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FINAL REPORT OF A MISSION
CARRIED OUT IN
MEXICO
FROM 13 FEBRUARY TO 21 FEBRUARY 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 Authorities of Mexico are given as endnotes.

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) mission to Mexico, carried out from 13 to 21 February 2008 as part of the published programme of FVO inspections on residue controls in third countries.

The objective of the mission was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, including the controls on the distribution and use of veterinary medicinal products and feed additives, the use of which may give rise to residues in such products. The evaluation was based on the standards set out in Council Directive 96/23/EC, and other relevant Community legislation in this field, including legislation on the control and distribution of veterinary medicinal products. The mission assessed the performance of the competent authorities and other officially authorised entities involved in residues and veterinary medicinal product controls and the legal and administrative measures put in place to give effect to the relevant Community requirements with regard to import of food of animal origin into the EU. Attention was paid to examining the implementation of corrective actions promised by the competent authority in response to recommendations made in the report of a previous FVO mission to Mexico (DG(SANCO)/7713/2005) in September 2005.

This mission identified several shortcomings in the application of residues and veterinary medicines controls, in respect of commodities currently exported to the EU or which are planned to be exported. Several of these shortcomings were present also at the time of the previous FVO residue mission in 2005 and not rectified in line with the deadlines set by the Competent Authority in the action plan provided in response to the recommendations of the previous mission report. In particular, hormones and beta-agonists are authorised for growth promotion in inter alia horses (meat of which is currently exported to the EU), pigs and bovines. In the absence of a functioning 'split system', ensuring that animals which may be slaughtered for the EU market have not been treated with such substances, Mexico does not comply with Community requirements in Article 29 of Council Directive 96/23/EC and Council Directive 96/22/EC concerning the export of meat from potentially treated animals. There are no follow-up procedures in place to investigate the reasons for residues detected under the national residue control plan and no infringement procedures, which means that no actions are taken to prevent recurrence of the violations. This is exacerbated by weak controls on the use of veterinary medicines and failure to implement or control the prescription system for veterinary medicines which has been legally required for several years. There is also limited laboratory capability at present, which limits the scope of substances included in the residue control programme to only a small fraction of those veterinary medicinal products authorised for the tested species. Regarding the commodities for which Mexico is listed in Commission Decision 2004/432/EC, the guarantees provided by the Competent Authority regarding the residue status of honey and eggs can be considered equivalent to the minimum levels laid down in Community legislation while for (aquaculture) shrimp and meat of equidae improvements are necessary before the Competent Authority can provide such guarantees. With regard to pigs and poultry, for which Mexico is not listed in Commission Decision 2004/432/EC, the residue control in these commodities is not in line with the

requirements of Article 29 of Council Directive 96/23/EC.

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ABBREVIATIONS & SPECIAL TERMS USED IN THE REPORT

Abbreviation	Explanation
AOZ and AMOZ, AHD and SEM	Marker residues of the nitrofurans furazolidone, furaltadone, nitrofurantoin and nitrofurazone respectively
CA	Competent Authority
CCA	Central Competent Authority
CENAPA	<i>Centro Nacional de Servicios de Constatación de Salud Animal</i> - National Centre for Animal Health Certification Services
CONAPESCA	<i>Comisión Nacional de Acuacultura y Pesca</i> - National Fishing and Aquaculture Commission
DG(SANCO)	Health and Consumer Protection Directorate General
EC	European Community
EEC	European Economic Community
EMA	<i>Entidad Mexicana de acreditación A.C.</i> - Mexican National Accreditation body
EU	European Union
FVO	Food and Veterinary Office
Group A, B	<p>Categories of substances listed in Annex I to Council Directive 96/23/EC:</p> <p>A1 Stilbenes</p> <p>A2 Thyrostats</p> <p>A3 Steroids</p> <p>A4 Zeranol</p> <p>A5 Beta-agonists</p> <p>A6 Substances listed in Annex IV to Council Regulation (EEC) No 2377/90</p> <p>B1 Inhibitors (antimicrobials)</p> <p>B2a Anthelmintics</p> <p>B2b Coccidiostats</p> <p>B2c Carbamates and pyrethroids</p> <p>B2d Sedatives</p> <p>B2e NSAIDs</p> <p>B2f Others (e.g. corticosteroids)</p>

Abbreviation	Explanation
	B3a Organochlorines including PCBs B3b Organophosphorus compounds B3c Chemical elements B3d Mycotoxins B3e Dyes B3f Others
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
MRL	Maximum Residue Limit
NRCP	National Residue Control Plan
PROTLCUEM	<i>Proyecto de Facilitación del Tratado de Libre Comercio entre México y la Unión Europea</i> , Co-financed project for the facilitation of free trade between Mexico and the EU.
RASFF	Rapid Alert System for Food and Feed
SAGARPA	Secretaria de Agricultura, Ganadería, Desarrollo Rural, Pesca y Alimentación - Agriculture, Livestock, Rural Development, Fisheries and Food Secretariat
SENASICA	<i>Servicio Nacional de Sanidad, Inocuidad y Calidad Agroalimentaria</i> - National Service for Health, Food Safety and Food Quality
SOP	Standard Operating Procedure
TIF	<i>Tipo Inspeccion Federal</i> - Federal Inspection type (of establishment)
VMP	Veterinary Medicinal Product

1 INTRODUCTION

The mission took place in Mexico from 13 to 21 February 2008. The mission team comprised two inspectors from the Food and Veterinary Office (FVO) and one national expert. 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 13 February 2008 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 held.

2 OBJECTIVES OF THE MISSION

The objective of the mission was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, including the controls on the distribution and use of veterinary medicinal products (VMPs) and feed additives, the use of which may give rise to residues in such products. The mission was based on the evaluation of the equivalence of Mexico's standards to Council Directive 96/23/EC and other relevant Community legislation in this field, including legislation on the control and distribution of VMPs. The mission focussed on the roles of the competent authorities at central and regional levels, the legal and administrative measures in place to give effect to the relevant EU requirements, controls with regard to residues and VMPs and their operation, and the performance of residue laboratories. Attention was paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues mission to Mexico (DG (SANCO)/7713/2005) in September 2005. The table below lists sites visited and meetings held in order to achieve that objective.

Meetings/Visits		n	Comments
Competent Authorities	Central	2	Opening and closing meetings with the National Service for Health, Food Safety, and Food Quality (SENASICA) under the Agriculture, Livestock, Rural Development, Fisheries, and Food Secretariat (SAGARPA)
	Regional	2	Meetings at the SAGARPA State Offices in Zacatecas and Jalisco
Laboratories		2	Two meetings with the National Centre for Animal Health Certification Services (CENAPA)
Farms		1	One major poultry farm
Establishments		2	One meeting with the official veterinarian from an egg processing plant; one horse slaughterhouse exporting horse meat to the EU
Other sites		3	One professional feed mill manufacturing medicated pre-mixtures for bovines, pigs and poultry; one wholesaler/pharmacy dealing with veterinary medicinal products; one horse dealer providing horses for slaughter for the EU market

3 LEGAL BASIS FOR THE MISSION

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

- Article 21 of Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products, and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC;
- Article 45 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules;
- Commission Decision 98/139/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 Member States.

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 SUMMARY OF PREVIOUS FVO MISSION RESULTS

This mission is the second residues mission to Mexico. The previous FVO residues mission report (DG(SANCO)/7713/2005 MR Final) identified severe deficiencies in the area of residues and VMP control. That report and the action plan submitted by the CA in response to the recommendations in the report have been published on the website of the Health and Consumer Protection Directorate-General.

4.2 COUNTRY STATUS IN RELATION TO SUBMISSION OF RESIDUES CONTROL PLAN

In 2002 Mexico was de-listed for pig meat. Following the previous FVO residues mission in 2005 the Mexican Competent Authority requested de-listing of milk and bovine, poultry and rabbit meat. In commission Decision 2004/432/EC (Official Journal L154, 30/04/2004 p. 44), as last amended by Commission Decision 2008/105/EC (Official Journal L38, 13/02/2008, p. 9), the Mexican National Residue Control Plan (NRCP) is approved in accordance with Council Directive 96/23/EC for equidae, aquaculture products, eggs and honey. The 2007 NRCP and 2006 results were submitted to the Commission Services in March 2007. In 2007 the Mexican CA applied for re-listing in Commission Decision 2004/432/EC of pig and poultry meat.

4.3 RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS FOR CONSIGNMENTS FROM MEXICO

In 2003 and 2004 seven residues findings in consignments from Mexico were reported under the RASFF. Five notifications concerned streptomycin residues in honey and one reported two different sulphonamides (sulphamerazine and sulphadimidine), also in honey. In addition, one RASFF alert in 2003 notified the finding of a nitrofurantoin metabolite (AOZ) in spray-dried egg albumin. There were no RASFF notifications in 2005-2007, with regard to residues of veterinary medicines or contaminants, in commodities imported from Mexico.

4.4 PRODUCTION AND TRADE INFORMATION

Detailed information on the quantities of food commodities (of animal origin) produced in Mexico in 2006, as well as those exported to the EU in 2007 was supplied by the Mexican Competent Authority as follows:

Commodity	National production	Export to the EU (tons)
	2006	2007
Equidae	32,777 animals	4,706
Pigs	14,276,329 animals	-
Poultry	2,463,797 ton	-
Eggs (dried egg albumin exported)	2,290,062 ton	201
Shrimp (farmed)	88,000 ton	95 (Jan-Aug)
Honey	51,419 ton	27,997

5 MAIN FINDINGS

5.1 LEGISLATION

With regard to the use of hormonal substances and beta-agonists for growth promotion, the use of the beta-agonist clenbuterol, chloramphenicol and crystal violet in feedingstuffs was banned for food producing animals by the Mexican Official Standard (NOM), NOM-061-ZOO-1999. In June 2004 diethylstilbestrol was banned for all animals and clenbuterol, metronidazol, tinidazol, rodinazol, dimetridazole (nitroimidazoles), chloramphenicol and olaquinox were banned for use in all food producing animals, except horses for which use of metronidazole would still be allowed (NOM-064-ZOO-2000). There are no restrictions in national legislation with regard to the use of natural or synthetic steroids, zeranol and beta-agonists other than clenbuterol, as growth promoters for food producing animals. Nor are thyrostatic substances or stilbenes other than diethylstilbestrol specifically prohibited under Mexican legislation.

Since the FVO residues mission in 2005, two new Laws with relevance for the residues sector have been passed in Mexico. The Sustainable Fisheries and Aquaculture General Law of 2007 transfers the responsibility for all measures and actions related to food safety in aquaculture and fisheries products from the National Fishing and Aquaculture Commission (CONAPESCA) to the National Service for Health, Food Safety, and Food Quality (SENASICA), thus giving SENASICA the responsibility for residues control in all commodities. The Federal Law of Animal Health of 25 July 2007 provides *inter alia* the legal basis for SENASICA to define and conduct all components of a residue control programme, to establish maximum residue limits for all commodities, to set withdrawal times for veterinary medicinal products (VMP), to ban active substances, to revoke licences for VMPs, to issue licences for VMPs for a specific time period, to require traceability throughout the food chain and to define infringement procedures in case of violations. No national regulations have yet been issued detailing how e.g. infringement

procedures should be implemented.

In addition, NOM-004 is in the final stages of a major amendment which will introduce national maximum tolerance limit for all substances and all commodities included in the 2007 NRCP. For substances which have a "zero tolerance", the NOM will list minimum required detection levels. The CA expects this new version of the NOM to enter into force at the end of 2008, which would make the new maximum tolerance levels legally binding in the 2009 NRCP. The maximum tolerance limits will be listed in an annex to the NOM which, according to the CA, will make it possible to amend the list when necessary.

The mission team noted that:

- until the new version of NOM-004 has entered into force, NOM-004-ZOO-1994 as amended in 2001 is the legal basis for residues control. This NOM covers bovines, swine, equidae, sheep/goat, farmed deer and poultry. The listed maximum tolerance limits cover only a few pharmacologically active substances and contaminants and they are often higher than those listed in Community legislation, as previously described in the FVO report DG SANCO 7713/2005, (hereafter referred to as the 2005 residue report);
- for three of the four commodities exported to the EU (eggs, honey and aquaculture products) there is currently no national legislation outlining the details of a residue control and no legally binding maximum tolerance limits;
- the draft for the new NOM-004 comprises maximum tolerance limits for zilpaterol in bovines and ractopamine in bovines and pigs, which are currently not exported to the EU. Both substances are banned in the EU;
- a number of the maximum tolerance limits listed in the draft for the new version of NOM-004 are not in line with the listed in Council Regulation 2377/90, in particular with regard to differences between species in the Community legislation. For example, maximum tolerance limits are laid down for sulphonamides in honey and eggs as well as for a number of anthelmintics, tranquilisers and pyrethroids for equidae, none of which have maximum residues limits (MRL) laid down in Community legislation;
- the new NOM-004 will introduce maximum tolerance limits only for the substances included in the 2007 NRCP, for which methods of detection are available in the laboratory, and not for all the pharmacologically active substances authorised for use in food producing animals in Mexico;
- in their response to recommendations 2 and 3 in the 2005 report (DG SANCO 7713/2005) the CA stated that the updated NOM-004 would be harmonised with Community legislation and that it would be adopted in 2006.

5.2 NATIONAL RESIDUE CONTROL PLAN

5.2.1 Planning

Within The Agriculture, Livestock, Rural Development, Fisheries, and Food Secretariat (SAGARPA) the National Service for Health, Food Safety, and Food Quality (SENASICA) is responsible for the drafting of the National Residue Control Plan (NRCP) with the assistance of the Farm and Field, Aquaculture and Fisheries Food Safety General Directorate (DGIAAP) and the national reference laboratory, i.e. the National Centre for Animal Health Certification services (CENAPA). An Inter-Ministerial Committee has been set up to plan, monitor and evaluate the NRCP.

This Interministerial Committee to Evaluate and Monitor National Programmes for Toxic Residues and Contaminants in Animal Products and By-Products (*Comité Intersecretarial para la Evaluación y Seguimiento de los Programas Nacionales de Residuos Tóxicos y Contaminantes en Productos y Subproductos de Origen Animal*) comprises several experts from the relevant competent authorities as well as representatives of stakeholders.

The mission team noted that:

- a central co-ordinator for the NRCP had been appointed directly prior to this mission;
- the general layout of the NRCP and the range of commodities included in the plan are in line with EU requirements. In addition, each sample is tested for all the substances included in the NRCP for that particular commodity;
- the stakeholders in the Inter-Ministerial Committee include representatives for the farmers and for the pharmaceutical industry, who are thereby informed about the scope and limitations of the residue controls;
- all responsible authorities are involved in the planning of the NRCP. Most relevant data are available to the planning committee with the exception of usage pattern and consumption figures for VMPs. These have not been made available to the planning committee in spite of the fact that the pharmaceutical industry is represented in the planning committee;
- in their response to Recommendation 4 in the 2005 mission report the CA stated that sample numbers for commodities intended for export to the EU would be based on Council Directive 96/23/EC. However, in the 2007 NRCP this is the case only for equidae, honey and eggs.
- for shrimp the sample numbers in the 2007 NRCP was 100. Based on Council Directive 96/23/EC ca 350 shrimp samples would be required. If the Codex approach is used, the 100 samples are aimed at detecting at least one violation with a confidence level of 95% provided that the violation prevalence in the sampled population is at least 5%. This is not an approach which can be considered equivalent to the targeted sample numbers required under Council Directive 96/23/EC;
- since the 2005 residue mission, a number of species/analyte group combinations specified in Council Directive 96/23/EC have been added to the NRCP. However, the following are not covered in the 2007 NRCP for the species relevant for this mission:
 - o A6: nitroimidazoles are not included, although essential to include for equines

and deemed highly desirable to include for eggs;

- o B3e: malachite green/leucomalachite green, although essential to include for aquaculture products. The CA stated that these dyes would be included in the 2008 NRCP;
- of the active substances which have been prohibited in Mexico, nitroimidazoles and olaquinox have never been tested for in the NRCP;
- residues of a substantial number of relevant pharmacologically active substances, which are authorised for use in food producing animals, are not tested for under the NRCP. These include for example:
 - o for equidae: boldenone (A3), ampicillin, ceftriazone, gentamicin, sulphamethoxazole, tylosin (B1), closantel, febantel, imidocarb (B2a), acepromazine (B2d), phenylbutazone, metamizol/dipyrone (B2e), dexamethason (B2f),
 - o for farmed shrimp: norfloxacin, florfenicol, flavophospholipol, oxytetracycline (B1);
 - o for eggs: amoxicillin, ampicillin, enrofloxacin, florfenicol, gentamicin, lincomycin, norfloxacin, thiamphenicol and numerous others (B1);

With regard to commodities for which Mexico is currently not listed in Commission Decision 2004/432/EC, the mission team noted that:

- for pigs the 300 samples in the 2007 NRCP were based on Codex Alimentarius (Joint FAO/WHO Food Standards Programme. Codex Alimentarius, Volume 3. Residues of Veterinary Drugs in Foods. 2nd Ed., 1996) aimed at detecting at least one violation with a confidence level of 95% if the violation prevalence in the randomly sampled population is at least 1%. This approach is usually considered to give a detection level which is equivalent to the targeted sample numbers required under Council Directive 96/23/EC. Based on Council Directive 96/23/EC ca 7,000 targeted samples would be required;
- for poultry the sample number in the 2007 NRCP was 100. Based on Council Directive 96/23/EC ca 12,000 poultry samples would be required. If the Codex Alimentarius approach is used, the 100 samples are aimed at detecting at least one violation with a confidence level of 95% provided that the violation prevalence in the sampled population is at least 5%. This is not an approach which can be considered equivalent to the targeted sample numbers required under Council Directive 96/23/EC;
- A6: nitroimidazoles are not included, although essential to include for pigs and poultry;
- residues of a substantial number of relevant pharmacologically active substances, which are authorised for use in food producing animals, are not tested for under the NRCP. These include for example:
 - for poultry: amoxicillin, ampicillin, enrofloxacin, florfenicol, gentamicin, lincomycin, norfloxacin, thiamphenicol and numerous others (B1);

- for pigs: boldenone (A3), numerous antimicrobials (B1), clorsulon (B2a), flumethrin (B2c), acepromacine (B2d), phenylbutazone (B2e) and carbadox (B2f);
- on-farm sampling for group A substances is not planned (Council Directive 96/23/EC foresees on-farm sampling for bovines, porcines and poultry).

5.2.2 Implementation

The NRCP is broken down by SENASICA to detail number of samples, sampling dates, commodities, and establishments/farms for each State. These sampling plans are distributed during March to the coordinators for the sampling in each State. The plans for sampling in TIF slaughterhouses and the TIF egg processing establishment are sent to the State TIF Co-ordinators. For aquaculture shrimp, the plans are sent to the Aquaculture Health State Commissions and to the National Commission for Aquaculture and Fisheries, while for honey the plans are sent to the SAGARPA State offices and to the States' co-ordinators for the Control of the African Bee.

All samples are collected by official staff and all samples can be traced back to the farm of origin. All samples, accompanied by uniform sample forms, are sent directly to the CENAPA laboratory according to instructions in the official sampling letters. In contrast to the situation in 2005, all sampling and analyses are now financed by the Government.

The mission team noted that:

- all samples are taken by official staff and samples can be traced back to the farm of origin;
- sampling starts in March/April and finishes in mid December. This is an improvement in the sample distribution compared to 2005 but no sampling is planned for the first 2.5 months of the year ([see CA comment at the end of this report](#));
- samples for the NRCP are split at slaughterhouses, one portion being held frozen under the supervision of the Official Veterinarian in the TIF establishment, the other portion being sent to CENAPA. Samples are packed into polystyrene containers and sealed by fixing a label, signed by the Official Veterinarian, to the package. The signed label is then covered with transparent sealing tape. However, the tape and seal can be removed and replaced which makes it impossible to check if the sample has been tampered with between packaging and arrival in the laboratory ([see CA comment at the end of this report](#)).

5.2.3 Supervision of implementation

SENASICA is the over-all coordinator of the supervision of the NRCP. The NRCP coordinator in SENASICA is responsible for the supervision of shrimp sampling. The central TIF coordinator in SENASICA is responsible for the supervision of the sampling of meat and eggs. The Federal Honey coordinator is responsible for the supervision of the honey sampling. There are also State TIF Supervisors who are responsible for the supervision of sampling in the TIF establishments.

The mission team noted that:

- in October 2007 CENAPA had presented an overview to the coordinators at central level of how many samples had been received for analysis per commodity. Apart from this summary no evidence was seen of supervision by State supervisors or the federal coordinators during the sampling year ([see CA comment at the end of this report](#));
- sampling during 2007 had mostly been performed in accordance with the sampling plans;
- for equidae, aquaculture shrimp and honey the number of samples analysed in 2007 were in accordance with what was planned in the NRCP;

With regard to commodities for which Mexico is currently not listed in Commission Decision 2004/432/EC, the mission team noted that:

- for bovines and pigs, there had been 5% and 12% under-sampling, respectively, in 2007. The central TIF coordinator stated that the under-sampling of pigs had been caused by the closure of one slaughterhouse. The samples assigned to this slaughterhouse had not been re-assigned to other slaughterhouses.

5.2.4 Other residues control programmes

5.2.4.1 Official testing of honey before export

As described in the report of the 2005 residue mission, a prerequisite for the issuing of health certificates is a compliant residue testing result for chloramphenicol, streptomycin, fluvalinate, coumaphos, nitrofurans and sulphonamides in each lot. Sulphonamides and nitrofurans had been added to the requirements since the 2005 residue mission. For compliance no detectable levels of chloramphenicol, streptomycin, fluvalinate or nitrofurans are accepted. For sulphonamides (and coumaphos) a tolerance level of 0.1 mg/kg is applied, although no residues of antimicrobials in honey are acceptable in the EU.

5.2.4.2 Official testing for clenbuterol in bovines

The competent authority informed the team that a separate testing programme had been implemented to control the ban on the beta-agonist clenbuterol in bovines, for which Mexico is currently not listed in Commission Decision 2004/432/EC. Clenbuterol was prohibited through NOM-064-ZOO-2000. Results from this programme showed that many findings of clenbuterol had been made. An advertising campaign about the prohibition had started when the Federal Law of Animal Health of 2007 provided a legal basis for infringement procedures in case of violations.

5.2.4.3 Establishment own-checks

Establishments may operate own-control systems for *inter alia* residues and other quality parameters. There is no obligation to inform the competent authority of the extent of the

programme or non-compliant test results.

5.2.5 Follow-up of non-compliant results

SENASICA is responsible for the follow-up of non-compliant results. Compliant test results for meat and eggs are notified by the laboratories to the owner and to the official veterinarian of the TIF establishment, with copies to SENASICA. Non-compliant results are immediately reported from CENAPA to SENASICA and to the TIF State supervisor who will forward it to the official TIF veterinarian in the slaughterhouse.

According to written procedures provided to the FVO by the CCA the TIF State supervisor is to send a copy of the laboratory result to the manager of the establishment, the official TIF veterinarian must establish the farm of origin of the non-compliant sample and he is requested to report to CCA with an explanation for the possible cause of the detected residues and a description of any corrective actions. In addition, the State supervisor shall inform the CCA of which corrective actions have been taken together with the establishment and provide answers to five specific questions regarding the cause of the residue, actions to be taken by the establishment, controls to the effect of these actions, preventive measures and actions taken to prevent that products involved in the violation are placed on the market.

The mission team noted that:

- none of the TIF State supervisors or TIF official veterinarians interviewed were aware of the written procedures for follow-up;
- the CA had detected nitrofurans (furazolidone) in 2/116 horse samples in 2007. These samples were listed as "non-compliant" in results provided to the FVO prior to this mission, although no maximum tolerance limits for nitrofurans are included in the currently valid NOM-004-ZOO-1994;
- with regard to the findings of furazolidone in horses the TIF official veterinarian had notified SAGARPA that one horse was of Mexican origin while the other had been imported from the US for direct slaughter;
- the follow-up of these nitrofurans findings had been restricted to letters from the sampling officials to SAGARPA at central level, identifying the farm of origin. No investigations were conducted into the cause of the residues, no visits were made to the farm of origin and no measures were taken to prevent recurrence of the residues violation. The CA stated that no such actions could be taken since there are currently no maximum tolerance limits for nitrofurans laid down in national legislation;
- as a voluntary measure, the slaughterhouse visited retained the carcasses of the sampled horses until sample results were available. If residues were detected in muscle, the products would not be exported to the EU. If residues were detected only in liver or kidney no restrictions would be placed on the muscle meat from that animal;
- in 2006, cadmium was detected in all muscle samples from equines, however all results were below the national maximum tolerance limit of 2 mg/kg and thus not

considered non-compliant. In the EU the maximum level of cadmium in horse muscle is 0.2 mg/kg. Thus, the CA cannot ensure that exported meat from equines does not contain cadmium levels above the EU maximum level;

- in 2006, residues of sulphonamides under the national maximum tolerance limit of 0.100 mg/kg were detected in 10/195 honey samples. Tetracycline was detected in 1 sample but no national maximum limit has been set for this substance. These results were deemed compliant. There is no MRL in the EU for any antimicrobials in honey;
- in its response to recommendation 4 in the 2005 residue mission report the CA stated that procedures for effective follow-up of RASFF notifications would be established. However, no such procedures have been established.

With regard to commodities for which Mexico is currently not listed in Commission Decision 2004/432/EC, the mission team noted that:

- the CA had detected nitrofurans in a number of samples in 2007. These samples were listed as "non-compliant" in results provided to the FVO prior to this mission, although no maximum tolerance limits for nitrofurans are included in the currently valid NOM-004-ZOO-1994. In summary:
 - o 4/102 poultry muscle samples were non-compliant for AOZ (furazolidone) and 17/102 poultry muscle samples were non-compliant for AMOZ (furaltadone);
 - o 8/265 pig muscle samples were non-compliant for AOZ (furazolidone) and 2/265 pig muscle samples were non-compliant for AMOZ (furaltadone)
- in 2006, nitrofurans were detected in 31/300 pig samples and 39/90 poultry samples. All these samples were listed as "positive over the maximum tolerance limit" in the results for 2006 submitted to the Commission in 2007;

5.3 LABORATORIES

5.3.1 General description

All the samples for the NRCP are analysed in the National Centre for Animal Health Certification Services, CENAPA, which is also the national reference laboratory for residues in Mexico.

5.3.2 National Centre for Animal Health Certification Services (CENAPA)

CENAPA is designated as the National Reference Laboratory for Mexico. CENAPA carries out analysis of all of the samples for the Mexican NRCP. The laboratory has been accredited to ISO 17025 for 7 years. The accreditation body (EMA) performs annual audits. Many of the methods required for the NRCP are accredited to ISO 17025. The laboratory, through the internal Planning Committee, has established a list of priorities for analytical method development/validation /ISO accreditation for implementation in

2008. CENAPA has sent staff for training in France, Austria and Sweden and is a participant in a free-trade project with the EU which may facilitate exchange of laboratory staff.

The mission team noted that:

- a Quality Management System is in place, organised by a Quality Manager, and a Quality Manual is available. Standard Operating Procedures (SOP) for the analytical methods, and procedures for method validation, were in place and were laid out in a uniform format;
- the most recent audit by EMA was carried out on 4th April 2007 and close-out actions were inspected on the 28th May 2008. No major non-compliances were noted in work related to the NRCP;
- the Quality Assurance Manager carries out two internal (facility) audits every year. In July 2007, audits of the CENAPA methods for clenbuterol and chloramphenicol were carried out. No major non-conformances were noted in a very comprehensive review of both methods;
- basic laboratory equipment, for example pipettes are calibrated once every six months and criteria to determine the acceptability of the calibration have been established. Comparisons of new against old standards are made, but no criteria for the acceptability of the comparison have been established ([see CA comment at the end of this report](#));
- the Quality Assurance Unit have organised a number of proficiency tests for relevant veterinary drug residues. The participants have included CENAPA and a range of private and University laboratories in the country. CENAPA had a satisfactory z-score in most of the analyses. A poor z-score (-6.0) was obtained by CENAPA in a proficiency test of arsenic in water. The corrective and preventive actions taken by the laboratory were well documented. The sample was re-analysed after completion of these actions and a result, consistent with a satisfactory z-score, was obtained;
- the laboratory has 4 Liquid Chromatography – Tandem Mass Spectrometry (LC-MS/MS) systems and one Gas Chromatography – Tandem Mass Spectrometry system, along with other suitable laboratory equipment, which is a significant improvement over the situation that existed at the time of the previous FVO mission in 2005;
- the procedures in the SOP for validation of analytical methods were in accordance with the principles of Commission Decision 2002/657/EC;
- the list of methods, which the laboratory plans to develop, validate and accredit during 2008 includes the most relevant methods needed to extend the scope of the NRCP, with the exception of methods for screening and confirmation of nitroimidazoles. However, representatives from CENAPA stated that additional resources with regard to staff and consumables were needed if all these methods were to be validated during 2008;
- the SOP for the analysis of the four main nitrofurans metabolites by LC-MS/MS,

contained all relevant elements. Validation of this method was being undertaken according to the validation SOP which meets the requirements of Commission Decisions 2002/657/EC;

- validation of a sensitive LC-MS/MS method for three beta-agonists, according to Commission Decision 2002/657/EC is partially complete and validation of LC-MS/MS methods for thyrostats and benzimidazoles is under way;
- validation of a sensitive LC-MS/MS method for three beta-agonists, according to Commission Decision 2002/657/EC is partially complete and validation of LC-MS/MS methods for thyrostats and benzimidazoles is under way;
- the sample registration system is suitable for purpose – ownership of NRCP samples is not known to the analyst;
- samples are homogenised on receipt, stored frozen and aliquots collected by the individual analyst for the methods for which they are responsible. The possibility of drug metabolism in frozen, homogenised tissues has not been considered;
- the laboratory is responsible for deciding when a result is non-compliant. However, when residues are detected in a matrix where no maximum tolerance limit has been established (for example tetracycline in honey and nitrofurans in muscle) the finding is always recorded as being “below the tolerance limit”. This is the opposite position to that in the EU, where any confirmed finding is reported as non-compliant in the absence of an established MRL. The official staff in the establishment, in cooperation with the central authority, is responsible for deciding if these results are in line with the requirements of the target country;
- the latest draft version of NOM-004, which is awaiting legal approval, contains target minimum detection levels for a range of compounds which are prohibited in Mexico and/or The EU. These target levels were based on evaluation of published literature. However, some of these levels are unrealistically low and the laboratory staff observed that they would require revision in light of laboratory capabilities. For example, the laboratory is currently working on a new method for thyrostats to a detection level of 40 µg/L while the target detection level in the draft NOM-004 is 0.05 µg/L;
- CENAPA has not participated in external proficiency tests (PTs) in the field of VMP residues, mainly due to problems with paying bills in foreign currencies;
- as in 2005, chloramphenicol is confirmed with a GC method. According to validation data this method is capable of detecting chloramphenicol at the minimum required performance level set in Community legislation;
- in its response to recommendation 6 in the 2005 residues mission report the CA undertook to extend the scope of validated methods used for the NRCP to better reflect the substances used in Mexico. The methods pending validation in 2005 had indeed been validated but there are still numerous substances, authorised for food producing animals, which CENAPA does not have methods to detect.

5.4 VETERINARY MEDICINAL PRODUCTS (VMPS) AND MEDICATED

FEEDINGSTUFFS

5.4.1 Authorisation of VMPs

DG Animal Health within SENASICA is responsible for the regulation of all VMPs.

Thus, following the publication of the General Law on Sustainable Fisheries and Aquaculture in July 2007, SENASICA took over the responsibility for the registration of veterinary medicinal products for use in shrimp, previously administered by the Directorate for Fisheries and Aquaculture Regulation of the National Fishing and Aquaculture Commission (CONAPESCA). NOM-012-ZOO-1993 regulates the manufacturing and import of veterinary medicines. NOM-022-ZOO-1995 regulates the placing on the market of registered products by wholesalers, veterinary pharmacies and feedmills. Only those VMPs, medicated premixes and additives, feedingstuffs containing active substances and feedingstuffs of animal origin, which are registered with SAGARPA may be commercialised in Mexico. The products may only be used for the species included in the registration document. All authorised products must be labelled accordingly and carry a SAGARPA marketing authorisation number.

Until the adoption of the Federal Law on Animal Health in 2007 the competent authority did not have the legal basis to issue time-limited authorisations for VMPs, to cancel market authorisations for VMPs, or to implement infringement procedures when non-compliances are detected.

The use of chloramphenicol and clenbuterol in feed for food producing animals was prohibited through NOM-061-ZOO-1999. NOM-064-ZOO-2000 prohibited the use of diethylstilbestrol in any animal species, prohibited all use of CAP, clenbuterol, olaquinox, tinidazole, ronidazole and dimetridazole in food producing species and restricted the use of metronidazole to horses, cats, dogs and wildlife. It also introduced a classification and prescription system for VMPs. These rules came into force 27 June 2004. However, as described in the report from the 2005 residue mission, the CA and the pharmaceutical industry had agreed that the implementation of these rules would not be checked by the CA before April 2006 and initially only at manufacturer/wholesaler level.

According to Article 11 of Council Directive 96/22/EC, Member States are not permitted to import from third countries meat or products obtained from animals to which substances with a thyrostatic, oestrogenic, androgenic and gestagenic action, or beta agonists have been administered for growth promotion purposes.

The mission team noted that:

- there was no evidence that CAP, clenbuterol and diethylstilbestrol are authorised for use (or are used) in food producing animals, with the exception of the authorised use of clenbuterol for therapeutic purpose in horses;
- in contrast to the findings of the 2005 residue mission, VMPs containing nitroimidazoles, which are listed in Annex IV of Council Regulation (EEC) No 2377/90, and banned under national legislation, are authorised for use only in pets;
- NOM-064-ZOO-2000 does not classify all pharmacologically active substances authorised for use in food producing animals. For example arsenicals have not been classified;

- SENASICA is currently working on a project to develop specific rules for the use of VMPs in shrimp farming. This project was already ongoing in CONAPESCA at the time of the residue mission in 2005.
- as noted the 2005 mission report, numerous substances referred to in Article 11 of Council Directive 96/22/EC are authorised for use as growth promoters in food producing animals in Mexico. Some examples are:
 - o for horses: boldenone and testosterone for injection;
 - o for pigs (this commodity is not listed for Mexico in Commission Decision 2004/432/EC): boldenone, nandrolone and testosterone for injection and the beta-agonist ractopamine as feed additive;
- several VMPs containing nitrofurans listed in Annex IV to Council Regulation (EEC) No. 2377/90 are authorised for use in food producing animals. Examples relevant for the scope of this mission are:
 - o furaltadone *inter alia* for pigs and poultry;
 - o furazolidone *inter alia* for horses, pigs and poultry;
- the CA has contacted the pharmaceutical industry requesting the companies to implement a voluntary ban on nitrofurans in products intended for use in food producing animals. The companies were encouraged to either withdraw the VMP from the market or to alter the formula of an existing product. The altered formula was registered by SAGARPA under the same product name and registration number as the one containing the nitrofurans compound, provided that the indication was the same. There was no requirement for the manufacturer, wholesaler or pharmacy to abandon sale of the earlier version of the product. Thus, two products with the same name and SAGARPA registration number could be sold containing totally different active substances;
- several VMPs containing active substances not listed in Annexes I-III to Council Regulation (EEC) 2377/90, including acepromazine, phenylbutazone, and several arsenicals, are authorised for use in food producing animals;
- antibiotic feed additives, such as virginiamycin and flavophospholipol, which have been prohibited from use as additives in animal feedingstuffs in the EU are authorised for use as growth promoters in shrimp ([see CA comment at the end of this report](#)). These two additives are also authorised for pigs and poultry and carbadox is authorised for pigs.

5.4.2 Distribution and use of VMPs

VMPs may legally be sold to livestock owners from manufacturers, wholesalers, retailers and veterinary practitioners. NOM-064-ZOO-2000 provides the guidelines for classification and prescription of veterinary medicines. A Resolution of 25 June 2004 classifies authorised active substances into three different groups based on the prescription type: group 1 - quantified prescription for VMPs handled only by a veterinarian; group 2 - prescription by veterinarian but handled by individuals; and group 3 “over-the-counter” products. With regard to those hormonal substances whose use as

growth promoters is prohibited in food producing animals under Community legislation the Resolution generally classifies the implants under group 2 and the injectable substances under Group 1. Procedures for the implementation of the prescription system for class I VMPs were issued on 19 January 2007 and were sent out by the CCA to the SAGARPA State offices in April 2007. These instructions include a requirement for the State offices to issue specific authorisations for veterinarians who wish to prescribe class I VMPs and to report monthly to the CCA which veterinarians have received such authorisations.

Animal feed containing antibiotic additives or medicated feedingstuffs may be produced in commercial feed mills or in on-farm mixing facilities. All feedingstuffs containing pharmaceutically active substances that are placed on the market must be registered with SAGARPA and the registration number must be listed on the label.

The mission team noted that:

- in its response to recommendation 7 in the 2005 residue mission report the CA stated that the deadline for implementation of NOM-064-ZOO-2000 was December 2006. This deadline has not been met;
- instructions for implementation of the prescription system for class I VMPs ("quantified prescriptions"), sent out by the CCA, contained no deadline for the full implementation and did not mention the prescription system for class II VMPs ("simple prescriptions");
- the prescription system for class I VMPs as defined in NOM-064-ZOO-2000 was under implementation in two States (which had sent reports to the CCA), including one of the States visited by the mission team, while implementation was still pending in the other 30 States;
- in one State visited, 58 practitioners had been authorised to issue class I prescriptions by January 2008. The CA was unable to provide information on the total number of practitioners in this State or in the country;
- no quantified prescriptions (for class I VMPs) had yet been submitted to the wholesaler/pharmacy visited in the State where the prescription system was under implementation.

5.4.3 Controls on the distribution and use of VMPs

5.4.3.1 Controls at wholesale and retail level

The central level of SAGARPA is responsible for licensing of manufacturers and importers of VMPs, while the control of pharmacies is delegated to the SAGARPA State Offices. There are no guidelines or federal legal acts defining either the quality or quantity of inspections by the State Offices. It is a national legal requirement for veterinary pharmacies to have a SAGARPA approved veterinarian employed but there is no requirement for the approved veterinarian to be present in the pharmacy during opening hours.

The mission team noted that:

- controls of the implementation of NOM-064-ZOO-2000, with regard to labelling requirements (classification of VMPs) has been conducted by the CCA at manufacturer and wholesaler levels but no controls have started at retail level;
- in its response to recommendation 8 in the 2005 residue mission report the CA stated that verification programmes would be implemented to strengthen the controls of VMPs. These verification programmes do not cover the whole distribution chain for VMPs;
- the wholesaler business of the wholesaler/pharmacy visited had been inspected by the CCA during the previous 12 months. Inspections are carried out by local veterinarians who are accredited as auditors by SAGARPA Central level. The most recent inspection in October 2007 had included a recommendation to inform all the wholesaler's sales consultants about the prescription system, to introduce prescription forms and to record all sales of Class I VMPs in a log book, pending the full implementation of the prescription system;
- class I VMPs were sold from the wholesaler/pharmacy visited without quantified prescriptions from veterinarians. However, since 31 October 2007 such sales had been registered in a log book, detailing the trade name of the VMP, the quantity sold and the veterinarian ordering the product;
- a number of VMPs belonging to class I and class II were available for sale in the pharmacy without the standardised text about prescription type on the labels;
- the wholesaler/pharmacy visited had two VMPs for poultry for sale, under the same name and SAGARPA number, containing totally different pharmacologically active substances. One of them contained furaltadone (a furazolidine). It was not possible for the CA inspector or the pharmacist to know which was the currently authorised product, as the available list of authorised products only gives the product name and the SAGARPA number.

5.4.3.2 Controls in feed mills (medicated pre-mixes and medicated feedingstuffs)

Feed mills and on-farm mixers manufacturing medicated premixtures or medicated feed must be authorised by the CCA. The CCA (SAGARPA central level) makes an annual visit to renew the authorisation and update the list of authorised products. The routine supervision of feed mills for medicated feedingstuffs, and farms with on-farm mixing of medicated feed is delegated to the SAGARPA State Offices. There is no legal obligation for feed producers to control cross-contamination or homogeneity of the products.

The mission team noted that:

- in the feed mill visited, growth promoting additives, medicated premixes and coccidiostats were used routinely for production of medicated premixtures, intended for mixing in feed for cattle, pigs and poultry at feed mills or on farms;
- feed was produced in four lines. The medicated additives or premixes were added at the final mixing step. The lines were flushed between batches to prevent

cross-contamination, and feeds without pharmacologically active substances were produced in a dedicated line. The feed mill had an own check programme for homogeneity and also conducted tests for cross-contamination (nicarbazine) from breeder to layer poultry feed;

- in addition to the feed premixtures listed in the authorisation document for the feed mill, a large number of so called "special orders" were produced. These premixtures were produced to specifications from clients and were sold without being authorised and registered with SAGARPA. The vast majority of all premixtures for poultry were "special orders", i.e. sold without a SAGARPA registration number on the label, while for cattle and pigs, most of the produced premixtures were SAGARPA registered products;
- the feed mill had been inspected by the CCA in July and August 2007 and reports of these inspections were available. On the check lists checks for compliance with NOM-064-ZOO-2000, with regard to prescription class on labels, were included but such checks had not yet started in feed mills;
- no information could be obtained from the CA or the feed mill, on when the feed mill had last been inspected by the SAGARPA State office with regard to use of medicated premixes and additives;
- premixtures for pigs, containing *inter alia* amoxicillin, carbadox and flophenicol were sold daily without SAGARPA registration numbers;
- minerals for technical use were used as raw material for animal feed;
- some premixes used for preparation of premixtures did not have SAGARPA registration numbers.

5.4.3.3 *Controls on veterinary practitioners and farms*

The SAGARPA State Offices are responsible for the controls of veterinary practitioners and farms.

The mission team noted that:

- no federal legislation or guidelines have been issued;
- there is no legal requirement for inspections of VMP usage in veterinary practices or farms;
- there is no legal requirement for farmers to keep treatment records, with the exception of apiaries and shrimp farms;
- health documents accompanying other animals than equidae presented for slaughter in TIF slaughterhouses are not required to contain information or guarantees by the farmer or the approved veterinarian regarding banned substances or the respect of withdrawal times for authorised VMP.

5.4.3.4 *Sales declaration for equidae intended for slaughter*

The two TIF slaughterhouses approved for export of meat of equidae to the EU have

recently introduced a voluntary system of sales declarations for these equidae. This system has been developed within the framework of a project intended to facilitate trade, *Proyecto de Facilitación del Tratado de Libre Comercio entre México y la Unión Europea* (PROTLCUEM), which is co-financed by the EU and Mexico. Declarations are to be signed by the owner selling the animals to the trader and by the trader who delivers the animals to the slaughterhouse. The system has been implemented in order to ensure that equidae, from which meat may be exported to the EU, have not been treated with substances referred to in Article 29 of Council Directive 96/23/EC, i.e. those covered by Council Directive 96/22/EC. The two slaughterhouses have undertaken not to accept any sport or show horses or horses which have been treated with any pharmacologically active substances during the three months prior to slaughter. The standardised owner/trader declaration form requires a confirmation that the animal has not been used for shows or sports and yes/no answers to:

- - o whether the horse has been in his/her possession for three months;
 - o whether he/she is aware of the medicines listed in Annex I to Council Directive 96/23/EC;
 - o whether the animal has been treated with any such substance;
 - o whether the animal has been treated with any medicine authorised in Mexico during the past three months (if yes, the type of medicine, treatment date, animal identification and withdrawal time must be specified);
 - o whether the animal has been treated with medicines not authorised for equines (if yes, specification is required).

The mission team noted that:

- there is no national legislation laying down criteria, based on treatment declarations, for acceptance/ rejection of horses for slaughter in the TIF slaughterhouses approved for EU export;
- training for the TIF slaughterhouse staff implementing the sales declaration system had been provided within the framework of the PROTLCUEM project while training for horse dealers had been delegated to the slaughterhouses;
- the implementation and control of the sales declaration system was in the hands of the establishments and did not involve the official TIF veterinarians or other representatives from the competent authorities;
- the system is not yet applied to the numerous horses imported into Mexico from the US for direct slaughter;
- by referring to Annex I to Council Directive 96/23/EC the sales declaration form covers treatments with any pharmacologically active substance or contaminant belonging to any of the substance groups which should be included in a residue control plan according to this Directive. This is a much broader scope than what is covered by Council Directive 96/22/EC, which refers only to hormones and beta-agonists used for growth promotion;
- representatives for the TIF slaughterhouse, the official TIF veterinarian and the

horse dealer visited were not aware of which VMPs would/would not be covered by the substance groups listed on the sales declaration form (Annex I to Council Directive 96/23/EC);

- most equidae transported to slaughter receive topical treatments against ticks either on the farm of origin or during the transport. None of the persons involved in the training and implementation of the sales declaration system considered that these treatments were covered by any of the questions on the declaration form;
- in the slaughterhouse visited the system was said to be fully implemented from 1 February 2008. Documents were studied for three consignments of Mexican equidae accepted for slaughter since 1 February. One of the declarations fulfilled the slaughterhouse's requirements while one declaration stated that the seller had indeed owned the animals for three months, while the supporting movement declarations showed that this person had bought the horses 0-3 days before presenting them for slaughter. On the third declaration the owner had stated that he was not aware of the medicines in Annex I to Council declaration 96/23/EC, which according to the slaughterhouse policy would lead to the rejection of the 21 horses. However these animals had been accepted for slaughter;
- the horse trader visited had been informed about the sales declaration system by the slaughterhouse staff. The sales declaration system had been implemented in this slaughterhouse in the end of 2007. The horse trader stated that she often had to read the text and sign on behalf of illiterate owners, or let them sign by thumb print. Unless the owner agreed to sign the document she would not buy the horses. This dealer had two consignments of horses ready to be delivered to slaughter the following day and considered the accompanying documents to be in accordance with the requirements from the slaughterhouse. However, on one document the owner had stated that he had not owned the horse for three months and on the other no answers had been given regarding treatments. It could not be established by the mission team if these horses were subsequently accepted for slaughter.

6 CONCLUSIONS

6.1 LEGISLATION

1. Whilst there is a legal basis for the control of residues and contaminants in red meat and poultry, the delay in the amendment of national legislation for residues control of other commodities (e.g. shrimp, eggs and honey), and the lack of detailed legislation for follow-up and infringements in case of non-compliances militate against effective residue control.
2. Several of the current national maximum tolerance limits exceed those laid down in Community legislation. In addition, the draft of the new NOM-004 includes national tolerance limits for a number of species/substance combinations for which no maximum residue limits are laid down in Community legislation. This could result in situations where exported consignments would contain residues at levels which

do not meet Community requirements.

6.2 NATIONAL RESIDUE CONTROL PLAN

1. The national residue control plan follows the general requirements of Council Directive 96/23/EC regarding substance groups per commodity but nitroimidazoles (in Group A6) are not included. The residue control plan is limited in scope in relation to which VMPs are authorised and the pharmaceutical industry and farmers have access to information of which substances are tested for. These facts reduce the possibility for the competent authority to detect potential illegal use or misuse of VMPs and to guarantee that consignments exported to the EU meet Community requirements.
2. There is a lack of follow-up investigations of findings of residues at levels which exceed those laid down in Community legislation, also in commodities which are currently exported to the EU. Such investigations are mandated by the provisions of Chapters IV and V of Council Directive 96/23/EC and under Article 29 of said Directive, third countries are required to offer guarantees with an effect at least equivalent to, *inter alia*, such investigations. This undermines the effectiveness of the residue control programme in preventing that commodities exported to the EU contain residues of substances which are prohibited in the EU or residues exceeding the maximum residue limits and maximum levels laid down in Community legislation.
3. Although partly compensated by the fact that each sample is analysed for all substances, in relation to national production figures the number of samples for shrimp and poultry are insufficient to provide the competent authority with the information needed to ensure that the residue status of these commodities is equivalent to that obtained applying Council Directive 96/23/EC.
4. There is no "split system" in place to guarantee that animals slaughtered for the EU market have never been treated with the hormones and beta-agonists which are authorised and used for growth promotion in e.g. bovines, pigs and horses. This means that meat from potentially treated animal species does not fulfil the requirements of Article 29 of Council Directive 96/23/EC and in particular Council Directive 96/22/EC.
5. The compulsory pre-export testing of honey intended for export to the EU gives additional confidence in the residues status of this commodity. However, the scope of substances covered by this scheme is somewhat limited and the tolerance limits are not all in line with Community legislation.

6.3 LABORATORIES

1. Improvements have been made in the laboratory capability since the 2005 residues

mission with regard to equipment and range of methods. However, the still limited range of analytical methods and the fact that the methods for several substance groups are limited in scope severely limits the effectiveness of the national residue control programme.

2. The laboratory has identified and prioritised a large number of methods to be validated during 2008. The addition of these methods would strongly improve the scope of the residue control programme and thereby the basis for the guarantees provided by the CA with regard to the residue status of exported commodities. However, it is questionable whether the resources in the laboratory will be sufficient for all of these methods to be validated during 2008.

6.4 VETERINARY MEDICINAL PRODUCTS AND MEDICATED FEEDINGSTUFFS

1. A prescription system laid down in national legislation in 2004 is still not implemented. There are insufficient and inconsistent controls on the distribution of VMPs and their usage, no requirement for treatment records on all farms for food producing animals and a lack of detailed rules for infringement procedures if illegal use of VMPs is detected. These factors undermine effective controls on VMPs at retail and farm level.
2. The recently introduced sales declaration system for equidae is not under the responsibility of the competent authority. The system is not fully understood by the private parties involved, it does not cover all horses slaughtered in the EU exporting slaughterhouses and the rules within this voluntary system are not adhered to. This system does not currently provide the competent authority with sufficient information to ensure that meat of equidae exported to the EU fulfills the requirements of Art 29 of Council Directive 96/23/EC and Directive 96/22/EC.
3. The authorisation and use of VMPs containing pharmacologically active substances which are either banned or are not authorised for use in food producing animals in the EU is of concern, considering the absence of comprehensive national tolerance limits, restricted analytical capabilities and lack of an effective VMP control system. Cumulatively these factors may result in the presence of undesirable residues in exported commodities and weaken CA guarantees on the residue status of exported consignments.

6.5 OVERALL CONCLUSION

This mission identified several shortcomings in the application of residues and veterinary medicines controls, in respect of commodities currently exported to the EU or which are planned to be exported. Several of these shortcomings were present also at the time of the previous FVO residue mission in 2005 and not rectified in line with the deadlines set by the Competent Authority in the action plan provided in response to the recommendations of the previous mission report. In particular, hormones and

beta-agonists are authorised for growth promotion in *inter alia* horses (meat of which is currently exported to the EU), pigs and bovines. In the absence of a functioning ‘split system’, ensuring that animals which may be slaughtered for the EU market have not been treated with such substances, Mexico does not comply with Community requirements in Article 29 of Council Directive 96/23/EC and Council Directive 96/22/EC concerning the export of meat from potentially treated animals. There are no follow-up procedures in place to investigate the reasons for residues detected under the national residue control plan and no infringement procedures, which means that no actions are taken to prevent recurrence of the violations. This is exacerbated by weak controls on the use of veterinary medicines and failure to implement or control the prescription system for veterinary medicines which has been legally required for several years. There is also limited laboratory capability at present, which limits the scope of substances included in the residue control programme to only a small fraction of those veterinary medicinal products authorised for the tested species. Regarding the commodities for which Mexico is listed in Commission Decision 2004/432/EC, the guarantees provided by the Competent Authority regarding the residue status of honey and eggs can be considered equivalent to the minimum levels laid down in Community legislation while for (aquaculture) shrimp and meat of equidae improvements are necessary before the Competent Authority can provide such guarantees. With regard to pigs and poultry, for which Mexico is not listed in Commission Decision 2004/432/EC, the residue control in these commodities is not in line with the requirements of Article 29 of Council Directive 96/23/EC.

7 CLOSING MEETING

A closing meeting was held on 21 February 2008 with representatives of the central competent authority. At this meeting, the inspection team presented the main findings and preliminary conclusions of the mission. The authorities did not express disagreement and stated that they would take what ever actions were necessary in order rectify the identified shortcomings.

8 RECOMMENDATIONS

The competent authorities were invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within 25 working days of receipt of a draft of this mission report.

No.	Recommendation
1	To ensure that there are legal provisions for residue controls, including defined maximum residue tolerance levels for all relevant substances, as well as legal provisions for follow-up investigations of detected non-compliances in line with the requirements of Article 29 of Council Directive 96/23/EC for all commodities for which Mexico is listed in Commission Decision

No.	Recommendation
	2004/432/EC.
2	To ensure that commodities exported to the EU are not derived from animals treated with hormones or beta-agonists for growth promotion in order to fulfil the requirements of Article 29 of Council Directive 96/23/EC and Council Directive 96/22/EC.
3	To ensure that the maximum tolerance limits applied for commodities intended for export to the EU are in line with the maximum residue limits for veterinary medicinal products (Council Regulation (EEC) No 2377/90), maximum levels for pesticides (Council Directive 86/363/EEC) and maximum limits for contaminants (Commission Regulation (EC) No 1881/2006) applicable under Community legislation. This is to ensure that the guarantees provided about the residue status of commodities exported to the EU is at least equivalent to those provided under Council Directive 96/23/EC.
4	To ensure that the national residue control plan for commodities intended for export to the EU includes sufficient sample numbers, covers all mandatory substances (including nitroimidazoles and dyes, where relevant) and that the scope of substances included in the plan is representative for the substances which are authorised for, possibly misused in, or may be used illegally in the species concerned. This is to ensure that the guarantees provided about the residue status of commodities exported to the EU is at least equivalent to those provided under Council Directive 96/23/EC.
5	To ensure that the scope of substances covered by the national residue plan is not known to the pharmaceutical industry, establishments or farmers subject to controls so that the controls are unforeseen and unexpected as required under Community legislation (Annex III to Council Directive 96/23/EC). This is to ensure that the guarantees provided about the residue status of commodities exported to the EU is at least equivalent to those provided under Council Directive 96/23/EC.
6	To ensure that, when residues are detected in Commodities intended for export to the EU at levels exceeding those in Community legislation, follow up actions are taken by the competent authority to investigate the cause of the violation and to prevent recurrence. These procedures should have an effect at least equivalent to that provided for in Chapters IV and V of Council Directive 96/23/EC. This is to ensure that the guarantees provided about the residue status of commodities exported to the EU is at least equivalent to those provided under Council Directive 96/23/EC.

No.	Recommendation
7	To ensure that the number of available validated laboratory methods is extended to allow the necessary broadening of the scope of the national residue control plan, in particular for nitroimidazoles, dyes, non-steroidal anti-inflammatory drugs and antimicrobial substances, for the commodities for which Mexico is listed in Commission Decision 2004/432/EC. This is to ensure that the guarantees provided about the residue status of commodities exported to the EU is at least equivalent to those provided under Council Directive 96/23/EC.
8	To improve the requirements on, and controls of, the use of veterinary medicinal products by veterinary practitioners and on farms. The record keeping by farmers and veterinary practitioners should provide the Competent Authority with sufficient information to allow follow-up investigations of non-compliances detected under the national residue control plan. The effect of such provisions should be at least equivalent to that of Article 10 of Council Directive 96/23/EC.

COMPETENT AUTHORITY RESPONSE TO THE RECOMMENDATIONS

The competent authority response to the recommendations can be found at the following link:

http://ec.europa.eu/food/fvo/ap/ap_mexico_7772_2008.pdf

9 COMPETENT AUTHORITY COMMENTS ON THE REPORT

9.1 CONCERNING 5.2.2

In the response to the draft report the Mexican Competent Authority stated that planning of the 2009 NRCP will take place in November 2008 to ensure that sampling starts in January 2009.

9.2 CONCERNING 5.2.2

In the response to the draft report the Mexican Competent Authority stated that a general sampling procedure will be developed by June 2008 for all the species in the programme, including tamper-resistant containers.

9.3 CONCERNING 5.2.3

In the response to the draft report the Mexican Competent Authority stated that a procedure will be developed by June 2008 to increase the supervision of the sampling during the year and where necessary to re-assign sampling.

9.4 CONCERNING 5.3.2

In the response to the draft report the Mexican Competent Authority stated that a procedure will be developed by June 2008 for defining the criterion of acceptability for new standards.

9.5 CONCERNING 5.4.1

In the response to the draft report the Mexican Competent Authority stated that the website listing products available on the Mexican market is an unofficial list produced by the pharmaceutical industry. This list may contain inconsistencies. There is no official list of VMPs authorised for shrimp.

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 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
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
Status of residue 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 β -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
Medicated feedingstuffs and additives		
Directive 90/167/EEC	OJ L 92, 7.4.1990, p. 42–48	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community
Regulation (EC) No 1831/2003	OJ L 268, 18.10.2003, p. 29–43	Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition
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
Directive 2002/69/EC	OJ L 209, 6.8.2002, p. 5–14	Commission Directive 2002/69/EC of 26 July 2002 laying down the sampling methods and the methods of analysis for the official control of dioxins and the determination of dioxin-like PCBs in 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