FINAL REPORT OF AN AUDIT
CARRIED OUT IN
UKRAINE
FROM 05 SEPTEMBER 2016 TO 16 SEPTEMBER 2016
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 in Ukraine, carried out from 5 to 16 September 2016, as part of the published DG Health and Food Safety audit programme.

The objective of the audit was to evaluate whether official controls concerning residues and contaminants in live animals and animal products offer adequate assurance that the products and animals concerned, eligible for export to the European Union (EU), do not contain residues of veterinary medicinal products, pesticides and contaminants at concentrations in excess of EU maximum limits. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit. Attention was also paid to examining the implementation of corrective actions indicated in response to recommendations made in the report of a previous residues audit in Ukraine in October 2010.

Overall, the report concludes that the planning of the Ukrainian residue monitoring plan, which takes into account many relevant factors, includes the requisite substance groups, is prepared in a timely manner and largely supports the guarantees provided by the residue monitoring plan approved by the EU. In addition, the performance of the laboratory network has greatly improved since the last residues audit, increasing confidence in the reliability of results. However, the plan’s effectiveness is compromised by the narrow scope of testing for some substance groups, budgetary constraints which have impeded the timely testing of samples, inappropriate sampling strategies, and follow-up investigations not always implemented in a timely fashion.

As regards the current low frequency of official controls on the distribution and use of veterinary medicinal products, the restrictions imposed by national legislation reduce the capacity of such controls to supplement the guarantees provided by the residue monitoring plan as regards the residue status of products eligible for export to the EU.

The report contains recommendations to the central competent authority aimed at rectifying the shortcomings identified and enhancing the implementing and control measures in place.
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<td>State Service of Ukraine on Food Safety and Consumer Protection</td>
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<td>CVO</td>
<td>Chief State Veterinary Officer</td>
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<tr>
<td>ELISA</td>
<td>Enzyme-linked immuno-sorbent assay</td>
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<td>GFAAS</td>
<td>Graphite Furnace Atomic Absorption Spectroscopy</td>
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<td>ISO</td>
<td>International Organisation for Standardisation</td>
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<td>LC-MS/MS</td>
<td>Liquid Chromatography-(Tandem) Mass Spectrometry</td>
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<td>LIMS</td>
<td>Laboratory Information Management System</td>
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<td>MRL</td>
<td>Maximum Residue Limit</td>
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<td>NRL</td>
<td>National Reference Laboratory (the State Scientific and Research Institute for Laboratory Diagnostic and Veterinary Sanitary Expertise)</td>
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<td>RASFF</td>
<td>Rapid Alert System for Food and Feed</td>
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<td>RMP</td>
<td>Residue Monitoring Plan</td>
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<td>SOP</td>
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1. **INTRODUCTION**

The audit took place in Ukraine from 5 to 16 September 2016. The audit team comprised two auditors from DG Health and Food Safety. The audit was undertaken as part of DG Health and Food Safety's planned audit programme. Representatives from the central competent authority, the State Service of Ukraine on Food Safety and Consumer Protection, accompanied the audit team during the whole audit.

An opening meeting was held on 5 September with the central competent authority, which is responsible for the monitoring of residues and contaminants in live animals and animal products and for controls on veterinary medicinal products as well as the authorisation of veterinary medicinal products. At this meeting, the objectives of, and itinerary for, the audit were confirmed and the control systems were described by the authorities.

2. **OBJECTIVES OF THE AUDIT**

The objective of the audit was to evaluate the performance of the Ukrainian competent authority and other officially authorised entities in their implementation of official controls concerning residues and contaminants in live animals and animal products, in order to assess whether these controls offer adequate assurance that the products and animals concerned, eligible for export to the European Union (EU) do not contain residues of veterinary medicinal products, pesticides and contaminants at concentrations in excess of EU maximum limits. Since the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on the monitoring of residues, the national rules governing the control systems in these areas were also part of the audit.

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


The audit focused on the legal and administrative measures in place to implement the relevant national requirements and on the performance of the competent authority in meeting these requirements. In addition, attention was paid to examining the implementation of corrective actions promised in response to relevant recommendations made in the report of a previous DG Health and Food Safety audit in Ukraine in 2010 (DG(SANCO) 2010-8451 MR Final).

The table below lists the sites visited and meetings held in order to achieve the audit objective.
## MEETINGS/ VISITS

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<th>COMPETENT AUTHORITIES</th>
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| LABORATORIES | 3 | The governmental laboratories in Kiev, Dnipro and Lviv |

| OTHER SITES | 9 | One wholesaler and one retailer of veterinary medicinal products, one honey collection centre, one rabbit slaughterhouse, one geese and duck farm, one aquaculture farm, one rabbit farm, one dairy farm and one bee keeper. |

### 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;
- Article 29 of Directive 96/23/EC.

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

Ukraine is listed in the Annex to Commission Decision 2011/163/EU with a residue monitoring plan (RMP) approved in accordance with Directive 96/23/EC for bovine, porcine, poultry, aquaculture, milk, eggs and honey. In addition, the competent authority requested that its RMP for rabbits is also approved and this commodity listed in the Annex to the above Decision. In March 2016, Ukraine provided the 2016 RMP and 2015 results to the Commission services for all of the above-mentioned commodities.

#### 4.2. Summary of the previous residues audit

The previous audit on official controls on residues, pesticides and contaminants and on the use of veterinary medicinal products was in October 2010 (DG(SANCO) 2010-8451 MR Final). The report of this audit (henceforth referred to as the 2010 report) was published on the website of DG Health and Food Safety.¹

The report concluded that the competent authority had taken steps to strengthen the system of residue controls and in doing so, had addressed several recommendations made in the report of a previous residue audit in 2007. The 2010 report identified problems with delays in obtaining analytical results from laboratories and the need to further

strengthen the effectiveness of follow-up activities thus better ensuring that prohibited pharmacologically active substances were not used in food producing animals.

4.3. Rapid Alert System for Food and Feed (RASFF) notifications

From the 2010 audit until 1 August 2016 there were four RASFF notifications for residues of veterinary medicinal products, all of which occurred in two consignments of honey in 2015. The residues concerned were the antibiotics streptomycin, tetracycline, sulphonamides, chloramphenicol and metronidazole, the latter two substances being explicitly banned from use in food producing animals in the EU.

4.4. Production, Trade Information and Specific Import Requirements

In 2015, Ukraine exported poultry (28 155 tonnes), heat treated egg products (1 272 tonnes), milk products (200 tonnes) and honey (26 000 tonnes) to the EU. The national production volumes were 460 600 cattle, 4.8 million pigs, 2.5 million tonnes of poultry (chicken, geese and turkey), 39 092 tonnes of aquaculture, 2.6 million tonnes of bovine milk, 723 966 tonnes of eggs, 26 800 tonnes of rabbit meat and 66 215 tonnes of honey.

5. FINDINGS AND CONCLUSIONS

5.1. Residue monitoring

5.1.1. Competent authorities

1. The Unit on Monitoring of Veterinary Residues and other Contaminants of the Directorate on Food and Feed Safety within the Department of Food Safety and Veterinary Medicine of the central competent authority is responsible for planning, supervising and reporting on the implementation of the national RMP. While the central competent authority resides under the Ministry of Agrarian policy and Food of Ukraine, the Head of the central competent authority reports directly to the Cabinet of Ministers of Ukraine. The central competent authority was created through the reorganisation of the State Veterinary and Phytosanitary Service by combining it with the State Inspection of Ukraine on Consumer Rights Protection and the State Sanitary and Epidemiological Service of Ukraine. This reorganisation was implemented in April 2016.

2. The regional and district offices of the central competent authority in the 24 regions and the city of Kiev are responsible for implementing the RMP including carrying out follow-up activities in the case of non-compliant results.

5.1.2. Planning

Legal requirements

Article 29 of Directive 96/23/EC.

The following list of legislation and elements thereof is provided for informative purposes, encompassing the various aspects of Union legislation applicable to this section of the report as regards the obligations of EU Member States.

Articles 3 to 7 of, and Annexes I to IV to, Directive 96/23/EC; Commission Decision 97/747/EC; Article 11(2) of Council Directive 96/22/EC; Article 11 of Regulation (EC)
Findings

3. Article 8 of the national Law on ‘Safety and Quality of Food Products’ (Law on Food Safety) provides the legal basis for the planning and implementation of the RMP. The central competent authority approved the 2016 RMP by means of Order No 2452 of December 2015.

4. As required in Article 29 of Directive 96/23/EC, the central competent authority drafts an annual RMP to provide guarantees with an effect at least equivalent to those provided for in said Directive.

5. Similar to EU requirements 2, the planning process of the annual RMP includes the input of the National Reference Laboratory (NRL), the State Scientific and Research Institute for Laboratory Diagnostic and Veterinary Sanitary Expertise.

6. Similar to EU requirements 3, the central competent authority took certain risk factors into account in the planning of the 2016 RMP. These included production volumes, availability of validated analytical methods, and, pharmacologically active substances contained in the veterinary medicinal products authorised for use in food producing animals (with the exception of rabbits). The audit team noted that the central competent authority does not have mechanisms to identify, for the purpose of residue planning, the most frequently used substances in food producing animals. Several relevant substances are not yet included in the RMP due to the lack of validated analytical methods (see also finding 8).

7. The central competent authority has designed the 2016 RMP in line with EU legislation 4 with regard to the number of samples to be taken (based on national production) and the groups and subgroups to be analysed for in the different commodities concerned. Recommendation no 1 of the 2010 report has been addressed with regard to testing for dyes in aquaculture. The central competent authority designed the plans for bovine milk and eggs in line with the specific EU legislation 5 in this regard.

8. Although the 2016 RMP complies with EU rules as regards the numbers of samples taken and the substance groups analysed, in general the scope of testing (i.e. the range of analytes tested for within each substance group) is limited. In particular, the audit team noted the following:
   - Two substances are tested for in subgroup A3 (19-nortestosterone and 17-beta-estradiol). Other steroids which are commonly analysed in the Member States are not tested for, e.g. boldenone, trenbolone, stanozolol, megestrol, and melengestrol.

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4 Annexes I to IV to Directive 96/23/EC and Decision 97/747/EC.
5 Chapter 1 and 2 of the Annex to Decision 97/747/EC.
• One substance is tested for in subgroup A4 (zeranol). The main metabolite of zeranol (taleranol) is not included, nor is the fungal metabolites of zearalanone which can give rise to natural zeranol and needs to be analysed to help differentiate between illegal treatment with zeranol and feed contamination with *Fusarium* spp. Toxins. No testing of zearalanone and taleranol is carried out to distinguish between residues caused by natural source or by prohibited use of growth promoters.

• Three substances are tested for in subgroup A5 (clenbuterol, salbutamol and cimaterol). Member States would normally also include other compounds such as ractopamine or and zilpaterol.

• In subgroup A6, whilst chloramphenicol and nitrofurans are included in the scope of testing, there is no testing for nitroimidazoles in bovine animals and no testing for nitrofurans and nitroimidazoles in rabbits.

• In subgroup B1, a reasonably broad range of antimicrobial classes are tested (including tetracyclines, sulphonamides, tylosin, benzylpenicillin, amoxicillin, ampicillin, enrofloxacin, norfloxacain, streptomycin and erythromycin). Testing does not include though other antibiotics which have marketing authorisations in Ukraine for food producing animals (apramycin, cloxacillin, colistin, flofencicol, flumequine, gentamycin, kanamycin, lincomycin, norfloxacain, spectinomycin and tiamulin) and are used in various authorised veterinary medicinal products (see also findings 59 and 60). Recommendation no 1 of the 2010 report has therefore only been partially addressed.

9. Whilst the indicated levels of actions for most of the substances included in the RMP correspond with the respective maximum residue limits (MRLs) in EU legislation, in a few cases the national levels of action (there are as yet no national MRLs in Ukraine) are higher than the EU MRLs for these substances. For example, the anthelmintics levamisole and fenbendazole (B2a) in bovine milk have a national level of action of 100 ppb. In the EU, levamisole cannot be used in animals producing milk for human consumption, and for fenbendazole the MRL is 10 ppb. As regards heavy metals, the national maximum level for lead in honey is 300 ppb compared to 100 ppb in the EU.

**Conclusion on planning**

10. While planning of the RMP takes into account many relevant factors and the requisite substance groups are included, the reliability of the guarantees offered by the RMP is undermined by a number of factors, notably the narrow scope of testing for some substance groups.

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6 Table 1 of the Annex to Regulation (EU) No 37/2010.
5.1.3. Implementation

Legal requirements

Article 29 of Directive 96/23/EC.

The following list of legislation and elements thereof is provided for informative purposes, encompassing the various aspects of Union legislation applicable to this section of the report as regards the obligations of EU Member States.


Findings

11. Similar to the situation in the EU 8, Articles 11 and 12 of the national law on ‘Veterinary Medicine’, provide officials with the legal power to carry out official controls including sampling under the RMP.

12. Order No 2452 of December 2015 provides the legal basis for the 2016 RMP. By means of a 2015 Executive Order, the central competent authority provided the sampling breakdown of the 2016 RMP to the regional offices.

13. Order No 88, of July 2014, provides general instructions on the planning and implementation of the RMP. The regional offices report to the central competent authority and the NRL where and when they plan to take the samples with sampling being distributed over the year, similar to the situation in the EU 9.

14. A guideline (adopted by Orders of the Chief State Veterinary Officer -CVO- from March 2006 and September 2011) provides instructions on sampling, sample integrity, transport and storage conditions and includes a sampling report template similar to that used by EU Member States 10. At the rabbit slaughterhouse visited, official staff had some problems to demonstrate how sampling would be carried out in line with these instructions, as they were not sufficiently specific for sampling of rabbit meat or rabbit liver.

15. To date, the central competent authority has not provided an instruction on the criteria for selection and targeting of sampling. The audit team noted that sampling was not always appropriate with regard to the selection of farms or with the selection of substances to be tested for: a) in one region visited, samples had been allocated to a few establishments (4 out of 29), which had expressed their wish to be sampled due to export activities; b) live breeding poultry (not yet intended for slaughter) were sampled on-farm for testing muscle and liver for antimicrobials or anthelmintics, which is inappropriate as the

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9 Point 2.1 of the Annex to Decision 98/179/EC.
10 Decision 98/179/EC.
animals may well have been in the middle of an authorised treatment and a ‘non-compliant’ result would be meaningless; and c) the sampling of mixed honey from several producers (rather than from an individual producer) at the honey collection centre minimises the chances of detecting a non-compliant result (due to dilution). During the audit, the central competent authority started to draft an instruction to rectify this situation.

16. The regional authorities’ offices are responsible for providing training to the officials within their region. Similar to what would have been expected in EU Member States 11, the regional offices visited had provided training on RMP sampling and follow-up investigations of non-compliant results. Since 2014, staff of the central competent authority and the NRL had attended Better Training for Safer Food training courses funded by the European Commission.

17. In response to the 2010 report, in 2013 the Chief Veterinary Officer issued an Order which provided instructions on improving the implementation of the RMP, including various reporting requirements on the annual implementation of the RMP. Similar to what would have been expected in EU Member States 12, this Order also defines the competent authorities responsible for the supervision of the implementation of the RMP. Although the district and regional offices as well as the NRL fulfil their quarterly reporting obligations as required by this Order, the audit team could not ascertain the degree of implementation of the RMP due to incomplete, incoherent or insufficiently detailed reports.

18. In 2016, despite the timely approval of the RMP by the central competent authority, the analysis of many samples could not start in time, as the Cabinet of the Ministers of Ukraine approved the state budget for consumables needed for the analyses of samples under the RMP only in July. As a consequence, until July 2016, the NRL could only analyse approximately 1,600 samples of the 4,294 samples planned for the first half of 2016. At the time of the audit, progress had been made in that 4,080 samples of the 4,294 samples had been analysed, while 3 tenders for the purchase of consumables were still on-going. Recommendation no 2 of the 2010 report has not been fully addressed with regard to timely analysis of the samples in the first half of 2016 (the regional laboratory in Lviv could analyse the samples in the first half of 2016 as planned, using its own budgetary resources).

19. Official staff members transport samples under the RMP personally to the laboratories, which ensures their integrity similar to what would have been expected in EU Member States 13. Recommendation no 3 of the 2010 report has been addressed.

**Conclusion on implementation**

20. While the administrative preparation of the RMP is timely and there are numerous reporting requirements for its implementation, several factors including budgetary constraints and inappropriate sampling strategies have reduced the reliability of the guarantees of the plan.

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12 Article 4(2) of Directive 96/23/EC.
13 Point 2.9 of the Annex to Decision 98/179/EC.
5.1.4. Other residue monitoring programmes

Legal requirements

Article 29 of Directive 96/23/EC.

The following list of legislation and elements thereof is provided for informative purposes, encompassing the various aspects of Union legislation applicable to this section of the report as regards the obligations of EU Member States.

Articles 9 and 11 of Directive 96/23/EC.

5.1.4.1. Official programmes for residue testing

Findings

21. A chloramphenicol testing programme in milk and dairy products has been implemented. The regional offices are responsible for planning the sampling under this programme and reporting on its implementation and the results obtained. Under this programme the laboratories analyse samples using a screening test. There is no obligation to use confirmatory analytical methods. Since 2014, follow-up investigations on farms with screening positive results are no longer undertaken due to a Moratorium (see also finding 59).

22. Based on Article 62 on the ‘Law on Food Safety’, the regional and district offices take samples for pre-export testing; these are analysed in the accredited state veterinary laboratories. The scope of analyses takes account of the requirements of the importing food business operators. In the event of a non-compliant result, district officials do not issue a veterinary export certificate. The laboratories report non-compliant results not only to the food business operators in question but also to the central competent authority and the regional offices and inspectors of the district offices have to decide whether the product can be placed on the domestic market or not.

5.1.4.2. Establishments’ own-checks for residues

Findings

23. Similar to the situation in the EU 14, food business operators may operate own control programmes. National legislation though does not require that food business operators inform the competent authorities of non-compliant results under their own-checks, which is expected in the EU 15.

24. The honey collection centre visited, took honey samples from each bee keeper before purchase and, before export, samples representative of the consignment to be exported. The scope of testing included the prohibited substances chloramphenicol, nitrofurans and metronidazole (subgroup A6). In 2015, 12 honey samples were non-compliant for chloramphenicol (6) and nitrofurans (6), representing 4 % of around 300 bee keepers delivering honey to the collection centre. To date in 2016, four samples have tested non-compliant for chloramphenicol. The competent authority was not informed of these results as there is no legal obligation for the food business operator to do so.

14 Article 9(b) of Directive 96/23/EC.
Conclusion on other residue monitoring programmes

25. While pre-export testing and establishments’ own-checks provide assurances on the residue status of exported consignments, the usefulness of these other programmes and establishments’ own-checks to underpin guarantees provided by the RMP is limited due to the lack of a legal obligation for food business operators to report non-compliant own-check results to the competent authorities, thus depriving the authorities from a useful source of information on the inappropriate use of veterinary medicinal products.

5.1.5. Follow-up of non-compliant results

Legal requirements

Article 29 of Directive 96/23/EC.

The following list of legislation and elements thereof is provided for informative purposes, encompassing the various aspects of Union legislation applicable to this section of the report as regards the obligations of EU Member States.

Articles 13, 16, 17, 18, 19, 23, 24, 27 and 28 of Directive 96/23/EC.

Findings

26. Under the 2015 RMP, there were a number of non-compliant results, 2 for chloramphenicol (0.66 ppb in bovine and 0.379 ppb in rabbit muscle), 1 for furazolidone (1.76 ppb in chicken muscle, and 1.6 in follow-up sample), and 1 for DDT (25.4 ppb in fish muscle and 4.69, 2.81 and 1.93 in follow-up samples). In addition, there were RASFF notifications for honey in 2015 (see section 4.3 of this report).

27. Similar to the situation in the EU, the central competent authority issued instructions on follow-up activities which require that district officials report on the outcome of follow-up investigations within 10 days of being informed of a non-compliant result. The Order requires that in the event of non-compliant results for prohibited substances and Group B substances, products from the food business operator can only be placed on the market after 5 follow-up samples have been analysed and are compliant.

28. The audit team selected a number of follow-up files for evaluation. Those concerning the non-compliant results of the RASFF notifications for honey in 2015 demonstrated timely follow-up activities of the competent authority (within 1 month) and identified that the food business operators did not have a system in place to trace back to the bee keepers who delivered the non-compliant honey. In one case (representing two notifications), the food business operator had closed its business and in another case the honey consignment containing the residues was destroyed.

29. Regarding the follow-up file for a non-compliant result under the 2014 RMP in pig muscle (detection of 3.4 ppb chloramphenicol), the follow-up investigation took place 2 months after the result was available. All 5 follow-up samples were also non-compliant for chloramphenicol. There was no evidence in the file, that the food business operator had not placed pig meat on the domestic market (see finding 27). An administrative fine

16 Article 8(1) of Regulation (EC) No 882/2004 and Articles 16 to 18 of Directive 96/23/EC.
was issued and the food business operator closed its business 1 month after the follow-up activities had been carried out.

30. Regarding a follow-up file for a non-compliant result under the 2015 RMP (3.4 ppb chloramphenicol detected in rabbit muscle), the sample took 1 month to be delivered to the laboratory and the follow-up investigation took place 2 months after the result was available. The food business operator did not keep the nationally required treatment record. In contrast to the previous finding, all 5 follow-up samples were compliant and an administrative fine was issued.

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

31. While national legislation in place provides instructions which should ensure timely and effective follow-up of non-compliant results, in the examples selected by the audit team, follow-up investigations were delayed (with one exception) and this has the potential to reduce the effectiveness of the investigations.

### 5.1.6. Laboratory Network

#### Legal requirements

Article 29 of Directive 96/23/EC.

The following list of legislation and elements thereof is provided for informative purposes, encompassing the various aspects of Union legislation applicable to this section of the report as regards the obligations of EU Member States.


#### Findings

32. In 2016, the laboratory network in Ukraine comprises six governmental laboratories, the NRL and five Regional State Laboratories of Veterinary Medicine.

33. Similarly to the situation in the EU 17, the State Scientific and Research Institute for Laboratory Diagnostic and Veterinary Sanitary Expertise has been designated to function as the NRL for residue analysis under the RMP (see also finding 5). The NRL’s functions include the provision of the following:

- Regular, well-structured and comprehensive training to the regional laboratories and in addition, visits of technical staff when needed to solve an analytical problem or to provide hands-on training.
- Proficiency tests for regional laboratories (WET-TEST). Up to six different rounds are planned annually and in 2015, these covered chloramphenicol and nitrofurans (in eggs and honey), sulphathiazole and pesticides (in milk), and beta-agonists (in liver). Target residue concentrations in the test samples matched the applicable minimum required performance level (MRPL)/MRL levels laid down in EU legislation or those recommended by the EU Reference Laboratories 18. The NRL

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17 Article 14 of Directive 96/23/EC.
applied to be accredited as a proficiency test provider according to EN ISO/IEC 17043 and the national accreditation body recently accepted the application;

- Confirmatory analysis of all non-compliant screening results obtained in the regional laboratories before the report of the analytical result is issued (Order No 2452 of 2015).

34. In line with EU legislation 19, all six laboratories are accredited in accordance with the standard EN ISO/IEC 17025 by the national accreditation body, the National Agency on Accreditation of Ukraine. Accreditation certificates are valid for 5 years and their expiry dates for the different laboratories range between August 2017 and December 2019.

35. In line with EU legislation 20, the NRL and the regional laboratories have validated all of the methods used for analysing samples under the RMP which are included in their respective scopes of accreditation.

36. The NRL and two regional laboratories visited operate a Laboratory Information Management System (LIMS). Whilst the LIMS at the NRL allows monitoring of sample turnaround times, this function was not operational in the two regional laboratories.

37. Order No 39 of 2013 establishes a target 2-week turnaround time (from sample receipt to result). This target is not monitored and sample reports evaluated by the audit team demonstrated that the NRL had processed about 50% of the samples within this target period, whereas in the two regional laboratories visited, more than 50% of samples were processed within this time limit.

38. At the NRL, the audit team examined confirmatory methods for analysis of nitrofurans (A6) by LC-MS/MS in all matrices tested under the RMP, for anticoccidials (B2b) in muscle by LC-MS/MS and quality control data for lead in honey by GFAAS:

- In response to the 2010 report, the standard operating procedure (SOP) for method validation had been improved and is now comprehensive and provides for adequate tools for validation and approval of analytical methods.

- The method for nitrofurans was fit for purpose in all matrices with the exception of muscle of rabbit, turkey and sheep, though validations for those matrices were completed before the closing meeting of the audit.

- The LC-MS/MS method for anticoccidials in poultry and pig muscle was most recently validated in 2014 for monensin, salinomycin, narasin, diclazuril and nicarbazin (dinitrocarbanilide) at three concentration levels (2.5; 5.0 and 7.5 µg/kg). For monensin and salinomycin, these three levels were higher than the respective MRLs (2 µg/kg) laid down in EU legislation 21, and therefore only partly suitable to demonstrate the fitness of the method to reliably detect concentrations of these two ionophores in the matrices in question. During the time of the audit the method was also validated for nicarbazin, diclazuril, salinomycin and narasin, in rabbit and sheep muscle at concentration levels corresponding to relevant MRLs applicable to those matrices in the EU.

19 Article 12 of Regulation (EC) No 882/2004 and Section 1.2 of the Annex to Decision 98/179/EC.
• For quality control and identification purposes, internal standards for several analytes were available. A matrix blank followed by a control sample is included in each analytical run. There were criteria for evaluation of control results and control charts were maintained allowing for long term trends in method performance to be seen as required in point 5.9.1 of EN ISO/IEC 17025 (the same was noted in the 2 regional laboratories).

• For the control charts maintained for coccidiostats, the spiking concentration levels (ranging from 10-50 µg/kg depending on the compound) were sometimes too high to meet the level of interest in the EU.

• A comprehensive quality control plan was in place and adhered to for the method for lead in honey. Control materials of plant origin or fish meal instead of spiked samples were used to control the method performance (the same was noted for the two regional laboratories).

39. During the last 3 years, the NRL participated in a number of relevant proficiency tests organised by a commercial provider. The results were largely satisfactory and, where problems were identified, the NRL applied precautionary or corrective actions.

40. The two regional laboratories in Lviv and Dnipro, are responsible for testing thyrostats (A2) in urine, zeranol (A4) in urine and liver, beta-agonist (A5) in urine and liver, carbamates and pyrethroids (B2c) in muscle and honey, organochlorine compounds (B3a) in muscle, milk, eggs, and honey, organophosphorus compounds (B3b) in muscle, milk and honey, heavy metals (B3c) in muscle, kidney, milk and honey. In addition, the laboratory in Lviv carries out testing for chloramphenicol, nitrofurans (A6) and sulphonamides (B1) in urine, muscle, milk, eggs and honey.

41. Two documents, a SOP for general aspects and a ‘Methodical Instruction’ of 2015 provide the requirements for sample reception which includes temperature control of the sample. In the event that a sample is unfit for analysis, a sample rejection protocol is drafted and together with the sample is provided to the official delivering the sample. The responsible district office has to take a new sample. The laboratories store the samples under monitored conditions.

42. In the regional laboratory in Dnipro, the audit team examined analytical methods used for screening of zeranol (A4) in liver by ELISA, thyrostats (A2) in urine, beta-agonists (A5) in urine and liver by LC-MS/MS, and lead (B3c) in honey by GFAAS and in the laboratory in Lviv, the methods used for screening of chloramphenicol (A6) in rabbit muscle and honey by ELISA, beta-agonists (A5) in liver by LC-MS/MS and lead (B3c) in honey by GFAAS. All the methods were validated at three concentration levels covering the screening target concentrations as recommended by the EU Reference Laboratories 22 and to the extent equivalent to that required by EU legislation 23.

43. Both regional laboratories participated in all rounds of inter-laboratory comparisons WET-TEST with satisfactory results (see finding 34).

23 Article 3 and Annex I to Decision 2002/657/EC.
Conclusion on laboratories

44. Due to the significant progress in laboratory performance made since the 2010 audit concerning the validation and accreditation of analytical methods and evidenced by the overall satisfactory performance of the laboratories in proficiency tests, the central competent authority can have confidence in the reliability of the analytical results obtained by the current network of laboratories.

5.2. Veterinary medicinal products

5.2.1. Competent authorities

45. Based on the national Law on ‘Veterinary Medicine’, the Unit on Licensing and Registration of Veterinary Medicines of the Directorate of State Control within the Department of Food Safety and Veterinary Medicine is the competent authority for issuing marketing authorisations for veterinary medicinal products. It registers the applications forwarded by either the State Scientific Research Control Institute for Veterinary Medicinal products and Food Additives or the State of Scientific Control Institute of Biotechnology and Strains of microorganisms after a recommendation from the State Pharmacological Commission of Veterinary Medicine. Since 2015, the Ministry of Health is responsible for ‘criteria of health indicators’ which include national MRLs of veterinary medicinal products in products of animal origin.

46. The offices of the regional and district competent authorities are responsible for carrying out controls on the distribution and use of veterinary medicinal products.

5.2.2. Authorisation, distribution and use

Legal requirements

Article 29 of Directive 96/23/EC.

The following list of legislation and elements thereof is provided for informative purposes, encompassing the various aspects of Union legislation applicable to this section of the report as regards the obligations of EU Member States.


Findings

47. Similar to the situation in the EU 24, Article 67 of the Law on ‘Veterinary Medicine’ requires a registration certificate before a veterinary medicinal product (including premixes for the production of medicated feedingstuffs and coccidiostats) can be placed

24 Directive 2001/82/EC.
on the market. The competent authority issues a marketing authorisation for a renewable period of five years. The same law also rules that only products for the purpose as registered can be used in food producing animals (no off-label use).

48. The list of registered products is publicly available on the central competent authority’s webpage. The information provided on this webpage does not include the withdrawal period to be respected.

49. Similarly to the situation in the EU, national legislation (Order No 15 of 2002) prohibits the use of certain substances in food-producing animals: nitrofurans, ronidazole; dapsone; chloramphenicol; dimetrizadole; colchicine; chlorpromazine; chloroform and metronidazole.

50. At the time of the audit, the list of veterinary medicinal products registered for use in food-producing animals in Ukraine did not contain any pharmacologically active substances prohibited for use in such animals in the EU.

51. Article 67 of the Law on ‘Veterinary Medicine’ states that the national MRL for certain pharmacologically active substances (e.g. hormones with gestagenic, androgenic or thyreostatic effect) cannot be higher than the MRLs provided for in the Codex Alimentarius.

52. In contrast to the situation in the EU, national MRLs are not yet established. The MRLs drafted in 2010 were not approved and since 2015, the Ministry of Health has not yet established such a list. Recommendation no 7 of the 2010 report has therefore not been addressed. At the manufacturer/wholesaler visited, the available files and documents did not identify which MRLs the manufacturer uses as a reference for the calculation of the product-specific withdrawal period indicated on the leaflet for the various tissues of the animal species for which the product can be used in line with its registration.

53. Order No 133 of 14 August 2007 provides for labelling requirements of registered veterinary medicinal products similar to EU requirements, (active ingredients, registration and batch number, target species, dosage, withdrawal period, expiry date). In contrast to EU requirements, part of the information can be provided only on the leaflet, including the withdrawal period. At the retailer visited, the leaflet was not available for 1 carton of around 30 bottles of a veterinary medicinal product containing streptomycin. It was not clear, how the retailer would inform buyers of the withdrawal period for this product, as neither the label on the bottle nor the webpage of the central competent authority provided this information (see finding 50).

54. Similar to EU requirements, national legislation restricts the distribution of veterinary medicinal products to companies (wholesaler) authorised for this purpose. Nevertheless, since the enforcement of the Moratorium in August 2014 (see finding 66), the competent authority cannot enforce the renewal of expired licences and new companies can start a business without a licence.

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27 Table 1 of the Annex to Regulation (EU) No 37/2010.
28 Article 58 of Directive 2001/82/EC.
29 Article 65 of Directive 2001/82/EC.
55. Partly similar to EU requirements, national legislation foresees record keeping requirements for sales of veterinary medicinal products made by wholesalers and retailers. While at the wholesaler visited, the record kept contained information to identify both the sellers and buyers of products, the record of the retailer visited, contained only information to identify the sellers but not the buyers.

56. In contrast to the situation in the EU, farmers can purchase most veterinary medicinal products without a veterinary prescription; a veterinary prescription is required for narcotics.

57. Similar to EU requirements, national legislation requires farmers (including beekeepers) to keep records on treatments and Order No 308 of 27 August 2009 provides a template for these records which also includes the date of treatment, product name and withdrawal period).

**Conclusion on authorisation, distribution and use**

58. While the present range of pharmacologically active substances used in veterinary medicinal products nationally authorised for use in food producing animals is similar to EU requirements, some aspects of the authorisation and distribution of these products differ considerably from EU legislation, in particular with regard to the lack of nationally established MRLs (see conclusion 10) and the fact that a veterinary prescription for most of the products used in food producing animals is not required.

### 5.2.3. **Official controls**

#### Legal requirements

Article 29 of Directive 96/23/EC.

The following list of legislation and elements thereof is provided for informative purposes, encompassing the various aspects of Union legislation applicable to this section of the report as regards the obligations of EU Member States.


#### Findings

59. Since 2014, official controls are subjected to a number of new legal acts. The first of these is the Moratorium, approved in 2014 by the Parliament of Ukraine, aimed at facilitating business and improving the economy. Based on this Moratorium, in the period between 1 August 2014 and 31 June 2015, official controls of establishments (including farms, slaughterhouses, processing plants, manufacturers and distributors of veterinary medicinal products or veterinary practitioners) were only permitted if they were explicitly authorised in advance by the Cabinet of Ministers of Ukraine (done so in case of African swine fever). The validity of the Moratorium has been prolonged until 1 January 2017.

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30 Article 65 and Article 66(2) of Directive 2001/82/EC.
31 Article 67 of Directive 2001/82/EC.
60. The opinion of the Ministry of Justice is that the Moratorium can no longer be applied to sanitary and phytosanitary issues. Based on this opinion, the central competent authority requested the regional offices to draft a plan of official controls for 2017. This annual plan has yet to be approved by the Ministry of Economy and Trade and will be published on its webpage.

61. Order No 402 of 2015 of the Cabinet of Ministers, established three risk categories (low, medium and high), and restricted ‘planned’ official controls for low risk establishments (e.g. manufacturers and distributors of veterinary medicinal products) to one control every 5 years, medium risk establishments (e.g. farms) to one control every 3 years, and high risk establishments (e.g. slaughterhouses) to one control per year, irrespective of the outcome of the previous control. Sampling under the RMP and follow-up investigations are deemed to be ‘un-planned’ controls and are not affected by this Order. Current national legislation requires planned controls to be announced to the food business operator at least 10 days in advance.

62. The Law on Food Safety requires that planned official controls can only be carried out in line with legally registered checklists. The registration has to be carried out by the Ministry of Justice, which delays the updating of checklists. So far, not all checklists drafted by the central competent authority are registered (e.g. a checklist for rabbit farms), and some are not updated, for example, the checklist for controls of EU-approved honey processing plants. The latter does not cover whether elements of the Hazard and Analysis Critical Control Points system are in place in processing plants, although this is a pre-requisite to sign a veterinary certificate for export of honey to the EU.

63. The Law of State Control (still in draft form) aims to align national legislation with the requirements of Regulation (EC) No 882/2004. The central competent authority expects this draft legislation to come into force at the end of 2016, with a 1-year transitional period. Once adopted, it will overrule Order No 402 and its requirement for pre-notification of official controls.

64. The State Scientific Research Control Institute for Veterinary Medicinal products and Food Additives organises a) every 2 years, conferences on developments in veterinary drugs which officials of the competent authority’s regional and district offices attend, and b) since 2015, 1 day seminars for officials and wholesalers. So far, these seminars have taken place in five regions.

65. The central competent authority has drafted various nationally approved templates for the conduct of official controls (see finding 62) on wholesalers/retailers and farms with regard to the use of veterinary medicinal products and has also issued a template for recording treatments of food producing animals with veterinary medicinal products. As stated in finding 62, the Ministry of Justice has yet to register the checklist to be used for the controls of rabbit farms.

66. In the wholesalers/retailers and farms visited, the audit team noted that the reduced intensity of official controls (see finding 61) has affected the frequency and depth of the district offices controls.

67. As described in the 2010 report, there are no specific national legal requirements for the production of medicated feed.
Conclusion on official controls

68. The reduced frequency of official controls on the distribution and use of veterinary medicinal products reduces the capacity of such controls to supplement the guarantees provided by the RMP as regards the residue status of products eligible for export to the EU.

5.3. Follow-up of previous recommendations

The table below summarises the follow-up to the relevant recommendations made in the 2010 report (DG(SANCO) 2010-8451 MR Final.

<table>
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<tr>
<th>N</th>
<th>Recommendation in 2010 report</th>
<th>Findings in current audit</th>
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| 1  | To expand the scope of testing carried out under the national residue control plan taking account of those medicinal products used in each sector, in order to have an effect at least equivalent to that provided for in Council Directive 96/23/EC. In particular for all dyes (group B3d) used in aquaculture production and for antibiotics (group B1). | Addressed for dyes tested for in aquaculture, see finding 7.  
Addressed insufficiently for B1 substances, see finding 8. |
| 2  | To ensure that sampling is in line with the requirements laid down in point 2 of the Annex to Commission Decision 98/179/EC and that testing is implemented in accordance with the plan, regarding the timing of sampling and timely analysis of samples so that the implementation of the plan has an effect at least equivalent to that provided for in Council Directive 96/23/EC. | Not fully addressed for first half of 2016, see finding 18.                                                   |
| 3  | To ensure that official samples are adequately sealed in accordance with the requirements of Commission Decision 98/179/EC.                                                                                                                                                              | Addressed, see finding 19.                                                                                   |
| 4  | To ensure that follow-up on non-compliant test results has an effect equivalent to that of Article 16-18 of Directive 96/23/EC.                                                                                                                                                           | Not fully addressed, see finding 27.                                                                           |
| 5  | To ensure that all analytical methods used under the national residue control plan, regardless of the laboratory in which they are performed, are validated to a standard equivalent to Articles 3 and 4 of Commission Decision 2002/657/EC and are demonstrably ‘fit for purpose’ taking into account requirements described in part 2 of Annex 1 and Article 4 of this Decision. | Addressed, see finding 35.                                                                                   |
To consider enforcing the Law on Veterinary Medicine of Ukraine in that pharmacologically active substances which fall under the definition of veterinary medicinal products laid down in this law are either authorised according to the law or prohibited for use in food producing animals, in order to have an effect equivalent to Article 7 of Directive 96/23/EC.

To consider establishing maximum residue limits under national law in order to avoid legal uncertainty with regard to detection limits of methods used and non-compliant test results in the residue control plan, and to have an equivalent effect to Article 7, fourth indent, of Directive 96/23/EC.

6. **OVERALL CONCLUSION**

As regards the current low frequency of official controls on the distribution and use of veterinary medicinal products, the restrictions imposed by national legislation reduce the capacity of such controls to supplement the guarantees provided by the residue monitoring plan as regards the residue status of products eligible for export to the EU.

Overall, the report concludes that the planning of the Ukrainian residue monitoring plan, which takes into account many relevant factors, includes the requisite substance groups, is prepared in a timely manner and largely supports the guarantees provided by the residue monitoring plan approved by the EU. In addition, the performance of the laboratory network has greatly improved since the last residues audit, increasing confidence in the reliability of results. However, the plan’s effectiveness is compromised by the narrow scope of testing for some substance groups, budgetary constraints which have impeded the timely testing of samples, inappropriate sampling strategies, and follow-up investigations not always implemented in a timely fashion.

7. **CLOSING MEETING**

A closing meeting was held on 16 September 2016 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The central competent authority stated that they would take whatever actions were necessary in order to address the areas for improvement identified during the audit. In particular, the competent authority had already drafted an instruction revising its sampling strategy under the RMP and the NRL had finalised the validation of its laboratory methods for rabbit meat (see findings 15, 38 and 39).
The competent authority is 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.

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<th>No</th>
<th>Recommendation</th>
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| 1  | To ensure that 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 and used, so that the guarantees provided under Article 29 of Directive 96/23/EC remain effective.  
*Recommendation based on conclusion 10.*  
*Associated finding 8.* | |
| 2  | To ensure effective implementation of the residue monitoring in particular with regard to the sampling strategy, so that the guarantees provided under Article 29 of Directive 96/23/EC remain effective.  
*Recommendation based on conclusion 20.*  
*Associated finding 15.* | |
| 3  | To ensure implementation of effective follow-up activities of non-compliant test results, so that the guarantees provided under Article 29 of Directive 96/23/EC remain effective.  
*Recommendation based on conclusion 31.*  
*Associated findings 29 and 30.* | |

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>
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<td>Food Law</td>
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<td>Monitoring of residues and contaminants in food of animal origin</td>
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<td>Regulation</td>
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<td>Reg. 124/2009</td>
<td>OJ L 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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**Veterinary Medicinal Products**

<table>
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