FINAL REPORT OF AN AUDIT
CARRIED OUT IN
CHINA
FROM 07 TO 21 NOVEMBER 2013
IN ORDER TO EVALUATE THE CONTROL OF RESIDUES AND CONTAMINANTS IN LIVE
ANIMALS AND ANIMAL PRODUCTS INCLUDING CONTROLS ON VETERINARY
MEDICINAL PRODUCTS

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

This report describes the outcome of a Food and Veterinary Office (FVO) audit in China, carried out between 7 and 21 November 2013, as part of the published programme of FVO audits on the monitoring of residues in live animals and animal products in European Union (EU) Member States and in third countries.

The objective of the audit was to evaluate the implementation of national measures, aimed at the control of residues and contaminants in live animals and animal products, in order to assess whether these systems offer adequate assurance that the products and animals concerned are within the specified residue limits laid down in EU legislation. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit. 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, in general, the system of residues controls in China offers guarantees with an effect equivalent to those provided for by EU rules concerning those commodities in the export-oriented scheme for which China has an EU approved residue monitoring plan (poultry, aquaculture, eggs, rabbits and honey). Planning and implementation of the residue monitoring plan and follow-up of non-compliant results are generally satisfactory, notwithstanding some omitted information in the residue monitoring plan submitted to the Commission services and continued uneven distribution of sampling over the year. Extensive own-checks and compulsory official pre-export testing for residues provide additional assurances on the residues status of products exported to the EU.

The laboratory network is performing well and the competent authorities can rely on the testing results issued. There is a regulatory framework and system in place for the authorisation of veterinary medicinal products, establishing maximum residue limits and setting withdrawal periods and for the afore-mentioned commodities the system offers similar guarantees to that in the EU, although differences exist concerning some MRLs and certain products authorised for use in honey bees. Regular controls are performed on the distribution and use of veterinary medicinal products. Overall very significant progress has been made in addressing most of the recommendations of the last FVO residues audit in 2009.

The report makes a number of recommendations to the Chinese competent authorities, aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.
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<table>
<thead>
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<th>Explanation</th>
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<tbody>
<tr>
<td>AQSIQ</td>
<td>General Administration for Quality Supervision, Inspection and Quarantine</td>
</tr>
<tr>
<td>CAIQ</td>
<td>Chinese Academy of Inspection and Quarantine</td>
</tr>
<tr>
<td>CCalpha / CCbeta</td>
<td>Decision Limit / Detection Capability</td>
</tr>
<tr>
<td>CIQ</td>
<td>Entry-Exit Inspection and Quarantine Bureau</td>
</tr>
<tr>
<td>CNAS</td>
<td>China National Accreditation Service</td>
</tr>
<tr>
<td>DG(SANCO)</td>
<td>Health and Consumers Directorate-General</td>
</tr>
<tr>
<td>EC</td>
<td>European Community</td>
</tr>
<tr>
<td>EOS</td>
<td>Export-Oriented Scheme</td>
</tr>
<tr>
<td>EU</td>
<td>European Union</td>
</tr>
<tr>
<td>FVO</td>
<td>Food and Veterinary Office</td>
</tr>
<tr>
<td>Group A, B</td>
<td>Categories of substances listed in Annex I to Council Directive 96/23/EC:</td>
</tr>
<tr>
<td>IQTC</td>
<td>Guangdong Inspection and Quarantine Technical Centre</td>
</tr>
<tr>
<td>ISO</td>
<td>International Organisation for Standardisation</td>
</tr>
<tr>
<td>LC-MS/MS</td>
<td>Liquid Chromatography-(Tandem) Mass Spectrometry</td>
</tr>
<tr>
<td>LIMS</td>
<td>Laboratory Information Management System</td>
</tr>
<tr>
<td>LoD</td>
<td>Limit of Detection</td>
</tr>
<tr>
<td>LoQ</td>
<td>Limit of Quantification</td>
</tr>
<tr>
<td>ML</td>
<td>Maximum Level</td>
</tr>
<tr>
<td>MoA</td>
<td>Ministry of Agriculture</td>
</tr>
<tr>
<td>MRL</td>
<td>Maximum Residue Limit</td>
</tr>
<tr>
<td>MRPL</td>
<td>Minimum Required Performance Limit</td>
</tr>
<tr>
<td>P.R.C.</td>
<td>People's Republic of China</td>
</tr>
<tr>
<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
</tr>
<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
</tr>
</tbody>
</table>
1 INTRODUCTION

The audit took place in China from 7 to 21 November 2013. The audit team comprised two auditors from the Food and Veterinary Office (FVO) and one expert from a European Union (EU) Member State. 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 7 November 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 at central and regional levels, the legal and administrative measures in place to give effect to the relevant EU requirements, controls with regard to residues and veterinary medicinal products and their operation, and the performance of residue laboratories. Attention was paid to examining the implementation of corrective actions promised in response to recommendations made in the report of a previous FVO residues audit to China (DG (SANCO)/8187/2009) in November 2009. The table below lists sites visited and meetings held in order to achieve that objective.

<table>
<thead>
<tr>
<th>Meetings/Visits</th>
<th>N</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Competent Authorities</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Central</td>
<td>2</td>
<td>Opening and closing meetings with the General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) and Ministry of Agriculture (MoA)</td>
</tr>
<tr>
<td>Regional</td>
<td>5</td>
<td>Meetings with the provincial authorities of AQSIQ Entry-Exit Inspection and Quarantine Bureaus (CIQ) in Guangdong, Jilin and Zhejiang provinces. Meetings with the provincial authorities of MoA in Guangdong and Zhejiang provinces</td>
</tr>
<tr>
<td>Laboratories</td>
<td>5</td>
<td>Five Governmental laboratories</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Veterinary Drug Supervisory Institute of the People's Republic of China (P.R.C.) under MoA</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Chinese Academy of Inspection and Quarantine under AQSIQ</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Laboratory of CIQ in Guangzhou (Guangdong province)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Laboratory of CIQ in Changchun (Jilin province)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Laboratory of CIQ in Hangzhou (Zhejiang province)</td>
</tr>
<tr>
<td>Farms</td>
<td>3</td>
<td>One shrimp farm, one tilapia farm and one rabbit farm, all belonging</td>
</tr>
</tbody>
</table>
### Meetings/Visits

<table>
<thead>
<tr>
<th>Meetings/Visits</th>
<th>N</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>to the Export-Oriented Scheme (EOS)</td>
<td>4</td>
<td>Shrimp, tilapia, rabbit and honey processing plants within the EOS</td>
</tr>
<tr>
<td>Establishments</td>
<td>4</td>
<td>One wholesaler and three retailers of veterinary medicinal products in Guangdong, Jilin and Zhejiang provinces</td>
</tr>
</tbody>
</table>

#### 3 Legal Basis

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


- 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;

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


##### 4.2 Summary of previous FVO audit reports

The residues sector was most recently inspected by the FVO in 2006 (DG(SANCO)/8294/2006 MR Final) and 2009 (DG(SANCO)/2009-8187 MR Final). The reports of both audits (henceforth referred to as the 2006 and 2009 FVO audits respectively) have been published on the website of the Directorate – General for Health and Consumers here: [http://ec.europa.eu/food/fvo/ir_search_en.cfm](http://ec.europa.eu/food/fvo/ir_search_en.cfm). The most recent report concluded that there was a comprehensive control system in place concerning residues in food of animal origin and the use of veterinary medicinal products in food producing animals, underpinned by a well-equipped laboratory network. Notwithstanding some of the shortcomings identified, for example concerning the follow-up of non-compliant results and incomplete validation of some analytical methods, it was concluded that significant progress had been made relative to the findings of previous FVO residues audits and that the control system for residues in food of animal origin and the guarantees provided by this system could in general be considered to be equivalent to those provided for by Union legislation.
Since the 2009 audit there were 30 RASFF notifications for residues of veterinary medicinal products until November 2013. Six of these involved the detection of nitrofurans/furazolidone in shrimp, two cases of sulphonamides in tilapia, one case of nitrofurans in crayfish, nine cases of chloramphenicol in casings, two cases of nitrofurans/ furazolidone in casings, two cases of toltrazuril in chicken, one case of chloramphenicol in rabbit meat, three cases of lincomycin in honey, one case of metronidazole in honey, one case of lincomycin and erythromycin in honey and two cases of leuco-malachite green in caviar and tilapia.

4.4 Production and Trade Information

The 2013 Chinese residue monitoring plan included the following data on estimated export volumes of animal products to the EU. The export-oriented scheme (EOS) has been described in the 2006 and 2009 FVO audit reports. Total production data for farms and establishments in the EOS were not provided. Commission Decision 2002/994/EC (as amended) sets out certain protective measures with regard to products of animal origin imported from China, including the testing before dispatch of consignments for chloramphenicol, nitrofurans and its metabolites and also the testing of aquaculture consignments for malachite green, crystal violet and their metabolites.

Estimated exports to the EU in 2013 (based on export volume in 2012)

<table>
<thead>
<tr>
<th>Commodity</th>
<th>Estimated export volume to EU (tonnes)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frozen fish fillet</td>
<td>350000</td>
</tr>
<tr>
<td>Sea-caught shrimp</td>
<td>35000</td>
</tr>
<tr>
<td>Crayfish</td>
<td>15000</td>
</tr>
<tr>
<td>Farmed shrimp</td>
<td>4000</td>
</tr>
<tr>
<td>Eel</td>
<td>1000</td>
</tr>
<tr>
<td>Casings</td>
<td>42000</td>
</tr>
<tr>
<td>Honey</td>
<td>51000</td>
</tr>
<tr>
<td>Rabbit meat</td>
<td>5000</td>
</tr>
<tr>
<td>Poultry meat</td>
<td>10000</td>
</tr>
</tbody>
</table>

5 Findings and Conclusions

5.1 Residue Monitoring

5.1.1 Competent authorities involved

A description of the main competent authorities involved in the controls of residues and veterinary medicines and contaminants has been provided in the 2006 and 2009 FVO audit reports. The General Administration for Quality Supervision, Inspection and Quarantine (AQSIQ) is responsible
for exported commodities and the Ministry of Agriculture (MoA) is primarily responsible for the control and supervision of production for the domestic market.

5.1.2 Planning of residue monitoring plan

Legal Requirements

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

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

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

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

Findings

The planning process for the residue monitoring plan has been described in the 2006 and 2009 FVO audit reports. In summary, separate plans are developed by AQSIQ (covering farms and establishments in the EOS) and MoA (principally covering production intended for the domestic market). These separate plans are then combined and a composite residue monitoring plan is sent to the Commission services by the beginning of April each year. The audit team was informed that there has been no change to the legal basis for the residue monitoring plan in China since the last audit in 2009. The audit team noted that:
➢ The 2013 residue monitoring plan sent to the Commission services included all samples to be taken by the Entry-Exit Inspection and Quarantine Bureau (CIQ) and by MoA. The plan is designed to run from January to December each year.

➢ In preparing the plan relevant factors are taken into account, including the results from the previous year (especially non-compliant results), outcome of pre-export testing, RASFF notifications and risk alerts received from importing countries, prohibited medicines and particular requirements of importing countries, as well as available data on the use of veterinary medicines. Minutes of meetings were available to show the preparatory steps in compiling the residue monitoring plan each year, including consultations organised with relevant experts.

➢ In most cases where non-compliant results had been detected during implementation of the 2012 residue monitoring plan, the number of samples planned for that substance/commodity was increased in the 2013 plan. In those cases where the planned sample number was reduced (e.g. nicarbazin in chickens, enrofloxacin and ciprofloxacin in eel) the audit team was informed that the reduced sample numbers were due to lower expected production volumes.

➢ The 2013 plan specifies changes made concerning substances to be tested for compared to the 2012 plan. For example zilpaterol and spectinomycin were added to the list of substances tested for in chickens, while testing for dapsone in honey and melamine in aquaculture fish, shrimp and eel were discontinued.

➢ Overall the scope of substances tested for was satisfactory, taking into account available veterinary medicinal products. For some commodities there is scope for the range of substances tested for to be possibly extended, for example lasalocid and narasin in chickens, doxycycline in eggs, emamectin in fin fish, robenidine, lasalocid, narasin, salinomycin and maduramicin in rabbits.

➢ Variation in export volumes and exported animal products and species are taken into account in preparing the plan. The 2013 plan included estimated export volumes of animal products to the EU (based on 2012 data) and figures for domestic production output.

➢ Since the EOS essentially operates as a split system separate from production for the domestic market, the failure to provide data on total production in the EOS which could be exported to the EU means that the equivalence of sample numbers planned and taken compared to the requirements of Council Directive 96/23/EC cannot be assessed, although it is stated in the plan that the sampling levels are in accordance with the requirements of Council Directive 96/23/EC.

➢ The EOS also encompasses production which is destined to be exported to countries other than the EU and additional commodities which are not exported to the EU and for which there is not an EU approved residue monitoring plan.

➢ The plan sent to the Commission services each year does not mention the MRLs or action levels of substances tested for, thus preventing an assessment of whether these MRLs are in accordance with EU limits. These MRLs and action levels are listed in the separate MoA and AQSIQ plans developed nationally, used as the basis for implementation by the
Concerning the authorisation of veterinary medicinal products, the MRLs in MoA Order No. 235 of 3 November 2008 are generally in line with, or lower than, those established in the EU. There are, however, some exceptions, such as the Chinese MRLs for deltamethrin and oxolinic acid in fish which are higher than those in the EU (see also section 5.3.1).

Conclusions on planning of the residue monitoring plan

Planning of the residue monitoring plan is comprehensive, timely and well-coordinated. Relevant commodities, substances and substance groups are tested for and appropriate data are taken into account, such as previous non-compliant results and RASFF alerts as well as information on medicines used, although the plan sent to the Commission services does not include MRLs or action levels for the substances tested for. In the absence of data on total production in the EOS which could be exported to the EU, the appropriateness of sample numbers planned and taken in terms of equivalence to the requirements of Council Directive 96/23 could not be assessed.

5.1.3 Implementation of the residue monitoring plan

Legal Requirements


Findings

AQSIQ and MoA residue monitoring plans are developed and implemented separately. According to the “Technology specifications of residues monitoring of animals and animal-origin foodstuffs for export” (document reference SN/T 3197/2012), AQSIQ arranges a meeting of experts from local CIQ offices to arrange implementation of the residue monitoring plan. Local or branch CIQ staff are responsible for implementing the plan, taking and delivering samples and performing associated inspections and official controls. The MoA plan is issued having been reviewed by the National Expert Committee on Veterinary Drug Residues, and its implementation is based on the Regulations on Administration of Veterinary Drugs and the Residue Monitoring Programme on Animals and Foodstuffs of Animal Origin of the P.R.C. (Nongmufa 1999 No. 8). The MoA plan is issued to provincial livestock and veterinary authorities and residue testing laboratories, with official staff also responsible for taking, delivering and testing these samples. Given that the MoA plan generally does not involve taking samples in EOS farms or establishments, this section will concentrate on
implementation of the AQSIQ plan. The audit team noted that:

➢ AQSIQ is responsible for issuing the annual residue monitoring plan to CIQ offices and collecting and reporting the overall results. Provincial CIQ offices develop more detailed month-by-month plans for implementing that portion of the residue monitoring plan allocated to their province and also supervise progress made in implementing the plan. Monthly reports are submitted by CIQ offices to AQSIQ detailing implementation of the residue monitoring plan at local level and the audit team saw that plans had been implemented as foreseen with the targeted number of samples being taken. In this way **recommendation No. 2** of the 2009 report has been addressed.

➢ Detailed implementation workplans are developed at local or branch CIQ level considering the samples allocated to be taken, including selecting the farms or establishments to be sampled and deciding when sampling will take place. Seasonal feeding, production and medicine usage factors are taken into account in deciding when and where sampling should take place.

➢ Staff from local or branch CIQ offices are responsible for taking samples and delivering these to the designated testing laboratories. Generally CIQ laboratories analyse samples taken for the CIQ plan and MoA laboratories analyse samples taken under the MoA plan.

➢ AQSIQ has issued written instructions to staff on the selection of animals and farms to be sampled and the taking, identification, packaging, storage and transport of samples. Sampling is normally carried out randomly and unannounced. In the aquaculture sector the audit team saw that processors often accompanied CIQ staff performing inspections on EOS farms and were given one day’s advance notice of such inspections. Although sampling for the residue monitoring plan could take place during such inspections, the decision on whether or not sampling was planned was not announced in advance to the processor or farmer.

➢ Staff had received training on how to perform their tasks and were provided with appropriate equipment, including for the sealing and transport of samples. Samples were generally sent promptly to the designated laboratories for testing.

➢ According to the standard SN/T 3197-2012, once samples are received, AQSIQ, MoA and the laboratories have agreed a turnaround time of 15 working days to complete the testing, with up to 30 days possible in certain cases. This turnaround time was generally complied with in the cases seen by the audit team, although in one of the provinces visited, due to internal difficulties in the testing laboratory, some samples in 2013 took up to five months for results to be issued. In case of non-compliant results, such a long turn-around time could hamper the timely and effective follow-up of such cases.

➢ Honey collection bases (similar to honey collection centres) are registered with CIQ in the provinces where the EOS honey processing plant they supply is located. When the honey collection base is located in a different province to the processing plant, this means that normally only CIQ staff in the province of the processing plant are aware of the EOS registration of the honey collection base. Therefore CIQ officials in the other province could

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1 In their response to the draft report the competent authorities confirmed that they had already identified this problem in July 2013 and that corrective measures had been taken with follow-up in October 2013 to confirm that the agreed turnaround times were now being complied with.
be unaware that a honey collection base in their territory exists or is registered to supply a processing plant in another province, which could impact on the targeting of sampling and possible coordination of follow-up in case of non-compliant results, given that CIQ staff are normally not authorised to perform official sampling, inspections or follow-up outside of their own province².

➢ Bee farmers are registered with honey collection bases but are not formally individually registered with CIQ as part of the EOS. This means that any bee farmer could be eligible to register with an EOS honey collection base in order for their honey to be exported³. The audit team was informed that there is a 10-15% higher price for EOS honey compared to honey produced for domestic consumption.

➢ The audit team also examined a case where honey from a farmer not registered with an EOS honey collection base was submitted to an EOS processing plant. This honey (contaminated with metronidazole) was submitted as part of a consignment from a farmer registered with an EOS honey collection base by one of his employees who also kept bee hives and produced honey but who was not registered with an EOS collection base⁴.

➢ As in 2009, sampling is not evenly distributed throughout the year. For example in one province visited, in 2012 no samples were taken in January, October, November or December. The audit team was informed that no samples are taken in January due to public holiday periods and no samples are planned for November or December in order to complete all sampling by October and have test results and reports available before the end of the year. In this way recommendation No. 1 of the 2009 report has not been fully addressed.

➢ In another province the audit team saw that rabbit sampling took place in 2012 over three consecutive days in April and one day in September, although sampling was more evenly distributed in 2013. Also in this province honey sampling in 2012 took place over the course of four days in September within a six day period and in 2013 took place over three successive days in September and one day in October. Although rabbit sampling was distributed broadly across a range of farm suppliers, for honey sometimes the same barrels/lot of honey were repeatedly sampled over consecutive days (although normally tested for different substance groups), which raises a concern regarding the possible clustering of sampling⁵.

Conclusions on implementation of the residue monitoring plan

The residue monitoring plan is generally implemented as planned, with the foreseen number of samples being taken although sampling is often not very evenly distributed throughout the year. Reports on implementation of the plan and samples taken are regularly submitted by provincial

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2 In their response to the draft report the competent authorities stated that if any non-compliances were found in the administration of honey collection bases the registration of the base would be cancelled and in serious cases the export status of associated processing establishments would be suspended.
3 In their response to the draft report the competent authorities stated that any bee farmers not compliant with relevant requirements would not be registered.
4 In their response to the draft report the competent authorities stated that CIQ has urged related enterprises to strengthen training for registered bee farmers and will strengthen the supervision on registered bee farmers using feed.
5 In their response to the draft report the competent authorities confirmed that in this province sample collection would be planned to be evenly distributed during the whole honey production period (about one month) in the future.
offices to AQSIQ, thus helping to ensure that the sample numbers planned overall are complied with.

5.1.4 Other residues monitoring programmes

Legal Requirements


5.1.4.1 Pre-export testing for residues

Findings

Commission Decision 2002/994/EC (as amended) sets out certain protective measures with regard to products of animal origin imported from China, including the testing before dispatch of consignments for chloramphenicol, nitrofurans and its metabolites and also the testing of aquaculture consignments for malachite green, crystal violet and their metabolites. The audit team noted that:

➢ AQSIQ-CIQ organise the compulsory pre-export analysis of each consignment prior to certification for export to the EU in line with the requirements of Commission Decision 2002/994/EC.

➢ These analyses are performed in CIQ laboratories, on samples taken by official CIQ staff. CIQ staff issue export certificates for the consignments in question following their inspection, quarantine and completion of testing with satisfactory results.

➢ Testing turnaround requirements are less than one week.

5.1.4.2 Establishment own-checks

Findings

The establishments and processing plants visited by the audit team operated their own in-house 100% pre-harvest or pre-production checks for EU-prescribed residues (mainly nitrofurans and chloramphenicol). All of these processors were also performing inspections and checks on supplying farms and apiaries, including checks on the use of veterinary medicinal products. The audit team noted that:

➢ The company own-check laboratories seen were equipped to a similar standard as the CIQ approved laboratories conducting pre-export tests, and running identical National Standard methods. Staff were trained and knowledgeable, appropriate quality control samples were run and these laboratories also participated in relevant proficiency tests.
➢ The honey processing plant visited had detected residues several times in incoming product in 2012 and 2013: three cases involved sulphonamides, five findings of streptomycin, two cases of fluoroquinolones, one tetracycline and one nitroimidazole case. In each case the affected honey was returned to the supplier and could be submitted for processing elsewhere, while CIQ was only informed of these findings by means of a summary report submitted by the processor at the end of the year. This summary report mentioned five cases of residues being detected in incoming honey, but did not specify the substances identified, and also stated that the processor had identified deficiencies among some of its suppliers concerning record-keeping of treatments with veterinary medicinal products.

➢ The shrimp and tilapia processing plans visited were also performing routine pre-harvest, in-process and end-product testing for residues. The audit team examined one case where quinolones were detected in a pre-harvest check performed by the shrimp processing plant. When the farmer refused to allow the processor to take a follow-up sample CIQ was informed. CIQ staff were also prevented by the farmer from taking any follow-up samples and a few weeks later the farmer was removed from the EOS.

Conclusions on other residues monitoring programmes

The compulsory pre-export testing scheme is well-resourced and highly standardised, using national standard methods and this, together with the extensive own check testing performed by processing companies, serves to strengthen the overall guarantees offered by the residue monitoring plan on the residues status of commodities 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

AQSIQ and CIQ are empowered under the Food Safety Law of the P.R.C. and the Product Quality Law of the P.R.C. to carry out follow-up investigations of non-compliant results and RASFF notifications and to impose sanctions and penalties where appropriate. Typically local CIQ offices perform investigations to trace back the source of the contamination and, depending on the outcome, the EOS registration of the farm or enterprise may be suspended or cancelled. More

6 In their response to the draft report the competent authorities informed that bee farmers would be trained to make them aware of the legislation of importing countries and that companies exporting to the EU would be required to strictly check raw materials, semi-finished products and end-products to comply with EU requirements.

7 In their response to the draft report the competent authorities informed that if enterprises detect residue problems during own-checks they should immediately suspend purchasing raw materials from the farm and from then the farm is excluded from the EOS. At the same time enterprises would inform CIQ in order to conduct a follow-up investigation and sampling. If violations were detected on the farm CIQ would cancel its registration and the entire process may take several weeks.
serious cases would be submitted to AQSIQ and the enterprise could be included in the “List of Export Food Safety Risk Alert Notifications”. MoA and its local veterinary authorities are similarly authorised to perform follow-up investigations concerning non-compliant residue results and to impose sanctions as necessary. The audit team noted that:

- Technical standard SN/T 3197-2012 sets out written instructions for staff on performing follow-up investigations in case of non-compliant results being detected, including the taking of follow-up samples, restrictions to be placed on the farm or establishment involved, recall of products already exported or a block on shipping if the product has not yet been exported.

- Non-compliant results are promptly notified (normally on the same day) from the testing laboratories to the sampling authority (e.g. to the CIQ and local sampling unit CIQ office in case of samples taken from EOS farms and establishments). Non-compliant results are also notified to AQSIQ which maintains an overview of the non-compliant results reported.

- Local CIQ offices also routinely inform local government, including MoA and the local government veterinary or fisheries bureau, of non-compliant results reported since there also may be implications for residues sampling in domestic production supervised by MoA. MoA are also involved in and informed of the outcome of follow-up investigations led by CIQ for samples taken in EOS farms and establishments.

- In the cases seen by the audit team farms were promptly visited by CIQ inspectors to investigate the reasons for the non-compliant result and to take follow-up samples as appropriate. In all cases seen by the audit team it was possible to trace non-compliant product back to the farm of origin and in the majority of cases the source of the residue was identified. Certain farms were removed from the EOS on foot of the non-compliant results detected. There was also evidence of collaboration and exchange of information between CIQ and MoA in following up these non-compliant results. In this way recommendation No. 3 of the 2009 report has been addressed.

- Detailed files were available concerning the follow-up of RASFF notifications in consignments exported to the EU. In the cases seen by the audit team, appropriate, timely and effective measures had been taken.

**Conclusions on follow-up of non-compliant results**

The follow-up of non-compliant results and RASFF alerts was well-documented and generally timely and effective, including collaboration and the transmission of information between the different services involved.

### 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

5.2.1 General description

Findings
China has two parallel networks of approved laboratories for testing national residue monitoring plan samples; those under the MoA and those under AQSIQ. The MoA network is intended to test samples of products for domestic consumption, whilst the AQSIQ network tests samples from the EOS.

Each of the networks has its own designated reference laboratories. The MoA network currently has four reference laboratories for veterinary medicinal residues, respectively located in the China Institute of Veterinary Drug Control, China Agricultural University, Huazhong Agricultural University and South China Agricultural University. Each reference laboratory has its own responsibility, responsible for testing methods research and amendment, as well as testing on certain categories of medicinal residues (for details, please refer to MoA Order No. 1624). The AQSIQ network has nine reference laboratories, each having designated responsibility for specific substance groups. AQSIQ reference laboratories are designated each year by means of their inclusion in the published annual residue monitoring plan. The audit team noted that:

- The responsibilities of AQSIQ reference laboratories are defined in Industrial Standard SN/T 3197-2012. These mirror the national reference laboratory responsibilities in Article 33 of Council Regulation 882/2004/EC, along with additional responsibilities relating to keeping abreast of the legal requirements of trading partner countries and for providing an avenue for challenge-analysis should this be requested by a food business operator.

- Similarly, the Chinese Academy of Inspection and Quarantine (CAIQ), one of the nine AQSIQ reference laboratories, publishes "National Standard" methods. These are widely used within the AQSIQ network, and also within the laboratories of food business operators conducting own-check analyses, although there is no obligation for the approved laboratories to use these methods. Rather, AQSIQ has a guidance document for method performance characteristics (2011/405, issued in November 2011), specifically validation guidelines. The requirements are similar and generally equivalent to those in Commission Decision 2002/657/EC, although fewer replicates are required for precision studies and it uses limit of detection (LoD) and limit of quantification (LoQ) terminology rather than CCalpha and CCBeta. In this way recommendation No. 7 of the 2009 report has been satisfactorily addressed.

5.2.2 On the spot visits in the laboratories

The audit team visited one MoA laboratory and four AQSIQ laboratories. The audit team noted that:
There is a general requirement from the MoA and AQSIQ that approved laboratories are accredited to ISO 17025 by the China National Accreditation Service (CNAS). All laboratories visited had accreditation that covered the scope of the methods seen. CNAS inspect laboratories approximately once every 18 months. The inspections involve multiple auditors over many days, and include witnessing the analysis of a "blind" quality control sample.

The CNAS inspection reports that the audit team saw had relatively few findings. All non-compliances seen were satisfactorily addressed by the laboratory in question, and signed-off by their internal quality assurance department. There were, however, very limited requirements from CNAS for the laboratory to provide evidence of root-cause analysis (a requirement of ISO 17025). Evidence was seen at each laboratory of a comprehensive system of internal audits, providing additional assurance to the CNAS audits.

The issue of a challenge analysis had not arisen in any of the laboratories visited. The practical approach to providing a second sample for potential challenge analysis varied between provinces. In Guangdong, each sample was split in the laboratory, with one portion reserved for challenge analysis. In Beijing, each sample was also split, but the audit team was told that the producer had no right to demand the second sample; any challenge would need to entail re-sampling. In Jilin and Hangzhou, two samples were collected and the laboratory received them in individually sealed bags, storing one untouched for future challenge.

There was an effective system in place for anonymising the sample details within the laboratories. The form accompanying each sample received at the laboratory was not the original sampling form, but rather a second "sample submission" form that gave neither the establishment/farm name nor the sample collection date.

All laboratories visited were well-equipped with LC-MS/MS instrumentation which provided suitable capacity, selectivity and sensitivity to run all of the test methods demanded by the national residue monitoring plan. Staff were trained and knowledgeable, with comprehensive training records available, and all instruments seen were being operated correctly and appropriately. Laboratories had appropriate calibration and check procedures for instruments and equipment, and these procedures were followed and regularly checked.

There were sufficient staff and equipment in place to perform the tasks related to the residue monitoring plans, and results for the samples that were seen by the audit team in the laboratories were reported within the required turnaround time.

All examples of method validation seen in all laboratories visited, whether following AQSIQ 2011/405 or the laboratory's own validation protocol, provided suitable repeatability, reproducibility, LoD, LoQ and uncertainty characteristics. They all used the Commission Decision 2002/657/EC identification points approach to confirmation. Although the numbers of replicates for precision estimation (as prescribed in AQSIQ rule 2012/83) were fewer than would typically be used to comply with Commission Decision 2002/657/EC, the validation protocols used could demonstrate equivalent assurance to those used by EU Member States. In this way recommendation No. 5 of the 2009 audit has been addressed.
Laboratories participated in appropriate proficiency test schemes, planning their participation and collating their results. All results seen were satisfactory. AQSIQ reference laboratories organised regular proficiency tests for both approved AQSIQ laboratories and also for companies' own-check laboratories. Examples seen included EU-banned drugs (beta-agonists) at concentrations approaching the method LoQ. In this way recommendation No. 6 of the 2009 report has been addressed.

Examples of fit-for-purpose method validation files were seen in all of the laboratories visited. All method standard operating procedures (SOPs) seen were controlled, within date, and supported by an appropriate validation file.

Reference standards were appropriately stored and controlled in segregated rooms or areas.

### 5.2.2.1 The Veterinary Drug Supervisory Institute of the Peoples’ Republic of China, Beijing, reference laboratory under MoA

**Findings**

The Institute has a wide range of responsibilities relating to veterinary and animal health, including veterinary medicinal product safety data assessment. In addition to acting as a reference laboratory, and developing and validating MoA standard methods, the laboratory is responsible for the analysis of approximately 300 MoA residue monitoring plan samples per year. These samples are received once per quarter. The audit team noted that:

- The Institute had run a method-specific training course in both 2012 and 2013 and had accepted staff from other MoA laboratories for training. Two proficiency test schemes were organised, each with one round per year.

- The Institute had facilities to raise animals of known medication history for use as blank controls. Blank samples and spikes were run as controls alongside test samples. In the examples seen (nitrofurans in poultry, using the MoA standard method) the lowest spiking concentration was at 2 μg/kg i.e. four times the LoQ (best practice for screening assays is to spike at the LoQ). In the examples seen, the signal-to-noise ratio of the spike samples was sufficient to provide assurance that the LoQ could be comfortably achieved on the day.

### 5.2.2.2 Chinese Academy of Inspection and Quarantine Laboratory (CAIQ) Beijing, reference laboratory under AQSIQ

**Findings**

This laboratory does not receive a regular sample allocation within the AQSIQ residue monitoring plan, but acts as a subcontractor for analyses where approved laboratories do not have validated methods or testing capacity. It also undertakes some confirmatory tests. The laboratory is designated as a reference laboratory for thyrostats, nitrofurans, chloramphenicol, hormones, glucocorticoid steroids, non-steroidal anti-inflammatory drugs and dioxins/PCBs. The audit team noted that:

- In 2013 the laboratory had tested 440 residue monitoring plan samples to date (eight of which were confirmations), a substantial increase on the 35 tested in 2012.
➢ The research and development team was equipped with a variety of LC-MS/MS models encompassing most of the common source designs on the market, giving a very flexible resource for method development, optimisation and troubleshooting.

➢ CAIQ ran regular training for AQSIQ approved laboratories on specific topics within its remit, although within the last two years these topics had not included any related to veterinary medicine residues.

➢ The laboratory runs a laboratory information management system (LIMS) which includes a well-controlled electronic document management system.

➢ Examples were seen of glucocorticoid chicken samples sub-contracted from XinJiang CIQ accompanied by sample submission forms completed by XinJiang CIQ. CAIQ staff had no access to data on sample collection dates, or whether the samples had spent any time at the XinJiang laboratory prior to subcontracting. For the samples seen, turnaround times within the CAIQ laboratory were within the 15 day target.

➢ Balances for weighing both samples and standards were contained within the same room, but individual balances were reserved for standards only or for samples only. No evidence was seen of cross-contamination.

➢ Blank samples and spikes at the LoQ are run along with each batch of samples.

➢ Evidence was seen that CAIQ participated in meetings where the residue monitoring plan for the EOS was planned, and where programmes of work were agreed for the AQSIQ reference laboratories.

5.2.2.3 Guangdong Inspection and Quarantine Technical Centre (IQTC), Guangzhou, under AQSIQ

Findings
Veterinary drug residues analysis is conducted by the Instrument Testing Department, which has 33 of the IQTC's 96 staff. Samples are received and reported through the separate General Affairs and Customer Service Department.

In addition to annually testing approximately 1,400 residue monitoring plan samples per year, the Instrument Testing Department also tests pre-export certification samples and samples for pesticide residues; a total of some 6,000 samples per year. The audit team noted that:

➢ Residue monitoring plan samples are received once per month and many tests were started in parallel. Relative to the well-equipped instrument rooms, the room for sample extraction had more limited equipment (for example a single blender, a single nitrogen blow-down station). Staff did not view this as a significant restriction, and no evidence was seen of an adverse effect on turnaround times.

8 In their response to the draft report the competent authorities noted that the technology centre food laboratory of Guangdong CIQ is equipped with two bulk food grinders, five food bruisers, four N-EVAPs (two more arriving shortly having recently concluded an open tender for purchasing) and four rotary evaporators which can fully meet the requirements for residue control sampling.
➢ The IQTC’s turnaround requirement for residue monitoring plan samples is 30 calendar days from receipt at the laboratory. This contradicts the central AQSIQ requirement of 30 calendar days to report a confirmed result, but 15 working days for a screening analysis. The AQSIQ target is also measured from the date of sampling, rather than the date of receipt at the laboratory. The majority of IQTC’s samples (i.e. those other than residue monitoring plan samples) are on seven day turnaround time requirements (mainly pre-export tests).

➢ When the sample is received at the laboratory the entire sample is homogenised prior to splitting and storing a reference sample in case of a challenge analysis. This is not ideal, as it gives the food business operator a potential defence that the sample could have been contaminated during the homogenisation process. Mincing can also shorten the shelf-life of some sample-type or residue combinations.

➢ The laboratory had a documented procedure for the acceptance and rejection criteria of samples.

➢ Standards were appropriately stored in a segregated room.

➢ In practice, the laboratory tests for a wider range of residues within some substance groups (e.g. quinolones) than those reported in the annual residue monitoring plan and results submitted to the Commission services. Staff explained that the annual plan and results reflect the minimum common coverage of each of the approved laboratories in the network, and that some laboratories test for a wider scope.

5.2.2.4 Technical Centre of the Jilin Entry-Exit Inspection and Quarantine Bureau, Changchun, under AQSIQ

Findings
The residues testing laboratory was established within the Technical Centre in 2012. In addition to veterinary residues, the residues testing laboratory has responsibility for substances such as mycotoxins and additives. They are allocated approximately 500 AQSIQ residue monitoring plan samples per year plus approximately 500 residues samples from other sources (mycotoxins, additives, pre-export tests and private samples), approximately 10% of the Technical Centre’s throughput as a whole. Sample reception, registration, storage and disposal are undertaken by a separate Technical Centre team, the Comprehensive Affairs Division. The audit team noted that:

➢ The walk-in freezer for storage of counter-analysis samples was efficiently organised, and samples were easy to retrieve.

➢ The rooms for sample extraction and clean-up were spacious and well-equipped.

➢ The laboratory does not currently have a mechanism to filter residue monitoring plan samples from other samples on LIMS or to run summary reports on national residue monitoring plan sample turnaround times, as other samples have different turnaround requirements9.

9 In their response to the draft report the competent authorities noted that it is planned to upgrade their software in 2014 to achieve this function.
➢ LIMS has a record of the date the sample was received at the laboratory, but not the sampling date; this information is only held by the Animal Inspection and Quarantine Division of CIQ.

➢ The Technical Centre do not use the central AQSIQ laboratory validation guidelines 2011/405, but rather have their own protocol. In the example seen the experimental design and data generated were equivalent to the AQSIQ guidelines.

➢ For an example seen using test method GB/T 20756-2006 (for chloramphenicol, thiamphenicol, florphenicol), LC-MSMS transitions were only acquired for florphenicol parent drug, when the sample request form specified florphenicol amine. The sample was reported as "florphenicol", leaving a potential ambiguity for the Animal Inspection Department as to whether the amine was measured in the event that they have to make a decision on compliance/non-compliance with EU MRLs. In practice, no samples had been found positive for florphenicol (parent) above the laboratory's reporting limit of 1 ug/kg, which in this case (rabbit muscle) is 1% of the EU MRL (total florphenicol, measured as the amine) of 100 ug/kg.

5.2.2.5 *Inspection and Quarantine Technical Centre of Zhejiang CIQ, Hangzhou, under AQSIQ*

**Findings**

The Veterinary Drugs and Cosmetics Laboratory sits within the Food Safety Department, which is in turn within the Foodstuffs Institute of the Technical Centre. The laboratory processes six to seven thousand AQSIQ national residue monitoring plan samples per year, of which approximately 250 are honey. It is the designated AQSIQ reference laboratory for sulphonamides and levamisole. Sample reception is handled by a separate team within the Foodstuffs Institute. The audit team noted that:

➢ For honey, two independently sealed samples are received. One is retained in case of a challenge analysis by the producer (this had never occurred in practice, and staff explained that if it were then follow-up sampling would be instigated irrespective of whether a producer's challenge was still underway). Honey samples were stored at room temperature in a well-organised storeroom along with other food and drink samples received by the Technical Centre.

➢ Regular check weights were used for balances in between the annual calibrations, although in the case of the balance used for weighing reference standards the interval between checks was longer than ideal (monthly, compared to weekly for the sample balances). This means that - were a checkweight to fail specification - all results generated from standards prepared in the previous month would be questionable. This situation had not happened in practice, and staff also explained that new sample solutions are compared to those previously prepared, as an additional check for any error or bias in their preparation.

➢ Evidence was seen that method validation had been refreshed and renewed as national guidelines for validation had evolved. This had encompassed change-

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10 In their response to the draft report the competent authorities stated that staff training, management and internal supervision will be strengthened to completely eradicate the occurrence of such incidents.
control relating to the installation of a new LC-MSMS, although the laboratory did not have a specific protocol as to how to handle such change-control or in what circumstances re-validation would be appropriate. A change-control procedure is not a specific requirement of ISO 17025, but would usually be expected in a 17025-accredited laboratory.

Conclusions on laboratories

Individual laboratories visited were well-controlled with no systemic findings that would undermine confidence in the test results. Methods were validated prior to use, daily quality control checks were run, and there was external quality assurance such as proficiency testing and external audits. Equipment was fit for purpose, and staff well trained. The network of reference laboratories and approved laboratories works well to share best practice and the competent authority can have confidence overall in their laboratories' 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 and meet the requirements of Article 11(2) of Directive 96/22/EC.


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

Findings

The authorisation, distribution and use of veterinary medicinal products in China have been previously described in the 2006 and 2009 FVO audit reports. China has an extensive body of legislation governing this area and key documents in relation to the scope of the audit are:

- Regulations on the Administration of Veterinary Drugs (Order of the State Council No. 404).
- Measures for Registration of Veterinary Drugs (MoA Order No. 44).
- Administrative Measures for Development of New Veterinary Drugs (MoA Order No. 55).
- Administrative Measures for Approval Numbers of Veterinary Medicinal Products (MoA Order No. 45).
- List of maximum residue limits (MoA Order No. 235 of 3 November 2008).
- List of withdrawal periods (MoA Order No. 278 of 22 May 2003).
- Lists of banned and abolished veterinary medicinal products (MoA Announcement No. 193; Joint MoA and China Food and Drug Administration Announcement No. 227; MoA Bulletin No. 235; MoA Announcement No. 560; MoA Order No.176).

New pieces of legislation introduced since the 2009 FVO audit include:

- Veterinary quality management standards (MoA Order No. 3 of 15 January 2010, to take effect from 1 March 2010).
- Feed and feed additives production licence management approach (MoA Decree No. 3 of 2 May 2012).
- New feed and new feed additives management approach (MoA Decree No. 4 of 2 May 2012).
- Feed additives and feed additive premix product approval number management approach (MoA Decree No. 5 of 2 May 2012).
- Feed production enterprise licence conditions and mixed feed additives manufacturing licence conditions (MoA Notice No. 1849 of 22 October 2012).
• Feed and feed additives administrative licensing application materials required (MoA Notice No. 1867 of 29 November 2012).

• Feed production enterprise licence conditions and mixed feed additives manufacturing licence conditions (MoA Notice No. 1849 of 22 October 2012).

• Feed and feed additives administrative licencing application materials required (MoA Notice No. 1867 of 29 November 2012).

• Veterinary prescription and non-prescription drug management approach (MoA Order No. 2 of 11 September 2013, to take effect from 1 March 2014).

• Veterinary prescription drug types catalogue - first batch (MoA Bulletin No. 1997 of 30 September 2013, to take effect from 1 March 2014).

The audit team noted that:

➢ The list of banned substances is generally similar to those banned in the EU. There was no evidence that substances which are banned in the EU are authorised for use in poultry, aquaculture, rabbits or honey bees.

➢ The MRLs in MoA Order No. 235 of 3 November 2008 are generally in line with, or lower than, those established in the EU. There are, however, some exceptions, such as the Chinese MRLs for deltamethrin and oxolinic acid in fish which are higher than those in the EU\(^\text{11}\). The audit team also noted that erythromycin and phenothiazine are authorised for use in honey bees\(^\text{12}\), whilst no MRLs have been established for these substances in the EU. In this regard recommendation No. 8 of the 2009 report has not been fully addressed.

➢ There was no evidence that antibiotics, other than erythromycin, are authorised for use in honey bees in China. In this regard recommendation No. 8 of the 2009 report has been partially addressed.

➢ The CIQ in Shandong province, the only province currently permitted to export poultry meat to the EU, has banned the use of certain antibiotics as feed additives on poultry farms from which poultry meat can be exported to the EU. In this way recommendation No. 9 of the 2009 report has been addressed. Contrary to the situation found in 2009, olaquindox is no longer authorised for use in poultry.

➢ The MoA sets default withdrawal periods per active substance/dosage form/target species combination. The list of withdrawal periods was published on 22 May 2003 and has not been updated since then. Withdrawal periods of new active substance/dosage form/target species combinations are included in individual authorisation decisions (though still

\(^{11}\) In their response to the draft report the competent authorities stated that China is now revising relevant standards according to the progress on the use of latest science and technology and will promulgate and update the information in a timely way.

\(^{12}\) In their response to the draft report the competent authorities stated that according to 2013 MoA Order No. 2002 on the regulation of veterinary medicinal products instructions model erythromycin used in honey is forbidden to be produced and used after 1 March 2014. According to the 2010 version of veterinary medicinal products instructions phenothiazine can be used in honey, although after MoA issued Order No. 1845 in 2012 the quality standard of this product was abolished and so phenothiazine cannot be produced or used after the promulgation of this Order.
applying by default to all commercially marketed forms of the product). The same approach applies to MRLs, of which a list was published on 3 November 2008. MRLs and withdrawal periods (as well as target species, indications for use and warnings) are also included in semi-official vademecums which are updated every 5 years. The most recent vademecum was published in 2010, whilst parts of the 2005 vademecum also continue to be valid. In some provinces visited, local authorities had produced lists supplementary to the vademecums or consolidated lists for drugs authorised to be used in certain target species (e.g. aquaculture and honey bees) to be used as a reference list by inspectors or establishments.

➢ The MoA has published on the internet a database of authorised veterinary medicinal products. The available information is, however, limited to approval number, name of the manufacturer, generic name, trade name, active pharmaceutical ingredient and strength. It does not provide information on target species, indications for use or withdrawal periods13.

➢ Following recently published legislation (see above) many veterinary medicinal products which may give rise to residues will be available on veterinary prescription only as of 1 March 2014.

Conclusions on authorisation, distribution and use of veterinary medicinal products

Rules on the distribution and use of veterinary medicinal products in food producing animal are largely equivalent to EU legislation and recently adopted rules on prescriptions have the potential to further control the use of these products, thus reducing the likelihood of residue violations. Concerning honey, a small number of substances authorised to be used in China are not authorised in the EU and have no EU MRL, which in case of their use could potentially lead to residue violations in honey exported to the EU.

5.3.2 Controls on the distribution and use of veterinary medicinal products

Legal Requirements

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

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

13 In their response to the draft report the competent authorities stated that they have noticed this problem and are now rectifying it, with the information concerning some medicinal products being improved and as a next step work will take place to continuously improve the database.
Findings

The MoA is responsible for controls on distributors of veterinary medicinal products and the use of these products on farms. However, controls on farms within the EOS are generally carried out by CIQ. The audit team noted that:

➢ Distributors of veterinary medical products (there is no legal distinction between wholesalers and retailers) are required to be licensed with MoA at county level. Beekeeper associations which distribute veterinary medicinal products for honey bees on a non-profit basis to their members only are exempted from this requirement to be licensed.

➢ The distributors visited by the audit team (other than the beekeeper association) held a current licence for the activities carried out. The facilities and records had been inspected by MoA with a frequency varying from once per year to more than once per month. Inspections could take the form of a regular, routine inspection or a more specific and targeted inspection, the latter for example concerning checks for illegal or falsified medicines. Such targeted inspections were announced in advance and the distributor was requested to check their stock against a list of unique product identifiers associated with the illegal or falsified medicines under investigation. Routine inspections were generally unannounced.

➢ County MoA offices report to provincial offices on the number of inspections carried out and the results. The results showed that falsified medicines had been found at a small proportion of distributors and that shortcomings in the storage and records of medicines were also identified. In such cases the audit team saw that appropriate corrective actions and sanctions had been put in place, thus confirming the effectiveness of such controls.

➢ According to Article 38 of Chapter 6 and Article 62 of Chapter 8 of the Regulations on Administration of Veterinary Drugs, all farms shall keep records of the use of veterinary medicinal products. Within the framework of the EOS, poultry, rabbit and aquaculture farms are also required to maintain records of the use of veterinary medicinal products. Detailed treatment records were present on the aquaculture farms visited. The farms had been regularly inspected by local CIQ officials and occasionally by MoA inspectors.

➢ Beekeepers producing honey and/or royal jelly for the EU market are obliged to be registered with their CIQ registered honey collection base, but are not directly registered with the CIQ. The beekeeper association visited required its members to keep records of the use of veterinary medicinal products. Treatment records of previous production seasons were submitted annually to the beekeeper association. Those available for review by the audit team did not mention the use of any unauthorised products. Treatment records for the current honey season were still with the beekeepers, who generally travel over large distances within the country with their hives. For that reason beekeepers are normally not inspected by officials of CIQ or MoA.

➢ The veterinary medicinal products seen at the distributors and farms visited were all labelled

14 In their response to the draft report the competent authorities stated that if any non-compliances were found during the administration of honey collection bases, the base's registration would be cancelled. In serious cases and where exporting processing enterprises bear management responsibility the competent authorities would suspend to accept their export declarations.
and the label texts included inter alia the approval number, batch number, expiry or use-by date, active ingredient(s), strength, target species, route of administration, dosage and where appropriate a withdrawal period. On one label there was a pictogram of a target species of a food producing animal which was not mentioned as a target species in the label text. According to the vademecum of 2010 the product could be used in that target species.

➢ The audit team observed that MoA inspectors from the central, provincial and county authorities, as well as inspectors from the CIQs, generally used the vademecums as well as the online database as a reference for authorised products, although it was explained that only the officially published product information was authoritative. Lacking a central repository of such product information with current details on established MRLs, withdrawal periods and indications for use, the inspectors had no reliable means to verify the accuracy of the label and leaflet texts of products available at retailers and on farms\textsuperscript{15}.

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

Similar to the situation observed during the 2009 FVO audit, the controls on the distribution and use of veterinary medicinal products in the distribution chain are numerous, documented and appear to be generally effective.

### 5.4 Follow-up of relevant recommendations made in previous FVO report on residues (DG-SANCO 2009-8187 MR Final)

<table>
<thead>
<tr>
<th>No.</th>
<th>Recommendation</th>
<th>Findings</th>
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<tbody>
<tr>
<td>1</td>
<td>With regard to sampling under the NRCP, review the current practice observed in MoA Jiangsu and ensure that sampling is carried out more uniformly throughout the whole year in order to give guarantees equivalent to those foreseen in point 2.1. of the Annex to Commission Decision 98/179/EC.</td>
<td>This recommendation has not been fully addressed (see section 5.1.3 and recommendation No. 1 of this report).</td>
</tr>
<tr>
<td>2</td>
<td>In order to have an effect equivalent to that foreseen by Article 4 (b) and (c) of Council Directive 96/23/EC, take measures which will more result in more effective supervision of residue testing activities.</td>
<td>This recommendation has been addressed (see section 5.1.3).</td>
</tr>
<tr>
<td>3</td>
<td>In order to give guarantees equivalent to those foreseen in Articles 16 – 18, 22 and 23 of Council Directive 96/23/EC, improve the co-ordination of follow-up activities undertaken by both CIQ and MoA in order to have a clear overview of all of the actions taken and eventual outcomes when non-compliant results have been detected.</td>
<td>This recommendation has been addressed (see section 5.1.5).</td>
</tr>
<tr>
<td>5</td>
<td>Both AQSIQ and MoA should review their current validation guidelines and mandate the calculation of performance parameters such as between-day reproducibility in order to give guarantees equivalent to</td>
<td>This recommendation has been addressed (see section 5.2.2).</td>
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</table>

\textsuperscript{15} In their response to the draft report the competent authorities stated that they have noticed this problem and are now rectifying it, with the information concerning some medicinal products being improved and as a next step work will take place to continuously improve the database.
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<td><strong>6</strong></td>
<td>In order to demonstrate that analytical methods used in the laboratories are fit for purpose and provide guarantees equivalent to Article 5 of Commission Decision 2002/657/EC, ensure that national proficiency test providers use spiking (fortification) levels for the preparation of test materials which are sufficiently low to reflect likely residue concentrations which would be found in practice. (For example, spiking levels for authorised substances should be set close to the MRL; for illegal substances, levels should be set close to the LOQ of the analytical methods used).</td>
<td>This recommendation has been addressed (see section 5.2.2).</td>
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<td><strong>7</strong></td>
<td>Ensure that all of the analytical methods listed in the national residue control plan are validated to a standard equivalent to that required by Article 3(c) of Commission Decision 2002/657/EC and update the AQSIQ and MoA validation guidelines accordingly.</td>
<td>This recommendation has been addressed (see section 5.2.1).</td>
</tr>
<tr>
<td><strong>8</strong></td>
<td>In respect of honey exported to the EU which has been derived from bees treated with pharmacologically active substances authorised in China but not in the EU, ensure that measures are in place to guarantee that such exports comply with Community MRLs as laid down in the Annex to Regulation (EC) No 470/2009. Where no such Community MRLs exist, it should be ensured that there are no detectable residues in product exported to the EU.</td>
<td>This recommendation has not been fully addressed (see section 5.3.1 and recommendation 3 of this report).</td>
</tr>
<tr>
<td><strong>9</strong></td>
<td>In respect of poultry meat exported to the EU which has been derived from chickens reared using feed additives which have been banned in the EU (e.g. bacitracin, flavomycin and virginiamycin), ensure that measures are in place to guarantee that such exports comply with Community MRLs as laid down in the Annex to Regulation (EC) No 470/2009. Where no such Community MRLs exist, it should be ensured that there are no detectable residues in product exported to the EU.</td>
<td>This recommendation has been addressed (see section 5.3.1).</td>
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### 6 OVERALL CONCLUSIONS

In general the system of residues controls in China offers guarantees with an effect equivalent to those provided for by EU rules concerning those commodities in the export-oriented scheme for which China has an EU approved residue monitoring plan (poultry, aquaculture, eggs, rabbits and honey). Planning and implementation of the residue monitoring plan and follow-up of non-compliant results are generally satisfactory, notwithstanding some omitted information in the residue monitoring plan submitted to the Commission services and continued uneven distribution of sampling over the year. Extensive own-checks and compulsory official pre-export testing for residues provide additional assurances on the residues status of products exported to the EU. The laboratory network is performing well and the competent authorities can rely on the testing results.
issued. There is a regulatory framework and system in place for the authorisation of veterinary medicinal products, establishing maximum residue limits and setting withdrawal periods and for the afore-mentioned commodities the system offers generally similar guarantees to that in the EU, although differences exist concerning some MRLs and certain products authorised for use in honey bees. Regular controls are performed on the distribution and use of veterinary medicinal products. Overall very significant progress has been made in addressing most of the recommendations of the last FVO residues audit in 2009.

7 CLOSING MEETING

A closing meeting was held on 21 November 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 stated that they would take whatever actions were necessary in order to address the recommendations of the report.

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.

<table>
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<tr>
<th>No.</th>
<th>Recommendation</th>
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<tr>
<td>1.</td>
<td>Ensure that information included in the residue monitoring plan provided to the Commission services is complete including total production data for the export-oriented scheme for those commodities which could be exported to the EU and action levels and MRLs for substances tested for, taking into account the requirements of Council Directive 96/23/EC.</td>
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<td>2.</td>
<td>Ensure that sampling is carried out at variable intervals spread out over the whole year in order to provide guarantees at least equivalent to the requirements of the Annex to Commission Decision 98/179/EC.</td>
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<td>3.</td>
<td>In respect of honey exported to the EU which has been derived from bees treated with pharmacologically active substances authorised in China but not in the EU, ensure that where no such Community MRLs exist for these substances, as laid down in the Annex to Regulation (EC) No 470/2009, measures are in place to guarantee there are no detectable residues of these substances in product exported to the EU.</td>
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The competent authority's response to the recommendations can be found at:
http://ec.europa.eu/food/fvo/rep_details_en.cfm?rep_inspec...
## ANNEX 1 - LEGAL REFERENCES

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<th>Official Journal</th>
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<td><strong>Food Law</strong></td>
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<td><strong>Monitoring and sampling of residues in food of animal origin</strong></td>
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<tr>
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<td>Official Journal</td>
<td>Title</td>
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<td><strong>Approval of residue monitoring plans submitted by third countries</strong></td>
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<td><strong>Validation of analytical methods for residues and Minimum Required Performance Limits</strong></td>
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<td><strong>Bans on the use of hormones and beta-agonists for growth promotion in food producing animals</strong></td>
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<td><strong>Maximum Residue Limits for veterinary medicinal products in food of animal origin</strong></td>
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<td><strong>Maximum Residue Levels for pesticide residues in food of animal origin</strong></td>
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<td><strong>Maximum Levels for contaminants in food</strong></td>
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<td><strong>Authorisation of veterinary medicinal products</strong></td>
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<td><strong>Medicated feedingstuffs and additives</strong></td>
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