FINAL REPORT OF AN AUDIT
CARRIED OUT IN
ALBANIA
FROM 16 TO 25 OCTOBER 2018
IN ORDER TO
EVALUATE THE CONTROL OF RESIDUES AND CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS INCLUDING CONTROLS ON VETERINARY MEDICINAL PRODUCTS
Executive Summary

This report describes the outcome of an audit carried out in Albania from 16 to 25 October 2018 as part of the European Commission’s Directorate-General for Health and Food Safety planned work programme.

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 measures indicated in response to specific recommendations made in the reports of the previous residues audit to Albania.

Overall, the report concludes that whilst Albania has a residue monitoring plan in line with minimum EU requirements, the current control system for residues in food of animal origin is largely undermined by its limited implementation due to a lack of sufficient laboratory resources.

There is a low risk of residue violations from consignments exported to the EU insofar as EU-prohibited substances are concerned; this is due to the well-functioning authorisation system in place for veterinary medicinal products. Controls on the distribution and use of veterinary medicinal products nevertheless need to be strengthened.

The report contains recommendations addressed to the Albanian competent authorities aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.
# TABLE OF CONTENTS

1. **INTRODUCTION** .......................................................................................................1  
2. **OBJECTIVES AND SCOPE** .....................................................................................1  
3. **LEGAL BASIS FOR THE AUDIT** ............................................................................2  
4. **BACKGROUND** .....................................................................................................2  
   4.1. Country status in relation to EU-approval of residue monitoring plans ............2  
   4.2. Summary of previous Commission audits on residues .................................2  
   4.3. Rapid Alert System for Food and Feed notifications from 2016 to date ..........2  
   4.4. Production, Trade Information and Specific Import Requirements...............2  
5. **FINDINGS AND CONCLUSIONS** ............................................................................3  
   5.1. Residue monitoring ............................................................................................3  
   5.2. Veterinary medicinal products ..........................................................................11  
   5.3. Follow-up of previous recommendations made in report DG(SANTE)  
       2012-6536 ........................................................................................................14  
6. **OVERALL CONCLUSION** ......................................................................................15  
7. **CLOSING MEETING** ............................................................................................15  
8. **RECOMMENDATIONS** ..........................................................................................16  

Annex 1 – Legal References
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>DDAFRD</td>
<td>Directorate of Program Development for Agriculture, Food Safety and Rural Development</td>
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<tr>
<td>DDPLM</td>
<td>Directorate of Deregulation, Permits, Licenses and Monitoring</td>
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<tr>
<td>DDT</td>
<td>Dichlorodiphenyldichloroethane</td>
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<tr>
<td>ELISA</td>
<td>Enzyme-linked immuno-sorbent assay</td>
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<tr>
<td>FSVI</td>
<td>Food Safety and Veterinary Institute</td>
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<tr>
<td>GC-MS/MS</td>
<td>Gas Chromatography-(Tandem) Mass Spectrometry</td>
</tr>
<tr>
<td>Group A, B</td>
<td>Categories of substances listed in Annex I to Council Directive 96/23/EC:</td>
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<tr>
<td>HPLC–FD</td>
<td>High Performance Liquid Chromatography/Fluorimetric Detector</td>
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<td>ISO</td>
<td>International Organization for Standardization</td>
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<td>MARD</td>
<td>Ministry of Agriculture and Rural Development</td>
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<td>MRL</td>
<td>Maximum Residue Limit</td>
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<tr>
<td>MRPL</td>
<td>Minimum Required Performance Limit</td>
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<td>NFA</td>
<td>National Food Authority</td>
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<tr>
<td>RVS</td>
<td>Regional Veterinary Services</td>
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<tr>
<td>SCRVMP</td>
<td>State Commission for Registration of veterinary medicinal products</td>
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<tr>
<td>SOP</td>
<td>Standard Operating Procedure</td>
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</table>
1. **INTRODUCTION**

The audit took place in Albania from 16 to 25 October 2018 as part of the European Commission's Directorate-General for Health and Food Safety planned work programme. The audit team comprised two auditors from the Directorate-General for Health and Food Safety and one expert from a European Union Member State.

An opening meeting was held on 16 October with representatives of the Directorate of Program Development for Agriculture, Food Safety and Rural Development (Drejtoria e Programeve të Zhvillimit të Bujqësisë, Sigurisë Ushqimore dhe Zhvillimit Rural, DDAFRD), the Directorate of Deregulation, Permits, Licenses and Monitoring (Drejtoria e Derregullimit, Lejeve, Licencave dhe Monitorimi, DDPLM), the Food Safety and Veterinary Institute (Instituti i Sigurisë Ushqimore dhe Veterinarisë, FSVI), the State Commission for Registration of Veterinary Medicinal Products (Komisioni Shtetëror iProdukteve Mjekësore Veterinare, SCRVMP), the National Food Authority (Autoriteti Kombëtar i Ushqimit, NFA) and the regional veterinary services (Agjencia Rajonale e Shërbimit Veterinar dhe Mbrotjjes së Bimëve, RVS) of Durres, Elbasan, Vlore and Tirana. At this meeting, the team confirmed the objectives, scope and the itinerary of the audit and requested the information required for the successful completion of the audit. Representatives from the DDAFRD and DDPLM accompanied the audit team during the whole audit.

2. **OBJECTIVES AND SCOPE**

The objective of the audit was to evaluate:

- the implementation of the residue monitoring plan for those animals and animal products (eggs, goats, sheep and aquacultured finfish) for which Albania is listed in the Annex to Commission Decision 2011/163/EU;

- the reliability of the guarantees in ensuring that the commodities eligible for export to the European Union (EU) do not contain residues of veterinary medicinal products, pesticides and contaminants exceeding EU maximum limits;

- the measures taken in response to the outcome of the previous audit during which residue monitoring for the above commodities was evaluated (DG (SANCO) 2012/6536–MR Final).

In terms of scope, the audit covered:

- production of eggs, goat meat, sheep meat and aquacultured finfish.

- official controls on the use of veterinary medicinal products having a direct bearing on the residues status of the above commodities, as well as the national rules governing the authorisation and distribution of veterinary medicinal products (including those administered via feed), since they have an impact on residues monitoring.

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

<table>
<thead>
<tr>
<th>Competent Authorities</th>
<th>Meetings/Visits</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central</td>
<td>2</td>
<td>Opening and closing meetings with the DDAFRD, the DDPLM, FSVI, SCRVMP and RVS of Durres, Elbasan, Vlore and Tirana.</td>
</tr>
<tr>
<td>Regional</td>
<td>2</td>
<td>Meetings with the RVS in the Durres and Estaban regions.</td>
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</tbody>
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<thead>
<tr>
<th>Laboratory</th>
<th>1</th>
<th>FSVI laboratory</th>
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</thead>
<tbody>
<tr>
<td>Farms</td>
<td>3</td>
<td>One farm for aquacultured finfish, one laying hen farm, one goat and sheep farm.</td>
</tr>
<tr>
<td>Establishments</td>
<td>3</td>
<td>One processing establishment for aquacultured finfish, one slaughterhouse for goats and sheep and one egg collection centre.</td>
</tr>
<tr>
<td>Other Sites</td>
<td>3</td>
<td>One wholesaler, one wholesaler/retailer and one retailer distributing veterinary medicinal products.</td>
</tr>
</tbody>
</table>

### 3. Legal Basis for the Audit

The audit was carried out under the general provisions of EU legislation, and in particular Article 46 of Regulation (EC) No 882/2004 and Article 21 of Directive 96/23/EC. Full legal references are provided in Annex 1. Legal acts quoted in this report refer, where applicable, to the last amended version.

### 4. Background

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

Albania 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 eggs, goats, sheep and aquacultured finfish.

#### 4.2. Summary of previous Commission audits on residues

The topic was audited in 2008 and 2012. The most recent audit report (DG(SANCO)/2012-6536 – MR Final) (henceforth referred to as the 2012 audit) concluded that the planning of the residue monitoring plan largely adhered to the guarantees provided for by the EU approved plan, but had a limited scope of testing relative to the availability of veterinary medicinal products on the market. It identified significant shortcomings with regards to the implementation of the residue monitoring plan, as the plan was largely not implemented as planned, due to limited laboratory resources and as analytical methods were not validated. In addition, there was no suitable internal quality control programme for analyses in place. These shortcomings weakened the reliability of the guarantees provided by the approved residue monitoring plan.

#### 4.3. Rapid Alert System for Food and Feed notifications from 2016 to date

Since 2015 there have been no Rapid Alert System for Food and Feed notifications for residues of veterinary medicinal products in eggs, goats, sheep and aquacultured finfish.
4.4. **Production, Trade Information and Specific Import Requirements**

In 2017, Albania exported to the EU 1,306 tonnes of eggs, 1,563 tonnes of aquacultured finfish (781 tonnes of sea bream, 67 tonnes of sea bass and 735 tonnes of trout). No meat products derived from goats and sheep were exported as Albania is not listed in Annex II to Regulation (EU) No 206/2010 with regard to veterinary certificates for fresh meat.

5. **FINDINGS AND CONCLUSIONS**

5.1. **Residue monitoring**

5.1.1. **Competent authorities**

1. The Ministry of Agriculture and Rural Development (MARD) is the competent authority in charge of residues monitoring. Two of its directorates are involved in the residue monitoring plan. The DDAFRD is responsible for drafting the plan and the DDPLM is responsible for its implementation as well as for the follow-up of non-compliant results in cooperation with the NFA.

2. The RVS within the four Regional Agencies for Veterinary Service and Plant Protection Service, perform inspections and carry out sampling for the residue monitoring plan. Samples are sent by the RVS to the FSVI for analysis. In the event of non-compliant results, the RVS conduct follow-up investigations in collaboration with the regional NFA services which are responsible for controls on feed and food hygiene.

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\(^1\) provides the basis for the planning and implementation of the residue monitoring plan.

4. When planning the annual residue monitoring plan, the DDAFRD in consultation with the DDPLM, RVS and FSVI, takes into account commodity production volumes in different regions, non-compliances found in previous years and pharmacologically active substances authorised for species covered in the residue monitoring plan (see also findings No 6 and No 7). However, the audit team found that the residue monitoring plan submitted to the Commission in March of each year did not fully take into account information on the FSVI’s capability to analyse samples (see also findings No 11, No 12 and No 29) nor the range of pharmacologically active substances in frequently used veterinary medicinal products. The latter is not similar to EU requirements.\(^2\) Thus recommendation No 1 of the 2012 audit report has not been addressed.

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\(^1\) Article 81 of Law No 10465 of 29 September 2011; Regulation No 1 of 17 March 2000; Minister’s Order No 15 of 5 October 2010 and Minister’s Order No 139/1 of 7 April 2017.

\(^2\) Article 7 of Council Directive 96/23/EC.
5. The 2017 and 2018 plans covered all of the essential substance groups required. The number of samples for eggs, goats, sheep and aquacultured finfish are based on the annual national production volume, similar to what is required in the EU, with a number of samples planned for eggs (221 in 2018), goats (317 in 2018), sheep (596 in 2018) and aquacultured finfish (28 in 2018), that is slightly higher than the required minimum in the EU.

6. The scope of testing for substance groups meets the EU minimum criteria and has been extended compared to 2012 for all species covered by the residue monitoring plan. In 2018 the following substances per substance group were added:

**Sheep and goats:** Group A3: oestrogenic and gestagenic substances, Group B1: beta-lactams and macrolides (sheep/goats), aminoglycosides (sheep), tetracyclines (goats).

**Aquaculture:** Group A3: 17 alpha ethinly-testosterone and methyl testosterone, Group B1: beta-lactams, macrolides and aminoglycosides.

**Hen eggs:** Group B1: beta-lactams, macrolides, aminoglycosides and lincosamides.

However, while the majority of authorised active pharmaceutical ingredients in veterinary medicinal products are included in the scope of the residue monitoring plan, several frequently used ones, according to sales records in wholesalers and pharmacies visited by the audit team, are not. These are, for example:

**Sheep and goats:** Group B1: colistin, doxycycline and cephalexin, Group 2a: albendazole and nitroxinil.

The competent authority informed the audit team that they will aim to widen the scope of substances to be included in future residue monitoring plans.

7. Levels of action/decision limits in the residue monitoring plan are clearly indicated and are suitable to detect concentrations at, and below, the respective EU Minimum Required Performance Levels/Maximum Residue Limits/Levels (MRPLs and MRLs, respectively) or Maximum Levels (MLs) applicable in the EU. National law requires that MRLs and MLs need to comply with those of the EU.

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**Conclusions on planning of residue monitoring**

8. The planning of the residue monitoring complies with the minimum requirements of and adheres to the guarantees provided for by the EU-approved plan, but it is weakened by the fact that the scope of the residue monitoring plan does not fully take into account the existing analytical capacity of the laboratory and the range of authorised veterinary medicinal products that are available.

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**5.1.3. Implementation of the residue monitoring plan**

**Legal Requirements**

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3 Article 5 and Annexes II and IV to Directive 96/23/EC.
4 Article 6 and Annexes I to IV to Directive 96/23/EC.
5 Article 1 and the Annex to Commission Decision 97/747/EC.
7 Minister’s Order No 139/1 of 07.04.2017.
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

9. Instructions\textsuperscript{8,9,10} are in place which aim to ensure the uniform implementation of the residue monitoring plan, including sampling. These are similar to those in the EU except for the fact that the sampling instructions for aquaculture samples require that samples to be analysed for substances in Group A shall be taken only from fish to be placed on the market for consumption and not from fish at all stages of farming. The latter is not similar to EU requirements.\textsuperscript{11} For substances in Group B, samples are correctly required to be taken from fish ready to be placed on the market. In addition, the sampling instructions created by the DDPLM to ensure that the right matrix was taken by RVS staff responsible for sampling had not been updated since 2012 and were not fit for purpose in that for some analytes, the incorrect matrix for sampling was indicated (see also finding No 27).

10. Similar to the situation in the EU,\textsuperscript{12} sample collection is unannounced, thus recommendation No 4 of the 2012 audit report has been addressed. In the establishments visited by the audit team, farmers and operators confirmed that this requirement had been adhered to. All samples are taken by official staff.

11. The recent residue monitoring plans evaluated by the audit team were largely not implemented as planned for all species and commodities. This was evidenced by the lack of implementation of the:

- 2017 residue monitoring plan as follows: Hen eggs: No tests for Group A6 – nitroimidazoles; fewer substances tested than planned in Group B1 and Group B2b. Aquaculture: No tests for Group A3, Group B2a, Group B3a, Group B3d; fewer substances tested than planned in Group A1, Group A6, and Group B1. Sheep/goats: No tests for Group B2d and Group B2e; fewer substances tested than planned in Group A1, Group A2, Group A3, Group A4, Group B1, Group B2a (not clear which substances have been tested), Group B2b and Group B2c; fewer samples tested than planned for substance Group A1, Group A2, Group A3, Group A6 (only chloramphenicol required), Group B1, Group B2a, Group B2b, Group B2c, Group B3a and Group B3d.

- 2018 residue monitoring plan (status 24 October 2018) as follows: Hen eggs: fewer substances tested than planned in Group B1 (7 out of 10 tested) and Group B2b (1 out of 4 tested). Aquaculture: No tests for Group B2a; fewer substances tested than planned in Group B1 (9 of 14 tested) and Group B3d (1 of 2 tested). Sheep/goats: fewer substances tested than planned in Group A3 (2 out of 5 tested), Group B1 (8 out of 11 tested), and Group B2b (1 out of 4 tested). Thus recommendation No 2 of the

\textsuperscript{8} Annual Ministers Order for the approval of the national residue monitoring plan.
\textsuperscript{9} Guidelines No 14 of 20.06.2011 on the completion of levels and frequency in taking samples as provided by the Regulation No 1 of 17 March 2000 on the measures to monitor certain substances and residues in live animals and animal products. Guidelines No 2836/1 of 25 June 2012 for sampling and sending samples to the laboratory.
\textsuperscript{10} Ministers Order No 4 of 30.01.2013 on the unification of procedures, methods and documentation for the functioning of laboratories.
\textsuperscript{11} Point 1 of Chapter 3 of the Annex IV to Directive 96/23 EC.
\textsuperscript{12} Article 12 of Directive 96/23/EC.
The DDPLM, DDAFRD and the FSVI staff met, informed the audit team that budgetary and procurement rules, as well as staff shortages were among the key reasons for the incomplete implementation of the residue monitoring plans. The audit team found that a first step to start to rectify this situation had been taken with the implementation of a contract between the FSVI and a laboratory group in Belgium, which since August 2018 conducts screening and confirmatory methods for substance Groups A2 (thyrostats) and B2e (non-steroidal anti-inflammatory drugs). This laboratory can also be used for confirmatory analysis for all substance groups and substances in the event of non-compliances found in FSVI screening tests.

The audit team was also informed that the FSVI will be tasked with providing the MARD with a plan on how to achieve the full implementation of the 2019 residue monitoring plan. This plan will be based on a comprehensive analysis of the: a) matrices, substance groups and substances to be monitored, b) required validation of methods and c) the availability of external accredited laboratories for outsourcing of analysis, which together will determine the required resources. The audit team found that the FSVI staff met had a clear understanding of the matrices, substance groups and substances to be monitored and also which methods required validation.

There is a system in place for the coordination and supervision of residue control activities at different levels (central and regional, etc.), collection of data, application of corrective measures as well as the submission of annual data. However, the audit team found that it is not fully effective, as: a) a shortfall in samples to be taken in 2018 had only be rectified by the DDPLM after the audit team raised this with the DDPLM; b) sampling instructions which were not fully fit for purpose had not been adjusted since 2012 (see finding No 9 and No 27) and c) the fact that information about samples being frequently clustered were available but no action was taken to rectify this shortcoming. Thus recommendation No 2 of the 2012 audit report has not been fully addressed with regards to supervision and coordination.

Sampling activities were not spread over the whole production period for eggs, aquacultured finfish, sheep and goats. Sampling took place from June to December when the laboratory was able to analyse samples. Several examples of multiple sampling from one producer were seen by the audit team at several establishments visited. This is not similar to what is required in the EU. Thus recommendation No 3 of the 2012 audit report has not been addressed.

The sampling reports reviewed by the audit team at central level, processing plants, farms and the laboratory visited, included information similar to what is required in the EU. Samples could be traced based on the name of the establishment and the sampling date. The competent authority stated it would amend the sampling form to be able to not only identify the farm, but on laying hen farms also the stables, or on aquaculture farms also the ponds or nets from which samples were taken.

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13 Article 1 and point 2.1 of the Annex to Decision 98/179/EC.
14 Article 1 and point 1.1 of the Annex to Decision 98/179/EC.
15 Article 1 and point 2.3.3.1 of the Annex to Decision 98/179/EC.
16 Article 1 and point 2.7 of the Annex to Decision 98/179/EC.
17. Samples are taken, stored and transported to the laboratories only by official staff, preventing sample substitution, similar to what is required in the EU.\textsuperscript{17} Sampling materials are adequate and tissue samples are stored and transported frozen or refrigerated to ensure the stability of analytes, which is similar to what is required in the EU.\textsuperscript{18,19} (See also finding No 26)

**Conclusion on implementation of residue monitoring**

18. The residue monitoring plan is largely not implemented as planned, thus not supporting the guarantees provided by Article 29 of Directive 96/23/EC. In addition, it is further weakened by not spreading sampling over the whole production period, sample clustering, sampling of inappropriate matrices in some cases and not taking samples for analysis of substances in Group A from all stages of production from fish.

5.1.4. **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.

**Findings**

19. The DDPLM and the NFA are jointly responsible for follow-up investigations of non-compliant results. If a non-compliant result is found by a screening method or, if available, by a confirmatory method (see also finding No 12), the laboratory has to inform the MARD, its DDPLM, the NFA and the RVS concerned, which, based on these results, will have to implement follow-up measures. The RVS concerned focuses in its follow-up investigation on the potential misuse of veterinary medicinal products on farms and, if required by the NFA, takes follow up samples at farms and processing establishments. The NFA is responsible for the forward and backward tracing of affected food products at farms and processing establishments and for the follow-up at the feed mills, traders of feed or food and food retailers concerned. The NFA also has the power to seize and destroy affected products and to stop the export certification for the establishments concerned and is required to inform export markets in the event of a product recall. A farm’s registration or a processing establishment’s authorisation to export can be withdrawn. Thus overall measures are in place to handle non-compliances which are similar to EU requirements.\textsuperscript{20} Documented follow-up procedures\textsuperscript{21} are in place, which describe the measures to be taken in the event of non-compliances being detected. These include, *inter alia*, identifying and eliminating the source of the non-compliance, identifying the farm of origin, taking follow-up samples, tracing and recalling products, checking veterinary medicinal treatment records, and verifying and analysing feed sources. These are similar to what is required in the EU.\textsuperscript{22}

\textsuperscript{17} Article 1 and point 2.6 of the Annex to Decision 98/179/EC.
\textsuperscript{18} Article 1 and point 2.6 of the Annex to Decision 98/179/EC.
\textsuperscript{19} Article 1 and point 2.9 of the Annex to Decision 98/179/EC.
\textsuperscript{20} Articles 16, 17 and 18 of Directive 96/23/EC.
\textsuperscript{21} Articles 13 and 47 of Law No 9863 of 28 January 2008 on food. Annual Ministers Order for the approval of the National Residues Monitoring Plan.
\textsuperscript{22} Articles 16, 17 and 18 of Directive 96/23/EC.
20. The following non-compliances were found from 2016-2018: in 2016, two samples from sheep were non-compliant for the corticosteroid dexamethasone; in 2017, one egg sample was non-compliant for Dichlorodiphenyltrichloroethane (DDT) and one for aldrin and dieldrin; in 2018, one egg sample was non-compliant for DDT.

21. The audit team evaluated the follow-up investigations of the aforementioned non-compliant samples. Measures taken by the competent authority were found to be largely in accordance with the requirements laid down in Articles 16 - 19 and 23 of Directive 96/23/EC. However, the respective official reports did not always provide auditable information on what investigations had been carried out (e.g. check of on-farm treatment records, feed used, whether the reason for the non-compliance had been identified and if the affected product had been destroyed. The DDPLM staff met by the audit team stated that they intended to modify the documented procedure for follow-up investigations, to specifically require that all elements of the follow-up investigation be included in the official report.

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

22. National rules for follow-up investigations and the exclusion of non-compliant products from export to the EU, combined with clear instructions on how to conduct follow-up investigations, largely guarantee the effectiveness of follow-up in the event of non-compliances.

### 5.1.5. 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**

23. The current laboratory network comprises two laboratories. The governmental FSVI laboratory within the Department of Toxicology and Residues Monitoring and an external laboratory in Belgium which has been subcontracted by the FSVI.

24. Similar to the situation in the EU, both laboratories are accredited to the International Organization for Standardization (ISO) standard 17025. The FSVI is accredited by the national accreditation body, the Directorate of Accreditation (Drejtoria e Përgjithshme e Akreditimit), and the external laboratory by the Belgian Accreditation Body (BELAC)). Both accreditation bodies are members of the International Accreditation Forum. The FSVI has had annual visits by the Albanian Directorate of Accreditation. Non-conformities found during those visits have been rectified and in the 2018 audit no non-conformities were found. The FSVI is accredited with a fixed scope of accreditation.

25. The FSVI’s accreditation certificate is valid until November 2020 and includes in its scope only two methods for residue determination: High Performance Liquid Chromatography/Fluorimetric Detector (HPLC-FD) method for nicarbazin in eggs (Group B2b) and Gas Chromatography-Tandem Mass Spectrometry (GC-MS/MS).

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23 Point 1.2. of the Annex to Decision 98/179/EC.
method for pesticides and poly-chlorinated biphenyls (PCBs) (24 substances) in eggs and milk (Group B3a). The external laboratory has validated methods for all substance groups, substances and matrices of relevance for the residue monitoring plan. It has been subcontracted to conduct the screening and confirmatory method for substance Groups A2 (thyrostats) and B2e (non-steroidal anti-inflammatory drugs).

26. The audit team visited the FSVI laboratory in Tirana which has an agreed turnaround time from sample reception to the reporting of the results for substances in Group A of 10 days and for substances in Group B of 30 days. These turnaround times were met in 93% and 53% in 2016 and 2017, respectively. However, the delays did not affect the reliability of the analysis of stability-sensitive substances as (a) storage conditions at the laboratory were adequate, (b) samples for Group A2 (thyrostats) were quickly sent to the external laboratory, and (c) samples for Group B1 (beta-lactams) were not analysed. The audit team was informed by staff met in the laboratory that delays were largely caused by lack of laboratory materials (test kits). However, putatively non-compliant results of samples that can be analysed are reported immediately to the MARD, DDPLM, NFA and RVS.

27. Similar to what is required in the EU,\textsuperscript{24} instructions and procedures are in place to ensure that samples of inadequate quality are not accepted for testing. However, the audit team found several cases in which the originally intended substance to be analysed for was changed by the laboratory, due to the wrong matrix having been sampled or due to the fact that no kits for the intended substance were available (see also finding No 9). In addition, official sample instructions had not been updated since 2012 and in some cases required an incorrect matrix to be sampled, in contrast to what the laboratory needed. To date the laboratory has not informed the official staff responsible for sampling in the event of the wrong matrix being sampled but it has notified staff in the event of inadequate sample quality (amount, degradation etc). Samples are unambiguously identified and stored in suitable premises with temperature control.

28. The audit team examined several analytical methods and found that progress had been made with regards to method availability since the 2012 audit. However, despite these efforts a large number of substance/matrix analyses included in the residue monitoring plan, cannot be implemented (see findings No 11 and No 12), thus recommendations No 2 and No 5 of the 2012 audit report have not been addressed. The FSVI staff met stated that this was due to the limited resources for analytical materials (chemicals and ELISA test kits), lack of analytical instruments, insufficient space in the laboratory premises and insufficient number of personnel. This was also highlighted in the FSVI internal audit reports, which are part of the laboratories’ quality management systems according to ISO 17025.

29. The following methods were examined by the audit team:

- **ELISA screening methods:** The majority of non-authorised and authorised substances are tested by ELISA screening methods. A general Standard Operating Procedure (SOP) for performance of the screening methods is in place.\textsuperscript{25} However,
the laboratory has not validated/verified the performance of any ELISA screening method, which is not similar to EU requirements.\textsuperscript{26} The laboratory staff met by the audit team explained that this is due to several reasons, such as ELISA kits coming every year from different companies due to contractual agreements, often also in insufficient quantity and the lack of staff to process both regular samples and validation samples. Due to these issues, no schedule for ELISA screening method validation has been developed. Thus \textbf{recommendation No 5} of the 2012 audit report has not been addressed with regards to the validation of the ELISA methods. However, each batch of samples is accompanied by quality control samples (e.g. spiked matrix- and blank samples). Spiking is carried out at the levels of interest in the EU i.e. MRL/MRPL, using either certified reference standards or by the analytical standard provided by the ELISA kit manufacturer, which is similar to EU requirements.\textsuperscript{27} Control charts or other methods to monitor quality of results are maintained. Thus while the ELISA methods are not fully validated/verified they can still provide largely reliable results ensuring that MRL and MRPL violations are detected.

- \textbf{Instrumental methods} for screening and confirmatory purposes: a) HPLC-FD for Group B2a in sheep and goat liver and milk; b) GC-MS/MS for Group B3a, B3b and B2c (pyrethroids) in sheep/goat fat, fish, milk, eggs and honey; c) Liquid Chromatography Tandem Mass Spectrometry for Group A6 (nitroimidazoles) in sheep/goat plasma, fish, eggs and honey plus for Group B2c (carbamates) in sheep/goat kidney fat and honey. All these methods were validated similar to what is required in the EU.\textsuperscript{28} The confirmatory method for 10 analytes of Group B1 in muscle had recently been implemented and verified and is ready for full validation. The Atomic Absorption Spectrometry method is validated for Group B3c (heavy metals) in sheep/goat kidney, fish, milk and honey and a new Inductively Coupled Plasma instrument for analysis of heavy metals is in the process of being implemented. All validated methods have SOPs and procedures for quality assurance are in place, similar to EU requirements,\textsuperscript{29} thus \textbf{recommendation No 6} from the 2012 audit has been addressed.

The sensitivity of the methods used was sufficient as spiking concentration levels are equal or lower than the applicable MRPLs\textsuperscript{30} and MRLs.\textsuperscript{31}

30. The FSVI laboratory has participated in several proficiency tests for several substance-matrix combinations of relevance to the residue monitoring plan, similar to what is required in the EU\textsuperscript{32} and mostly with satisfactory results. In the event of unsatisfactory results, corrective actions were taken (e.g. tetracycline in fish muscle, 2016, z-score obtained -4.0, calculation of concentration was corrected).

31. Staff responsible for analyses were well informed and trained in the analytical methods used, as well as in the specific instrument operation and quality assurance system.

\textsuperscript{26} Article 3(a) of Decision 2002/657/EC, point 2.2 of the Annex to Decision 2002/657/EC.
\textsuperscript{27} Article 5 of Decision 2002/657/EC.
\textsuperscript{28} Article 3(a) of Decision 2002/657/EC.
\textsuperscript{29} Article 3(a) of Decision 2002/657/EC.
\textsuperscript{30} Annex II to Decision 2002/657/EC.
\textsuperscript{32} Point 1.2 of the Annex to Decision 98/179.
Conclusions on laboratories

32. The performance of the residue laboratories largely supports the reliability of results for the methods used. However, the fact that several substance groups and many substances within a given group were not analysed as foreseen in the residue monitoring plan or that screening methods were not fully verified/validated, undermines the guarantees provided by the residue monitoring plan approved by the EU.

5.2. Veterinary medicinal products

5.2.1. Competent authorities

33. The SCRVMP which belongs to the DDAFRD is responsible for the registration and for the issuing of marketing authorisations for veterinary medicinal products. The National Business Centre, after approval of the DDAFRD is responsible for the legal authorisation and listing of wholesalers as well as for pharmacies selling veterinary medicinal products for food-producing animals. Official controls on the distribution of veterinary medicinal products are conducted by the RVS at importers, wholesalers, pharmacies and on their use at farms.

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

34. Similar to what is required in the EU, national legislation describes the legal provisions for marketing authorisation (registration), distribution and use of imported veterinary medicinal products. The registration procedures are also legally defined. There are no manufacturers of veterinary medicinal products or medicated feed in Albania, thus all veterinary medicinal products are imported. There are currently no authorised medicated feed or medicated premixes for the manufacturing of medicated feedingstuffs in Albania.

35. Only veterinary medicinal products which are authorised and registered in Albania can be circulated and used. The distribution of imported veterinary medicinal products needs to take place through licensed wholesalers. This is similar to what is required in the EU and could be confirmed by the audit team at the wholesalers and pharmacies visited.

36. At present, 13 companies have a licence to import and distribute nationally registered veterinary medicinal products to 108 licensed pharmacies. Wholesalers can also, on prescription, sell to large farms which employ a full time veterinarian.

37. The veterinary medicinal products seen by the audit team in the establishments visited (wholesalers, pharmacies and farms) had, with one exception, valid registrations. The

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33 Directive 2001/82/EC.
34 Law No 10465 from 29.09.2011 and amended by law No 70/2013.
35 Article 5 of Directive 2001/82/EC.
36 Article 65 of Directive 2001/82/EC.
audit team also found that stocks of products, whose registration period had ended, could still be sold until the stock had been used up provided that the expiry date had not elapsed. The wholesalers met, which also imported veterinary medicinal products, were aware of the relevant national and also EU legislation and could explain how they ensured that only products authorised for use in Albania were imported. In particular, all of these operators kept copies of registrations for the products they had imported or planned to import.

38. National legislation\textsuperscript{37} prohibits the authorisation and use of veterinary medicinal products for food-producing animals using pharmacologically active substances which are not allowed in the EU for food-producing animals, apart from Group A3 (steroids) which can be authorised for zootechnical purposes, which is similar to what is required in the EU.\textsuperscript{38,39} No veterinary medicinal products are registered for sex-inversion in aquacultured finfish.

39. Off-label use of veterinary medicinal products is not allowed, which is stricter compared to the situation in the EU.\textsuperscript{40} Similar to what is required in the EU,\textsuperscript{41} national rules do foresee that veterinary medicinal products for "food-producing" animals, which have a withdrawal period, need to be sold based on a veterinary prescription.\textsuperscript{42}

40. Labelling requirements for veterinary medicinal products\textsuperscript{43} are similar to what is required in the EU.\textsuperscript{44} The audit team could confirm at the wholesalers and pharmacies visited that these had been adhered to. Furthermore, label instructions were available, with a few exceptions, in the Albanian language,\textsuperscript{45} which is an improvement versus the 2012 audit.

41. The requirement to maintain on-farm records for use of veterinary medicinal products is similar to that in the EU.\textsuperscript{46} In addition, food chain information similar to that in the EU\textsuperscript{47} is provided to slaughterhouses for the slaughtering of small ruminants.

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**Conclusion on the authorisation, distribution and use of veterinary medicinal products**

42. The legal framework governing the marketing, authorisation, distribution and use of veterinary medicinal products for food-producing animals is broadly similar to that foreseen in EU legislation and supports the guarantees required by Article 29 of Directive 96/23/EC.

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**5.2.3. Official controls**

**Legal Requirements**


\textsuperscript{38} Directive 96/22/EC and Table 2 of the Annex to Regulation (EU) No 37/2010.

\textsuperscript{39} Article 5 of Council Directive 96/22/EC.

\textsuperscript{40} Article 11 of Directive 2001/82/EC.

\textsuperscript{41} Article 67(aa) of Directive 2001/82/EC and Article 8 of Directive 90/167/EEC.

\textsuperscript{42} Article 99 of order No 370 from 29.7.2014.

\textsuperscript{43} Article 46 of order No 370 from 29.7.2014.

\textsuperscript{44} Article 58 of Directive 2001/82/EC and Article 6 of Council Directive 90/167/EEC.

\textsuperscript{45} Article 101 of order No 370 from 29.7.2014.

\textsuperscript{46} Article 10 of Council Directive 96/23/EC.

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

43. Official controls on the distribution of veterinary medicinal products are carried out twice a year at wholesalers and pharmacies. Staff from the DDAFRD met by the audit team stated that veterinary practices employing more than three veterinarians are also subject to inspection but, at the time of the audit, there were no records available to corroborate that such inspections had been carried out. Controls on the use of veterinary medicinal products are also conducted by the RVS at egg collection centres and farms, including aquaculture-, poultry- and small ruminant farms.

44. Checklists are used for controls on the distribution and use of veterinary medicinal products.

- However, the checklists used for farms which are part of the inspection report, do not provide any specific details on the type of checks carried out on veterinary medicinal product records. Thus it is not possible to verify if for example: the withdrawal periods had been recorded and observed, authorised veterinary medicinal products had been used or labelling requirements had been adhered to. In one small ruminant farm visited by the audit team, on-farm treatment records were present but incorrectly filled in (no withdrawal period indicated for some of the treatments administered). These shortcomings had not been identified in the previous inspection reports. Checks on the presence and content of prescriptions are not recorded in these checklists either, making it impossible to verify if they are carried out.

- Similarly, the checklist used for wholesalers and pharmacies of veterinary medical products does not include aspects covering their authorisation, labelling or prescription requirements. The inspectors met by the audit team stated that in some cases they had carried out reconciliation checks on the quantities of veterinary medicinal products sold and present in stock or on the presence of prescriptions but these checks were not recorded in the inspection reports seen. DDAFRD staff met by the audit team stated that they intended to amend the above checklists to allow a more detailed verification of the requirements relating to controls on veterinary medical products.

45. Checklists of past inspections were available for all establishments visited. In the inspection reports examined, corrective actions were requested by the inspectors and follow-up inspections were carried out on time. The follow-up inspection reports available showed that the non-conformities had been corrected by the operators.

46. While of off-label use is not possible under national legislation, the audit team noted that it had happened in one of the farms visited (prescription of anticoccidials authorised for poultry were used for the treatment of sheep and goats) and it was not reported as a nonconformity in the inspection reports seen.

47. The audit team found at farms, pharmacies and wholesalers visited that national prescription requirements had largely not been complied with, as prescriptions did not contain the required national information (e.g. indication, way of administration and withdrawal period not noted) and veterinary medicinal products requiring prescriptions
were sold without prescription. The aforementioned shortcomings were not reported in the past inspection reports seen at these establishments.

48. There are no controls on the use of anticoccidials categorised as feed additives (e.g. diclazuril, monensin) although the audit team noted that they are imported for use by on-farm mixers, as there are no commercial feed mills in Albania which produce such products. Based on the documentation examined and the information obtained from the wholesalers met, such anticoccidials are used in broiler feed and the labels seen indicated that they were not authorised for laying hens.

Conclusions on official controls

49. Whilst there is an official control system in place to ensure that legal requirements on the distribution and use of veterinary medicinal products and controls are implemented in accordance with planned arrangements, their effectiveness is weakened by the fact that controls on national prescription and on-farm treatment records requirements are limited in scope and not well-documented.

5.3. Follow-up of previous recommendations made in report DG(SANTE) 2012-6536

The table below summarises the follow-up to the relevant recommendation(s) made in report DG SANTE 2012/6536-MR Final

<table>
<thead>
<tr>
<th>No</th>
<th>Recommendation</th>
<th>Findings</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Ensure that information included in the residue monitoring plan provided to the Commission services is accurate and that the scope of testing carried out under the residue monitoring plan includes all relevant substances in line with the range of veterinary medicinal products on the market taking into account the requirements of Article 7 of Council Directive 96/23/EC.</td>
<td>Not addressed: See findings 4 and 6 and recommendation 1 of this report.</td>
</tr>
<tr>
<td>2</td>
<td>Ensure that implementation of the residue monitoring plan is co-ordinated and supervised centrally as required by Article 4 of Council Directive 96/23/EC, in order to ensure that the residue monitoring plan is implemented in line with planned arrangements.</td>
<td>Partially addressed: See findings 11 and 14 and recommendation 2 of this report.</td>
</tr>
<tr>
<td>3</td>
<td>Ensure that sampling is carried out in variable intervals spread over the whole year, avoiding multiple sampling from the same sites and ensuring legal integrity of samples (sealing) in order to provide guarantees at least equivalent to the requirements of the Annex to Commission Decision 98/179/EC.</td>
<td>Not addressed: See finding 15 and recommendation 3 of this report.</td>
</tr>
<tr>
<td>4</td>
<td>Ensure that sampling is carried out without prior notice as required by Article 12 of Council Directive 96/23/EC.</td>
<td>Addressed: See finding 10.</td>
</tr>
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</table>
5. Ensure that all analytical methods used under the residue monitoring plan for monitoring residues of veterinary medicinal products are adequate in terms of their detection capabilities and are validated to a standard equivalent to Article 3 of Commission Decision 2002/657/EC, and are demonstrably ‘fit for purpose’ taking into account requirements described in part 2 of Annex I to and Article 4 of this Decision.

Not addressed: See finding 29 (first bullet point) and recommendation 4 of this report.

6. Ensure that appropriate laboratory quality control procedures are carried out in the Food Safety and Veterinary Institute in accordance with Article 5 to Commission Decision 2002/657/EC.

Addressed: See findings 29 and 30.

6. **OVERALL CONCLUSION**

Whilst Albania has a residue monitoring plan in line with minimum EU requirements, the effectiveness of the current control system for residues in food of animal origin is undermined by its limited implementation due to a lack of sufficient laboratory resources.

There is a low risk of residue violations from consignments exported to the EU insofar as EU-prohibited substances are concerned, due to a well-functioning authorisation system in place for veterinary medicinal products. Controls on the distribution and use of veterinary medicinal products nevertheless need to be strengthened.

7. **CLOSING MEETING**

A closing meeting was held on 25 October 2018 with representatives of the DDAFRD, DDPLM, FSVI, NFA and the regional veterinary services of Durres. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities had no comments and stated that they would take all actions necessary in order to address the areas for improvement identified during the course of the audit.
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.

<table>
<thead>
<tr>
<th>No</th>
<th>Recommendation</th>
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| 1  | To ensure that the residue monitoring plan provided to the Commission services takes into account the laboratories' capacity for processing samples and all relevant substances in line with the range of veterinary medicinal products on the market, so that the guarantees provided for under Article 29 of Directive 96/23/EC remain effective.  
*Recommendation based on conclusion: 8.*  
*Associated findings: 4 and 6.* |
| 2  | To ensure the implementation of the residue monitoring plan in line with planned arrangements so that the guarantees provided for under Article 29 of Directive 96/23/EC remain effective.  
*Recommendation based on conclusion: 18.*  
*Associated findings: 11, 12, 13, 14.* |
| 3  | To ensure that sampling is carried out at variable intervals spread over the whole year, avoiding multiple sampling from the same sites and ensuring that samples to be analysed for substances in Group A are taken from fish at all stages of farming so that the guarantees provided under Article 29 of Directive 96/23/EC remain effective.  
*Recommendation based on conclusion: 18.*  
*Associated finding: 15.* |
| 4  | To ensure that all analytical methods used for the residue monitoring plan are verified/validated, so that the guarantees provided under Article 29 of Directive 96/23/EC are effective.  
*Recommendation based on conclusion: 32.*  
*Associated finding: 29.* |

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

### ANNEX 1 – LEGAL REFERENCES

<table>
<thead>
<tr>
<th>Legal Reference</th>
<th>Official Journal</th>
<th>Title</th>
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<tr>
<td>Directive</td>
<td>OJ L No, Date, p.</td>
<td>Description</td>
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<td>Regulation</td>
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<tr>
<td>Reg. 333/2007</td>
<td>88, 29.3.2007, p. 29-38</td>
<td>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</td>
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<tr>
<td>Reg. 124/2009</td>
<td>40, 11.2.2009, p. 7-11</td>
<td>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</td>
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<td>Directive</td>
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