention was to de-list South Africa for all product groups from the residue third country list.

During a meeting in September 2007 between representatives of the South African Ministry of Agriculture and DG SANCO the continued listing of South African wild and farmed game was agreed, conditional to the reception of certain deliverables. At another meeting on 19 November 2007 DG SANCO stressed the need for the competent authority to submit quarterly reports of analytical results for the 2007/2008 plan to the FVO in order to provide evidence of the implementation of the current plan. These reports should also contain the results of serum samples in ostriches. The South African delegation agreed.

Despite a reminder sent by mail on 11 December 2007 such reports have not yet been received, which means that the plan for 2007/2008 has not yet been implemented and put into practice. Therefore I must urge you to transmit all of the results for the first two quarters by the end of January at the latest and to regularly provide updates for the following quarters. The FVO will have to evaluate these results in order to assess whether the controls can be considered equivalent to those required by EC legislation.

If the quarterly results are not transmitted by the specified date or if the evaluation should result in a negative outcome the Commission will have no choice but to de-list South Africa also for farmed and wild game at the next available opportunity.

In addition, the FVO has now finished its evaluation of the latest results your services transmitted in December 2007.

These results suggest that there is contradicting information. According to the table we received on 31 October 2007, 605 samples were listed as tested (retrospective survey of serum samples in ostriches) for all listed substances. Notwithstanding the indication that

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some samples were pooled, it led the FVO to the overall conclusion that this deliverable had generally been complied with.

The most recent results however, transmitted in December 2007, contained a new table for "farmed game ostrich retrospective survey" which lists 635 samples as planned, but no samples analysed and Dr Maja confirms in her cover letter that no results are yet available.

This contradiction is highly disturbing and means, if confirmed that the deliverable concerning the retrospective survey of serum samples in ostriches has not been complied with.

If your services confirm that the retrospective survey of serum samples has not been initiated yet and will not finalised by the end of January the same will apply as in the case of the non-reception of quarterly results, i.e. the de-listing of South Africa for all product groups at the next available opportunity.

You also may wish to be informed that another Commission audit of South Africa's residue monitoring programme will be carried out, if possible, during the course of the first semester of 2008.

Yours sincerely,

Robert Madelin

Cc: Messrs P. Tod, P. Brunet, CAB
Messrs M. Maya, W. Makabanyane, ZA Mission
Messrs C. Alvares Antolinez, J. McEvoy, Ms L. Englund, DG SANCO
Mr J. Peydro Ayznar, EC Delegation, Pretoria
Messrs L. Briet, D. Chard, EU Delegation ZA
Mr M. Leysen, DG DEV

EUROPEAN COMMISSION
HEALTH & CONSUMER PROTECTION DIRECTORATE-GENERAL
Directorate F - Food and Veterinary Office

DG(SANCO)/2007-7585 MR Final

FINAL REPORT OF A MISSION

CARRIED OUT IN SOUTH AFRICA

FROM 12 TO 21 JUNE 2007

CONCERNING THE EVALUATION OF THE CONTROL OF RESIDUES AND CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS, INCLUDING CONTROLS ON VETERINARY MEDICINAL PRODUCTS

Please note that factual errors in the draft report have been corrected. Clarifications provided by the South African Competent Authorities are given as footnotes, in bold, italic, type, to the relevant part of the report.

23/10/07 - 53440

EXECUTIVE SUMMARY

This report describes the outcome of a mission carried out by the Food and Veterinary Office (FVO) in South Africa, from 12 to 21 June 2007. The mission was part of a series of FVO missions on residue controls in third countries.

The objective of the mission was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, including the controls on the distribution and use of veterinary medicinal products and feed additives, the use of which may give rise to residues in such products. The evaluation was based on the standards set out in Council Directive 96/23/EC, and other relevant Community legislation in this field, including legislation on the control and distribution of veterinary medicinal products. The mission assessed the performance of the competent authorities and other officially authorised entities involved in residues and veterinary medicinal product controls and the legal and administrative measures put in place to give effect to the relevant Community requirements.

It is concluded that although a residue control plan for all EU listed commodities is available and a competent laboratory network is in place, the overall residue control system is dysfunctional as evidenced by an absence of any laboratory testing for several years. Thousands of samples have been taken and never analysed. In the absence of any results, the competent authority can not guarantee that food of animal origin exported to the EU complies with Community residues limits. On the veterinary medicines side a wide variety of growth promotants with hormonal effects (natural and synthetic hormones, beta-agonists, zeranol) are registered as implants and feed additives for cattle, pigs, sheep, and ostriches. These products are freely available and their distribution and use is not controlled. Whilst South Africa currently does not export beef to the EU (due to the delisting of the approved bovine meat establishments), there is no split system in place for this commodity guaranteeing that hormonal growth promotants have never been used in animals, meat from which is eligible for export to the EU. For the other species for which a split system is required – sheep and ostriches - split systems are in place. However they are not comprehensive, their implementation is weak and commitments given after the 2003 and 2005 FVO missions with regard to the control of farms supplying the EU market have not been fulfilled. The net effect is that for sheep and ostriches, the latter being an important export commodity for the EU market, the guarantees given by the competent authority regarding freedom from treatment with hormonal growth promotants can not be relied upon.

Overall, the absence of testing and poor controls on veterinary medicines means that the EU can have no confidence in the residues status of food of animal origin exported from South Africa as the system does not provide guarantees with an effect equivalent to those provided for by Community law.

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

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Act 36	Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947	HPLC	High Performance Liquid Chromatography
Act 54	Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972	ISO	International Standardisation Organisation
Act 101	Medicines and Related Substances Act 101 of 1965	LC/MS-MS	Liquid Chromatography-(Tandem) Mass Spectrometry
AMOZ, AOZ	Marker residues of the nitrofurans furaltadone and furazolidone	LIMS	Laboratory Information Management System
CA	Competent Authority	LOD	Limit of Detection
CCA	Central Competent Authority	LOQ	Limit of Quantification
DG(SANCO)	Health and Consumer Protection Directorate General	MCC	Medicines Control Council, under the Ministry of Health
EC	European Community	MRL	Maximum Residue Limit
EEC	European Economic Community	NRCP	National Residue Control Plan
ELISA	Enzyme-Linked ImmunoSorbent Assay	OVI	Onderstepoort Veterinary Institute
EU	European Union	RASFF	Rapid Alert System for Food and Feed
FVO	Food and Veterinary Office	SANAS	South African National Accreditation System
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC: A1 Stilbenes A2 Thyrostats A3 Steroids A4 Zeranol A5 Beta-agonists A6 Substances listed in Annex IV to Council Regulation (EEC) No 2377/90 B1 Inhibitors (antimicrobials) B2a Anthelmintics B2b Coccidiostats B2c Carbamates and pyrethroids B2d Sedatives B2e NSAIDs B2f Others (e.g. corticosteroids) B3a Organochlorines including PCBs B3b Organophosphorus compounds B3c Chemical elements B3d Mycotoxins B3e Dyes B3f Others	SOP	Standard Operating Procedure
		VMP	Veterinary Medicinal Product
		VPN	Veterinary Procedural Notice

CONVENTIONS USED IN THE REPORT

Bullet points marked thus ➢ indicate findings made by the mission team on the basis of observations on the spot or assessment of information received.

1. INTRODUCTION

The mission took place in South Africa from 12 to 21 June 2007. The mission team comprised two inspectors from the Food and Veterinary Office (FVO). The mission was undertaken as part of the FVO's planned mission programme, evaluating control systems and operational standards in this sector. Representatives from the central competent authority (CCA) accompanied the inspection team during the whole mission. An opening meeting was held on 12 June 2007 with the CCA. At this meeting, the objectives of, and itinerary for, the mission were confirmed by the inspection team and the first discussions with the CCA officials were conducted.

2. OBJECTIVES AND SCOPE OF THE MISSION

The objective of the mission was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, including the controls on the distribution and use of veterinary medicinal products (VMPs) and feed additives, the use of which may give rise to residues in such products. This evaluation was carried out in order to verify if South Africa is able to provide guarantees which have an effect at least equivalent to those provided for in Council Directive 96/23/EC[1] and other relevant Community legislation in this field, including legislation on the control and distribution of VMPs. The mission focused on the role of the competent authorities (CA), legal and administrative measures in place to give effect to the relevant EU requirements with regard to import of food of animal origin into the EU, controls with regard to residues and VMPs, and the performance of residue laboratories. The following sites were visited and meetings were held with:

VISITS			Comments
Competent Authorities	Central	2	Opening and closing meetings with the Department of Agriculture and the Department of Health
	Province	2	State Veterinary Offices in Northern and Western Cape Provinces
	Region	1	Regional Veterinary Office in Randfontein (Gauteng Province)
LABORATORIES			
National reference laboratory		1	Onderstepoort Veterinary Institute (residues laboratory)
Private laboratory		1	One private laboratory analysing NRCP samples
FARMS		4	Two export registered sheep farms, one export registered ostrich farm, one crocodile farm.
OTHER SITES		1	One pharmacy/wholesaler for medicinal products
		1	One EU export approved sheep abattoir
		1	Feed mill producing feed for sheep, cattle, pigs, poultry, horses and wild game

[1] EU legal acts quoted in this report are listed in Annex 1 and refer, where applicable, to the last amended version.

3. LEGAL BASIS FOR THE MISSION

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

- Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;
- Council Directive 96/23/EC 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;
- Commission Decision 98/140/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in third countries.

4. BACKGROUND

4.1. COUNTRY STATUS IN RELATION TO SUBMISSION OF RESIDUES CONTROL PLANS

In Commission Decision 2004/432/EC as last amended by Commission Decision 2007/362/EC, the South African National Residues Control Plan (NRCP) is approved for bovine, ovine/caprine, swine, poultry, milk, wild game, farmed game, and honey.

4.2. SUMMARY OF PREVIOUS MISSION RESULTS

This was the first FVO mission to evaluate the South African control system for residues of veterinary medicines and contaminants in food of animal origin. A number of missions to South Africa have been carried out by the FVO in 2001, 2003 and 2005 in order to evaluate animal health controls and public health control systems for fresh meat, ratite meat and wild game meat (DG(SANCO)/7605/2005, DG(SANCO)/9200/2003 and DG(SANCO)/3247/ 2001). The reports of these missions are available on the □ealth and Consumer Protection Directorate General web site: http://ec.europa.eu/food/fvo/ir_search_en.cfm. These missions partially covered residues-related issues such as the availability and control of veterinary medicines and hormonal growth promotants as well as the registration of farms. The missions identified significant deficiencies in the control of hormonal growth promotants, farm registration and the animal identification system. The 2005 mission concluded that many of the guarantees given by the CCA in response to the 2003 report had not been implemented. Following the outcome of the 2005 mission, South Africa imposed an auto-suspension regarding exports to the EU of fresh bovine meat. Due to the non-implementation of a Non-□ormone Treated Cattle Programme (proposed by the South African CA) the Commission Service de-listed in the second half of 2006 all South African fresh bovine meat and bovine meat product establishments approved for export to the EU.

4.3. RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS FOR CONSIGNMENTS FROM SOUTH AFRICA CONCERNING RESIDUES

From 2005 to date there have been no findings of residues of veterinary medicinal products reported under the RASFF.

4.4. PRODUCTION AND TRADE INFORMATION

Detailed information on the quantities of food commodities (of animal origin) produced in 2006 and the amounts exported to the EU in 2005 and 2006 were supplied by the CCA.

Commodity	National production 2006	Exported to the EU 2005	Exported to the EU 2006
Bovine meat	2,039,692 animals	-	11.7 tonnes
Sheep meat	4,416,208 animals	4.3 tonnes	2.5 tonnes
Pork	2,223,955 animals	-	-
Poultry meat	369,561,616 animals	-	-
Milk (bovine) and milk products	2,611,000 tonnes	nd	16.1 tonnes
Wild game meat	72,736 animals	444.3 tonnes	242.5 tonnes
Ostrich meat	166,805 animals	695.2 tonnes	2145.2 tonnes
Crocodile meat	2,719 animals	3 tonnes	12 tonnes
□oney	1,600 tonnes*	nd	nd

nd = no data available
* estimated

The mission team noted that:

- in 2006, 16 tonnes milk products were exported to one EU member state, however the CA of the province with the only EU approved milk establishment in South Africa informed the mission team that this plant had not exported any milk products to the EU in recent years. No explanation could be provided by the CCA during the mission[2];
- according to these data, in 2006 bovine meat was exported to the EU, in spite of the auto-suspension of exports to the EU.

5. MAIN FINDINGS

5.1. THE NATIONAL RESIDUE CONTROL PLAN AND OTHER RESIDUES CONTROL PROGRAMMES

5.1.1. Planning of the NRCP

The NRCP is drafted by the NRCP national coordinator in the Directorate of Animal □ealth under the Department of Agriculture. The CCA stated that the NRCP is based on the requirements of Council Directive 96/23/EC. The annual NRCP covers the financial year from 1 April to 31 March[3]. The NRCP is fully financed by the Directorate of

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2 *In its response to the draft report the South African Competent Authority stated that it could find no evidence that milk had been exported to the EU in 2006 and added that 16 tonnes of milk from the UK had been transited through South Africa en route to Malawi.*

3 In this report the NRCPs will be referred to by the year when the sampling starts, i.e. the NRCP for 1 April 2007 – 31 March 2008 = 2007 NRCP

Animal □ealth. The national coordinator provides the break down of the NRCP (=sample grids) for the export-approved establishments in each province.

With regard to the planning procedure the mission team noted that:

- the main residues laboratory, Onderstepoort Veterinary Institute (OVI), which was recently appointed as national reference laboratory by the CCA, has a limited input in the drafting of the NRCP;
- there is no information available concerning the usage and sale patterns for VMPs which would allow those most frequently used VMPs to be identified and included within the scope of the NRCP[4];
- the 2007 NRCP was submitted in time to the Commission services for all commodities listed;
- for the 2007 NRCP, the national coordinator sent out several 'sampling grids' to the provinces and regions at the end of May by e-mail while other provinces were reportedly informed verbally;

With regard to the South African 2007 NRCP, in comparison to the requirements of Council Directive 96/23/EC the mission team noted that:

- all substance groups, specified in Annex II to Council Directive 96/23/EC, are included with the exception of A1 (stilbenes) and B2e (NSAIDs) for poultry[5];
- the residue plan for crocodiles was mistakenly listed under "aquaculture products" which is not a listed commodity for South Africa in Commission Decision 2004/432/EC. □owever, the mission team was informed by the CCA that the residue plan for crocodile meat will be presented under the heading "farmed game" for which South Africa is listed. In any case the plan for crocodiles covers all mandatory substance groups for farmed game;
- with regard to wild game, these animals are sometimes treated with VMPs (mainly against parasites). Consequently in addition to contaminants (the only substance group required by Council Directive 96/23/EC) the NRCP for wild game also includes testing for residues of several veterinary medicines though the species to be sampled and tested are not specified[6];
- sample figures are calculated based on the total export figures and not on the national production figures as laid down in Council Directive 96/23/EC. According to the CCA, a "split system" guaranteeing freedom from treatment with hormonal growth promotants and beta-agonists for growth promotion is implemented for sheep, ostriches, crocodiles, wild game and milk, and therefore only animals and animal products for the export have to be sampled. In addition, in the 2007 NRCP it is not possible to distinguish between the number of samples, number of animals sampled

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4 ***In their response to the draft report the South African Competent Authority stated that sales of VMPs in monetary terms are available through the Animal Health Industry Statistics.***

5 ***In their response to the draft report the South African Competent Authority stated that poultry will be excluded from the NRCP.***

6 ***In their response to the draft report the South African Competent Authority stated that the harvest of wild game species varies year by year so it is difficult to specify wild game species in the NRCP. However, it is possible to specify species in the results.***

and number of analyses (according to Council Directive 96/23/EC a minimum number of animals has to be controlled). Therefore it could not be evaluated if the number of samples to be taken is in line with the requirements of the Directive[7];

- on-farm sampling of bovines is included in the 2007 NRCP. No on-farm sampling is planned for the export registered sheep and ostrich farms (see also 5.3.3.3)[8];
- the 2007 NRCP does not reflect the performance of the OVI in that many analytical methods listed in the NRCP are not available in the laboratory (see also 5.2.2). In addition, for the existing methods, several of the limits of detection (LODs) quoted in the NRCP differ from those in the laboratory;
- the scope of testing for steroids (A3) is limited, since the natural hormones which are included in several registered hormonal growth promotants are not tested for[9];
- in the group A5 (beta-agonists), ractopamine, a registered growth promotant for pigs is not included in the NRCP at all;
- poultry and pigs are not tested for residues of roxarsone, an arsenical, which is authorised in South Africa but is not authorised in the EU;
- two (AOZ and AMOZ) of the four stable nitrofuran metabolites are included in the 2007 NRCP;
- for honey the LODs and decision limits for several antibiotics are very high (streptomycin 150 µg/kg, tetracyclines 200 µg/kg, and sulphonamides 100 µg/kg). For these substances there are no Community Maximum Residues Limits (MRLs) in honey therefore the LODs should be as low as possible (preferably 10 – 50 µg/kg)[10];
- a national Regulation under the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 lays down MRLs for residues of veterinary medicines and stock remedies in food stuffs. Many of these national MRLs differ from EU limits. According to the CCA, these national MRLs are not applicable for food intended for the export to the EU. In the 2007 NRCP the EU MRLs according to Council Regulation (EEC) No 2377/90 are specified as action/decision limits but these limits have no national legal basis.

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7 ***In their response to the draft report the South African Competent Authority stated that the sample number in the NRCP will in the future reflect the number of animals sampled.***

8 ***In their response to the draft report the South African Competent Authority stated that on-farm sampling of ostriches will be included in future NRCPs.***

9 ***In their response to the draft report the South African Competent Authority stated that the comments made about the differences concerning limits of detection between the laboratory and the NRCP have been noted as well as the issues of limited testing of natural hormones, and will be addressed.***

10 ***In their response to the draft report the South African Competent Authority stated that ractopamine has been added to the scope. The comments concerning nitrofuran metabolites are noted. The current NRCP has been amended to exclude honey, pigs and poultry, but the comments regarding roxarsone and antibiotic levels in honey are appreciated.***

5.1.2. Implementation of the NRCP

All samples are taken by official staff from the provincial and regional veterinary administrations. All samples are sent to the OVI where they will be analysed or forwarded to subcontracted analytical laboratories.

The mission team noted that:

- instructions ("veterinary procedural notices"=VPNs) are in place detailing *inter alia* sample volumes, transport and storage of NRCP samples. These instructions include most of the relevant requirements for sampling laid down in Council Directive 96/23/EC and Commission Decision 98/179/EC;
- according to the results of the 2004 NRCP most of the number of samples planned to be taken were actually taken and tested;
- the mission team was informed, that for the 2005 NRCP 85% of the results had been sent from the OVI to the national co-ordinator but to date these results had not been assessed (with regard to compliance or non-compliance) or summarised;
- no results are available for the 2006 or 2007 NRCPs to date. Samples were taken during 2006 and continue to be taken for the 2007 NRCP by the provincial and regional authorities. However these samples have been stored (mostly un-registered) in freezers at the OVI waiting for analysis (see also 5.2.2)[11];
- in respect of the 2006 plan, the sum of samples to be taken listed in the sample grids did not correspond with the sample figures in the NRCP. In addition, both substantial under-sampling as well as over-sampling was found in the regions/provinces visited. In order to compensate for under-sampling the OVI stated that they would split samples and analyse the sub-samples to reach the target figures. In the event of too many samples having been submitted for a specific substance group, the laboratory stated that they would select the target number of samples for analysis and discard the rest[12];
- according to the sample documentation in the private laboratory visited, in the sampling year 2005 up to 19 samples had been taken on one day in one abattoir for the analysis of the same substances/substance group. This clustering of samples does not comply with the national VPN, nor is it in line with Council Directive 96/23/EC or Commission Decision 98/179/EC;
- in the sample grids for the 2006 and 2007 NRCPs some provinces were provided with monthly sample figures while all other provinces/regions received annual sample grids. The mission team was informed that these monthly sample grids were in fact typing errors and that the sample numbers given in all grids were total numbers for the sampling year. However, in one province visited this error had led to a huge over-sampling in 2006, which had not triggered any reaction from the OVI or the national coordinator;

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[11] ***In their response to the draft report the South African Competent Authority stated that the availability of results for 2005/6 and 2006/7 has been addressed. As a result the control plan has been reduced to only include the products that are listed for and exported to the EU.***

[12] ***In their response to the draft report the South African Competent Authority stated that over-sampling and under-sampling and potential splitting of samples will be addressed.***

- in one region visited two EU approved abattoirs for ostriches and wild game were not included in the sampling grids for 2006 and 2007 which is in contrast to Council Directive 96/23/EC. In addition, the ovine samples were all collected from an abattoir not approved for export to the EU;
- in one province visited all milk samples were taken on export registered dairy farms;
- urine samples from beef farms are taken by the CCA, together with the province officials. In 2006 all urine samples had been taken from two farms in one province;
- traceability back to the farm of origin is possible for all samples taken, with the exception of honey. The mission team was informed that honey samples had been taken in supermarkets without any traceability to the apiaries. According to the OVI documents no honey samples had been submitted to date under the 2006 or 2007 NRCPs;
- samples are stored frozen at the sampling level before being batched and sent by courier to the OVI. In one province visited samples were stored for two to three months before dispatch. Samples from the 2006 NRCP were still in the freezer waiting for dispatch. In the EU approved sheep abattoir visited, samples were routinely stored for 4 to 6 weeks before dispatch. For those residues which display time and/or temperature-dependent instability, this practice reduces the possibility of detecting residues of these substances in samples stored for long periods[13];
- in the EU approved sheep abattoir visited, animals from all registered export farms had been sampled during 2006. However, sampling took place only from June to the beginning of January and in the end of June 2007 sampling had not started for the 2007 NRCP.

5.1.3. Supervision of implementation of NRCP

The mission team noted that:

- the national coordinator does not supervise the sampling by the provinces/regions during the sampling year (Article 3 of Council Directive 96/23/EC)[14] ;
- in spite of the fact that none of 8000 samples taken under the 2006 and 2007 NRCPs have been tested by the OVI, no corrective actions by the national coordinator or the CCA were initiated;
- the OVI does not have access to the annual sample grids sent out from the national coordinator to the provinces/samplers. Therefore the OVI can not check the fulfilment of the targeted number of samples scheduled for the provinces per sampling year upon receipt of the samples;
- in one province and in one region visited, co-ordinators were assigned for the NRCP sampling. These co-ordinators did not have the power to ensure that sampling was

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13 ***In their response to the draft report the South African Competent Authority stated that the regular dispatch of samples from relevant provincial collection officials will be addressed.***

14 ***In their response to the draft report the South African Competent Authority stated that it is not possible for the national coordinator to supervise sampling in the provinces. The national coordinator will however tighten up the monitoring of the NRCP and ensure that the necessary quantities of samples are collected and analysed on an ongoing basis. No corrective action has been taken because no results were available until recently. A SOP has been drafted however to address this in the future.***

carried out as foreseen and no corrective actions had been documented in cases of under-sampling.

5.1.4. Other residue control programmes

The mission team noted that:

- in two provinces visited, tissue samples were taken regularly at abattoirs by meat inspectors and screened for inhibitors. In one province, screened positive samples were sent for confirmation to the OVI and in parallel, on-farm follow-up visits were made. These additional residues programmes were paid for by the provinces;
- in the sheep abattoir visited, additional samples had been taken from animals with injection sites or other signs of recent treatment and these animals had been excluded from the export to the EU. The samples had been sent to the OVI, however no results had been received by the CA[15];
- in the sheep abattoir visited, in the scope of a voluntary private own-check programme, random urine samples were regularly taken and analysed in a private laboratory for stilbenes, zeranol and antimicrobials (in 2004 also for beta-agonists). Results had been made available to the official veterinarian and all results checked by the mission team were compliant.

5.1.5. Follow-up of non-compliant results

The mission team noted that:

- there are no official procedures for follow-up of non-compliant NRCP results. Each violation is handled on a case by case basis. A standard operating procedure (SOP) was drafted on follow-up actions, however this SOP is not implemented and is not yet in use[16];
- non-compliant results were found in samples collected for the 2004 NRCP (including *inter alia* the beta-agonist zilpaterol in bovines, the thyrostat tapazol in pigs and the antimicrobials tylosin and oxytetracycline in honey) but no follow-up was conducted due to the fact that the results were only made available in June 2006 to the provinces and regions;
- one private laboratory visited had provided results from the sampling year 2005 to the OVI in March 2007 including 2 non-compliant findings in bovine fat of melengestrol acetate, an authorised hormonal growth promotant. According to the OVI these results had been forwarded to the national co-ordinator but no further action had been taken. There is no "split system" in place for bovines, but in 2005 no export of beef to the EU took place[17].

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[15] ***In their response to the draft report the South African Competent Authority stated that it will investigate the results of these injection site samples.***

[16] ***In their response to the draft report the South African Competent Authority stated that an SOP for follow-up has recently been put in place and that non-compliant results will be followed up.***

[17] ***In their response to the draft report the South African Competent Authority stated that significant attempts will be made to improve the turnaround time in the future.***

5.2. LABORATORIES

5.2.1. General description

Five laboratories are involved in the testing of the NRCP samples. All NRCP samples are delivered to the residue laboratory of the OVI. After registration and storage in the OVI samples may be sent to the Agricultural Research Council – Institute for Soil Climate and Water as well as three private laboratories. These laboratories are responsible for testing of stilbenes (A1), thyrostats (A2), hormones (A3), zeranol (A4), beta-agonists (A5), carbamates and pyrethroids (B2c), organochlorine and organophosphate pesticides (B3a and B3b), and chemical elements (B3c). Before 2006, all laboratories tested the samples after a tender procedure, while in 2006 a Memorandum of Understanding was signed between the Department of Agriculture and the Agricultural Research Council, of which the OVI is part, giving the OVI full responsibility for analyses and subcontracting. In May 2007 the OVI laboratory was appointed as the national reference laboratory for all substance groups and commodities.

The mission team visited the OVI residue laboratory and one private laboratory.

The mission team noted that:

- the residues laboratory of the OVI and the three private laboratories testing NRCP samples are accredited to ISO 17025 by the national accreditation body SANAS, while the Agricultural Research Council – Institute for Soil Climate and Water is in the process of accreditation according to ISO 17025;
- OVI is in the process of subcontracting the above mentioned four laboratories for the 2006 NRCP samples, however no contracts have yet been signed and, in addition, no contract has been drafted for the 2007 NRCP;
- OVI residues laboratory is responsible for auditing the laboratories which will be subcontracted, in particular with regard to availability of analytical methods and validation records as well as traceability of results.

5.2.2. Residue Laboratory of the Onderstepoort Veterinary Institute (OVI)

The mission team noted that:

- there is a comprehensive and well-organised quality management system in place, including a quality manager and a quality manual. Regular vertical and horizontal audits are conducted. A number of analytical methods (mainly □PLC and microbiological methods) are included in the scope of accreditation;
- a validation SOP is available containing all essential requirements (e.g. reproducibility, repeatability, recovery, linearity, standard deviation, signal-to-noise ratios, LOD, LOQ). Validation data are summarised in validation reports and only methods with complete validation reports are accredited. Several ELISA methods used are not validated (e.g. chloramphenicol in milk and muscle, the nitrofuran metabolites AOZ and AMOZ in muscle and trenbolone in muscle);
- fortified calibration curves and in-house control samples are used regularly;
- the laboratory has participated regularly in international proficiency tests for residues methods (mostly for antimicrobials and chloramphenicol), generally with satisfactory

results. In case of unsatisfactory results corrective actions have been taken and supervised by the quality manager;

- the head of the laboratory has participated in several workshops/seminars organised by European residues laboratories and has established scientific contacts with European laboratories;
- appropriate instrumentation is in place for most of the residue methods however there is a considerable lack of staff as seven of 18 posts are vacant at the moment[18];
- samples are screened for antimicrobials by a commercially available microbiological test. There are several □PLC methods in place to confirm, identify and quantify the substance/s;
- several chemical analytical methods listed for this laboratory in the 2007 NRCP did not exist (e.g. for benzimidazoles, levamisole, anticoccidials, sedatives, flunixin, phenylbutazone, streptomycin and sulphonamides in honey);
- there is no confirmation method in place for zilpaterol;
- the □PLC method for tetracyclines in honey is not sensitive enough (LOD=50 µg/kg, LOQ=100 µg/kg);
- samples are not registered upon arrival but are stored in freezers until eventually checked and registered in the LIMS, often months after arrival;
- according to the OVI management, the budgets for analysing the NRCP samples for the financial years 2006/7 and 2007/8 are still not available and the budget for 2006/7 will not be available before September 2007. Therefore at the moment none of the samples for the 2006 NRCP (in total 5899 samples), nor those sampled for the 2007 NRCP (ca 2000 samples), have been analysed and are stored in freezers. In addition, 15% of the samples from the 2005 NRCP have not yet been analysed by the OVI[19].

5.2.3. Private laboratory for residues analysis

For the 2005 NRCP this private laboratory has analysed thyrostats (A2), gestagens (A3), nitroimidazoles (A6), and carbamates (B2c) in different matrices and commodities.

The mission team noted that:

- the laboratory has extensive expertise in mass spectrometric analysis of a huge variety of drugs in urine and blood samples from animals and humans. The laboratory is equipped with state-of-the-art instruments and an adequate number of experienced staff is in place;
- there is a well-organised quality management system in place, including a quality manager and a quality manual. Fortified calibration curves and blind check samples are used regularly;

[18] ***In their response to the draft report the South African Competent Authority stated that recruitment of staff is ongoing and that procurement of laboratory equipment is being processed.***

[19] ***In their response to the draft report the South African Competent Authority stated that samples from 2005/6 relating to 1826 analyses have recently been sent to a MS laboratory.***

- the laboratory regularly participates in proficiency tests, mainly of urine samples for human drugs and doping substances. It has been planned that the laboratory will participate also in food proficiency tests via the OVI or that internal check samples will be prepared by the OVI;
- a validation SOP was in place containing all essential method performance parameters. In addition, two methods (gestagens in fat and thyrostats in muscle) were also validated according to Commission Decision 2002/657/EC by means of a commercially available software programme;
- for all analytical methods standardised SOPs and validation reports were available. All substances for the NRCP are analysed by LC/MS-MS methods;
- in the nitroimidazoles (Group A6) only dimetridazole was reported, however the analytical method detects in parallel also metronidazole and ronidazole. The metabolites are not included in the method;
- the samples for the 2005 NRCP were only dispatched to the laboratory from the OVI at the end of 2006/beginning of 2007. An investigation of the documents revealed that this batch also contained samples from the 2003 and 2004 NRCPs. All analysis results had been forwarded to the OVI.

5.3. VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

5.3.1. Authorisation of Veterinary Medicinal Products, medicated feedingstuffs and feed additives

Before registration, all veterinary medicinal products, medicated feedingstuffs and feed additives are classified into one of eight "schedule" classes as defined in the Medicines and Related Substances Act 101 of 1965 (Act 101). This classification is the responsibility of the Medicines Control Council (MCC) under the Ministry of □ealth. A "schedule 0" classification means that the product may be sold without any restrictions in an open shop.

Should the applicant so wish, these products may be registered by the Department of Agriculture under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947 (Act 36). The veterinary medicinal products, medicated feedingstuffs and growth promotants registered under Act 36 are referred to as "stock remedies". The MCC may also allow registration under Act 36 for schedule 1-3 products. All other products must be registered under Act 101 by the MCC. The MCC may also allow the import and use of unregistered products under special circumstances (special licence use) and this procedure is mostly applied to vaccines.

Since 2003 all registrations of products under Act 101 are valid for 5 years after which a re-evaluation of the registration should take place. Prior to 2003 the product registrations had no time limit and these products are in the process of being re-evaluated and transferred to five year registrations. Registrations of products under Act 36 are renewed annually provided a fee is paid by the registration holder.

Drug withdrawal times are set by the Act 101 and Act 36 registering bodies, based on documentation from the registration applicant and on the MRL requirements of the Foodstuffs, Cosmetics and Disinfectants Act 54 of 1972 (Act 54) which is under the responsibility of the Ministry of □ealth.

All veterinary drugs on the market, registered under Acts 36 and 101, are listed in a *vademecum* which is published quarterly by the pharmaceutical industry.

The mission team noted that:

- hormonal growth promotants, i.e. progesterone, oestradiol, testosterone, trenbolone, melengestrol acetate and the beta-agonist zilpaterol are freely available 'stock remedies' and are registered for use in bovines. Most of these products are available as implants;
- products containing zeranol, a non-hormonal growth promotant with an oestrogenic effect, are freely available stock remedies as implants registered for use in cattle, sheep and ostriches. The mission team was informed by the CA that the registered indications for ostriches were in the process of being withdrawn following an initiative from the ostrich industry;
- one product containing the beta-agonist ractopamine, is registered as a growth promotant for pigs, under "schedule 0" both under Act 101 (veterinary medicine) and Act 36 (stock remedy). According to the CA this product is currently not on the market;
- roxarsone, an arsenic compound for growth promotion, is registered for use in pigs and poultry;
- other growth promotants (with mainly antibacterial activity) containing *inter alia* carbadox (pigs), olaquindox (pigs, poultry), zinc bacitracin (bovine, ovine, pigs, poultry), virginiamycin (bovine, pigs, poultry), and tylosin phosphate (bovine, pigs, poultry) are freely available stock remedies[20]. All of these substances are forbidden for use as feed additives in the EU but are not suitably tested for in the South African NRCP;
- sedatives, tranquilisers, steroidal and non-steroidal anti-inflammatory drugs and sex hormones for therapeutic use are all "schedule 3" to "schedule 5" drugs. They are registered under Act 101 and can only be prescribed or sold by a veterinarian;
- the CA informed the mission team that no VMPs containing thyrostats, stilbenes, chloramphenicol, nitroimidazoles, nitrofurans or malachite green are currently registered for use in food producing animals. No such products were listed in the *vademecum* for January-March 2007;
- the vast majority of other veterinary medicinal products used for food producing animals, e.g. all antibiotic and coccidiostatic growth promotants, numerous antimicrobials, all antiparasitic remedies (against internal and external parasites) and bovine somatotropin, are registered under Act 36 and are thus freely available;
- there are no procedures in place to notify for example, veterinary practitioners, pharmacists, inspectors and farmers of amendments and changes of registered

[20] ***In their response to the draft report the South African Competent Authority stated that carbadox is no longer approved through Act 36 of 1947, and has not been since 2006. It has however been erroneously published in the "index of veterinary specialties (IVS)". The IVS will be informed to remove the product from its publication. In addition a circular to the effect that carbadox is not approved will be published on the Act 36 website b 8 October 2007.***

products such as the recent de-registration of ostriches as target species for one of the zeranol implant products;

- an amendment to Act 54 had been drafted in February 2006, introducing an MRL of 0.00 mg/kg in all commodities except honey, for all active substances listed in Annex IV to Council Regulation (EEC) No 2377/90 with the exception of dimetridazole. The draft also proposed an MRL of 0.00 mg/kg for carbadox, cefuroxime (only in cow milk), diethylstilbestrol, ipronidazole, organic arsenicals, phenylbutazone and phoxim (only in cattle). The CA could not provide any timetable for the possible adoption of this amendment.

5.3.2. Distribution and use of VMPs

All preparations registered under Act 36 are freely available and may be sold directly to farmers by *inter alia* farm shops, supermarkets, pharmacies, wholesalers and veterinarians. There are no requirements for registration or authorisation of the retailers involved unless the preparations are classed as a "group 1 poison" for which licensing of the retailer is required under the □azardous Substances Act[21].

For preparations registered under Act 101, manufacturers, wholesalers and pharmacies must be licensed by the MCC for a period of two years at a time. Registered veterinarians may also sell Act 101 preparations.

The mission team noted that:

- manufacturers, wholesalers and distributors are currently registered with the MCC, according to the CA the licensing procedures laid down in national legislation (Section 22C in Act 101) have not been fully implemented.

5.3.3. Controls on VMPs

5.3.3.1. At manufacturer, wholesale and retail levels

The MCC is responsible for inspections of manufacturers, wholesalers and pharmacies dealing with Act 101 products. These inspections focus mainly on good manufacturing/distribution practices.

The Department of Agriculture is responsible for inspections of the manufacturers and distributors of products registered under Act 36. During these inspections so-called "clean" (fully compliant) or "dirty" reports are issued. The inspections mainly check that all relevant products offered for sale are registered under Act 36.

The mission team noted that:

- the pharmacy/wholesaler visited had been inspected during 2007 under Act 101 and Act 36, respectively, and inspection reports were available;

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[21] ***In their response to the draft report the South African Competent Authority stated that the draft policy of stock remedies in ZA, published in the official gazette on 29 September 2006, gives allowance for the licensing of sellers and the provision of appropriate and reliable advice to farmers or users. This gives the opportunity for the Act or Regulations (that would follow on) to address issues of the effective controls on the distribution and use of stock remedies.***

- no updated lists of registered products, indicating target species and withdrawal times, are available from the Act 101 and Act 36 registrars to the inspectors on the spot;
- the inspectors (Act 36) check that the products have national registration numbers, but do not check that the indications, target species and withdrawal times quoted on the labels correspond to what is registered;
- during the most recent inspection (according to Act 36), one product with a false registration number (found because the number was higher than those used in South Africa) and one product without a registration number had been identified and corrective actions had been initiated;
- in the pharmacy/wholesaler visited an implant containing zeranol was available with target species sheep and ostrich on the label. The indication for ostrich on this implant had been deregistered. The mission team was informed by the CA (Act 36) that the responsibility to inform the retail chain about such changes, and to ensure implementation, lies with the registration holder. After deregistration of a VMP stocks at retail level are sold out.

5.3.3.2. In feed mills

Feed mills are registered for feed production under Act 36 by the Province State Veterinarian. All feed products are registered under Act 36 by the CCA, with annual renewals provided a fee is paid by the registration holders.

The mission team noted that:

- the feed mill visited had been inspected regularly under Act 36 and inspection reports were available[22];
- in the feed mill visited, a flushing procedure (between the production of medicated and non-medicated feed batches) was in place but no analyses had been performed by the company or the CA to assess the homogeneity of mixing or extent of cross contamination between batches. This is a requirement under Community legislation (Article 4 of Council Directive 90/167/EEC);
- in the feed mill visited, no testing scheme was in place by the company or the authorities to control the levels of e.g. environmental contaminants (pesticides, heavy metals) or mycotoxins in feed. This is a requirement under Community legislation (Article 3 of Directive 2002/32/EC of the European Parliament and of the Council);
- in the feed mill visited, premixes containing pharmacologically active substances for feed production were stored together with non-medicated additives and finished products. This is in breach of national legislation (Regulation 1087 under Act 36) and Community legislation (Article 4 of Council Directive 90/167/EEC).

5.3.3.3. On export registered farms ("split system")

VPNs have been issued by the Department of Agriculture for registration of cattle and sheep farms producing meat for the European Community as well as for ostrich, crocodile and wild game farms producing meat for export in general. VPNs have also been issued for milk establishments (covering certain requirements for the supplying

[22] ***In their response to the draft report the South African Competent Authority stated that feed mills are also inspected by provincial state veterinarians.***

dairy farms) producing milk products for export. The farms and establishments have to apply for registration and the registration is renewed every year. A minimum of one inspection per year, by officials from the province veterinary offices, is mandatory before registration or re-registration.

The mission team noted that:

- updated lists of export registered farms are kept by the provinces. There is no national list of all EU export registered farms;
- the VPN for cattle farms is not implemented. According to the CA no beef farms have been registered for the export to the EU;
- on the export registered sheep and ostrich farms visited, inspections had been performed in accordance with the relevant VPNs. Drug stock records, drug application records and tick control records as required under the VPN were in place;
- all VPNs, with the exception of that for dairy farms, require written annual declaration by the owner that no administration will take place of production enhancers/growth stimulants or of any substance that is a beta-agonist or has an estrogenic, androgenic, gestagenic or thyrostatic effect;
- the VPNs for sheep and beef farms stipulate that feed can only be purchased from feed mills approved by the National Directorate of Animal □ealth. Feed mills can only be approved provided that they do not produce feed with growth promotants or keep growth promotants on the premises. □owever, no approval procedure has been implemented and therefore no feed mills are yet approved;
- the VPNs for ostrich, crocodile, wild game and dairy farms do not contain any restrictions with regard to feed suppliers[23]. The export registered ostrich farm visited received feed exclusively from a commercial feed mill producing feed mainly for dairy cows and ostriches but also for sheep, pigs and beef cattle. The feed mill had one production line and used several premixes and additives, however the mission team could not verify if growth promotants had been used in the feed mill;
- following the 2003 FVO mission, the CA undertook to implement the analyses of growth promotants in feed samples from sheep farms by June 2004. □owever, the OVI management informed the mission team that up to now no methods are available for any residue analyses in feed;
- the VPNs for sheep farms stipulate that feed samples are to be taken on farm during the inspections for analysis to prove freedom from growth promotants. In one province visited, several feed samples had been taken in 2006 from EU export registered sheep farms. These samples had been submitted to the OVI for analysis, but no results had been received. □owever according to the OVI management, no feed samples had been received[24];

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23 *In their response to the draft report the South African Competent Authority stated that the VPNs for ostrich, crocodile and wild game (and for dairy farms when relevant for export) will be amended with regard to feed suppliers.*

24 *In their response to the draft report the South African Competent Authority stated that the samples for analysis of feed for growth promotants will be sent to overseas laboratories. Only feed manufactured in establishments which are not registered as dedicated (those not keeping growth promotants) will be included in this plan.*

- none of the VPNs stipulate any physical checks for implants in live animals at farm level. In addition, the *ante mortem* and meat inspection procedures in EU export approved abattoirs do not include physical checks for implants before or after slaughter[25];
- in respect of those animals, meat from which is destined for the EU market, there are no requirements for sampling of urine or blood from live animals on farm to control the illegal use of growth promotants. Following the 2003 FVO mission the CA undertook to implement on-farm sampling of urine from ostriches and sheep by June 2004. This had not been done[26];
- the VPNs allow purchase of animals from unregistered farms provided that the animals are kept on the export registered farm for a minimum of 3 months prior to slaughter. Thus it is possible that such animals could have been treated with hormonal growth promotants or beta-agonists for growth promotion purposes prior to entry onto the export registered farm[27];
- medicines treatment records are not required for the whole life span of the animals in all VPNs. Such records are required only for the last three months prior to slaughter if the animals are not born on the farm. The maintenance of medicines treatment records is required by Community law (Article 10 of Council Directive 96/23/EC)[28];
- according to the VPNs for sheep and beef farms, all animals must be individually marked and registered in the stock register. However in practice, EU export registered sheep farms are only required to mark all sheep with a unique farm identity mark (tattoo) in one ear. In the abattoir visited the official veterinarian informed the mission team that these tattoos cannot be read in many instances since the most common breed of sheep have black heads and ears with dark skin. Thus it cannot be excluded that sheep meat from non-export registered farms has been exported to the EU.

6. CONCLUSIONS

6.1. NATIONAL RESIDUE CONTROL PLAN

(1) The South African residues control system is ineffective and dysfunctional. In light of the fact that several thousand samples taken from April 2006 to date have not been

[25] ***In their response to the draft report the South African Competent Authority stated that the requirement for ante and post mortem examination for implants has been incorporated into the VPN for ostrich and will be a requirement also for post mortem inspection of game.***

[26] ***In their response to the draft report the South African Competent Authority stated that the matrix for on-farm sampling of ostrich has been changed to serum and that serum samples from the past 14 months are being analysed.***

[27] ***In their response to the draft report the South African Competent Authority stated that the VPN will be changed to allow only purchase of animals from other registered and controlled export farms.***

[28] ***In their response to the draft report the South African Competent Authority stated that once animals can only be bought from another export registered farm treatment records will be available for the entire life of the animals. Specific electronic sheep tagging systems are in place in some provinces, and are under investigation in other provinces.***

analysed at all by the OVI and that the analyses for the previous sampling year 2005/2006 were neither completed nor the results assessed and summarised means that the residue content of all commodities has been unknown since April 2005. The absence of any residue testing results for several years means that the competent authority can not guarantee that food of animal origin exported to the EU complies with Community residues limits.

(2) Notwithstanding the lack of laboratory testing carried out under the national residue control plan, it can be said that the plan is designed generally in accordance with the requirements of Council Directive 96/23/EC. □owever, the plan does not reflect the performance of the involved laboratories in that many analytical methods listed either do not exist or have different sensitivity. These factors reduce confidence in guarantees given by the competent authority.

(3) Notwithstanding the lack of laboratory testing, the facts that export figures (and not production figures) are taken as basis for the calculation of sample numbers and that in general number of samples and analyses are mixed in the plan, this means that the minimum sample frequencies laid out in Council Directive 96/23/EC are not always fulfilled. This is compounded by a lack of supervision as evidenced by substantial under- and over-sampling, clustering of sampling and failure to sample from relevant EU-approved establishments. Thus the South African national residue control plan can not be said to offer guarantees with an effect equivalent to those provided for in Council Directive 96/23/EC.

(4) There are no procedures for the follow-up of non-compliant residue control plan results. In addition, effective follow-up actions are hindered by the fact that analysis results are not received until years after the sampling. This eliminates the possibility to find the source of residues and to prevent recurrence.

6.2. LABORATORIES

(1) In spite of the lack of laboratory testing, from a technical perspective the laboratory network is competent and almost all laboratories are accredited. Notwithstanding the fact that some of the analytical methods listed in the national residue control plan are not yet available or validated, there are no technical reasons why the laboratory network should not be in a position to carry out analyses under the NRCP.

6.3. VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

(1) Most veterinary medicinal products, medicated feedingstuffs and feed additives for use in food producing animals, including growth promotants with hormonal effects for several species (cattle, pigs, sheep and ostriches), are freely available in South Africa. The controls of the distribution and use of these products are currently insufficient to detect possible misuse or illegal use of these products. Thus South Africa can not provide guarantees with an effect at least equivalent to those provided for in Community legislation, particularly Council Directives 96/22/EC and 96/23/EC.

(2) The fact that many substances which are specifically banned for use in food producing animals in the EU (e.g. carbadox, olaquindox, roxarsone, virginiamycin etc) are authorised and freely available in South Africa and are neither subject to effective control with regard to their use, nor are included in the scope of analytical testing, means that food of animal origin exported to the EU may contain residues of these

substances and thus do not comply with Community requirements (Article 11 of Regulation (EC) No 178/2002 of the European Parliament and of the Council and Article 30 of Council Directive 96/23/EC).

(3) Whilst there is a system for export approval of farms designed *inter alia*, to provide a 'split system' guaranteeing that growth promotants have not been used, the system does not cover all relevant commodities (beef is not included), is not comprehensive and there are several gaps in its implementation. Guarantees in regard to the split system given by the CCA after former FVO missions have not been implemented. In respect of ostriches which are exported to the EU, the current split system cannot provide guarantees that ostrich meat exported to the EU has not been derived from animals treated with growth promotants having oestrogenic, androgenic or gestagenic effect. Thus South Africa does not comply with the requirements of Article 11 of Council Directive 96/22/EC.

6.4. OVERALL CONCLUSION

Although a residue control plan for all EU listed commodities is available and a competent laboratory network is in place, the overall residue control system is dysfunctional as evidenced by an absence of any laboratory testing for several years. Thousands of samples have been taken and never analysed. In the absence of any results, the competent authority can not guarantee that food of animal origin exported to the EU complies with Community residues limits.

On the veterinary medicines side a wide variety of growth promotants with hormonal effects (natural and synthetic hormones, beta-agonists, zeranol) are registered as implants and feed additives for cattle, pigs, sheep, and ostriches. These products are freely available and their distribution and use is not controlled. Whilst South Africa currently does not export beef to the EU (due to the delisting of the approved bovine meat establishments), there is no split system in place for this commodity guaranteeing that hormonal growth promotants have never been used in animals, meat from which is eligible for export to the EU. For the other species for which a split system is required – sheep and ostriches - split systems are in place. However they are not comprehensive, their implementation is weak and commitments given after the 2003 and 2005 FVO missions with regard to the control of farms supplying the EU market have not been fulfilled. The net effect is that for sheep and ostriches, the latter being an important export commodity for the EU market, the guarantees given by the competent authority regarding freedom from treatment with hormonal growth promotants can not be relied upon.

Overall, the absence of testing and poor controls on veterinary medicines means that the EU can have no confidence in the residues status of food of animal origin exported from South Africa as the system does not provide guarantees with an effect equivalent to those provided for by Community law.

7. CLOSING MEETING

A closing meeting was held on 21 June 2007 with representatives of the CCA. At this meeting, the inspection team presented the main findings and preliminary conclusion of the mission. The CCA did not express any major disagreement with the findings and preliminary conclusion.

8. RECOMMENDATIONS

In order to provide guarantees with an effect at least equivalent to the provisions of Community law concerning the control of residues of veterinary medicines and contaminants in animals and animal products (Council Directive 96/23/EC), the competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below (insofar as these apply to products of animal origin eligible for export to the EU), within 25 working days of receipt of this mission report.

National Residue Control Plan

(1) To consider involving OVI as the designated national reference laboratory in the planning of the annual residue control plan in order to ensure that the plan reflects the actual capability and performance of the involved laboratories.

(2) As the plan is based on Council Directive 96/23/EC, to ensure that the number of samples to be taken is in accordance with this Directive and with Commission Decision 97/747/EC.

(3) To ensure that in respect of those pharmacologically active substances which are authorised for use in food producing animals in South Africa but which have been expressly banned in the EU (e.g. carbadox etc), the plan is amended to include such substances in the scope of testing for those commodities eligible for export to the EU.

(4) To supervise the implementation of the national residue control plan in order to avoid under-sampling and to ensure the sampling of all EU approved establishments over the whole year (Council Directive 96/23/EC).

(5) To ensure a timely transport and analysis of all samples taken to facilitate an effective and prompt follow-up of non-compliant results and to enable the CCA to report the summarised results in due time to the Commission Services (Council Directive 96/23/EC).

Laboratories

(6) To improve the routines for sample registration and analysis in order to provide timely results to the CCA (Council Directive 96/23/EC).

(7) To ensure that all analytical methods listed in the national residue control plan are developed and validated (Council Directive 96/23/EC).

Veterinary medicinal products

(8) To amend the requirements for export approved farms and improve the controls of animals on these farms, so that no animals, which may be slaughtered for the European market, are treated with beta-agonists, stilbenes, thyreostats or growth promotants with oestrogenic, gestagenic or androgenic effect at any time from birth to slaughter. Thus the CCA would be able to provide guarantees that the production for the European market complies with Article 11 of Council Directive 96/22/EC.

(9) To ensure that treatment records on export registered farms cover the whole lifespan of the animals and list all types of medication in order to provide guarantees equivalent to those provided for by Articles 10 and 29(1) of Council Directive 96/23/EC.

(10) To increase the effectiveness of the controls on the distribution and use of all veterinary medicinal products, feed additives and medicated premixes. The checks on export approved farms and in feed mills producing feed for such farms should enable the CA to

provide credible guarantees that animal products exported to the EU do not contain residues at concentrations exceeding those limits and levels laid down in Community legislation (Council Regulation (EEC) No 2377/90 and Council Directive 86/363/EEC).

(11) In respect of those substances which are specifically banned for use in food producing animals in the EU (e.g. carbadox, olaquindox, roxarsone, virginiamycin etc) but which are authorised and freely available in South Africa, implement a system which will guarantee that detectable residues of these substances are not present in food of animal origin exported to the EU in accordance with Article 11 of Regulation (EC) No 178/2002 of the European Parliament and of the Council.

9. COMPETENT AUTHORITY RESPONSE TO RECOMMENDATIONS

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

http://ec.europa.eu/food/fvo/ap/ap_south_africa_7585_2007.pdf

ANNEX I: APPLICABLE COMMUNITY STANDARDS

General Food and Feed Law
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. Official Journal L 031, 01/02/2002 pp. 1-24.
Audits by the Commission Services
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. Official Journal, L 165, 30/04/2004 pp. 1–141, corrected and republished in Official Journal, L 191, 28/05/2004 pp. 1-52.
Commission Decision 98/140/EC of 4 February 1998 laying down detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in third countries. Official Journal L 38, 12/02/1998 pp. 14-16.
Residues Monitoring and Sampling
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. Official Journal L 125, 23/05/1996 pp. 10-32.
Commission Decision 97/747/EC 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. Official Journal L 303, 06/11/1997 pp. 12-15.
Commission Decision 98/179/EC 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. Official Journal L 65, 05/03/1998 pp. 31-34.
Status of residue monitoring plans for third countries
Commission Decision 2004/432/EC of 29 April 2004 on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC. Official Journal L 154, 30/04/2004 pp. 44-50 corrected and republished in Official Journal, L 189, 27/05/2004 pp. 33-39, as last amended by Commission Decision 2007/362/EC of 16 May 2007. Official Journal, L 138, 30/05/2007 pp. 18-23.
Validation of analytical methods for residues
Commission Decision 2002/657/EC of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results. Official Journal L 221, 17/08/2002 pp. 8-36.
Bans on the use of hormones and beta-agonists for growth promotion in food producing animals
Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stock farming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EC. Official Journal L 125, 23/05/1996 pp. 3-9.
Maximum residue limits for veterinary medicines in food of animal origin
Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin. Official Journal L 224, 18/08/1990 pp. 1-8.

Maximum Residue Limits for pesticides in food of animal origin
Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues in and on foodstuffs of animal origin. Official Journal L 221, 07/08/1986 pp. 43-47.
Maximum Limits for Contaminants
Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs. Official Journal L 364, 20/12/2006 pp. 5-24.
Authorisation of veterinary medicinal products
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. Official Journal L 311, 28/11/2001 pp. 1-66.
Medicated feedingstuffs and additives
Council Directive 90/167/EEC of 26 March 1990, laying down conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community. Official Journal L 092, 07/04/1990 pp.42-48.
Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition. Official Journal L 268, 18/10/2003 pp. 29-43.
Directive 2002/32/EC of the European Parliament and of the Council of 7 May 2002 on undesirable substances in animal feed. Official Journal L 140, 30/05/2002 pp. 10-22.
Sampling methods and methods of analysis for contaminants in foodstuffs
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. Official Journal L 88, 29/03/2007, pp. 29-38.
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. Official Journal L 70, 09/03/2006 pp. 12–34.
Sampling methods for pesticides in foodstuffs
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. Official Journal L 187, 16/07/2002 pp. 30-43.

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EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate F - Food and Veterinary Office

DG(SANCO)/ 2008-7932 - MR - FINAL

FINAL REPORT OF A MISSION CARRIED OUT IN SOUTH AFRICA FROM 02 JULY TO 07 JULY 2008 IN ORDER TO EVALUATE THE CONTROL OF RESIDUES AND CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS, INCLUDING CONTROLS ON VETERINARY MEDICINAL PRODUCTS

Please note that factual errors in the draft report have been corrected. Clarifications provided by the Competent Authority are included in endnotes.

Executive Summary

This report describes the outcome of a follow-up mission carried out by the Food and Veterinary Office (FVO) in South Africa, from 2 to 7 July 2008.

The objective of the mission was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in farmed and wild game animals and animal products, including the controls on the distribution and use of veterinary medicinal products and feed additives, the use of which may give rise to residues in such products. The mission followed up on a previous FVO residues mission to South Africa in June 2007 - DG (SANCO)/2007-7585 MR Final. As a result of that mission, South Africa was removed from the list of those third countries with approved residue plans (Commission Decision 2004/432/EC) for bovine, ovine/caprine, swine, poultry, milk, and honey. For the two other commodities for which the country remained listed (wild and farmed game), the central competent authority gave a number of guarantees to the Commission services that the deficiencies observed during the 2007 mission had been resolved. However in June 2008 South Africa was also removed from the residues list for wild game because it was deemed that certain guarantees in respect of residues monitoring in wild game had not been met. The current mission focussed on the delivery of the guarantees promised in relation to both wild and farmed game since the last FVO mission and examined implementation of the residue monitoring plan for both commodities in both the 2007-2008 and current (2008-2009) sampling years.

It is concluded that the overall situation regarding residues controls in farmed and wild game has improved since 2007. Guarantees provided to the Commission services have been largely implemented. Notwithstanding the shortcomings in laboratory performance identified during the mission, with regard to ostrich and wild game for meat production, the current residue control system in South Africa provides guarantees with an effect at least equivalent to those provided for by Council Directive 96/23/EC.

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

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
Act 101	Medicines and Related Substances Act 101 of 1965
Act 36	Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947
AOZ and AMOZ, AHD and SEM	Marker residues of the nitrofuran drugs furazolidone, furaltadone, nitrofurantoin and nitrofurazone respectively
ARC-OVI	Agricultural Research Council's Onderstepoort Veterinary Institute
DG(SANCO)	Health and Consumers Directorate General
EC	European Community
ELISA	Enzyme-linked immunosorbent assay
EU	European Union
FVO	Food and Veterinary Office
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC: A1 Stilbenes A2 Thyrostats A3 Steroids A4 Zeranol A5 Beta-agonists A6 Substances listed in Annex IV to Council Regulation (EEC) No 2377/90 B1 Inhibitors (antimicrobials) B2a Anthelmintics B2b Coccidiostats B2c Carbamates and pyrethroids B2d Sedatives B2e NSAIDs B2f Others (e.g. corticosteroids) B3a Organochlorines including PCBs B3b Organophosphorus compounds B3c Chemical elements B3d Mycotoxins

Abbreviation	Explanation
	B3e Dyes B3f Others
HPLC	High Performance Liquid Chromatography
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
LOD	Limit of Detection
LOQ	Limit of Quantification
MRL	Maximum Residue Limit
NRCP	National Residue Control Plan
RASFF	Rapid Alert System for Food and Feed
SANAS	South African National Accreditation System
SOP	Standard Operating Procedure
VPN	Veterinary Procedural Notice

1 INTRODUCTION

The mission took place in South Africa from 2 to 7 July 2008. The mission team comprised two inspectors from the Food and Veterinary Office (FVO). Representatives from the central competent authority (the Department of Agriculture, Veterinary Service) accompanied the inspection team during the whole mission. An opening meeting was held on 2 July 2008 with the central competent authority. At this meeting, the objectives of, and itinerary for the mission were confirmed by the inspection team and the first discussions with the central competent authority officials were conducted.

2 OBJECTIVES OF THE MISSION

The objective of the mission was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in farmed and wild game animals and animal products, including the controls on the distribution and use of veterinary medicinal products and feed additives, the use of which may give rise to residues in such products. The mission followed up on a previous FVO residues mission to South Africa in June 2007 - DG (SANCO)/2007-7585 MR Final – hereafter referred to as the 2007 mission. As a result of the 2007 mission, South Africa was removed from the list of those third countries with approved residue plans (Commission Decision 2004/432/EC) for bovine, ovine/caprine, swine, poultry, milk, and honey. For the two other commodities for which the country remained listed (wild and farmed game), the central competent authority gave a number of guarantees to the Commission services that the deficiencies observed during the 2007 mission had been resolved. However in June 2008 South Africa was also removed from the residues list for wild game because it was deemed that certain guarantees in respect of residues monitoring in wild game had not been met. The current mission focussed on the delivery of the guarantees promised in relation to both wild and farmed game since the 2007 mission and examined implementation of the residue monitoring plan for both commodities in both the 2007-2008 and current (2008-2009) sampling years.

The following sites were visited and meetings held:

Meetings/Visits		n	Comments
Competent Authorities	**Central**	**2**	Opening and closing meetings with the Department of Agriculture
	Provincial	**1**	State Veterinary Office in Western Cape Province
Laboratories		**1**	National laboratory (semi-governmental) Agricultural Research Council Onderstepoort Veterinary Institute
		1	Private Laboratory analysing *inter alia*, ostrich serum samples taken under the on-farm programme
Farms		**2**	One export registered ostrich farm with private veterinarian in attendance, one wild game farm.
Establishments		**1**	EU export approved ostrich and wild game abattoir
Other sites		**2**	Pharmacy/wholesaler for medicinal products

3 LEGAL BASIS FOR THE MISSION

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

- Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;
- Council Directive 96/23/EC 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;
- Commission Decision 98/140/EC of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in third countries.

A full list of the legal instruments referred to in this report is provided in Annex 1.Legal acts quoted in this report refer, where applicable, to the last amended version.

4 BACKGROUND

4.1 COUNTRY STATUS IN RELATION TO SUBMISSION OF RESIDUES CONTROL PLANS

In Commission Decision 2004/432/EC as last amended by Commission Decision 2008/407/EC, the South African National Residues Control Plan (NRCP) is approved for farmed game (ostrich).

4.2 SUMMARY OF PREVIOUS MISSION RESULTS

The 2007 mission (DG (SANCO)/2007-7585 MR Final), the report of which has been published on the website of the Health and Consumers Directorate General (http://ec.europa.eu/food/fvo/ir_search_en.cfm) found a number of serious deficiencies in the South African residue control system. The major problems related to the lack of implementation of the residues testing programme across all commodities and the continued availability of hormonal growth promotants for use in several species. The 2007 mission report concluded that the EU could have no confidence in the residues status of food of animal origin exported from South Africa as the system did not provide guarantees with an effect equivalent to those provided for by Community law.

Eleven recommendations were made in the 2007 mission report and an action plan was provided by the central competent authority in response to each of the recommendations. The action plan is hyperlinked to the 2007 mission report here: http://ec.europa.eu/food/fvo/ap/ap_south_africa_7585_2007.pdf .

Information on the chronology of events that affected the status of South Africa in the list of those third countries with approved residue plans (Commission Decision 2004/432/EC) is provided in section 2 of the report.

4.3 RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS FOR CONSIGNMENTS FROM SOUTH AFRICA CONCERNING RESIDUES

From 2005 to date there have been no findings of residues of veterinary medicinal

products reported under the RASFF.

4.4 PRODUCTION AND TRADE INFORMATION

With regard to the production of ostrich and wild game, at present in South Africa there are a total of 1065 ostrich farms included in a database maintained by the industry body (the South African Ostrich Business Chamber). Of those, there are 463 farms producing ostriches for slaughter, the remainder being breeders, hatcheries and chick raisers and the farms are registered by the central competent authority. The majority of ostrich production is in the Western Cape Province, one of the nine provinces in South Africa. In 2007 the volume of ostrich meat produced was 3900 tonnes, 95% of which was exported to the EU. For wild game there are 500 registered farms of which 453 are registered for export of meat and the annual production is approximately 620 tonnes per annum. Almost 100% of the meat from wild game is exported to the EU. There are currently seven registered export establishments for ostrich and five for wild game meat processing.

5 MAIN FINDINGS

5.1 NATIONAL RESIDUE CONTROL PLAN

5.1.1 Planning of the National Residue Control Plan

A detailed description of the planning of the national residue control plan (NRCP) is given in DG (SANCO)/2007-7585 MR Final. For 2008-2009 the only commodities covered by the NRCP are wild game and ostrich. The plan runs from 1 April 2008 to 31 March 2009. The mission team noted that:

- in comparison to the 2007 mission, the main residues laboratory – the Agricultural Research Council's Onderstepoort Veterinary Institute (ARC-OVI) now assists in the drafting of the NRCP;
- the central competent authority stated that analytes tested for in ostrich were selected based on the veterinary medicines likely to be used and availability of analytical methods;
- for wild game a wide range of substance groups are tested for in excess of that required by Council Directive 96/23/EC (Gropu B3c – chemical elements). The central competent authority stated that it is using the results from this programme to underpin a risk assessment on the veterinary medicinal products used (if any) in wild game production;
- the numbers of samples specified in the plan and the breakdown of substance groups to be tested for are in accordance with Council Directive 96/23/EC. In comparison to the 2007 mission the scope of testing is comprehensive and includes analytes of particular concern (e.g. the beta-agonist zilpaterol) however some data in the 2008-2009 plan presented to the Commission services are incorrect:

- o the four nitrofurans metabolites are listed as being screened in the ARC-OVI by ELISA. The ELISA method only covers two of the four compounds – AOZ and AMOZ. AHD and SEM are not tested for and this was also noted in the 2007 mission report.(see Endnote) Similarly three stilbenes (Group A1) are listed in plan whereas only two are tested for;
- o in several cases the laboratories listed in the plan did not accord with those actually providing all of the analytical services;
- o the analytical methodology quoted for some of the analytes in the plan did not always match what was being done on the spot. The ARC-OVI uses a commercially available microbiological growth inhibition test for initial antibiotic residues screening and not the four plate test as indicated (see Endnote) and LC-MS/MS is used for screening and confirmation of carbamates, not GC-MS as listed;

- the 2008-2009 sampling year commenced on 1 April 2008. The plan was sent out to the provincial competent authorities in late March 2008. Tissue samples were allocated by establishment and by month and specify the matrix to be sampled and the analyte to be tested. The sampling instructions for officials are contained in a Veterinary Procedural Notice (VPN) which has been updated for the 2008-2009 sampling year;
- in addition to tissue sampling, the central competent authority has a programme of on-farm sampling (serum) for the export-registered ostrich farms. The 2008-2009 plan foresees the sampling of 5 ostriches per farm once a year. Samples are foreseen to be tested for substance groups A1, A3, A4 and A5 and the range of analyses included within each substance group is comprehensive;
- the plan for ostriches complies with Council Directive 96/23/EC in terms of the substance groups tested for and the number of samples to be taken. It includes testing for other substances and substance groups which have the potential to be used in ostriches (e.g. amitraz for tick control) or could be present as a result of feed contamination (mycotoxins). However one drug which is routinely used in ostrich production (praziquantel) for the control of intestinal tapeworms is not currently included in the plan; (see Endnote)
- the volume of throughput of each establishment was not taken into account in the sample allocation per establishment. This has led to a situation where in some of the smaller establishments with one or two suppliers multiple samples had been taken from these farms in order to meet the monthly allocation of samples for the establishment. This clustering of samples is not in accordance with the VPN or Council Directive 96/23/EC;
- the plan for wild game currently includes many substance groups which are not required under Council Directive 96/23/EC. The central competent authority considered that such testing was necessary in order to establish precisely what veterinary medicinal products may be used in the different wild game species. Industry representatives and the provincial competent authorities explained that veterinary medicinal products are used only on high value game breeds (e.g.

rhinocerous, sable antelope, roan antelope) which are kept for breeding purposes and trophy hunting only. It was claimed that the application of veterinary medicines in those species of wild game hunted for meat production (e.g. Springbok) is neither necessary, economically beneficial nor practically possible as these animals are roaming over areas between 5,000 and 50,000 hectares. This situation was confirmed by the mission team during the visit to a wild game farm.

5.1.2 Implementation of the NRCP and its supervision

All samples are taken by official staff from the provincial and regional veterinary administrations. In contrast to the situation seen during the 2007 mission, all samples are sent directly to the ARC-OVI which will either analyse the samples or send these to other laboratories for analysis.

With regard to the implementation of the 2007-2008 residue programme, which comprised three separate programmes: ostrich tissue samples taken at slaughter and tested for the full range of substances as required by Council Directive 96/23/EC; ostrich serum samples taken on-farm and tested for Group A substances (A1, A3, A4 and A5) and wild game tissue samples taken at establishments, the mission team noted that:

- the residue plan for ostrich tissue samples was completed on 15 April 2008. The results for the on-farm testing were completed on 15 June 2008. For wild game, the programme was completed on 15 April 2008. The central competent authority provided the Commission services with monthly updates of the progress made on implementation of the 2007-2008 plan from January 2008 onwards. There were no non-compliant results detected;
- the on-farm programme for residues of Group A substances in ostriches which was put in place by the central competent authority to provide additional guarantees on the control of banned EU-substances in ostrich production was structured so that five samples would be taken on two occasions from each registered export farm. The planned number of samples was 635 samples and 850 samples were taken and tested, however the number planned should have been 2315 (from 463 registered export farms) on the basis that sampling commenced in the second half of the sampling year in September 2007 and farms were sampled once. The central competent authority admitted that an error had been made in the number of samples specified in the 2007-2008 on-farm sampling plan sent to the Commission services. There were no non-compliant results detected in the on-farm programme;

With regard to the implementation of the 2008-2009 residue programme, the mission team noted that:

- for the ostrich sampling plan in establishments, practically all sampling foreseen to be carried out from April to June has been completed (57 samples taken out of 59 planned). For wild game, 23 samples were foreseen for April and May with 17 sampled in these months. The central competent authority informed the mission team that sampling of wild game had ceased in June after the delisting decision (hunting had stopped), however from the ARC-OVI records it was seen that some samples were taken in early June and a total of 28 wild game samples have been

registered in the ARC-OVI;

- for the on-farm programme for ostriches, the authorities requested to reduce the number of samples from 10 to 5 samples per export-registered farm per year. (see Endnote) Of the 2315 samples foreseen, 915 samples have been collected to date and submitted to the ARC –OVI. None of these samples have been sent yet from the ARC-OVI to the subcontracted private laboratory selected for this purpose. ARC-OVI staff stated that the sub-contracted laboratory had indicated that it did not wish to receive these samples until the end of July at the earliest. There is as yet no formal agreement in place between the ARC-OVI and the private laboratory in question. The private laboratory has indicated to ARC-OVI that it can only test up to 240 samples in total in 2008. ARC-OVI indicated that it intended to develop immunoassay-based screening methods for a number of the analytes to reduce the number of samples sent to the private laboratory for analysis;
- one private courier company is employed for the transport of all samples to the laboratory. In several examples selected at random by the mission team, the time taken for transport of the samples to the laboratory was no more than two days. Difficulties with transport of samples due to a change in the International Air Transport Association packaging regulations – which particularly affected the timely sending of samples taken in April - have been overcome;
- the central competent authority's decision to send all samples directly (rather than via a regional laboratory) to one laboratory (ARC-OVI) has resulted in a much more prompt submission of samples in comparison to the situation seen during the 2007 mission;
- at central level an audit system has been put in place to monitor the performance of the provincial veterinary offices and there is an annual plan to this effect. The same official in charge of checking samples on arrival at the ARC-OVI is responsible for carrying out these audits;
- several central competent authority audits of the sampling progress in establishments have been carried out and documentary evidence of this was presented to the mission team and confirmed in the establishment visited. In those establishments which had not sent samples promptly to the laboratory, a recommendation was made to send samples on a weekly basis;
- in the establishment visited, samples had been sent within one or two days of sampling and in general, over all of the establishments there was a trend indicating that samples were being submitted to the laboratory more quickly in June in comparison to April;
- sampling in the establishments is unforeseen by the owner of the animals in accordance with Council Directive 96/23/EC and Commission Decision 98/179/EC. Sampling on farm has to be arranged with the farmer in advance (to ensure that there are adequate staff to facilitate sampling) however, the farmer is unaware that residues samples are to be taken as the residues programme overlaps with the avian influenza monitoring programme;
- relatively few samples were incorrectly taken (i.e. wrong matrix sampled), however

in several cases examined at random by the mission team, the sample documentation had been incorrectly filled in by the samplers – e.g. incomplete identification of the farm and failure to record either the individual tag numbers of the ostriches sampled or the batch number of the lot being slaughtered;

- the central competent authority has instituted a system whereby a representative of the central competent authority has to be present at the laboratory for the opening of samples. The central competent authority stated that this officer was present in the laboratory two to three times every week. It was noted that samples were 2008-2009 samples were registered on two occasions in May and four occasions in June. Laboratory staff stated that this was due to the unavailability of the central competent authority official during some of this period;
- laboratory staff stated that the registration of samples was estimated to take five days and was said to be due to shortage of staff. In one example of a sample which had been incorrectly taken (fat instead of liver) on 7 May, the sample had been registered on 23 May but only notified by the ARC-OVI to the central competent authority on 26 June. The central competent authority did not know if a request had been made to take the correct matrix. An undertaking was given to the mission team by ARC-OVI management that this would be shortened immediately;
- of the 57 ostrich tissue samples submitted to date in the 2008-2009 sampling year, results were available for 19 (33%) which were tested in the ARC-OVI. Thus 49% of the samples scheduled for the ARC-OVI (39) had been tested to date. No results were available for those samples sent to the other three subcontracted laboratories. In the private laboratory visited, the first three samples of ostrich tissues had been received from the OVI on 26 June and had not been analysed to date. The first set of results from the ARC-OVI was generated on 30 June 2008;
- regarding supervision of the NRCP, each province has a co-ordinator of the plan who is responsible for disseminating the plan to each of the state veterinary offices and establishments collecting samples. The co-ordinator collates data and acts as conduit for communication between the sampling officials and the central competent authority. In the province visited in which four of the seven ostrich and wild game meat processing establishments are located, information had been transferred to the sampling officials promptly and it could be seen that the provincial co-ordinator had liaised with the central competent authority.

5.1.3 Follow-up of non-compliant results

The mission team noted that:

- whilst there were no confirmed non-compliant results in either the 2007-2008 programme and to date in the current sampling year, a new VPN has been elaborated and is available on the central competent authority website (http://www.nda.agric.za/).

5.2 LABORATORIES

5.2.1 *General description*

A detailed description of the laboratory network was given in DG (SANCO)/2007-7585 MR Final. For the 2008-2009 plan, the ARC-OVI is the national reference laboratory and the main laboratory involved in the programme. Samples are also analysed in three other private laboratories plus the Agricultural Research Council – Institute for Soil Climate and Water which is responsible for chemical element analyses.

The mission team noted that:

- the list of private laboratories specified in the plan differs from those actually used. Two other private laboratories are involved, one of which is foreseen to carry out the testing scheduled for the Institute for Soil Climate and Water. There are no formal agreements between the ARC-OVI and these two private laboratories. (see Endnote)

5.2.2 *Residue Laboratory of the Agricultural Research Council's Onderstepoort Veterinary Institute (ARC-OVI)*

The mission team noted that:

- the ARC-OVI was restructured following the 2007 mission with a new laboratory head appointed and other technical staff employed. Management estimate that the residues laboratory will be fully staffed within the year;
- ARC-OVI management confirmed that high level meetings with the central competent authority had resolved previously identified problems with the funding of residues analysis for the NRCP;
- the laboratory is well equipped and several pieces of new equipment for residues analysis (e.g. LC-MS/MS) have been purchased but have yet to be commissioned. The laboratory has also been extended and is currently being fitted out;
- when the previous laboratory manager (and technical signatory) had left in 2007 the laboratory lost its ISO 17025 accreditation status. The laboratory was re-inspected in February 2008 by the South African National Accreditation System (SANAS) and was finally re-accredited in June 2008 with three methods currently included in the scope of accreditation;
- several method standard operating procedures (SOPs) were selected at random by the mission team and examined. In general for ELISA methods and HPLC methods matrix-matched standard curves are employed (self-recovery) and 'positive' and 'negative' controls are run with every batch of samples. Quality control charts are maintained for every method;
- the ELISA method for the beta-agonist zilpaterol was based on a commercially available test kit. The SOP was based on the kit instructions. Errors in the SOP of this accredited method and in the validation file were noted (on preparation of samples only bovine kidney is specified in the SOP but none of the other matrices

actually tested – e.g. ostrich serum and ostrich kidney). No data were available on cross-reactivities of the antibody used in the kit, method reproducibility had not been performed (only repeatability on a single day). The limit of detection (LoD) quoted was at 5 µg/kg which is in line with the Community Reference Laboratory recommendation for this substance though the LoD quoted in the NRCP was 14 µg/kg;

- the quality control chart (see Endnote)for the zilpaterol ELISA method showed that it was out of statistical control on two occasions, however this may have been exacerbated by the approach taken in plotting ELISA quality control charts whereby the difference between the optical density of the buffer solution and the response of the spiked sample was plotted instead of the difference between the optical density of the matrix blank and the response of the spiked sample. It was not always possible to see what corrective action had been taken when ELISA methods were out of statistical control, however in some cases new batches of test kits had been used for subsequent samples;
- similar quality control issues were noted for the ELISA method for sulphonamides (no longer used for the NRCP) and that for chloramphenicol, both of which were frequently out of statistical control. In the latter case the quality control chart covered all of the matrices tested (animal tissues from different species and honey) and thus it was not possible to ascertain the performance of the method for discrete matrices. Again it was possible that the approach taken in plotting ELISA quality control charts had exacerbated the problem;
- the laboratory regularly participates in internationally recognised proficiency tests as required of an accredited laboratory. Since 2007 to date it has participated in 12 rounds of the United Kingdom's Food Analysis Performance Assessment Scheme (FAPAS), of which results have been satisfactory for eight. In the four proficiency tests with unsatisfactory results including the HPLC method for sulphonamides which had two consecutive unsatisfactory results for different reasons, some non-routine methods had been used. Corrective actions were recorded as required under the ISO standard;
- for methods currently unavailable in ARC-OVI, laboratory management stated that there are agreements with other laboratories. The mission team saw one of these documents with the private laboratory responsible for testing the majority of Group A samples and the on-farm ostrich samples. It is still in draft form though it has been agreed by letter with the other laboratory but not yet signed. Turnaround times from sample receipt to reporting were specified in the agreement;
- methods used in the subcontracted laboratories are obliged to be fully validated and the management of the ARC-OVI stated that there are declarations to this effect from each of the laboratories. This was not found to be the case by the mission team as in the private laboratory visited, not all of the methods used were fully validated.

5.2.3 Private laboratory for residues analysis

For the 2007-2008 programme this laboratory carried out all of the testing of the on-farm ostrich serum samples and is also scheduled to do all of this testing in the 2008-2009 programme. For the 2008-2009 programme the laboratory is listed in the plan as being also scheduled to test ostrich and wild game tissue samples for groups A1, A2, A3, A4, A5, A6 (nitroimidazoles only), B2b and B2c (carbamates only).

The mission team noted that:

- the laboratory is equipped with state-of-the-art instruments including LC-MS/MS and GC-MS/MS and an adequate number of experienced staff is in place;
- for the 2008-2009 programme the laboratory is testing fewer substance groups compared to the plan. Groups A1, A3 (androgenic steroids), A4 and A5 are being tested for in another private laboratory which is not currently identified in the plan;
- method SOPs were in place for all methods;
- there was a validation SOP in place which detailed the calculation of performance parameters such as CC-alpha and CC-beta. However repeatability and reproducibility were not included in the procedure;
- validation data were available for Group A2, A3 (gestagens), A6 (nitroimidazoles) and B2c (carbamates) in animal tissues. The methods for nitroimidazoles, gestagens and carbamates in tissue samples were examined by the mission team. Comprehensive validation files were not filed in the private laboratory but were stored in the ARC-OVI and some of these were presented during the inspection. The gestagens method used megestrol acetate as an internal standard even though this substance is freely available on the market for use in cattle and as such is not really suitable as an internal standard. CC-alpha, CC-beta, repeatability and reproducibility had been calculated for the method with the use of a commercially available statistical software package. Notwithstanding the internal standard issue, the method was fit for purpose;
- the software package had not been used for the calculation of performance parameters for either the nitroimidazoles or the carbamates methods. The limited validation data available demonstrated that the carbamates method was fit for purpose;
- the 5-hydroxy nitroimidazole metabolites (marker residues) were not being analysed for. Thus the method was not fit for purpose for dimetridazole as the hydroxy metabolite is the major residue detected in animals tissues. This omission is less important for metronidazole and ronidazole. This deficiency was also detected in the 2007 mission; (see Endnote)
- no validation files were available for the two LC-MS/MS methods used to screen the serum samples for a range of Group A substances. It could be inferred from the raw data that the methods used for analysis of serum samples were capable of meeting the limits specified in the plan for ostriches;
- laboratory staff identified haemolysis of samples and small sample volumes as a major impediment in analysing all of the ostrich serum samples received in 2007-2008 for all of the substances programmed. The central competent authority

was aware of the problem and had instructed field staff to take an adequate volume of serum and use the appropriate sampling containers to minimise the possibility of haemolysis;

- the serum samples from the 2007-2008 programme were completed in mid June. For the 2008-2009 programme, no analysis had been carried out to date. The first results for carbamates and gestagens are expected in mid August.

5.3 VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

5.3.1 Authorisation of veterinary medicinal products, medicated feedingstuffs and feed additives

A detailed description of the system for authorising veterinary medicinal products was given in DG (SANCO)/2007-7585 MR Final. The system has not changed substantially since the 2007 mission. Essentially pharmacologically active substances may either be registered under the Medicines and Related Substances Act 101 of 1965 (Act 101) or under the Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act 36 of 1947 (Act 36). All veterinary drugs on the market, registered under Acts 36 and 101, are listed in the 'Index of Veterinary Specialities' which is published quarterly by the pharmaceutical industry.

The mission team noted that:

- draft legislation on the authorisation of veterinary medicinal products has been produced and is currently out for public consultation. This aims to bring all veterinary medicines under one regulatory system (i.e. abolish the separation of products under Acts 36 and 101);
- both of the two previously marketed hormonal growth promotants for ostrich are no longer authorised and this was confirmed by the mission team in both wholesalers visited;
- in addition the South African Ostrich Business Chamber had written to each of its members reiterating the fact that these implants should not be used in ostrich production;

5.3.2 Controls on the distribution and use of veterinary medicinal products

A detailed description of the distribution system for veterinary medicinal products and the official controls applied was given in DG (SANCO)/2007-7585 MR Final and has not changed since the 2007 mission.

The mission team noted that:

- registered export-approved ostrich farms are obliged to individually identify the animals destined for slaughter from four months of age. Following the 2007 mission, the South African Ostrich Business Chamber has obliged all of the farmers to keep records of veterinary medicines used. On the ostrich farm visited, animals

examined were tagged and medicines records were maintained and up to date;

- the range of substances commonly used on ostrich farms includes antihelmintics (in particular tapeworm treatments with praziquantel) and ectoparasiticides for tick control (in particular permethrins and amitraz). The major clinical disease problem is air saculitis which is stress related and treated with macrolide antibiotics (in particular tylosin). It is noted that with the exception of praziquantel, all of the other substances are included in the residue plan;
- as a consequence of the control measure for Crimean-Congo Haemorrhagic fever (treatment with ectoparasiticides followed by quarantine in a segregated facility for two weeks prior to slaughter during which no further treatment with veterinary medicinal products is allowed), the withdrawal periods of all other authorised veterinary medicines for ostriches (including those commonly used) are automatically respected;
- the system of wild game husbandry was explained to the mission team on the farm visited. Wild game for meat production are not treated with veterinary medicinal products as there is no clinical need and it is not economically viable. The only animals treated are those species which are valuable as game trophies (e.g. Sable antelope, Roan Antelope and rhinoceros) and from which meat is not used for human consumption. The main treatment applied to such animals is the use of neuroleptanalgesics for immobilisation, transport to other farms and other veterinary procedures. It was seen in one of the wholesalers visited that significant quantities of neuroleptanalgesics had been ordered by veterinarians specialising in wild game practice. This was confirmed by the mission team on the wild game farm visited;
- inspections of both of the wholesalers visited by the mission team had been carried out by the central competent authority under Act 36. Reports of the inspections were available in one of the premises visited;
- all veterinary medicinal products in stock which were examined by the mission team were registered either under Act 36 or Act 101.

6 Conclusions

6.1 National Residue Control Plan

1. The 2007-2008 plan for both ostriches and wild game was largely completed by the end of the financial year though initial delays were seen in the progress of the wild game programme. The absence of non-compliant findings in these programmes gives confidence in the residues status of both ostrich and wild game meat.
2. Nothwithstanding the errors made in the calculation of the correct number of samples to be taken under the on-farm programme for ostriches, and the absence of formal validation data for some of the tests carried out under the programme and problems with sample quality experienced by the laboratory, the absence of any non-compliant results for residues of hormonal growth promotants and

beta-agonists, provides additional guarantees on the residues status of this commodity and evidence that these substances are not being used illegally or inadvertently in ostrich production.

3. In comparison to the situation observed in the 2007 mission, improvements have been confirmed in the planning of the NRCP, its implementation and procedures in place for carrying out follow-up investigations in case of non-compliant results.
4. Notwithstanding the technical errors in the information provided in the 2008-2009 plan, the plans for both ostrich and wild game are comprehensive in coverage and comply with Council Directive 96/23/EC. However, the decision of the central competent authority to test wild game species for an extensive range of residues which are extremely unlikely to be present in meat derived from those animals, goes beyond Community requirements and the additional guarantees on residues status of this commodity are therefore superfluous.
5. The current allocation of ostrich tissue samples to the establishments has inadvertently led to clustering of sampling from some farms in some establishments. This easily rectifiable problem means that implementation of sampling does not comply with either national guidelines or Community requirements and reduces the efficacy of the current plan.
6. For the 2008-2009 plan samples are being taken and submitted to the laboratory more promptly than in previous years and the central competent authority is actively auditing the progress being made by the provincial competent authorities in carrying out sampling.
7. Problems in the timely registration and analysis of these samples in the laboratories have persisted and have not been actively addressed by the central competent authority. These issues if not dealt with have the potential to undermine the effectiveness of the programme.

6.2 LABORATORIES

1. The fact that the laboratories carrying out the majority of the testing of samples under the NRCP are accredited gives the central competent authority a degree of confidence in the quality of results from these laboratories. However shortcomings in the performance of the laboratories visited and validation of analytical methods raise doubts on the performance of some analytical methods.
2. The absence of any formally agreed contracts between the ARC-OVI and other laboratories has the potential to delay progress in the implementation of testing under the 2008-2009 residues programme and thus could hamper the effective execution of the NRCP.

6.3 VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

1. Competent authority commitments on the prohibition of hormonal growth promotants in ostriches have been honoured and the results of testing have confirmed that these products have not been used in ostrich production in accordance with the requirements of Article 11 of Council Directive 96/22/EC.
2. The co-operation of the industry has been an important factor in implementing the hormonal growth promotant prohibition in practice and establishing the maintenance of medicines records on all ostrich farms – a key Community requirement (Article 10 of Council Directive 96/23/EC).

6.4 Overall Conclusion

The overall situation regarding residues controls in farmed and wild game has improved since 2007. Guarantees provided to the Commission services have been largely implemented. Notwithstanding the shortcomings in laboratory performance identified during the mission, with regard to ostrich and wild game for meat production, the current residue control system in South Africa provides guarantees with an effect at least equivalent to those provided for by Council Directive 96/23/EC.

7 Closing Meeting

A closing meeting was held on 7 July 2008 with representatives of the central competent authority. At this meeting, the inspection team presented the main findings and preliminary conclusion of the mission. The central competent authority did not express any major disagreement with the findings and preliminary conclusion and undertook to address the deficiencies identified during the course of the inspection.

8 Recommendations

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below (insofar as these apply to products of animal origin eligible for export to the EU), within 25 working days of receipt of this mission report.

No.	Recommendation
1	Correct factual inaccuracies in the 2008-2009 residue plan presented to the Commission services (e.g. marker residues, laboratories employed, analytical methods used.
2	Consider testing ostriches for residues of praziquantel in line with the use patterns of this drug.
3	Take account of husbandry practices in the structure of the plan for wild game and assess the risk of veterinary medicinal products being used in those species

No.	Recommendation
	hunted for meat production in light of the Community requirement (Annex IV to Council Directive 96/23/EC) and amend the plan accordingly.
4	Consider reviewing the on-farm programme for ostriches to ensure that an adequate number of samples of sufficient quality are taken in order to meet the epidemiological requirements established by the central competent authority.
5	Reallocate sampling in establishments in order to minimise the likelihood of clustering of sampling. (Clustering of sampling is to be avoided in accordance with Council Directive 96/23/EC, Commission Decision 98/179/EC and existing national guidelines on sampling)
6	Ensure that samples are registered in the ARC-OVI promptly, forwarded (if necessary) by ARC-OVI to sub-contracted laboratories without delay and analysed as soon as possible in order to facilitate effective follow-up actions in cases of non-compliance.
7	Ensure that all analytical methods listed in the national residue control plan are fit for purpose and validated to a standard equivalent to Commission Decision 2002/657/EC.
8	Ensure that all tasks delegated to each of the laboratories carrying out residues testing under the national residue control plan are clearly defined and agreed between the central competent authority and each laboratory (numbers of samples to be analysed, turnaround time from sample receipt to reporting etc) in order to provide guarantees with an effect at least equivalent to Council Directive 96/23/EC.

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

http://ec.europa.eu/food/fvo/ap/ap_south_africa_7932_2008.pdf

9 ENDNOTES

Concerning	Detail
Section 5.1.1	In its response to the draft report the South African Competent Authority stated that there are no current known methods for these metabolites in South Africa, and other avenues are being explored with a view either to sending these samples overseas or obtaining the method from elsewhere.
Section 5.1.1	In its response to the draft report the South African Competent Authority resubmitted the 2008 National Residue Control Plan and this change is reflected in the plan.
Section 5.1.1	In its response to the draft report the South African Competent Authority stated that this compound is now included in the 2008 National Residue Control Plan. (See response to recommendation 7).
Section 5.1.2	In its response to the draft report the South African Competent Authority

Concerning	Detail
	has reduced the number of samples to two per export farm following epidemiological advice. The number of registered export ostrich farms has also been reduced from 463 to 349 since 114 farms which have been inactive for the last 12 months have been deregistered. (See response to recommendation 4).
Section 5.2.1	In its response to the draft report the South African Competent Authority has indicated that formal agreements with a number of private laboratories are in the process of being negotiated and that one of the private laboratories is no longer involved in the programme. (See response to recommendation 8).
Section 5.2.2	In its response to the draft report the South African Competent Authority has indicated that quality control issues are beign addressed in the laboratories. (See response to recommendation 7).
Section 5.2.3	In its response to the draft report the South African Competent Authority has indicated that the 5-hydroxy metabolites have been ordered and that all requisite standards will be received by end August 2008. (See response to recommendation 7).

ANNEX 1 - LIST OF LEGISLATION REFERENCED IN THE REPORT

Reference	OJ Ref.	Detail
Audits by the Commission Services		
Regulation (EC) No 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
Decision 98/140/EC	OJ L 38, 12.2.1998, p. 14–16	98/140/EC: Commission Decision of 4 February 1998 laying down certain detailed rules concerning on-the-spot checks carried out in the veterinary field by Commission experts in third countries
Food Law		
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 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
Residues Monitoring and Sampling		
Directive 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

Reference	OJ Ref.	Detail
Decision 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
Decision 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
Status of Residues Monitoring Plans for Third Countries		
Decision 2004/432/EC	OJ L 154, 30.4.2004, p. 44–50, corrected and re-published in OJ L 189, 27.5.2004, p. 33	2004/432/EC: Commission Decision of 29 April 2004 on the approval of residue monitoring plans submitted by third countries in accordance with Council Directive 96/23/EC
Validation of analytical methods for residues		
Decision 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		
Directive 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 medicines in food of animal origin		
Regulation (EC) No 2377/90	OJ L 224, 18.8.1990, p. 1–8	Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin
Maximum Residue Levels for pesticides in food of animal origin		
Directive 86/363/EEC	OJ L 221, 7.8.1986, p.	Council Directive 86/363/EEC of 24 July 1986 on the fixing of maximum levels for pesticide residues

Reference	OJ Ref.	Detail
	43–47	in and on foodstuffs of animal origin
Maximum Limits for contaminants		
Regulation (EC) No 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		
Directive 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
Sampling methods and methods of analysis for contaminants in foodstuffs		
Regulation (EC) No 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
Regulation (EC) No 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
Regulation (EC) No 1883/2006	OJ L 364, 20.12.2006, p. 32–43	Commission Regulation (EC) No 1883/2006 of 19 December 2006 laying down methods of sampling and analysis for the official control of levels of dioxins and dioxin-like PCBs in certain foodstuffs
Sampling methods for pesticides in foodstuffs		
Directive 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