EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2017-6185

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
VIET NAM
FROM 15 TO 24 NOVEMBER 2017
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 DG Health and Food Safety audit in Viet Nam, carried out from 15 to 24 November 2017, as part of the published DG Health and Food Safety's programme of audits.

The objective of the audit was to evaluate the effectiveness of official controls on residues and contaminants in live animals and animal products eligible for export to the European Union (EU). The audit assessed the implementation of the residue monitoring plan and also covered the authorisation, distribution and use of veterinary medicinal products, given that these areas have an impact on the monitoring of residues. Attention was also paid to examining the implementation of corrective actions indicated in response to specific recommendations made in the reports of previous residues audits to Viet Nam in 2009 and 2012.

The planning of the residue monitoring plans follows the principles of Directive 96/23/EC, for the two commodities that Viet Nam exports to the EU, honey and aquaculture products, and the implementation of both plans follows planned arrangements. However, the guarantees provided by the aquaculture plan are weakened, amongst others, by not meeting the EU minimum required number of samples, not testing for some substances authorised in aquaculture, and not covering all steps in the production chain.

Follow-up measures in case of non-compliances in honey contribute to the prevention of reoccurrence. With regard to aquaculture, the effectiveness of follow-up measures is severely weakened as the primary responsibility of follow-up is passed to the operator, and animals or products in which prohibited substances had been detected are not excluded from the food chain.

In relation to the performance of residue laboratories, quality controls in place to monitor the methods' performance are weak. Arbitrarily decreased sensibility of analytical methods, and measurable levels of chloramphenicol reported as not detected, weakens the reliability of analytical results for samples under the residue monitoring plan and the official pre-export testing.

The combination of those shortcomings could be an underlying cause for the repeated RASFF notifications for Vietnamese aquaculture products exported to the EU, despite the implementation of 100% official pre-export testing and the establishments' own-checks on residues.

The legal framework governing the authorisation of veterinary medicinal products generally supports the adherence to the guarantees required by Article 29 of Directive 96/23/EC. The official control system in place on the distribution of veterinary medicinal products is implemented and largely effective. However, the current prescription system does not add assurances that the veterinary medicinal products are used appropriately.

The report contains recommendations to the competent authorities of Viet Nam aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.

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ABBREVIATIONS & DEFINITIONS USED IN THIS REPORT

DAH	Department of Animal Health
ELISA	Enzyme-linked immuno-sorbent assay
EU	European Union
EU RL	European Union Reference Laboratory
HACCP	Hazard analysis and critical control points
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
MARD	Ministry of Agriculture and Rural Development
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NAFIQAD	National Agro-Forestry-Fisheries Quality Assurance Department
NCVHI 1	National Centre for Veterinary Hygiene Inspection No. 1
RAHO6	Regional Animal Health Office No 6
RASFF	Rapid Alert System for Food and Feed

1. INTRODUCTION

The audit took place in Viet Nam from 15 to 24 November 2017 as part of the published DG Health and Food Safety's planned audit programme.

An opening meeting was held on 15 November with the Department of Animal Health (DAH), the Directorate of Fisheries and the National Agro-Forestry-Fisheries Quality Assurance Department (NAFIQAD), all under the Ministry of Agriculture and Rural Development (MARD). At this meeting, the objectives and the itinerary of the audit were confirmed and the control systems were described by the authorities. Representatives from the central competent authorities accompanied the audit team during the whole audit.

2. OBJECTIVES OF THE AUDIT AND AUDIT CRITERIA

The objective of the audit was to evaluate:

a) the adherence to the residue monitoring plan approved by the European Union (EU);

b) the reliability of the guarantees in ensuring that the commodities concerned do not contain residues of veterinary medicinal products, pesticides and contaminants exceeding EU maximum limits;

c) the measures taken in response to the outcome of the previous audit during which the above control systems were evaluated or reviewed (DG(SANCO)/2012-6535 [1]).

Since the national rules governing the authorisation, distribution and use of veterinary medicinal products (including those administered via feed) have an impact on residue monitoring, the control systems in these areas were also part of the audit.

The principal audit criteria against which fulfilment of the above objective was assessed comprise:

- Council Directive 96/23/EC, and
- Directive 2001/82/EC of the European Parliament and of the Council.

The following table lists the sites visited and meetings held in order to achieve the audit objective.

[1] http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3008

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	Central	2	Opening and closing meetings with representatives of the central competent authority, Hanoi
	Regional	2	Regional Offices (1 of DAH and 1 of NAFIQAD)
LABORATORIES		4	National Centre for Veterinary Hygiene Inspection No. 1 (NCVHI 1), 2 regional laboratories of NAFIQAD (Branch 4 and 6) and laboratory of the RAHO6
FARMS		3	1 Bee-keeper, 1 finfish farm and 1 crustaceans farm
ESTABLISHMENTS		3	2 Aquaculture processing establishments (1 for finfish and 1 for crustaceans) and 1 honey processing establishment
OTHER SITES		2	1 Wholesaler and 1 retailer of veterinary medicinal products

3. LEGAL BASIS FOR THE AUDIT

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

- Article 21 of Council Directive 96/23/EC;
- Article 46 of Regulation (EC) No 882/2004 of the European Parliament and of the Council.

A full list of the legal instruments referred to in this audit report is provided in Annex 1 and refers, where applicable, to the last amended version.

4. BACKGROUND

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

Viet Nam is listed in the Annex to Commission Decision 2011/163/EU with a residue monitoring plan approved in accordance with Directive 96/23/EC for aquaculture and honey.

4.2. Summary of previous audit results

Official controls on residues and contaminants and on the distribution and use of veterinary medicinal products were audited in 2009 and 2012. The most recent audit report (DG(SANCO)/2012-6535 MR Final) concluded that the control system in place largely adhered to the guarantees provided by the approved residue monitoring plan. Shortcomings were identified with regard to a limited distribution of honey samples over existing honey processing establishments and the production period, as well as the availability of the residue monitoring plan for aquaculture for food business operators. In the action plan, MARD addressed satisfactorily the recommendations included in the audit report.

4.3. Rapid Alert System for Food and Feed notifications

Since 2016 to September 2017, there had been no notifications via the Rapid Alert System for Food and Feed (RASFF) for honey. For aquaculture products there were 17 notifications (12 in 2016) related to residues of veterinary medicinal products for aquaculture products exported to the EU. The substances identified included substances prohibited in the EU for use in food producing animals

(chloramphenicol (1), malachite green (1) and nitrofurans (4)) as well as other antimicrobial substances (tetracyclines (6), sulphonamides (3) and others (2)).

Due to repeated detections of residues of banned substances in fishery products from Viet Nam, the European Commission has currently in place a number of active re-enforced checks on products from Viet Nam. Those regimes impose targeted testing at the EU borders in products originated from specific establishments, before the products can be released into the EU market.

4.4. Production, Trade Information and Specific Import Requirements

In 2016, Viet Nam exported about 1,260 tonnes, and in 2017 (until 15 September) about 1,500 tonnes of honey.

Between the 1 January 2016 and 31 August 2017, Viet Nam exported to the EU 489,753 tonnes of aquaculture products (201,057 tonnes of finfish and 288,696 tonnes of crustaceans).

Aquaculture products eligible for export to the EU are sourced from 1,480 hatcheries, 2,090 finfish and 1,224 crustacean farms. On the 1 September 2017, 419 establishments where included in the list of EU-approved establishments for fishery products. During 2016 and 2017, 211 out of them had exported aquaculture products to the EU.

The DAH has registered 44 honey processing establishments as eligible to export honey to the EU. They source honey from 2,292 bee-keepers.

5. FINDINGS AND CONCLUSIONS

5.1. Residue monitoring

5.1.1. Competent authorities

1. The DAH is responsible for planning of the residue monitoring plan for honey, and the National Centre for Veterinary Hygiene Inspection No 1 laboratory (NCVHI 1) is responsible for implementation, including analysing honey samples and coordinating follow-up activities in the case of any non-compliant results.
2. The NAFIQAD is responsible for planning and implementation, including follow-up activities, of the residue monitoring plan for aquaculture products.

5.1.2. Planning of residue monitoring

Legal Requirements

Article 29 of Directive 96/23/EC.

References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

Findings

3. National legislation [2] provides the basis for the planning and implementation of the residue monitoring plan for honey and aquaculture.

[2] For honey, Circular No. 08/2015/TT-BNNPTNT, dated 2 March 2015 and for aquaculture, Circular No. 31/2015/TT-BNNPTNT, dated 6 October 2015, both of MARD

4. In relation to the 2017 residue monitoring plan for honey:
   - The plan covers all of the required essential subgroups, similar to what is required in the EU [3];
   - It meets the respective EU maximum residue limits (MRLs) for amitraz and coumafos [4];
   - It contains decision limits for antibiotics which are in line or below the respective limits recommended by the European Union Reference Laboratories (EU RLs);
   - Even though the number of analytical results coincides with what is expected in the EU, the plan does not meet the minimum number of samples that would be expected in the EU [5];
   - The plan indicates a level of action/decision limit for lead (B3c) as '500 µg/kg', higher than the maximum level (ML) in the EU [6] (100 µg/kg).

5. In relation to the 2017 residue monitoring plan for aquaculture:
   - The plan covers most of the essential subgroups what would be expected in the EU [7]. However, meanwhile NAFIQAD explained why they dropped testing for mycotoxins (no detections of aflatoxin since a couple of years), there is no justification why polychlorinated biphenyls (PCBs) are not covered in the plan [8];
   - The plan includes testing for methyltestosterone (see finding 45);
   - Except for intensive farming of black tiger shrimps, the plan does not reach the minimum number of samples that would be expected in the EU (1 sample per 100 tonnes of annual production) [9]. For example, for the annual production of 402,512 tonnes of *Pangasius hypothalamus*, 807 samples are planned versus the 4,025 samples expected [10]. Some of the samples are tested for more than one substance;
   - Samples of shrimps issued from extensive farming are tested only for environmental contaminants (B3a and B3c). The competent authority justified the decision on the fact that such shrimps are neither fed nor treated [11];
   - The planning does not consider sampling at the 1,480 hatcheries. This hatcheries also supply larvae to the aquaculture farms applying extensive farming (see previous bullet point) [12];

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3 Annex II to Directive 96/23/EC

4 Table 1 of the Annex to Regulation (EU) No 37/2010

5 Chapter 4 of the Annex to Decision 97/747/EC

6 Article 1 and Annex to Regulation (EC) No 1881/2006

7 Annex II to Directive 96/23/EC

8 In their response to the draft report the competent authorities noted that PCBs had been included in the post harvesting monitoring program in 2012 and in the residues monitoring programme of 2013 but the result showed no detections of PCBs.

9 Chapter 3 of Annex IV to Directive 96/23/EC

10 In their response to the draft report the competent authorities noted that this sampling rate is justified based on the super-intensive production for pangasius (up to 500 tonnes per hectare) and therefore, the representativeness is still guaranteed with one sample taken at 1-hectare pond.

11 In their response to the draft report the competent authorities noted that in the past, results of inspection/supervision of extensive farms carried out by local authorities did not show any violation related to misuse of chemical substances, and there had not been any notifications from importing countries.

12 In their response to the draft report the competent authorities noted that they took samples at hatcheries before 2012. However, after 2012, the results of food safety conditions inspection/supervision of hatcheries did not show any violation related to misuse of chemical substances, therefore sampling at the hatcheries has not been included in the plan.

- The 2017 plan did not include testing for crystal violet and its leuco-metabolite [13]. The testing for crystal violet (not for leuco-crystal violet) started in August 2017, after the detection in a consignment exported to a non-EU country;
- It does not cover the four pharmacologically active substances (azadirachtin, bicozamycin, fosfomycin, ormetoprim) authorised for use in aquaculture in Viet Nam, but not authorised for use in food producing animals in the EU [14]. At the wholesaler visited, ormetoprim was the active pharmacologically active substance used in one of the three veterinary medicinal products containing antibiotics which were sold for finfish and shrimps (see findings 46 and 55). This shortcoming triggered **Recommendation 2** in the 2012 report, and was also highlighted in a previous report DG SANCO 2009-8188 [15].

- Fenbendazole is not included, a substance for which no MRL has been established in finfish in the EU;
- The plan applies some MRLs higher than the respective EU MRLs [16] (difloxacin 600 µg/kg versus 300 µg/kg, sarafloxacin 300 µg/kg versus 30 µg/kg, trifluralin 100 µg/kg (prohibited for use also in Viet Nam) versus no MRL established in the EU) [17].

Conclusions on planning of residue monitoring

6. While the planning of residue monitoring follows the principles of Directive 96/23/EC, the reliability of the guarantees offered by the residue monitoring plans are weakened by certain factors. These include not meeting the minimum required number of samples, not testing for some substances registered for use in aquaculture, action/decision limits not fully aligned with those applicable in the EU, and not sampling in hatcheries and extensive farming.

5.1.3. Implementation of the residue monitoring plan

Legal Requirements

Article 29 of Directive 96/23/EC.

References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

13 In their response to the draft report the competent authorities noted that testing for crystal violet and its leucometabolite was not included in the initial plan of 2017 as there was no information on violations related to misuse of chemical substances and no notifications from importing countries.

14 Table 1 of the Annex to Regulation (EU) No 37/2010

15 In their response to the draft report the competent authorities noted that NAFIQAD had implemented the action plan to address the 2012 audit's recommendation, meaning doxycycline, neomycin and ivermectin have been included for testing since 2013, right after receiving local authorities' information on the actual use of veterinary drugs in aquaculture containing these substances.

16 Table 1 of the Annex to Regulation (EU) No 37/2010

17 In their response to the draft report the competent authorities noted that this is due to typing mistakes in the plan.

Findings

7. In addition to the legal basis for the implementation of the residue monitoring plan (see finding 3), MARD issued instructions and checklists, on how to implement the residue monitoring plan for honey [18] and for aquaculture [19].
8. The **Recommendation 4** of the 2012 report referred to the sampling procedures under the residue monitoring plan for honey. Currently, the implementation of the plan for honey covers all establishments eligible to export honey to the EU and, similar to the situation in the EU [20, 21, 22]:
    - sampling was unforeseen and spread over the two harvesting seasons;
    - allowed quick traceability of the honey sample to the bee-keeper, as most of the samples are taken from honey of individual bee-keepers and all respective sampling reports included the information on the bee-keeper. The honey processing establishment visited had records available which listed the bee-keepers who had delivered the honey for a specific lot, thus providing full traceability;
    - ensured sample integrity and the stability of analytes as staff of NCVHI 1 take, seal and transport samples to the laboratory.
9. All 143 honey samples planned for the first honey harvesting season in 2017, had been analysed with a compliant result until 25 May 2017 and 103 samples planned for the second harvest had been analysed with compliant results until 18 October 2017.
10. With regard to the implementation of the residue monitoring plan for aquaculture:
    - Sampling takes place at farms and middlemen, unforeseen and spread over the year, similar to the situation in the EU [23];
    - sampling is not always done at marketing stage for the authorised veterinary medicinal products, contrary to the instruction;
    - information is recorded appropriately to allow the traceability back to the aquaculture farm, similar to the situation in the EU [24];
    - also similar to the situation in the EU [25], the competent authority ensures sample integrity and the stability of analytes as samples are transported in adequate and sealed packages to the laboratory;
    - sampling is carried out timely by officials and sample turnaround times in the laboratories were less than 14 days. Similar to the situation in the EU [26], reports on the implementation of the residue monitoring plan were frequently sent to the supervising competent authorities.

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18 Guidelines for collecting samples, monitoring veterinary hygiene and food safety for honey production and trading facilities, Appendix 1, 2, 3 and 4 to Circular No. 08/2015/TT-BNNPTNT, dated 2 March 2015, of MARD

19 Manual for development and implementation of the residue monitoring plan of NAFIQAD

20 Point 2.1 of the Annex to Decision 98/179/EC

21 Point 2.7 of the Annex to Decision 98/179/EC

22 Points 2.6 and 2.9 of the Annex to Decision 98/179/EC

23 Point 2.1 of the Annex to Decision 98/179/EC

24 Chapter 4 of the Annex to Decision 97/747/EC and Point 2.7 of the Annex to Decision 98/179/EC

25 Point 2.6 and 2.9 of the Annex to Decision 98/179/EC

26 Article 4 of Directive 96/23/EC

Conclusions on implementation of residue monitoring

11. The residue monitoring plan is implemented largely in line with planned arrangements thus supporting the guarantees offered under Article 29 of Directive 96/23/EC.

5.1.4. Other residue monitoring programmes

Legal Requirements

Article 29 of Directive 96/23/EC.

References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

5.1.4.1. Official pre-export testing for honey

Findings

12. As part of the certification procedure, each consignment of honey is subjected to official pre-export testing. Samples:
    - are taken by officials of the Regional Animal Health Office No 6 (RAHO6) [27] which is responsible for issuing veterinary health certificates for exports of honey to the EU;
    - are analysed in the laboratory of RAHO6 for chloramphenicol via ELISA and LC-MS/MS (see finding 35);
    - amounted in 2016 to 2,075 samples, and for the first nine months of 2017 to 1,529 samples. All results were compliant.

13. If an export consignment comprises more than one container of honey, staff takes a part of the sample from each container. Individual samples are blended into one sample for analysis, which reduces the probability to detect residues of chloramphenicol present in one individual container, when containers originate from different bee-keepers.

5.1.4.2. Official pre-export testing for aquaculture

Findings

14. National legislation [28] subjects each consignment of aquaculture products to official pre-export testing. The laboratories of NAFIQAD analyse pre-export samples of finfish and crustaceans for chloramphenicol, nitrofurans, malachite green and leuco-malachite green, enrofloxacin, and trifluralin; in addition, finfish for mercury, lead and cadmium ,and crustaceans for doxycycline and oxytetracycline.

15. In the first ten months of 2017, the NAFIQAD Branch 4 Office visited issued 5,746 veterinary health certificates for export to the EU. From January 2016 to November 2017, 13 samples from the pre-export testing resulted non-compliant (3 for leuco-

[27] Article 15 of Circular No. 08/2015/TT-BNNPTNT, dated 2 March 2015, of MARD

[28] Circular No. 48/2013/TT-BNNPTNT, 11 November 2013; Decision No. 2864/QĐ-BNN-QLCL, 14 November 2012; Decision No. 1471/QĐ-BNN-QLCL, 20 June 2012; official letters No.2440/QLCL-CL1 of 18/11/2014, No.157/QLCL-CL1 of 19/01/2015 and No. 1243/QLCL-CL1 of 13/5/2015

malachite green, 8 for tetracyclines, 1 for trifluralin and 1 for enrofloxacin). Non-compliant pre-export test results were subject to the same official follow-up as non-compliant results under the residue monitoring plan. The audit team evaluated the follow-up files for some of these non-compliances.

- One sample contained a high level of level of leuco-malachite green (366 µg/kg). The farmer confirmed the use of a drug of unknown content. The consignment was exported to another non-EU country which does not require export certificates.
- For another sample, taken in November 2016, containing also leuco-malachite green (4.2 µg/kg), the farmer confirmed the use of malachite green (which he had still in stock on farm) for disinfection of the pond. The aquaculture processing establishment kept this consignment in the freezer, and the competent authority had no actual information what the establishment decided to do with this consignment.
- For the third sample containing leuco-malachite green (4.9 µg/kg), the reason could not been established. The establishment had used this consignment for the production of feed (fish meal).
- For another non-compliant result (doxycycline), the farmer admitted that he continued the treatment until harvest, thus not respecting the applicable withdrawal period. The consignment was cooked and exported to another non-EU country.
- The reason for two other non-compliant results (high levels of doxycycline in samples of processed fishery products of the same processing establishment) was the contamination of the buttered bread crumbs used in the fishery product. The establishment used both consignments for the production of feed.

5.1.4.3. Establishment own-checks

Findings

16. The honey processing establishment visited tested honey from their suppliers for residues of chloramphenicol, tetracycline, streptomycin and fluoroquinolones with an in-house validated ELISA test-kit in the laboratory of the establishment. The detection limits of the ELISA method were suitable to detect these residues at a level similar to those applicable in the EU [29]. This testing of raw honey was a critical control point in the "hazard analysis and critical control points" (HACCP) of the establishment, requiring to stop further processing of the honey and informing the RAHO6 of the non-compliant result. Since 2013, all results had been compliant. The checklist for official controls of honey processing establishment includes checks on the HACCP, thus ensuring that officials of RAHO6 can certify the respective requirement of the EU veterinary health certificate for honey [30].

17. The four honey processing establishments which, in 2017, exported most of the honey consignments to the EU, carried out own-checks for residues prior to the

[29] Table 2 of Decision 2002/657/EC

[30] Commission Implementing Regulation (EU) No 2016/759

export. When issuing the veterinary health certificate, RAHO6 attached the analytical results of these checks to the respective certificates. All four establishments had sent their honey samples to accredited laboratories in the EU. At the honey processing establishment visited, these pre-export checks included, depending on the customer request, testing for chloramphenicol, nitrofurans, tetracyclines, sulphonamides, fluoroquinolones, erythromycin, lincomycin, tylosin, streptomycin and dihydrostreptomycin. Since 2013, all these analysis had compliant results.

18. The HACCPs of the two aquaculture processing establishments visited included, as a critical control point, the 100% pre-harvest testing for residues of incoming consignments of raw material.
    - Laboratories accredited under ISO 17025, using LC-MS/MS methods, analysed samples for a range of substances similar to the one of the residue monitoring plan. One establishment also tested for leuco-crystal violet, which is not tested for under the residue monitoring plan.
    - The detection limits of the LC-MS/MS methods were suitable to detect residues similar to the levels applicable in the EU [31].
    - The finfish processing establishment required also that the HACCP of its supplying farms includes a similar scope of testing for fingerlings, before these can be purchased from a hatchery (see finding 5). The establishment's follow-up activity, in response to the detection of leuco-malachite green in a sample, included the verification whether the records of the respective farmer contained the analytical results of the fingerlings he had purchased from the hatchery.
    - One establishment's HACCP included additional twice a year testing of each of its suppling farms for residues of the same substances as the pre-harvest testing and, in addition, of tetracyclines, praziquantel, heavy metals (lead, cadmium and mercury), dioxin and aldrin.
    - The establishments informed the local competent authority about non-compliant results of their own-checks.

Conclusions

19. Official pre-export testing of honey and aquaculture products for residues, combined with good traceability and extensive testing for residues included in the own-checks programme of the establishments visited strengthen the guarantees offered under Article 29 of Directive 96/23/EC.

5.1.5. Follow-up of non-compliant results

Legal Requirements

Article 29 of Directive 96/23/EC.

References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

[31] Table 2 of Decision 2002/657/EC

Findings

20. In addition to the 17 RASFF notifications for aquaculture products since 2016 (see point 4.3. of this report),

    - for honey, DAH reported 3 non-compliant results (1 chloramphenicol, 1 tetracycline and 1 doxycycline) under the 2015 residue monitoring plan. In 2016 and 2017 (until 31 August) all results had been compliant.
    - for aquaculture products, NAFIQAD reported in 2016 27 non-compliant results: 6 nitroimidozoles, 1 nitrofuran, 2 tetracyclines, 1 sulfonamides, 13 enro-/ciprofloxacin (prohibited for use in fish in Viet Nam, while in the EU [32] an MRL of 100 µg/kg in fish muscle applies), 1 ivermectin, 1 trifluralin and 2 malachite green.

21. For non-compliant honey, the national legislation [33] on follow-up activities were similar to what would be expected in the EU [34]. The follow-up measures for the three non-compliant results in honey detected in 2015, had been undertaken timely and were documented, similar to what is expected in the EU [35]. The measures comprised the investigation in the two honey processing establishments concerned, and the destruction of the non-compliant honey. The Regional Veterinary Offices took additional samples following the national instruction for follow-up, but those samples came from different bee-keepers (one had stopped the activity and the other one did not produce sufficient quantities). Those samples cannot be considered follow-up to the non-compliances.

22. In aquaculture products, instructions [36] on follow-up activities for non-compliant results under the residue monitoring plan and the official pre-export testing, differ from the situation in the EU [37], mainly:
    - the competent authority applies the same level of enforcement measures after the detection of prohibited substances or after the detection of authorised substances at levels above the MRL
    - when aquaculture animals are treated with prohibited substances, they are not excluded from the food chain. Farming continues until residues in follow-up samples are no longer detected or are detected below the EU minimum residue performance limits (MRPLs);
    - aquaculture products treated with prohibited substances can be put on the national market or can be exported to other non-EU countries having no restrictions on the use of these substances. In the event that Viet Nam would supply those products to non-EU countries listed for aquaculture in the Annex to Commission Decision 2011/163/EU, it is possible for those products to be in turn exported to the EU.

32 Table 1 of the Annex to Regulation (EU) No 37/2010
33 Chapter IV of MARD Circular No. 08/2015/TT-BNNPTNT, dated 2 March 2015
34 Articles 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Directive 96/23/EC
35 Articles 16, 17 and 18 of Directive 96/23/EC
36 Chapter IV of the Manual on the implementation of the residue monitoring plan of NAFIQAD
37 Articles 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Directive 96/23/EC

- the responsibility to identify the cause of the non-compliance is allocated to the food business operator, and the official investigation focuses on verifying the results provided by the food business operator [38].

23. The follow-up files evaluated by the audit team documented speediness; the laboratories delivered their analytical results within few days, and the administrative procedure started the next day.

24. In none of the files was evidence that samples from other ponds of the farm of origin had been taken to verify if residues of prohibited substances could also be detected in animals of these ponds, contrary to what would be expected in the EU [39].

25. National legislation [40] on follow-up measures in case of notifications via the RASFF includes, in addition, the suspension of the respective exporting aquaculture establishment from certification for export to the EU, until five consecutive follow-up samples had been analysed with a compliant result and corrective actions had been undertaken by the establishment.

Conclusions on follow-up of non-compliant results

26. Follow-up measures in case of non-compliant results in honey contribute to the prevention of reoccurrence, with prompt investigations and destruction of the affected products.

With regard to aquaculture, the effectiveness of follow-up measures is severely weakened as the primary responsibility of follow-up is passed to the operator, and animals or products in which prohibited substances had been detected are not excluded from the food chain.

5.1.6. Laboratories

Legal Requirements

Article 29 of Directive 96/23/EC.

References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

Findings

27. The laboratory network comprises the NCVHI 1, responsible for testing all honey samples under the residue monitoring plan, the laboratory of the RAHO6, responsible for testing all honey samples under the official pre-export testing, and six branch laboratory units of NAFIQAD, responsible for testing all aquaculture samples.

28. Similar to what is expected in the EU [41], all these laboratories are ISO 17025 accredited with the national accreditation body, Bureau of Accreditation Viet Nam

[38] In their response to the draft report the competent authorities noted that local authorities require in writing the concerned food business operator to carry out investigation and carry out their on-site investigation, not waiting for investigation result from food business operator.

[39] Article 23 of Directive 96/23/EC

[40] Circular No. 48/2013/ TT-BNNPTNT, dated 12 November 2013and Decision No. 3328/QD-BNN-QLCL

which is a full member of the International Laboratory Accreditation Cooperation. Those laboratories have nearly all their methods used for analysing samples under the residue monitoring plans and the official pre-export testing within their currently valid scope of accreditation.

29. If necessary, NAFIQAD can use in addition, private laboratories in Vietnam, designated by MARD for this purpose.

5.1.6.1. Laboratory network for honey, National Centre for Veterinary Hygiene Inspection No. 1 (NCVHI 1)

30. The laboratory has adequate procedures in place for the management of chemical standards, which are adhered to.

31. The audit team assessed
    a) the ELISA method for testing chloramphenicol, the nitrofuran metabolite AHD (A6), tylosin, streptomycin (B1),
    b) the LC-MS/MS method for testing chloramphenicol, nitrofuran metabolites, tylosin, erythromycin and lincomycin (B1) in honey, and
    c) the methods for testing chloramphenicol and tetracyclines (B1) in supplementary feed for honey bees. In this respect,
        - the instruction in place for method validation covered the relevant method performance parameters and all screening (ELISA) methods in use have been adequately validated and the method performance parameters calculated;
        - whilst the LC-MS/MS method for tylosin was validated at three concentration levels, for nitrofuran metabolites only one concentration level (0.5 µg/kg) was checked;
        - the methods for testing chloramphenicol and tetracyclines in supplementary bee feed were in the process of being validated and good recovery values had been reported so far.

32. The laboratory included at least two parallel quality control samples in each analytical run and similar to EU rules and ISO requirements [42], and monitored the performance of methods in use against the pre-defined criteria for recovery. Although control charts were maintained, long term trends in the method performance could not been seen, as data were kept for each calendar year separately.

33. Spiking concentration levels used in the ELISA and LC-MS/MS methods for tylosin and streptomycin (50 µg/kg) were higher than those recommended by the EURLs (recommended concentration for tylosin in honey is 20 µg/kg and for streptomycin 40 µg/kg) and for chloramphenicol (0.5 µg/kg) higher than the MRPL applicable the EU [43].

34. In 2016 and 2017, the laboratory subcontracted testing for heavy metals in honey to other official laboratories in Viet Nam, as the own measuring instrument was

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41 Point 1.2 of the Annex to Decision 98/179/EC.
42 Article 5 of Decision 2002/657/EC and ISO 17025 standard
43 Annex II to Decision 2002/657/EC

disqualified for this purpose by the maintenance service provider. While the contracts of the subcontracted laboratories required sample turnaround times of 10 working days, they did not define the requirements for method sensitivity and validation status. The analytical method of the laboratory with a contract valid for 2017, is validated and accredited for testing heavy metals in food at a concentration of 0.4 mg/kg which is too high for testing at EU Maximum limit 0.1 mg/kg [44]. The NCVHI 1 has recently purchased a new instrument which, once the method is developed, can ensure testing for lead with adequate sensitivity.

5.1.6.2.Laboratory network for honey, Regional Animal Health Office No 6 (RAHO6)

35. This laboratory analyses pre-export samples with a screening (ELISA) and a confirmatory method (LC-MS/MS) for chloramphenicol. SOPs for these methods and validation files evaluated by the audit team demonstrated that both methods were fit for purpose. In 2014, the laboratory participated successfully in proficiency tests organised by commercial providers. However, the laboratory decided to run confirmatory analyses only for screening results which detected more than 0.3 µg/kg of chloramphenicol, although the experimentally established limit of quantification for the screening method was 0.16 µg/kg. Moreover, the examination of quality checks operated at 0.3 µg/kg revealed, that analytical runs with recovery rates for a control sample as low as 43% had been accepted and included in method performance calculations. Such practices significantly increased the risk to interpret the detection of chloramphenicol as false compliant results.

5.1.6.3.Laboratory network for aquaculture, laboratories of NAFIQAD Branches No 4 and No 6

36. Both laboratories had procedures and instruction for sample reception and handling in place and samples were stored in adequately monitored conditions. Similar to the situation in the EU [45], for finfish samples, a sample contained muscle and skin in natural proportions thus allowing analytical results to be suitable to decide whether EU MRLs were met.

37. The audit team examined various screening and confirmatory methods and noted:
    - similar to what is expected in the EU [46], comprehensive method verification/validation studies have been carried out for all methods;
    - most of the methods were adequately validated (some of them in September 2017) with method performance parameters, including those specifically laid down in EU legislation [47], calculated. However, some of those parameters have never been used for presentation/validation of laboratory results;
    - both laboratories verified the fitness for purpose of the screening ELISA method used to test for chloramphenicol, at 0.1 µg/kg. Although the limit of quantification established at the laboratory of Branch No 4 was 0.04 µg/kg for finfish and 0.11 µg/kg for shrimp, and the cut-off level established by the

44 Article 1 and Point 3.1.23 of the Annex to Regulation (EC) No 1881/2006

45 EU MRLs are established for fish muscle and skin in natural proportions, Table 1 of the Annex to Regulation (EU) No 37/2010

46 Article 3(b), (c) and (d) of Decision 2002/657/EC, Guidelines for the validation of screening methods for residues of veterinary medicines of 20/1/2010

47 CCα and CCβ as laid down in Decision 2002/657/EC

laboratory of Branch No 6 was 0.16 µg/kg, both laboratories arbitrarily decided to send only samples exceeding 0.2 µg/kg for confirmation. This indicates that NAFIQAD accepts the detection of chloramphenicol in aquaculture products up to 0.2 µg/kg and the increased risk of false compliant results;

- in 2005, the laboratory of Branch No 4 validated the LC-MS/MS method for diethylstilbestrol (A1) and methyltestosterone (A3) in finfish. Whilst in 2005, the method was validated at concentration levels similar to those recommended by EU RLs, at the time of the audit, concentrations used to calibrate the instrument were 10 times higher. In addition, the laboratory arbitrarily increased the method detection and quantification limits of the LC-MS/MS method for nitrofuran metabolites to 0.5 µg/kg and 1.0 µg/kg, respectively for all four metabolites;
- quality controls on the everyday method performance were in place for each analytical run and similar to EU rules and ISO requirements [48], control charts to monitor trends were maintained. However, with each new quality control result, base line (mean) and warning lines were recalculated thus the trends in the method performance could not be clearly seen. In addition, quality control samples were run only after the calibration of the instrument. Such practice does not provide information on the quality of results at the end of analytical run, which could be very long;
- while the laboratory of Branch No 6 spiked quality control samples at limit of detection levels which were below the respective EU MRPLs and MRLs [49], thus checking the method performance at the concentration levels of interest in the EU, this was not the case for all analytes in the laboratory of Branch No 4. Here, quality control samples for malachite green and leuco-malachite green were spiked at 2.5 µg/kg, and for diethylstilbestrol and methyltestosterone at 5 µg/kg, which is too high to control the reliability of results at the EU level of interest of 1 µg/kg.

38. Since 2014, the laboratories of all six Branches participated in nationally organised inter-laboratory comparisons and in proficiency tests of commercial providers and EURLs, similar to what would be expected in the EU [50].

Conclusions on laboratories

39. While the performance of residue laboratories supports the guarantees offered under Article 29 of Directive 96/23/EC, quality controls in place to monitor the methods' performance are weak. Arbitrarily decreased sensibility of analytical methods and the fact that samples with measurable concentration levels of chloramphenicol are reported as not detected, weakens the reliability of analytical results for samples under the residue monitoring plan and the official pre-export testing.

48 Article 5 of Decision 2002/657/EC and ISO 17025 standard
49 Annex II to Decision 2002/657/EC and Annex to Regulation (EU) No 37/2010
50 Point 1.2 of the Annex to Decision 98/179/EC

5.2. Veterinary medicinal products

5.2.1. Competent authorities

40. DAH [51] is responsible for a) issuing marketing authorisations for nationally manufactured and imported veterinary medicinal products, and b) carrying out controls of manufacturers and importers. The sub-Departments of DAH are responsible for controls on distribution of these products at wholesalers, retailers, veterinary practitioners. Local authorities are responsible for controls on aquaculture farms and bee-keepers.

5.2.2. Authorisation, distribution and use

Legal Requirements

Article 29 of Directive 96/23/EC.

References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

Findings

41. Similar to what applies in the EU [52], the national legislation [53] describes the legal provisions and procedures for the authorisation/registration, distribution and use of veterinary medicinal products.

42. Similar to the situation in the EU [54], national legislation [55] provides for the prohibition of certain pharmacologically active substances. In addition to the substances prohibited in the EU, national legislation also prohibits the use of enro-/ciprofloxacin, fluroquinolones, cypermethrin, deltamethrin, trifluralin, trichlorfon and glycopeptides in veterinary medicinal products, animal feed, chemicals and disinfectants used in the production of aquaculture products.

43. DAH maintains a list of authorised veterinary medicinal products which is publicy available on the DAH's webpage. Similar to the situation in the EU [56], at present, national legislation [57] authorises four pharmacologically active substances (flumethrin, coumaphos, lactic acid and formic acid,) to treat honey bees. Also similar to the situation in the EU [58], several substances (16) can be used in aquaculture, including two (fenbendazol and praziquantel) for which, in the EU, no MRL has been established in finfish. Additional four substances (azadirachtin, bicozamycin, fosfomycin and ormetoprim) can be used, which are not authorised for use in food producing animals in the EU [59] (see finding 6).

44. Certain national requirements are more stringent than what would be required in the EU [60,61]:

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51 Decision No. 1399/2017/QD-BNN-TCCB
52 Articles 30-40 of Regulation (EC) No 726/2004
53 Veterinary Law 79/2015 and the Decree No. 35/2016/ND-CP
54 Article 11 of Council Directive 96/22/EC and Table 2 of the Annex to Regulation (EU) No 37/2010
55 Appendix I and II of Circular No 10/2016/TT-BNNPTNT, dated 1 June 2016, of MARD
56 Table 1 of the Annex to Regulation (EU) No 37/2010
57 Appendix I of Circular No 10/2016/TT-BNNPTNT
58 Table 1 of the Annex to Regulation (EU) No 37/2010
59 Table 1 of the Annex to Regulation (EU) No 37/2010
60 Article 11 of Directive 2001/82/EC

- the off-label use of veterinary medicinal products is not allowed [62];
- the feed produced commercially for aquaculture should not include antibiotics [63]. The use of antibiotics in feed for aquaculture is authorised when feed is produced on-farm.

45. Sex inversion in tilapia is practiced using methyltestosterone until 21 days age, as would be possible in the EU [64]. Methyltestosterone is not included in the list of authorised veterinary medicinal products in Viet Nam.

46. National MRLs for pharmacologically active substances in veterinary medicinal products are established by the Ministry of Health [65], similar to what applies in the EU [66]. DAH tries to verify during the authorisation process, whether the withdrawal period proposed by the manufacturer can meet these MRLs or the MRLs of importing countries, e.g. the EU [67]. In the case of ormetoprim (see findings 6 and 55) authorised for use in finfish with a withdrawal period of four days, the EU MRL might not be achieved within four days, because the method used by the manufacturer in the depletion study (ELISA) indicated a sensitivity of 50 µg/kg, which is not suitable to proof the absence of residues lower than 50 µg/kg.

47. If DAH cannot verify whether the applicable MRL is achieved, the withdrawal period so established based on the withdrawal periods provided for in the EU for off-label use [68].

48. Similar to the situation in the EU [69], national legislation provides for:
    - specific requirements for labelling of veterinary medicinal products [70];
    - wholesalers and retailers to be licensed (by local veterinary offices of DAH) before they can distribute or sell veterinary medicinal products; those licenses have to be renewed after 5 years,
    - personnel, facility and record keeping requirements for wholesalers and retailers on the distribution of veterinary medicinal products,
    - records on treatments to be kept by bee-keepers [71] and aquaculture farmers [72].

49. Similar to the situation in the EU [73], farmers and bee-keepers need a veterinary prescription to purchase veterinary medicinal products intended for use in food producing animals. Different to the situation in the EU [74], it is not required to limit the prescribed amount to the amount needed to treat the sick animals. Prescriptions can be issued by the responsible veterinarian of the retailer and can be used several times as they are not always kept by the retailer nor invalidated after their first use.

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61 Directive 90/167/EEC
62 Article 104 of the Veterinary Law
63 Article 6 of Decree 39/2017/NĐ-CP dated 4th April 2017
64 Article 5 of Directive 96/22/EC
65 Circular No 24/2013/TT-BYT, dated 14 August 2013, of Ministry of Health
66 Regulation (EC) No 470/2009
67 Table 1 of the Annex to Regulation (EU) No 37/2010
68 Article 11 of Directive 2001/82/EU
69 Article 58, 65 and 66 of Directive 2001/82/EC and Article 10 of Directive 96/23/EC
70 Article 27 of Circular 10/2016/TT-BNNPTNT, dated 1 June 2016, by MARD
71 Circular 08/2015/TT-BNNPTNT, dated 2 March 2015, by MARD
72 Circular 22/2014/TT-BNNPTNT dated 29 July 2014
73 Article 67(aa) of Directive 2001/82/EC
74 Article 67(d) of Directive 2001/82/EC

50. The bee-keeper visited kept records related to the use of veterinary medicinal products (on husbandry activities and on diseases, including prophylactic treatments applied to honey bees), and kept also veterinary prescriptions. In 2017, the veterinary practitioner had issued a prescription which included details on the use of the drug, but did not limit or indicate the quantity of the prescribed veterinary medicinal product (see previous finding).

51. The aquaculture farmers visited:
    - kept individual records for each pond and production cycle on husbandry activities and on treatments applied to the animals. The record templates used (in line with the national instruction) [75] did not require specifically recording withdrawal periods;
    - used commercial feed (see finding 44).

Conclusions on authorisation, distribution and use

52. The legal framework governing the authorisation of veterinary medicinal products generally supports the adherence to the guarantees required by Article 29 of Directive 96/23/EC. However, the current prescription system does not add assurances that the veterinary medicinal products are used appropriately

5.2.3. Official controls

Legal Requirements

Article 29 of Directive 96/23/EC.

References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

Findings

53. National legislation [76] provides details to determine the frequency of risk-based official controls of wholesalers and retailers. A minimum frequency for official controls on the use of veterinary medicinal products at aquaculture farms and of bee-keepers has not been established.

54. National legislation [77] also provides for instructions and checklists to record the outcome of official controls of wholesalers and retailers, bee-keepers and aquaculture farmers.

55. At the wholesaler and retailer visited, official controls had been carried out at the nationally required frequency. The officials had used correctly the respective checklist (see finding 52). At the wholesaler visited, the last official control included:
    - the inspection of a selection of veterinary medicinal products, based on the actual stocklist provided by the wholesaler, for labelling requirements, expiry date, authorisation number and matching quantities, and,

75 QCVN 02-20/2014 of the Directorate of Fisheries

76 Circular No 45/2014/TT-BNNPTNT, dated 3 December 2014, of MARD

77 Appendix XXIII promulgated of Circular No.13/2016/TT-BNNPTNT, dated 2 June 2016, of MARD, Appendix 2 promulgated with Circular No. 08/2015/TT-BNNPTNT, dated 2 March 2015, of MARD, and BB I promulgated with Circular No. 45/2014/TT-BNNPTNT, dated 3 December 2014, by MARD

- in addition, a sample of a veterinary medicinal product was taken, in order to verify whether the required temperature storage conditions had been met for this product.

56. The wholesaler visited, distributed three veterinary medicinal products which contained antibiotics. Ormetoprim was the active pharmacologically active substance used in one of these products (see findings 6 and 48).

57. The bee-keeper visited had records on official controls by the local veterinary offices. The checklist used for an official control included checks on record keeping requirements, including treatment of bees.

Conclusions on official controls

58. The official control system in place to ensure compliance with the legal requirements for the distribution of veterinary medicinal products is implemented and largely effective.

5.3. Follow-up of recommendations made in report DG(SANCO) 2012-6535

59. The table below summarises the follow-up to the relevant recommendations made in report DG(SANCO) 2012-6535

2	Ensure that all appropriate veterinary medicinal products are included in the scope of testing in the aquaculture residue monitoring plan, taking account of the availability of medicines on the domestic market, the likelihood of their use in the relevant production sector and residues detected in exported consignments, to the extent that guarantees provided should be at least equivalent to the requirements of Council Directive 96/23/EC.	The competent authority provided actions after the 2012 audit, but similar deficiencies are still noted and the recommendation is not addressed. *See finding 5, conclusion 6 and recommendation 1 of the current report.*
4	Ensure that sampling of honey is carried out at variable intervals spread out over the whole year, across a representative number of establishments and avoiding multiple sampling from the same sites in order to provide guarantees at least equivalent to the requirements of the Annex to Commission Decision 98/179/EC.	Addressed. *See finding 8 and conclusion 11 of the current report*.

6. OVERALL CONCLUSION

The planning of the residue monitoring plans follows the principles of Directive 96/23/EC, for the two commodities that Viet Nam exports to the EU, honey and aquaculture products, and the implementation of both plans follows planned

arrangements. However, the guarantees provided by the aquaculture plan are weakened, amongst others, by not meeting the EU minimum required number of samples, not testing for some substances authorised in aquaculture, and not covering all steps in the production chain.

Follow-up measures in case of non-compliances in honey contribute to the prevention of reoccurrence. With regard to aquaculture, the effectiveness of follow-up measures is severely weakened as the primary responsibility of follow-up is passed to the operator, and animals or products in which prohibited substances had been detected are not excluded from the food chain.

In relation to the performance of residue laboratories, quality controls in place to monitor the methods' performance are weak. Arbitrarily decreased sensibility of analytical methods, and measurable levels of chloramphenicol reported as not detected, weakens the reliability of analytical results for samples under the residue monitoring plan and the official pre-export testing.

The combination of those shortcomings could be an underlying cause for the repeated RASFF notifications for Vietnamese aquaculture products exported to the EU, despite the implementation of 100% official pre-export testing and the establishments' own-checks on residues.

The legal framework governing the authorisation of veterinary medicinal products generally supports the adherence to the guarantees required by Article 29 of Directive 96/23/EC. The official control system in place on the distribution of veterinary medicinal products is implemented and largely effective. However, the current prescription system does not add assurances that the veterinary medicinal products are used appropriately.

7. CLOSING MEETING

A closing meeting was held on 24 November 2017 with representatives of MARD. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities offered some clarifications and stated that they provide additional documents to evidence these clarifications.

Following the final meeting, on 28 November 2017, NAFIQAD forwarded its Instruction No.: 2277/QLCL-CL1 to the Regional and Provincial Authorities and the NAFIQAD Branches requesting to: a) identify the use of recently authorised pharmacologically active substances, e.g. ormetoprim, b) from 2018 onwards, to take samples at hatcheries for analysis of chloramphenicol, nitrofurans and malachite green and at extensive shrimp farms for analysis of chloramphenicol and nitrofurans, c) from December 2017 onwards, to analyse *Pangasius* samples for leuco-crystal violet, d) to use the possibility for targeted sampling if information available indicates to do so, and e) to immediately implement proper follow-up measures which can ensure that aquaculture products from farms in which prohibited substances had been detected, are not exported to the EU.

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 25 working days of receipt of this audit report.

No	Recommendation
1	To ensure that the design of the residue monitoring plan for aquaculture covers all relevant production stages and types of production (i.e. hatcheries and extensive farming), the testing covers active substances authorised in Viet Nam, and the plan fulfils the minimum number of samples required to allow that the guarantees provided under Article 29 of Directive 96/23/EC are effective. *Recommendation based on conclusion 6.* *Associated finding 5.*
2	To ensure that the residue monitoring plan for honey fulfils the minimum number of samples required to allow that the guarantees provided under Article 29 of Directive 96/23/EC are effective. *Recommendation based on conclusion 6.* *Associated finding 4.*
3	To ensure that commodities exported to the EU comply with the EU maximum residue limits when the corresponding national limits are greater, or that residues are not present when there is no established MRL in the EU, to allow that the guarantees provided under Article 29 of Directive 96/23/EC are effective. *Recommendation based on conclusion 7.* *Associated findings 4, 5 and 22.*
4	To apply a policy for the follow-up of non-compliant results, which can ensure that aquaculture products in which prohibited substances or authorised substances above the EU maximum residue limit have been detected, cannot be exported to the EU, so that the guarantees provided under Article 29 of Directive 96/23/EC are effective. *Recommendation based on conclusion 26.* *Associated finding 22, 24 and 37.*
5	To improve quality control checks at the national laboratories carrying out testing of samples under the residue monitoring plan so that: a) samples of measurable concentrations of prohibited substances are reported and verified by a confirmatory method; b) quality control checks are carried out at the end of analytical runs and at concentration levels corresponding to the levels of interest in the EU, to ensure that the guarantees provided under Article 29 of Directive 96/23/EC are effective.

	Recommendation based on conclusions: 39 *Associated findings and observations: 33, 34, 35 and 37.*

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

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2017-6185

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Audits by Commission Services		
Reg. 882/2004 - Article 46 (TC)	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
Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Monitoring of residues and contaminants 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

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
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
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
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
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
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
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. 315/93	OJ L 37, 13.2.1993, p. 1-3	Council Regulation (EEC) No 315/93 of 8 February 1993 laying down Community procedures for contaminants in food
Reg. 124/2009	OJ L 40, 11.2.2009, p. 7-11	Commission Regulation (EC) No 124/2009 of 10 February 2009 setting maximum levels for the presence of coccidiostats or histomonostats in food resulting from the unavoidable carry-over of these substances in non-target feed
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
Reg. 589/2014	OJ L 164, 3.6.2014, p. 18-40	Commission Regulation (EU) No 589/2014 of 2 June 2014 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012
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
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

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
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
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 beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
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