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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

EL SALVADOR

FROM 16 TO 24 JANUARY 2013

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

Executive Summary

This report describes the outcome of a Food and Veterinary Office (FVO) audit in El Salvador, carried out from 16 to 24 January 2013, as part of the published programme of FVO audits on the monitoring of residues in live animals and animal products in the European Union (EU) Member States and in third countries.

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, in order to assess whether these systems offer adequate assurance that the products and animals concerned are within the specified residue limits laid down in EU legislation. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit. The audit assessed the performance of the competent authorities and other officially authorised entities involved in residues and veterinary medicinal product controls and the legal and administrative measures put in place to give effect to the relevant EU requirements.

It is concluded that the structure of the residue monitoring plan in relation to the substance groups covered and numbers of samples is in line with Council Directive 96/23/EC and the scope of testing is generally broad. However, the effectiveness of the plan is undermined by the fact that a significant proportion of the scope is not decided by the competent authority, being based on the pre-export testing of a minority of exporting establishments. Furthermore, implementation of the plan is not in line with EU requirements, in particular due to the sampling strategy followed by the competent authority. The testing of blended honey reduces the chances for detection of residues, as does the prolonged storage of samples prior to analysis which has the potential to reduce the likelihood of detecting residues of certain substances (due to time-dependent analyte instability).

The strategy adopted by the competent authority for the follow-up of non-compliant results differs significantly from the approach taken in the EU. The fact that investigations are dependent on the availability of financial resources allied with a lack of legal powers for the competent authority to take measures/sanctions at farm level, poor co-operation between relevant official services, and, the dilution of non-compliant batches, collectively undermine the effectiveness of the residue control system.

With regard to the laboratories, notwithstanding the fact that several elements of a quality control system are in place in the national laboratories, the absence of validation and accreditation of methods allied with several deficiencies in analytical performance, undermine confidence in the reliability of results generated from the national laboratories. However, the majority of results reported under the residue monitoring plan come from an accredited private laboratory in the EU and, notwithstanding the fact that this cannot really be considered as official testing, based on the performance information available, the competent authority can have confidence in the reliability of these particular analytical results.

The regulatory system in place for veterinary medicinal products and the fact that prohibitions for use of certain substances in food producing animals in El Salvador is broadly similar to the situation in the EU, decreases the likelihood of residues of pharmacologically active substances occurring in honey. However, notwithstanding the efforts to raise awareness among bee-keepers on the use of veterinary medicinal products which could cause residues in honey, the widespread availability and use of unauthorised products for the treatment of honey bees and a lack of proper monitoring and enforcement by the competent authorities collectively undermine guarantees on the residues status of honey eligible for export to the EU.

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

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Abbreviations and definitions used in this report

Abbreviation	Explanation
AAS	Atomic Absorption Spectroscopy
AOAC International	Association of Analytical Communities
CIEX	*Centro de Trámites de Importaciones y Exportaciones*
CONACYT	*Consejo Nacional de Ciencia y Tecnología* (former national accreditation body)
CUA	*Código Único de Apicultor* (bee-keeper´s unique code)
DCARV	*División de Cuarentena Animal y Registro Veterinario* (Division of Animal Quarantine and Veterinary Register)
DG(SANCO)	Health and Consumers Directorate-General
DGG	*Dirección General de Ganadería* (Directorate General of Livestock)
DIPOA	*División de Inocuidad da Productos de Origen Animal* (Division of Safety of Animal Products)
EC	European Community
EEC	European Economic Community
EU	European Union
FVO	Food and Veterinary Office
GC - ECD	Gas chromatography – electron capture detection
GC - FPD	Gas chromatography – flame photometric detection
GC-MS	Gas Chromatography - Mass Spectrometry
GMP	Good Manufacturing Practice
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC:
IAAC	Inter American Accreditation Cooperation
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organisation for Standardisation
LCCP	*Laboratorio de Control de Calidad de Plaguicidas* (Laboratory for Quality Control of Pesticides)
LOD	Limit of Detection
LOQ	Limit of Quantification

LRSQB	*Laboratorio en Residuos de Sustancias Químicas y Biológicas* (Laboratory for Residues of Chemical and Biological Substances)
MAG	*Ministerio de Agricultura y Ganadería* (Ministry of Agriculture and Livestock)
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NSO	*Norma Salvadoreña Obligatoria* (Salvadoran Mandatory Standard)
OIRSA	*Organismo Internacional Regional de Sanidad Agropecuaria*
OSA	*Organismo Salvadoreño de Acreditación* (national accreditation body)
RASFF	Rapid Alert System for Food and Feed
RLV	*Red de Laboratorios Veterinarios y Control de Calidad* (Veterinary Laboratory Network)
RMP	Residue Monitoring Plan
RTCA	*Reglamentos Técnicos Centroamericanos* (Central American Technical Regulation)
SOP	Standard Operating Procedure
UIPA	*Unidad de Inocuidad de Productos Apicola* (Unit of Safety of Apiculture Products)

1 Introduction

The audit took place in El Salvador from 16 to 24 January 2013. The audit team comprised two auditors from the Food and Veterinary Office (FVO). The audit was undertaken as part of the FVO's audit programme, evaluating control systems and operational standards in the residues sector.

Representatives from the central competent authority responsible for control of residues in animals and animal products accompanied the audit team during the audit. An opening meeting was held on 16 January 2013 with the central competent authority responsible for implementing residue monitoring in live animals and animal products and representatives of the competent authority responsible for the authorisation of veterinary medicinal products. At this meeting, the objectives of, and itinerary for, the audit were confirmed and the control systems were described by the authorities.

2 Objectives

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, in order to assess whether these systems offer adequate assurance that the products and animals concerned are within the specified residue limits laid down in EU legislation. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit. The audit focussed on the roles of the competent authorities, the legal and administrative measures in place to give effect to the relevant EU requirements, controls with regard to residues and veterinary medicinal products and their operation, and the performance of residue laboratories. The table below lists sites visited and meetings held in order to achieve that objective.

Meetings/Visits		n	Comments
Competent Authorities	**Central**	**3**	Opening and closing meetings with the competent authorities and an additional meeting to collate and discuss documents requested by the audit team
Laboratories		**1**	Visit to the Laboratory for Residues of Chemical and Biological Substances (*Laboratorio en Residuos de Sustancias Químicas y Biológicas*)
Farms		**3**	Visits to three bee-keepers (apiaries)
Establishments		**3**	Visits to two honey processing plants (authorised for export to the EU) and to a honey collection centre
Other sites		**6**	Visits to four retail shops selling veterinary medicinal products and to three manufacturers of veterinary medicinal products

3 Legal Basis

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

- Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products, and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC;

- Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.
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A full list of the legal instruments referred to in this audit report is provided in the Annex and refers, where applicable, to the last amended version.

4 Background

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

Commission Decision 2011/163/EU indicates that El Salvador's residue monitoring plan is approved in accordance with Council Directive 96/23/EC for honey.

4.2 Summary of previous FVO audit reports

This was the first residues audit carried out in El Salvador.

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

There have been no RASFF notifications for residues of veterinary medicinal products in honey since 2000.

4.4 Production and Trade Information

Honey is the only food of animal origin which El Salvador exports to the EU. Detailed production data were included in the 2012 Residue Monitoring Plan (RMP) and are summarised in the table below.

Year	**2007**	**2008**	**2009**	**2010**	**2011**	**2012 (projection)**
Production (tonnes)	1289	1238	1347	2093	1678	1631
Total export (tonnes)	1096	1052	1145	1779	1426	1442

The competent authority stated that most of the honey has been exported to the EU (e.g. 95.3% of total export in 2011). According to data from COMEXT, El Salvador was the 12th largest exporter of honey (out of 42 countries) to the EU in 2011.

5 Findings And Conclusions

5.1 Residue monitoring

5.1.1 Competent authorities involved

The Division of Safety of Animal Products (*División de Inocuidad da Productos de Origen Animal* – DIPOA) of the Directorate-General of Livestock (*Dirección General de Ganadería* - DGG) within the Ministry of Agriculture and Livestock (*Ministerio de Agricultura y Ganadería* - MAG) is the competent authority for the RMP.

The Unit of Safety of Apiculture Products (*Unidad de Inocuidad de Productos Apicola* – UIPA) is a technical operational unit of DIPOA responsible for, inter alia, elaboration and implementation of the RMP, including follow-up of residue infringements.

5.1.2 Elaboration of the residue monitoring plan

Legal Requirements

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

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

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

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

Findings

National legislative acts which (generally) stipulate roles and powers of, inter alia, DGG services and provide requirements for honey and processing establishments are used as a legal basis for the RMP e.g. *Internal rules and functioning of the Ministry of Agriculture and Livestock* (Article 22) - *Executive Agreement No. 28 of 28.05.2010*, *Law on Plant and Animal Health - Legislative Decree No. 524 of 30.11.1995* (hereafter: *Law on Plant and Animal Health*), *Salvadoran Mandatory Standard* (*Norma Salvadoreña Obligatoria - NSO*) *67.19.01:08 "Honey. Specifications." (second update) - Executive Agreement No. 1006 of 07.11.2008* (hereafter: *NSO - Honey Specifications*) and *NSO on Good Manufacturing Practices for honey processing establishments - Executive Agreement No. 218 of 07.09.2007* (hereafter: *NSO - GMP*). The latter specifically mentions RMP (see Section 5.1.3).

UIPA elaborates the RMP within the first quarter of the year in order to submit it to Commission services by the end of March.

The audit team noted that:

- The RMP covers all substance groups specified in Annex II to Council Directive 96/23/EC and the required minimum numbers of samples as well as their distribution between substance groups are respected.
- Drafting of the RMP is carried out exclusively by UIPA. Laboratories are not involved in this process. This is in contrast to the situation in the EU Member States where laboratory involvement is required by Article 14 of Council Directive 96/23/EC.
- A significant proportion of substances included in the RMP i.e. all antimicrobials, are determined by the scope of pre-export testing carried out by two of the seven export establishments (see Section 5.1.3.). Testing for other substances under the RMP is largely based on the analytical capability of national laboratories. Amitraz and coumafos are tested both in the laboratory in the EU and in a national laboratory.
- There are no authorised veterinary medicinal products for honey-bees in El Salvador and "off-label" use is not permitted (see Section 5.3.1.). According to UIPA, information on substances used in apiculture is gathered through frequent contacts with bee-keepers. This is taken into account for RMP elaboration e.g. tylosin and fumagillin are not tested for as there are no indications of their use. According to the competent authority, if needed, additional substances would be added to the scope either by asking the two export establishments to broaden their pre-export testing or – resources permitting – by sending samples to suitable (foreign) laboratories directly by UIPA.
- The scope of testing in the 2012 RMP is generally broad and covers most of the relevant substances except for heavy metals. Lead and mercury were included in the 2011 and 2012 plans, however only mercury was tested for in 2011 (in spite of a non-compliant result for lead in 2010). UIPA explained this was due to problems with the analytical instrument in one of the national laboratories and that this is expected to be fixed soon. For the 2012 RMP these analyses have not been carried out yet (see Section 5.1.3.).
- National Maximum Residue Limits (MRLs) are provided in *NSO - Honey Specifications* which lays down specific maximum limits for 16 substances and a general maximum limit of 25 µg/kg for any other substance. MRLs for five substances are in line with EU limits whilst for the others there are no MRLs/Maximum Limits (MLs) established in the EU.
- In the 2012 RMP, national MRLs are indicated as action levels only for chloramphenicol and nitrofurans. For other substances (including those for which national MRLs exist), action levels either correspond to the limit of detection (LOD) of the analytical method or

are listed as a "general" maximum limit of 50 µg/kg. UIPA explained that in practice, its decision on non-compliance of a test result received from the laboratory in the EU is based on EU rules (assessment is provided on test report) whilst for results received from national laboratories, this decision is based on national limits provided in *NSO - Honey Specifications*.

- In addition to action levels, several other discrepancies were noted between the RMP and the actual situation on the ground. For example, most of the methods used by the laboratory in the EU and all LODs for analyses carried out in national laboratories were incorrectly stated in the plan.

Conclusions on planning of the residue monitoring plan

The structure of the RMP in relation to the substance groups covered and numbers of samples is in line with Council Directive 96/23/EC and the scope of testing is generally broad. However, the effectiveness of the plan is undermined by the fact that a significant proportion of the scope is not decided by the competent authority (i.e. is based on the pre-export testing of two food business operators). The inaccuracies of some data specified in the plan presented to the Commission services reduce confidence in the reliability of information provided by the competent authority.

5.1.3 Implementation of the residue monitoring plan

Legal Requirements

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

Findings

National legislation (see Section 5.1.2.) provides general legal powers for the competent authority to apply measures to ensure the safety of food of animal origin and to access food business operators´ establishments.

Honey processing establishments placing honey on the national market have to comply with the requirements of *NSO - GMP*. In practice, this applies also to export establishments. According to *NSO - GMP*, establishments may only receive honey from bee-keepers which are registered by DGG. For traceability reasons, establishments are obliged to take samples from all incoming honey (barrels) in duplicate – one for the establishment and one for the bee-keeper. Establishments are also required to take representative samples from each processed batch (lot) of honey. A batch is the content of a tank, usually containing six to seven tonnes of blended honey from different bee-

keepers. All samples taken by the establishments have to be kept for at least 12 months and according to UIPA, bee-keepers are advised to keep them for the same period. *NSO - GMP* also contains provisions on sampling rules for establishments and – among other GMP requirements – the obligation is to establish a traceability system (from export barrel via processing batch back to the bee-keepers).

NSO - GMP stipulates that RMP samples will be obtained from establishments´ batch samples which have to be available to MAG officials on request.

Currently there are seven processing establishments authorised by DGG/DIPOA to export honey. For every batch intended for export, establishments submit a request to DIPOA/UIPA for issuing a "Certificate for sample of honey for export" in which UIPA assigns a unique code to the export batch (which provides identification for RMP purposes in line with *NSO - GMP*). The request for issuing such a certificate contains information on all of the bee-keepers contributing honey to the export batch (including their respective quantities) and is accompanied by a sample of that batch.

The certificate states that samples may be analysed and the result shall be in accordance with national MRLs. This certificate is one of the pre-requisites for obtaining a health certificate for export (see Section 5.3.2.). These procedures are described in the DIPOA Quality Manual.

The audit team noted that:

- UIPA officials take approximately 65 samples annually from all export establishments (approximately five to 15 per establishment, depending on production volumes). Samples are randomly taken from samples of incoming honey kept by establishments in accordance with *NSO - GMP*. From these samples (collected by UIPA) a random selection of 32 samples from all establishments was analysed each year in national laboratories under the 2010 and 2011 RMPs (see Section 5.2.).
- Samples collected by UIPA have been stored and delivered all in one day to national laboratories in the first months of the year for the previous year's RMP. For example, in the case of the 2010 and 2011 RMPs, the national laboratories received samples in February 2011 and January 2012, respectively. Samples for the 2012 RMP have not yet been dispatched to national laboratories at the time of the FVO audit - UIPA explained the intention was to get feedback from this FVO audit first and then proceed with analyses accordingly. The sample records kept by UIPA did not contain the dates of initial sampling by the establishments or (with few exceptions) by UIPA. UIPA indicated that it would rectify this deficiency with immediate effect.
- According to UIPA, honey processing establishments exporting to the EU carry out routine pre-export testing of export batches. This testing is performed by laboratories in the EU in accordance with agreements between the establishments and EU importers which determine, inter alia, the scope of testing. UIPA receives the results of pre-export testing from two (of the seven) export establishments which together account for 37% of annual national production. The results have been made available to UIPA on a voluntary basis and reported under the RMP (thereby appearing to be official testing). UIPA does not have information on the extent of pre-export testing and related results for the other five export establishments.
- According to EU requirements, a minimum of 56 samples had to be taken under the 2011 RMP. Overall, this figure was exceeded with 109 samples and 364 test results reported. Of the 109 samples, 77 were from pre-export testing and 32 were analysed in national laboratories.

The audit team visited two export establishments, one of which is reporting the results of pre-export

testing to UIPA. Both establishments carried out pre-export testing of all EU-destined export batches. It was noted that:

- All RMP analyses (i.e. testing carried out in national laboratories and pre-export testing) are directly paid for by the export establishments.
- Sampling instructions for UIPA officials are included in the DIPOA Quality Manual, covering sampling in bee hives, barrels and tanks. Thee instructions are not followed for the RMP as all of the samples collected by UIPA are taken from samples already taken by the export establishments. This approach is not in line with the requirements of point 1.1. in the Annex to Commission Decision 98/179/EC.
- Although turnaround times for laboratory analyses are not systematically monitored, examples checked by the audit team for analyses carried out in 2011 and 2012 showed that these times were in general short (a few days in the EU laboratory and two weeks at the most in the national laboratories).
- Records related to RMP implementation were generally kept in good order. In addition, a database was designed by UIPA which contains all of the relevant information easily retrievable in electronic format and provides for supervision of RMP implementation.
- DGG (UIPA) keeps the National register of beekeepers. All bee-keepers visited by the audit team were registered by DGG and held a bee-keeper´s unique code (*Código Único de Apicultor* - CUA). In both establishments visited, registration of bee-keepers was routinely checked for all incoming honey. In some cases establishments arranged for registration on behalf of supplying bee-keepers and in such cases their registration status was recorded as "in process". Currently there are no specific requirements to be met by bee-keepers in order to be registered. According to UIPA, the main purpose of this registration is to ensure the traceability of honey.
- Both export establishments visited had an operational traceability system in place and were keeping samples of all incoming honey and of all export batches. Both establishments had been regularly inspected by UIPA for compliance with GMP rules.

Conclusions on implementation of the residue monitoring plan

The operational tools for supervision of implementation of the RMP and the good standard of record keeping should facilitate the effective implementation of the plan. However, in practice, implementation is not in line with EU requirements, in particular due to the sampling strategy followed by the competent authority and its reliance on the results of voluntary pre-export testing in place of official sampling and analysis. Furthermore, the effectiveness of the plan is weakened by the testing of blended honey which reduces the chances for detection of residues. The prolonged storage of samples prior to analysis also has the potential to reduce the likelihood of detecting residues of certain substances (due to time-dependent analyte instability).

5.1.4 Other residues monitoring programmes

Legal Requirements

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

of Council Directive 96/23/EC foresees the application of own-checks by food business operators.

Findings

As described in Section 5.1.3., the audit team was informed that establishments exporting honey to the EU carry out pre-export testing routinely. The audit team noted that:

- Both establishments visited have been carrying out pre-export testing of all EU-destined batches and results were available to the audit team. The results are not being checked by UIPA during its (GMP) inspections. According to UIPA, pre-export testing results (test reports) are not always available at the establishments as they may be kept at companies' headquarters on other locations or are not even received by companies/establishments because the importers retain them.

Conclusions on other residues monitoring programmes

Pre-export testing carried out by processing establishments generally underpins guarantees on the residues status of honey exported to the EU.

5.1.5 Follow-up of non-compliant results

Legal Requirements

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

Findings

There are no specific procedures/instructions in place for follow-up investigations in case of non-compliant residue results. According to UIPA, the current position of MAG is that national legislation does not provide the competent authority with the legal powers to take measures/impose sanctions in apiaries in such cases. Therefore actions taken include advising the bee-keepers concerned and general raising of awareness on adequate use of veterinary medicinal products through training and information campaigns.

The audit team was informed by UIPA that export processing establishments would report non-compliant results under their pre-export testing to UIPA on the basis of an informal agreement.

UIPA explained that in case of a non-compliant result for an export batch, the responsible bee-keeper is traced by analysing samples of incoming honey which was mixed into the batch. Testing focuses on bee-keepers with larger quantities in the batch and those who have contributed honey to non-compliant batches in the last two years. A list of the latter bee-keepers is kept by UIPA and was available to the audit team. If the results are negative, honey from the rest of the bee-keepers is analysed.

Samples for follow-up analyses are collected by UIPA at the export establishment and at bee-keepers, the latter samples being sent for analyses. However, the described procedure is only followed when resources for analyses are available. In other cases, all bee-keepers who supplied honey to the non-compliant batch are visited by UIPA and advised on the use of veterinary medicines.

Since 2010, there were six non-compliant results reported under the RMP for antibiotics (tetracyclines). These all came from the two export establishments reporting their pre-export testing results to UIPA. To date, no non-compliant results have been reported to UIPA from any of the other five export establishments.

The audit team examined follow-up files for non-compliant results from the 2011 and 2012 RMPs and noted that:

- In the 2012 tetracycline case UIPA sent follow-up samples of honey from all of the bee-keepers supplying the non-compliant batch to an accredited private laboratory in the EU. One sample contained a high concentration of tetracycline (444 µg/kg).
- The follow-up files for non-compliant export batches contained, inter alia, lists of bee-keepers which contributed honey to the batch. UIPA stated that these bee-keepers (either individuals found responsible for a residue infringement or all who contributed honey to a non-compliant batch) were visited and advised in all cases.
- Records of follow-up visits to bee-keepers are not kept. UIPA explained that due to the lack of legal powers for enforcement measures, these visits are carried out informally, with the emphasis on advice, rather than enforcement.
- Extensive and frequent training has been provided to bee-keepers, usually being organised by bee-keepers' associations and/or export establishments with participation of trainers from DGG (UIPA). Records of these events were made available to the audit team. This training often included topics related to the use of veterinary medicinal products (even though there are no such authorised products in El Salvador).
- All non-compliant results were attributed to the use of unauthorised veterinary medicinal products. In none of the cases were other relevant DGG services informed such as the Division of Animal Quarantine and Veterinary Register (*División de Cuarentena Animal y Registro Veterinario* – DCARV). DCARV has legal powers to carry out controls on the manufacture and distribution of veterinary medicinal products and to take enforcement measures (see Section 5.3.2.).
- The fate of non-compliant export batches is decided by establishments. According to UIPA, this is not specifically regulated in national legislation and the options available include placing of honey on the national market (if results are below national MRLs), industrial use, destruction or dilution. The latter option has been most commonly used and evidence of this approach was available at UIPA (honey from non-compliant batches had been mixed with other honey into new batches for which certificates were requested by the establishments). Such treatment is neither foreseen in EU legislation (Article 20 of Regulation (EC) 882/2004) nor in relevant international standards (paragraph 120 of Codex Alimentarius Guidelines CAC/GL 71-2009).
- In the establishments visited, the audit team was informed that in the case of non-compliant results another (back-up) sample from the same batch would be tested in order to exclude a laboratory error. If the repeated result is compliant, the batch would be exported.

Conclusions on follow-up investigations/actions

Whilst extensive training provided to bee-keepers has a potential to reduce the (re)-occurrence of residues of veterinary medicinal products in honey, the strategy adopted by the competent authority for the follow-up of non-compliant results differs significantly from the approach taken in the EU. The fact that investigations are dependant on the availability of financial resources allied with a lack

of legal powers for the competent authority to take measures/sanctions at farm level, poor co-operation between relevant official services, and, the dilution of non-compliant batches, collectively undermine the effectiveness of the residue control system.

5.2 Laboratories

Legal Requirements

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

5.2.1 General description

Findings

Two national (state) laboratories are currently involved in RMP testing of samples collected by UIPA: the Laboratory for Residues of Chemical and Biological Substances (*Laboratorio en Residuos de Sustancias Químicas y Biológicas* - LRSQB) and the Veterinary Laboratory Network (*Red de Laboratorios Veterinarios y Control de Calidad* - RLV).

Out of 24 samples annually received at LRSQB (see Section 5.1.3.), eight were analysed for organochlorine compounds (Group B3a), eight for organophosphorous compounds including coumafos (Group B3b), four for tau fluvalinate (group B2c) and four for amitraz (Group B2f). Eight samples annually received at RLV were analysed for heavy metals (Group B3c).

Pre-export testing of batches from two establishments (results of which are reported under the RMP – see Section 5.1.3.) are carried out in a private laboratory in the EU.

According to *Law on Plant and Animal Health*, official analyses can be done in any accredited laboratory of the national laboratory system.

LRSQB, RLV and the private laboratory in the EU are accredited to ISO 17025. However, methods used for the RMP are not included in the respective scopes of accreditation of the two national laboratories and none of the methods have been validated.

For the private laboratory in the EU, information on regular participation in proficiency testing schemes for residue testing of honey with largely satisfactory results was available at UIPA. The national laboratories had not participated in any proficiency testing schemes for residues or contaminants in honey.

5.2.2 On the spot visits in the laboratories

The audit team visited the LRSQB. With regard to RLV, UIPA provided the audit team with copies of the accreditation certificate, an overview of proficiency testing carried out and examples of recent equipment maintenance from the log-book for the AAS instrument including calibration results.

Findings

The LRSQB (together with the Laboratory for Quality Control of Pesticides - *Laboratorio de Control de Calidad de Plaguicidas* - LCCP) belongs to MAG and is administered by the *Organismo Internacional Regional de Sanidad Agropecuaria* (OIRSA), an intergovernmental organisation established to provide for technical co-operation between agricultural ministries of its nine member states. Residue analyses of food commodities have been carried out in LRSQB since 2000.

The audit team noted that:

- According to LRSQB, it carries out analyses for residues and contaminants in various food commodities and analyses for the RMP represent only a small proportion (24 samples per year).
- Since 2010, the LRSQB has been accredited by the national accreditation body *Organismo Salvadoreño de Acreditación* (OSA), formerly *Consejo Nacional de Ciencia y Tecnología* – CONACYT, a member of International Laboratory Accreditation Cooperation (ILAC) and Inter American Accreditation Cooperation (IAAC). The accreditation scope covers two analytical methods for residues - histamine in frozen and canned tuna and organophosphates (chlorpyrifos and metamidofos) in chili.
- Methods for RMP analyses of honey are described in two Standard Operating Procedures (SOPs) for tau-fluvalinate, amitraz and organophosphorous compounds including coumafos and organochlorines. According to LRSQB, both methods were adopted from the literature and modified. Use of AOAC International methods for, inter alia, pyrethroids, organophosphorous and organochlorine compounds and heavy metals is stipulated in the *NSO - Honey Specifications*.
- Deficiencies were noted in both SOPs. One did not include an analytical range for determination of substances in question and the other indicated the use of standard solutions of substances not included in the method's scope and did not provide clear information on instruments to be used.
- Analyses for the RMP are carried out with GC-MS, GC-ECD and GC-FPD instruments. The instruments are serviced annually. A maintenance logbook was in place for the GC-MS, used for a method examined by the audit team.
- Balances and thermometers are regularly checked including annual external checks while pipettes are only calibrated if used for accredited methods.
- Residue analyses are carried out by two analysts (chemical engineer and pharmacist). Their tasks and authorisations are listed in their personnel files and cover residue analyses in honey. No specific training has been provided to the staff in relation to these analyses.
- There were no SOPs in place for the validation of methods, calibration of measurement devices (e.g. balances, thermometers and pipettes) or laying down criteria for sample acceptance.
- Standard solutions were kept adequately separated from samples in a dedicated refrigerator.

Labels indicated preparation dates and the audit team was informed that a general expiry period of six months from the date of preparation applies to all standard solutions. This has been (orally) agreed in the laboratory and no information/document was available to demonstrate that this general expiry period was valid for all standard solutions.

- Analytical standards originated from a reliable source and certificates were available. Several had expired dates (e.g. chlorpyrifos) but some were valid at the time of the last RMP testing in 2012 (e.g. tau fluvalinate and coumafos). According to LRSQB, there were difficulties with importation of standards in the past and new standards are planned to be purchased this year with the assistance of OIRSA.
- Controls were carried out with each analytical run (series), using standard solutions and spiked (fortified) honey as positive control samples and a mixture of reagents and a diluent as negative control samples – not honey. Honey to be spiked was not checked for the absence of the analyte(s) in question. From the results obtained recovery was calculated according to the formula included in the method's SOP. Acceptance criteria for recovery were based on recommendations from an expert from the Food and Agriculture Organisation of the United Nations.
- According to LRSQB, calibration of analytical instruments was generally carried out when chromatographic columns are changed. The audit team noted that the last calibrations of instruments for organophosporous and organochlorine compounds were carried out in January 2013 and April 2012, respectively. For amitraz, coumafos and tau fluvalinate the last calibrations were carried out several years ago (in 2006, 2009 and 2010, respectively).
- The record keeping for controls and calibrations was not always in good order and some of the data/documents requested by the audit team were not available at the time of the visit (e.g. raw data of selected calibration for organophosphorous compounds and recovery calculation for a selected analytical run for amitraz).

Conclusions on laboratories

Notwithstanding the fact that several elements of a quality control system are in place in the national laboratories, the absence of validation, accreditation and proficiency testing for any of the methods used for the RMP, together with several deficiencies in performance such as irregular calibration of instruments and use of inappropriate (negative) control samples for analytical runs collectively undermine confidence in the reliability of results generated from the national laboratories. However, the majority of results reported under the RMP come from an accredited private laboratory in the EU and, notwithstanding the fact that this cannot really be considered as official testing, based on the performance information available, the competent authority can have confidence in the reliability of these particular analytical results.

5.3 Veterinary medicinal products and medicated feedingstuffs

5.3.1 Authorisation, distribution and use of veterinary medicinal products

Legal Requirements

Article 29 of Council Directive 96/23/EC states that guarantees offered by residue monitoring plans

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

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

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

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

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

Findings

MAG is the competent authority for veterinary medicinal products as regulated by *Law on Plant and Animal Health*, *Executive Power of the Republic of El Salvador – Legislative Decree No. 28 of 30.05.1980* and *Law on control of pesticides, fertilizers and products for agricultural use – Legislative Decree No. 315 of 10.05.1973*.

The DCARV within the DGG of MAG is responsible for the authorisation of veterinary medicinal products and for the licencing of manufacturers and distributors.

Rules for the authorisation and control of veterinary medicinal products and related products are laid down in the legally binding *Central-American Technical Regulation (Reglamentos Técnicos Centroamericanos - RTCA) number 65.05.51:8,* Annex 1 and 2 to *Resolution No. 257-2010 (COMIECO-LIX)* (hereafter referred to as the *RTCA*).

According to the *RTCA* the following substances are expressly prohibited to be used in honey bees (amongst other food producing animals): nitrofurans, chloramphenicol, sulphonamides (in feed), sulphathiazole (by any route of administration), organochlorides, vancomycin, dimetridazole,

strychnine, clenbuterol, stilbenes, malachite green and gentian violet (topical use permitted).

The production, marketing, import and export of narcotic and psychotropic substances and their precursors is controlled (Article 13 of the *Law Governing the Activities Relating to Drugs*). Other (veterinary) medicinal products, including those which may give rise to residues in food of animal origin, can be purchased without prescription of a health professional.

The *RTCA* stipulates that manufacturing licences, distribution/sales licences and marketing authorisations of veterinary medicinal products are valid for a renewable period of five years.

The audit team noted that:

- In the context of assessing applications for marketing authorisations DCARV applies MRLs set by the Codex Alimentarius if available. There are no Codex MRLs for honey.
- No veterinary medicinal products for honey bees were authorised at the time of the audit and there is no provision in national legislation allowing for "off-label" use of veterinary medicinal products.
- Bee-keepers in the EU are required to maintain records of treatments with veterinary medicinal products in accordance with Article 10 of Council Directive 96/23/EC and Chapter III of Annex I to Regulation (EC) 852/2004. There is no such requirement in national law in El Salvador. However, keeping of treatment records by bee-keepers has been actively promoted by non-governmental organisations, honey processing establishments as well as by the MAG (UIPA). Standardised record-keeping books have been made available to bee-keepers.

Conclusions on authorisation, distribution and use of veterinary medicinal products

The regulatory system in place for veterinary medicinal products and the fact that prohibitions for use of certain substances in food producing animals in El Salvador is broadly similar to the situation in the EU, decreases the likelihood of residues of pharmacologically active substances occurring in honey.

5.3.2 Controls on the distribution and use of veterinary medicinal products

Legal Requirements

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

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

rules governing control functions by the competent authorities are laid down in Articles 4, 9 and 13 of said Directive.

Findings

DCARV is responsible for the controls on manufacturing and the distribution chain of veterinary medicinal products. Powers to carry out controls, including the right of access to premises and to seize goods are derived from *Executive Power of the Republic of El Salvador – Legislative Decree No. 28 of 30.05.1980* and *Law on control of pesticides, fertilizers and products for agricultural use – Legislative Decree No. 315 of 10.05.1973*. Serious offences can be forwarded to the police. Veterinary medicinal products are produced both locally and imported.

The competent authority has no legal powers to carry out controls on the use of veterinary medicinal products at apiaries.

The audit team noted that:

- DCARV emerged from a reorganisation in the MAG in January 2011, at which the staffing level was significantly reduced. No regular controls have been carried out on manufacturers and distributors of veterinary medicinal products since then. DCARV is now mainly occupied with the processing of applications for marketing authorisations.

The audit team visited three manufacturing sites for, and four distributors (retail outlets) of, veterinary medicinal products. DIPOA was present at all of the visits, and DCARV at four visits (two of each type). The audit team also visited three apiaries and UIPA was present during these. It was noted that:

- None of the manufacturing and retail sites visited had been inspected by DCARV in the past two years.
- One manufacturing site had a licence as a distributor but not for manufacturing activities. This site produced an unauthorised amitraz-containing product intended for use in honey-bees. A plant protection product was used as the "active ingredient". The small label on the commercial pack was not in accordance with *RTCA* requirements as it only indicated a lot number and use-by date, and nothing with regard to target species, active ingredient(s), indications for use and precautions or withdrawal periods. This product had been sold to 258 apiaries in 2012.
- The two other manufacturing sites held a valid manufacturing licence, but there were no marketing authorisations for approximately half of the veterinary medicinal products produced in these facilities. Marketing authorisations had either never been granted or, if granted, had expired as far back as 1999. A furazolidone-containing premix was produced in one site, according to the company for use in poultry, although the use of furazolidone in all food producing species is prohibited in El Salvador. Both sites visited produced an oxytetracycline-containing product specifically indicated for use in honey bees, although the marketing authorisations had expired in 2004 and 2007 respectively. Together, these sites had produced approximately 10,000 commercial packs (available in 80 gramme, 100 gramme and one pound packages) in 2012.
- Two out of four distributors visited had no licence to sell veterinary medicinal products and all four had one or both of the oxytetracyline-containing products for honey-bees in stock and had sold these regularly in the previous 12 months. The products were mainly (but not exclusively) sold outside the honey production season.
- During the FVO audit, DCARV took immediate action by confiscating the unauthorised veterinary medicinal products in the manufacturing and retail sites visited, and producing,

inter alia, reports in relation to the lack of a distribution licence for retailers.

- The Division of Veterinary Services (*División de Servicios Veterinarios*) within DGG of MAG monitors the prevalence of bee diseases in El Salvador and visited 225 apiaries for this purpose in 2012. During the visits, hives are inspected for diseases and bee-keepers are given advice on disease control. The 2012 report on bee disease monitoring shows that 49% of apiaries had European foulbrood in the fourth quarter of the year. With regard to varrosis, 40% of the apiaries had an infection level of between zero and 5% and 9% had an infection rate of between 5 and 10%. In the apiaries visited detailed records of diseases and treatments were kept. The three apiaries had been affected by foulbrood at least once in the past two years and varrosis had been observed frequently outside as well as during the honey harvesting season. According to the treatment records, this condition was treated with amitraz and natural products such as eucalyptus oil whilst the foulbrood had been treated with calcium hydroxide (lime).
- Through meetings and courses, non-governmental organisations, honey processing establishments and DIPOA have raised awareness among bee-keepers of the risks of residues when using varrocides and antibiotics. Bee-keepers were advised not to use these outside the honey harvesting season in order to prevent residues. There has been no communication between UIPA and DCARV in relation to the (legality of) use of amitraz and oxytetracycline.

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

In spite of the fact that there are no authorised antimicrobial veterinary medicinal products for the treatment of honey bees in El Salvador, there is widespread availability and use of unauthorised products. Although efforts have been made to raise awareness among bee-keepers on the use of veterinary medicinal products which could cause residues in honey, the competent authorities' lack of controls on the manufacture, distribution and use of veterinary medicinal products, as well as a lack of communication between the relevant services, collectively undermine guarantees on the residues status of honey eligible for export to the EU.

6 Overall Conclusions

The structure of the residue monitoring plan in relation to the substance groups covered and numbers of samples is in line with Council Directive 96/23/EC and the scope of testing is generally broad. However, the effectiveness of the plan is undermined by the fact that a significant proportion of the scope is not decided by the competent authority, being based on the pre-export testing of a minority of exporting establishments. Furthermore, implementation of the plan is not in line with EU requirements, in particular due to the sampling strategy followed by the competent authority. The testing of blended honey reduces the chances for detection of residues, as does the prolonged storage of samples prior to analysis which has the potential to reduce the likelihood of detecting residues of certain substances (due to time-dependent analyte instability).

The strategy adopted by the competent authority for the follow-up of non-compliant results differs significantly from the approach taken in the EU. The fact that investigations are dependent on the availability of financial resources allied with a lack of legal powers for the competent authority to take measures/sanctions at farm level, poor co-operation between relevant official services, and, the dilution of non-compliant batches, collectively undermine the effectiveness of the residue control system.

With regard to the laboratories, notwithstanding the fact that several elements of a quality control system are in place in the national laboratories, the absence of validation and accreditation of methods allied with several deficiencies in analytical performance, undermine confidence in the reliability of results generated from the national laboratories. However, the majority of results reported under the residue monitoring plan come from an accredited private laboratory in the EU and, notwithstanding the fact that this cannot really be considered as official testing, based on the performance information available, the competent authority can have confidence in the reliability of these particular analytical results.

The regulatory system in place for veterinary medicinal products and the fact that prohibitions for use of certain substances in food producing animals in El Salvador is broadly similar to the situation in the EU, decreases the likelihood of residues of pharmacologically active substances occurring in honey. However, notwithstanding the efforts to raise awareness among bee-keepers on the use of veterinary medicinal products which could cause residues in honey, the widespread availability and use of unauthorised products for the treatment of honey bees and a lack of proper monitoring and enforcement by the competent authorities collectively undermine guarantees on the residues status of honey eligible for export to the EU.

7 Closing Meeting

A closing meeting was held on 24 January 2013 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities did not express disagreement and indicated the intention to rectify the shortcomings in due course.

Following the final meeting, the competent authority announced, inter alia, that for the 2012 RMP implementation (results not reported yet to the FVO), the 97 results from pre-export testing will not be reported and all necessary analyses will be performed in the 65 samples of honey collected by UIPA in 2012 (initially taken by establishments). From 2013 onwards, all RMP samples will be taken by UIPA directly from barrels of incoming honey and testing will continue to be arranged by the competent authority. In addition, the current position concerning the lack of legal powers for the competent authority to take measures/impose sanctions in apiaries in case of residue violations will be reconsidered.

8 Recommendations

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

N°.	Recommendation
1.	Ensure that information included in the RMP provided to the Commission services is accurate in order to provide guarantees at least equivalent to the requirements as laid down in Article 7 of Council Directive 96/23/EC.

N°.	Recommendation
2.	Ensure that the sampling strategy for the RMP provides guarantees at least equivalent to the requirements of point 1.1. in the Annex to Commission Decision 98/179/EC.
3.	Ensure that the follow-up of non-compliant results is always carried out by the competent authority and is effective in order to provide guarantees at least equivalent to the relevant requirements of Council Directive 96/23/EC (Articles 12, 13, 16-18, 23, 27 and 28).
4.	Ensure that any measures taken to achieve compliance of export batches with the EU rules specifically exclude dilution as required by Article 20 of Regulation (EC) 882/2004 and Codex Alimentarius Guidelines CAC/GL 71-2009.
5.	Ensure that all analytical methods used for the RMP are validated to a standard equivalent to Article 3 of Commission Decision 2002/657/EC, and are accredited in order to provide guarantees at least equivalent to the requirements of point 1.2. in the Annex to Commission Decision 98/179/EC.
6.	Ensure that controls on the distribution and use of veterinary medicinal products are carried out throughout the distribution chain – including on farms - in order that the residue monitoring plan provides equivalent guarantees to those foreseen in Council Directive 96/23/EC, in particular, Article 7, indent 1, of said Directive.

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

http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspection_ref=2013-6852

Annex 1 - Legal References

Legal Reference	Official Journal	Title
Audits by the Commission Services		
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Food Law		
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Monitoring and sampling of residues in food of animal origin		
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC

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

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

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

Legal Reference	Official Journal	Title
Reg. 252/2012	OJ L 84, 23.3.2012, p. 1-22	Commission Regulation (EU) No 252/2012 of 21 March 2012 laying down methods of sampling and analysis for the official control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EC) No 1883/2006
Sampling methods for pesticides in foodstuffs		
Dir. 2002/63/EC	OJ L 187, 16.7.2002, p. 30-43	Commission Directive 2002/63/EC of 11 July 2002 establishing Community methods of sampling for the official control of pesticide residues in and on products of plant and animal origin and repealing Directive 79/700/EEC