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DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2017-6290

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
THE RUSSIAN FEDERATION
FROM 09 OCTOBER 2017 TO 20 OCTOBER 2017
IN ORDER TO
EVALUATE THE CONTROL OF RESIDUES AND CONTAMINANTS IN LIVE ANIMALS AND ANIMAL PRODUCTS INCLUDING CONTROLS ON VETERINARY MEDICINAL PRODUCTS

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

Executive Summary

This report describes the outcome of a Directorate-General for Health and Food Safety audit in the Russian Federation, carried out from 9 to 20 October 2017.

The objective of the audit was to evaluate

(a) the adherence to, and the reliability of, the guarantees provided by the residue monitoring plans already approved by the EU;

(b) the guarantees provided by additional residue monitoring plans for commodities which the competent authority has requested inclusion in the Annex to Commission Decision 2011/163/EU (for farmed game - reindeer from regions other than Murmansk and Yamalo-Nenets, and for aquaculture products), and

(c) the implementation of national measures to provide assurances that the products exported to the EU comply with the residue limits laid down in EU legislation.

The audit also evaluated the implementation of corrective actions following the previous DG Health and Food Safety audit to the Russian Federation, DG(SANCO)/2014-7031.

The Russian Federation's annual residue monitoring plan is developed in good time, allowing its timely implementation, with sampling spread throughout the year (where appropriate). Nevertheless, two factors weaken the effectiveness of the plan. The absence of testing for residues of some commonly used veterinary medicinal products and the policy of sampling and testing processed products. The latter reduces the likelihood of detecting misuse of veterinary medicinal products at farm level due to both processing factors and dilution of residue concentrations in the final product. Whilst this approach is appropriate for determining exposure assessment of consumers, it does not satisfy the requirements of Directive 96/23/EC.

Whilst follow-up of non-compliant results was done in a timely manner, the competent authority's ability to identify the reason for the non-compliance is weakened by both the aforesaid sampling policy and the lack of a legal obligation for farmers to record medicinal treatments. .

In relation to the performance of the laboratory network, whilst progress has been made, relative to the 2014 report, confidence in the reliability of the results generated under the residue monitoring plan is still undermined by the fact that (a) not all methods are adequately verified/validated in all of the matrices tested, and (b) for a number of methods there are no adequate quality control measures in place. In particular, for residues of veterinary medicinal products in caviar and reindeer meat, there were no verification/validation data available concerning the performance of methods in the laboratories visited, responsible for testing these commodities.

As regards the authorisation and use of veterinary medicinal products and official controls thereon, not much has changed relative to 2014. The official control system on the distribution and use of veterinary medicinal products makes a very limited contribution to the guarantees on animal products' compliance with EU MRLs for residues of pharmacologically active substances.

Undertakings previously given on banning the use of a range of substances in food producing animals (similar to the situation in the EU) did not eventually happen. Thus it remains the case that substances explicitly banned in the EU remain on the market in the Russian Federation and can be purchased over the counter without any legal requirement to record their use in animals.

Whilst improvements in the plan are noted since 2014, the shortcomings identified in its implementation, allied with the free availability of veterinary medicines, weaken the

reliability of the guarantees provided by the plan.

The report contains recommendations to the Russian competent authorities, aimed at rectifying the shortcomings identified and enhancing the effectiveness of the control measures in place.

TABLE OF CONTENTS

ABBREVIATIONS & DEFINITIONS USED IN THIS REPORT

AOZ and AMOZ, AHD and SEM	Marker residues of the nitrofuran drugs furazolidone, furaltadone, nitrofurantoin and nitrofurazone respectively
CCα / CCβ	Decision Limit / Detection Capability
CSMVL	the Central Scientific and Methodical Veterinary Laboratory, Moscow
DG	Directorate-General
ELISA	Enzyme-linked immuno-sorbent assay
EU	European Union
EURL	European Union Reference Laboratory
GOST	State Standard of the Russian Federation
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC
HPLC-MS/MS	High Performance Liquid Chromatography-(Tandem) Mass Spectrometry
ILAC	International Laboratory Accreditation Cooperation
ISO	International Organisation for Standardisation
Leningrad IOVL	Leningrad *Interoblast* Veterinary Laboratory
MAFF	Ministry of Agriculture, Forestry and Fisheries
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
NCSFAP	National Centre for Safety of Fishery and Aquaculture Products, Moscow
RASFF	Rapid Alert System for Food and Feed
Rosselkhoznadzor	Federal Service for Veterinary and Phytosanitary Surveillance, the central competent authority
SIRANO	Computerized information system similar to the RASFF system
SOP	Standard Operating Procedure
Tver IOVL	Tver *Interoblast* Veterinary Laboratory
VGNKI	All Russian State Centre for Quality and Standardisation of Veterinary Drugs and Feeds, Moscow

1. INTRODUCTION

The audit took place in the Russian Federation from 9 to 20 October 2017. The audit team comprised two auditors from the Directorate-General (DG) for Health and Food Safety. The audit was undertaken following the request by the Russian competent authority - the Federal Service for Veterinary and Phytosanitary Surveillance (*Rosselkhoznadzor*) - to list additional plans in the Annex to Commission Decision 2011/163/EU.

An opening meeting was held on 9 October 2017 with the *Rosselkhoznadzor* which, is responsible for (a) the monitoring of residues and contaminants in live animals and animal products and for controls on veterinary medicinal products and feed additives, and (b) 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. Representatives from the *Rosselkhoznadzor* accompanied the audit team during the whole audit.

2. OBJECTIVES AND SCOPE OF THE AUDIT

The objective of the audit was to evaluate:

a) the adherence to, and the reliability of, the guarantees provided by the residue monitoring plans previously approved by the EU for: bovine, ovine/caprine, porcine, poultry, farmed game (reindeer from Murmansk and Yamalo-Nenets regions), milk, eggs and honey;

b) the guarantees provided by the residue monitoring plans for farmed game (reindeer from the rest of the Russian Federation) and aquaculture products, in order to provide an opinion on the request by the competent authority to include those commodities in the Annex to Commission Decision 2011/163/EU, and

c) the implementation of national measures to provide assurances that the products exported to the EU comply with residue limits laid down in EU legislation for residues of pharmacologically active substances (veterinary medicinal products), pesticides and contaminants. Since the national rules governing the authorisation, distribution and use of veterinary medicinal products and feed additives have an impact on residue monitoring, the control systems in these areas were also part of the audit.

The audit covered:

- the control system in place, aiming at ensuring compliance with the EU residue limits in commodities eligible for export or foreseen to be exported to export to the EU;
- the implementation of controls on the use of veterinary medicinal products which have a direct bearing on the residues status of the above commodities;
- the implementation and effectiveness of the measures taken in response to the recommendations following the previous audit on this subject, DG(SANCO)/2014-7031 (hereafter, the 2014 report).

The principal audit criteria against which fulfilment of the above objective was assessed is Council Directive 96/23/EC.

Further audit criteria are listed in each of the 'legal requirements' sections, with details provided in Annex 2.

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

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	Central	2	Opening and closing meetings with the *Rosseklhoznadzor*
	Regional	2	Territorial Administration of the *Rosseklhoznadzor* in the Komi Republic Territorial Administration of the *Rosseklhoznadzor* for the Novgorod and Vologda Regions
LABORATORIES		3	FGBI «Leningrad *Interoblast* Veterinary Laboratory» FGBI «Tver *Interoblast* Veterinary Laboratory» National Centre for Safety of Fishery and Aquaculture Products, Moscow
FARMS/ESTABLISHMENTS		6	Aquaculture farm (sturgeon) linked to a fishery products establishment Reindeer farm(er) with slaughterhouse and meat processing plant Dairy farm Feed mill producing medicated feed, Two retailer/Wholesaler of veterinary medicinal products

3. LEGAL BASIS FOR THE AUDIT

The audit was carried out under the general provisions of EU legislation, and in particular Article 46 of Regulation (EC) No 882/2004 and Article 21 of Council Directive 96/23/EC.

4. BACKGROUND

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

The Russian Federation has residue monitoring plans approved in accordance with Directive 96/23/EC for bovine, ovine/caprine, swine, poultry, milk, eggs, farmed game (limited to reindeer from Murmansk and Yamalo-Nenets regions) and honey. This is reflected in the Annex to Commission Decision 2011/163/EU as last amended.

In 2016 the *Rosseklhoznadzor* requested the inclusion of aquaculture in the list of approved residue monitoring plans, and to extend the approval of the plan for farmed game (reindeer) to the whole territory of the Russian Federation. During the preparation of the audit, and during the initial meeting, representatives of the *Rosseklhoznadzor* confirmed that, in relation to aquaculture, the specific commodity of interest to be included in the list is (sturgeon) caviar.

4.2. Summary of previous DG Health and Food Safety audits

Official controls on residues of veterinary medicines and contaminants in the Russian Federation were audited by DG Health and Food Safety in 2009 (DG (SANCO)/2009-8279), 2011 (DG (SANCO)/2011- 8905) and 2014 (DG(SANCO)/2014-7031). The reports of those audits and the actions proposed by the competent authority have been published on the Commission website [1].

Each of the audit reports pointed out shortcomings in the design and implementation of the residue monitoring plan, delays linked to the preannouncement of control visits and weakness of the follow-up actions. The continued use of unvalidated methods combined with a lack of quality controls in place undermined the reliability of the laboratory results. The reports successively concluded that the control system

[1] http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

of residues in the Russian Federation could not offer guarantees equivalent to those foreseen by EU legislation, and the competent authorities were requested to rectify the deficiencies identified.

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

In the last two years prior to this audit, the Russian Federation exported to the EU 301 consignments of animal products covered by the requirements of the residue monitoring plans (other commodities as wild caught fish, casings, composite products and raw materials for the production of gelatin and collagen) are also exported but are not required to be subject to residue monitoring under Directive 96/23/EC and the are no maximum residue limits (MRLs) for residues of pharmacologically active substances established in EU legislation).

Out of the 301 consignments, 22 were subject to laboratory testing at the borders (4 were tested for heavy metals and 18 for residues of veterinary medicinal products). Out of the 18 consignments above, 2 results triggered RASFF alerts: a detection of tetracycline in cheese in 2016 and a detection of chloramphenicol in honey in 2017.

5. FINDINGS AND CONCLUSIONS

5.1. Residue monitoring

5.1.1. Planning of residue monitoring

Legal Requirements

Article 29 of Directive 96/23/EC.

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

Findings

1. The process of drafting the residue monitoring plan remains as described in the 2014 report: the regional *Rosselkhoznadzor* offices provide statistics on production volumes, number of establishments, number of animals, similarly to the situation expected in the EU [2]. The laboratories calculate the number of samples and tests for every region under their responsibility, distributing the samples per quarter. If a regional laboratory has no capacity for testing a specific group of substances, analysis is allocated to one of the laboratories with federal responsibility. Each of these federal laboratories elaborates its own sampling plans. The overall federal plan is approved by the *Rosselkhoznadzor* and is revised each quarter to include suspect and follow-up samples (if any) or reallocate samples if necessary.
2. Once the plans are received in the regions, the regional *Rosselkhoznadzor* offices, in cooperation with the regional veterinary services allocate samples/tests to establishments. The officials interviewed explained that the allocation of sampling focuses more on exporting establishments and takes into consideration available intelligence (previous results, knowledge on the use of veterinary medicines in animals supplied to the establishment).

[2] Article 14 of Directive 96/23/EC.

3. Following the 2014 audit, the *Rosselkhoznadzor* changed the layout of the residue monitoring plan provided to the Commission to address **Recommendation 1** of the 2014 report. Even though residue monitoring covers both domestic production and imports, the information on domestic production is now provided separately.

4. During the audit it was confirmed that the numbers indicated in the 2017 plan still reflect the number of tests per group or analyte and not the number of samples taken (every sample can be tested for up to five "safety indicators": one or more veterinary medicines, contaminants). The *Rosselkhoznadzor* staff were able to extract from the database the actual number of samples planned for 2017. The number of samples still goes beyond the minimum numbers specified in EU legislation [3] and addresses part of **Recommendation 1** of the 2014 report.

5. In relation to the matrices covered:

   - Contrary to the situation in the EU [4], the plans do not include samples drawn from live animals during production, and;
   - The plans include samples from processed products (e.g. dairy products). MRLs in such products are included in Russian legislation, but stability of residues in processed products remains unknown and the ability to detect the presence of residues might be compromised by processing or dilution. This point was also part of **Recommendation 1** of the 2014 report, and remains unchanged.

6. In relation to reindeer, the production figures for farmed game refer only to this species. Since 2017, testing for reindeer includes residues of veterinary medicinal products (required for farmed game in the EU [3]). Until 2016, the plan for reindeer covered contaminants (appropriate if reindeer would be considered as wild game). The decision to reclassify reindeer from wild game to farmed game follows a recommendation from the Commission services, as the reindeers in question might receive veterinary treatments.

7. Since the 2014 audit, new legislation has been published establishing MRLs for aquaculture products - the Technical Regulation of the Eurasian Economic Union "Safety of Fish and Fish Products" TR EAEU 040/2016, adopted by Decision of the Eurasian Economic Commission No.162, of 18 October 2016.

8. The scope of testing in the plan is increasing progressively on the basis of laboratory capability, but it is still the case that some veterinary medicines reported as being used in the establishments visited during the audit (i.e. ciprofloxacin in the sturgeon farm; an avermectin in the reindeer farm; gentamicin in the dairy farm, and virginiamycin in the feed mill) were not covered in the testing of the samples from these operators in 2017. This situation has been recorded in successive SANTE audit reports since 2009 and thus **Recommendation 2** of the 2014 report remains to be addressed.

9. National MRLs are broadly in line with those applicable in the EU. In its reply to the pre-audit questionnaire, the *Rosselkhoznadzor* clarified that in the case of absence of limits established in Russian legislation, the limits stipulated in the Codex Alimentarius apply to products intended for export.

10. When a laboratory cannot test a specific matrix or any substances within a specific group of substances, then the federal central laboratories take over responsibility for the testing. If a regional laboratory can test for at least one substance in a group, then the sample will be tested there. This results in samples drawn from some

[3] Article 5(c) and Annex IV of Directive 96/23/EC and Article 1 and Annex to Decision 97/747/EC.
[4] Article 15 and Annex IV to Directive 96/23/EC

regions being subject to a limited range of testing within a substance group (e.g. group A6), whereas others may be redirected to a laboratory where a much more comprehensive range of analyses are performed for the same group. The scope of a laboratory for testing within a substance group is not taken into consideration at the planning phase.

Conclusions on planning of residue monitoring

11. The development of the residue monitoring plan is timely and allows for the implementation of the plan throughout the year. The effectiveness of the plan is partially weakened by not taking into account the pharmacologically active substances seen in use in the specific establishments visited by the audit team, and by including processed products in the matrices to be tested.

5.1.2. Implementation of the residue monitoring plan

Legal Requirements

Article 29 of Directive 96/23/EC.

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

Findings

12. The regional authorities received the 2017 plan before the end of 2016, allowing for timely implementation from the beginning of the year.

13. Sampling is carried out by inspectors of the *Rosselkhoznadzor* Territorial Administrations following national standards (GOST). In the examples reviewed by the audit team, the documentation of the sample allowed traceability to the date of production. From there, the traceability to the primary producer is based on the records of the food-producing establishments.

14. Visits to establishments (processing establishments and farms) by *Rosselkhoznadzor* officials must be preannounced under national rules. In order to keep the element of surprise when drawing samples, the officials join control visits of the regional veterinary services, which do not need pre-announcement. This is an improvement in relation to the situation described in the 2014 report and thus addresses **Recommendation 3** of that report. In this respect, the situation is now similar to that seen in the EU Member States [5].

15. Officials in charge of sampling identify the groups of analytes for which samples are to be tested in the sampling form that accompanies the sample to the laboratory. All forms reviewed during the audit were correctly and fully completed.

16. As was the case in 2014, clustered sampling still happens, in relation to the establishments selected, the sampling dates and the scope of testing. The *Rosselkhoznadzor* explained that a reason for this is the focus on exporting establishments but, in several cases reviewed, samples were seen to have been drawn in the same establishment on successive days for the same testing scope.

17. Samples are promptly delivered to laboratories and all the cases reviewed during the audit had been tested in a few days.

[5] Articles 12 and 15 of and Annex III to Directive 96/23/EC, and Article 1 and Annex to Decision 98/179/EC.

18. In relation to testing for group A6 substances, in one laboratory visited only one nitrofuran metabolite was covered in every matrix. This is different from the situation seen in the EU Member States where the metabolites of four nitrofurans are tested for (see finding 10). This is of relevance as, despite not having medicinal products with nitrofurans registered in the market, the number of detections is considerably high (see finding 23).

19. Laboratories report on the progress of the plan implementation via an electronic system named VESTA. A formal review is done every quarter and samples are reallocated to different regions or establishments if necessary. The final number of samples coincides with the numbers planned.

20. Since 2014, the *Rosselkhoznadzor* monitors electronically the timely testing of samples, the delivery of results and that samples with non-satisfactory results after screening are sent for confirmation to the VGNKI (the All Russian State Centre for Quality and Standardisation of Veterinary Drugs and Feeds, the central laboratory in Moscow). This is an improvement since the 2014 audit, addressing **Recommendation 4** and coincides with what would be expected in the EU [6]. Non-compliant results are notified directly to central *Rosselkhoznadzor* within 24 hours.

21. At the time of the audit the 2017 testing of reindeer for residues of veterinary medicinal products had not started (slaughter is seasonal, starting at the end of October). The competent authority noted that sampling takes place throughout the year, but until October 2017, the sampling focused on meat products produced after the 2016 slaughter season, and the testing covered contaminants.

Conclusions on implementation of residue monitoring

22. The competent authority ensures that the residue monitoring plan is implemented as planned and reviewed when necessary. The clustering of sampling and the limited analytical scope for some substance groups reduce the effectiveness of the plan. The implementation of the plan for reindeer in relation to veterinary medicinal products had not started so it could not be evaluated.

5.1.3. Follow-up of non-compliant results

Legal Requirements

Article 29 of Directive 96/23/EC.

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

Findings

23. Under the 2016 residue monitoring plan, the *Rosselkhoznadzor* reported the following detections of non-compliances for group A6 substances: 91 for chloramphenicol, 432 for nitrofurans and 58 for nitroimidazoles. In the Russian Federation there are no veterinary medicinal products registered for use in food producing animals containing nitrofurans (see finding 48). Chloramphenicol and metronidazole are included in veterinary medicinal products registered for use in food-producing animals – unlike in the EU where they are prohibited.

24. Non-compliant laboratory results are communicated in a timely manner to the *Rosselkhoznadzor* electronically. The SIRANO system (comparable to the Rapid

[6] Article 6(1) of Decision 2002/657/EC

Alert System for Food and Feed –RASFF- in the EU) manages the information about non-compliant results found under the national residue monitoring plan, and their follow-up.

25. Follow-up is responsibility of the *Rosselkhoznadzor* territorial administration offices. In principle, and as described in the 2014 report, follow-up visits to an establishment need the initial agreement of the prosecutor's office. However, the prosecutor's office is legally obliged to reply in less than 24h and, when a risk to animal, public health or environment is suspected, the agreement is not necessary.

26. The audit team examined the follow-up of several non-compliant results. Records of the actions undertaken were available for all the examples selected. Following the detection of non-compliant results, regional veterinary authorities were promptly informed, and were asked to perform follow-up actions and investigations. These follow-up actions could involve enhanced laboratory testing (samples taken from 10 consignments of the same commodity within not more than 3 months and tested for those criteria where non-compliance was previously detected). This is similar to what is required in the EU [7].

27. In all of the cases reviewed, non-compliant results were transmitted without delay and relevant follow-up actions were instituted promptly, including the immediate suspension of certification of products from the operators in question. Establishments where non-compliances have been confirmed are targeted in the next year's residue monitoring plan.

28. There is effective communication between the different regional authorities. One of the cases reviewed was a detection of contaminants in reindeer slaughtered in one region but coming from a different one. The notification to the region of origin allowed that follow-up was implemented in a timely manner.

29. One of the cases was a detection of chloramphenicol in honey at the EU border, notified to the *Rosselkhoznadzor* via the RASFF. During the investigation, the use of chloramphenicol was confirmed in the single primary producer from where the product originated (chloramphenicol is registered and authorised for use in the Russian Federation, but there are no medicines registered with this substance for honey bees) and a procedure for pre-export testing at this producer was put in place.

30. In contrast to what is expected in the EU [8] and as described in the 2014 report, the source of the contamination or use of medicine leading to the non-compliant result was rarely established when the product sampled has been produced using raw material from multiple sources (e.g. butter or milk from dairy plants). Even though the batch can be traced to the producers of the raw material, the success of the investigation is limited because veterinary medicines are available over the counter (without the need for a veterinary prescription) and treatments can be administered by the animal keeper without any legal obligation to keep treatment records. Thus **Recommendation 5** of the 2014 report has not been addressed.

31. For example, in one case concerning the detection of tetracyclines in cheese, the *Rosselkhoznadzor* inspectors visited the dairy plant where the sample was taken. The veterinary service inspected the three farms which had delivered the milk used to produce the batch of cheese and informed *Rosselkhoznadzor* that the substance was not included in the purchase records of any of the farms. In two cases, the report included copies of the list of medicines purchased by the farms. Given the inconclusive nature of the investigation, no enforcement or sanctions were imposed.

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7 Articles 16, 17 and 18 of Directive 96/23/EC.

8 Articles 13, 16 and 18 of Directive 96/23/EC.

Conclusions on follow-up of non-compliant results

32. The follow-up of non-compliant results is well documented and implemented in a timely manner. However, the ability to identify the source of the residue (and therefore to issue sanctions or order measures to prevent recurrence) is reduced in cases where samples have been drawn from processed products and, in general, is also hampered by the absence of a legal obligation to record treatments.

5.2. Laboratories

Legal Requirements

Article 29 of Directive 96/23/EC.

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

Findings

33. As in 2014, the laboratory network comprises 31 federal governmental laboratory units of which 2 belong to scientific-testing institutes, 10 are *Rosseklhoznadzor* reference centres and 19 are *Interoblast* (inter-regional) veterinary laboratories.

34. Compared to the 2014 audit, further significant progress has been made with regard to international accreditation. Similar to what is expected in the EU [9], all laboratories are now ISO 17025 accredited by the Federal Accreditation Service (*RusAccreditation*) (which has been a full member of the International Laboratory Accreditation Cooperation (ILAC) since July 2017). In addition, 15 laboratories are accredited by the Association of Analytical Centers (AAC) 'Analitica' (ILAC member since 2009), and the other 9 laboratories, by accreditation bodies in EU Member States.

35. As in the past, the *Rosseklhoznadzor* laboratories largely apply nationally standardised methods, so called GOST methods for which, according to the internationally established rules [10], verification is required to demonstrate the laboratory's capacity to operate them as intended. National legislation [11] provides requirements for laboratories accredited to ISO 17025 and guidelines [12] are in place on how to implement standardised methods and to verify their performance in a laboratory. Nevertheless, in contrast to what is required in the EU [13], based on the data provided by the competent authority, 24 laboratory units use some unverified/unvalidated methods and of those only 10 were reported as having the method validation/verification in progress.

36. The audit team visited three laboratories:

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9 Point 1.2. of the Annex to Decision 98/179/EC.

10 Point 5.4 of ISO 17025.

11 Federal Law No 412-FZ On accreditation within the national accreditation system in force since 1 July 2014 and as amended on 2 March 2016 and Order of the Ministry of Economic Development of the Russian Federation No 326 On the approval of the criteria for accreditation in force since 7 September 2014.

12 Metrological guidelines R 50.2060-2008 State system for ensuring the uniformity of measurements. Introduction of standardized methods of quantitative chemical analysis in the laboratory. Confirmation of compliance with the requirements.

13 Article 3(b), (c) and (d) of Decision 2002/657/EC, Guidelines for the validation of screening methods for residues of veterinary medicines of 20/1/2010, Article 28 of Regulation (EC) No 396/2005, Guidance document on analytical quality control and method validation procedures for pesticides residues analysis in food and feed, Article 1 and Annex to Regulation (EC) No 333/2007.

- The Leningrad *Interoblast* Veterinary Laboratory (Leningrad IOVL). This laboratory receives samples for testing from nine regions (St. Petersburg, Leningrad, Novgorod, Murmansk, Archangelsk, Komi, Karelia, Nenets), testing all commodities (including aquaculture and reindeer) under the residue monitoring plan.
- The Tver *Interoblast* Veterinary Laboratory (Tver IOVL). This laboratory receives samples from four regions (Tver, Yaroslav, Vologda and Pskov), testing all commodities except reindeer. In aquaculture (finfish) the scope of testing is limited to tetracyclines (B1), heavy metals (B3c), pesticides and polychlorinated biphenyls (B3a).
- The National Centre for Safety of Fishery and Aquaculture Products (NCSFAP) receives samples from the whole territory of the Russian Federation. The commodities tested are bovine, ovine, poultry and fish (muscle and caviar) under the residue monitoring plan.

37. In addition to being accredited to ISO 17025 by the *RusAccreditation,* all of these laboratories hold AAC 'Analitica' accreditation for a number of methods. However, Leningrad IOVL uses unverified/unvalidated methods for testing substance groups A1 in muscle, A4 in muscle and milk, bacitracin (B1) in muscle, milk, eggs and feed, macrolides (B1) in honey, avermectins (B2a) in milk and pyrethroids (B2c) in food products.
38. Procedures and instructions for sample reception and handling were in place and residue monitoring samples were stored in adequately monitored conditions at all laboratories visited. With regard to aquaculture (fish) samples, similar to the situation in the EU [14], both fish muscle and skin in natural proportions are taken to prepare a laboratory sample. Thus results of testing in such prepared fish samples can be used for the purpose of establishing whether EU MRLs are met or not.
39. Procedures in place for the management of chemical standards are adequate and adhered to in two of the visited laboratories. Only at the NCSFAP laboratory was there no clear instruction in place for handling expired standards. This shortcoming was rectified during the audit.
40. The audit team examined the following methods:
    - at the Leningrad IOVL:
        a. for chloramphenicol (A6) in muscle, milk, fish and honey by Enzyme-linked immuno-sorbent assay (ELISA), and
        b. for beta-agonists (A5) in muscle by High Performance Liquid Chromatography-(Tandem) Mass Spectrometry (HPLC-MS/MS);
    - at the Tver IOVL:
        a. for the nitrofuran metabolite AOZ (A6) in milk by ELISA,
        b. for tetracyclines (B1) in milk by HPLC-MS/MS, and
        c. for polychlorinated biphenyls (B3a) in fish by Gas Chromatography-(Tandem) Mass Spectrometry;
    - at the NCSFAP laboratory;
        a. for metronidazole (A6) within the multi-residue method for penicillins, sulphonamides, chloramphenicol and nitroimidazoles in

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

food products and food raw materials [15] according to GOST R 54904-2012 standard, and

b. for quinolones (B1) in fish, both by HPLC-MS/MS.

41. With regard to the method validation and quality controls in place, the audit team noted that the situation described in previous audit reports has not been corrected, and thus **Recommendation 6** of the 2014 report has not been addressed. Specifically:

At Leningrad IOVL:

a) The ELISA method for chloramphenicol in muscle, milk, fish and honey was adequately verified in each of these matrices. The staff stated that its performance was verified in bovine muscle only; muscles of other animal species (e.g. poultry or reindeer) have not been included in method verification experiments. Nevertheless, with regard to 'meat', the method verification protocol refers to 20 samples from bovine, porcine and poultry and includes muscle, liver and kidney. The method verification results for honey are not included in this protocol. Quality control samples spiked with chloramphenicol at concentrations below the Minimum Required Performance Limit [16] (MRPL) are run once every three months but acceptance criteria (e.g. for recovery) are not established. This approach does not provide information on the everyday method performance and from the perspective of EU rules is considered inadequate [17].

b) The method for beta-agonists was verified in 2015 for bovine muscle at concentration levels similar to those recommended by EU Reference Laboratories. In August 2017 the responsible analyst left the laboratory and a new staff member to operate this method is in the course of training. At the time of the audit, there were no other staff in place proficient to carry out this analysis. In contrast to what is required in the EU [18], there is no routine to include quality control samples in each analytical run and the staff stated that such a routine is only implemented for tetracycline analysis.

c) Although the laboratory receives samples of reindeer, none of the methods in operation have been verified/validated for testing residues of veterinary medicinal products in this matrix.

At Tver IOVL:

d) Similar to what is expected in the EU [19], comprehensive method verification/validation studies have been carried out for all methods checked by the audit team and all methods in use in this laboratory are verified/validated.

e) For tetracyclines and poly chlorinated biphenyls adequate quality controls on the everyday method performance are in place and similar to EU rules and ISO requirements [20], control charts to monitor trends are maintained. For ELISA methods, the frequency of controls is limited to once in every three months due to the lack of a sufficient supply of analytical standards. This practice is considered insufficient to monitor the reliability of results. Spiking

15 Applicable for testing milk, eggs meat and products thereof, poultry meat and products thereof, honey, fish and sea food.

16 Annex II to Decision 2002/657/EC.

17 Article 5 of Decision 2002/657/EC and ISO 17025 standard.

18 Article 5 of Decision 2002/657/EC and ISO 17025 standard.

19 Article 3(b), (c) and (d) of Decision 2002/657/EC, Guidelines for the validation of screening methods for residues of veterinary medicines of 20/1/2010, Article 1 and Regulation (EU) No 589/2014.

20 Article 5 of Decision 2002/657/EC and ISO 17025 standard.

concentration levels are below the respective EU MRPLs/MRLs and are thus suitable for checking the method performance at the concentration level of interest in the EU.

f) Different to the situation in the EU [21], only a single nitrofuran metabolite is tested for in each matrix: i.e. AOZ in milk and AMOZ in muscle.

At the NCSFAP laboratory:

g) Both methods checked by the audit team had been verified in line with national guidelines incorporated in the laboratory procedure on the evaluation of the suitability of analytical methods. Checks have been done only in fish, but the laboratory also tests bovine, porcine, poultry, milk and caviar samples.

h) For the EU-prohibited substance metronidazole, the performance of the method was verified at a concentration level 100 µg/kg. This concentration is over 30 times higher than that recommended by the respective EU Reference Laboratory. The sensitivity of the method actually allows for testing at the concentration levels expected in the EU and satisfies the requirements laid down in the recently approved Eurasian Economic Union legislation (see finding 7) [22], according to which no measurable concentration is allowed in fish. Staff interviewed were not aware of the above regulation.

i) Other nitroimidazoles are not tested for in fish in the samples sent to this laboratory, although nitroimidazoles are allowed in Russia and ronidazole, dimetridazole and ipronidazole are covered by the GOST method.

j) In contrast to what is required in the EU [23] quality control samples are run only for tetracycline analysis. Whilst matrix-matched calibration is routinely used for all analyses and matrix interference can be thus eliminated, the laboratory routinely includes samples of various matrices in the same analytical run so measurements are carried out based on calibration prepared in one matrix only, most likely fish.

k) Although the laboratory staff admitted that from the chemical analysis perspective, caviar is a most difficult fishery matrix, none of the methods in place had been verified/validated in this matrix.

42. Compliant results for residues of veterinary medicinal products are reported as a concentration measured (in case of no analyte presence, as below the method detection limit). This is fit for purpose, although strictly speaking it is different to the situation in the EU [24]. As regards the sensitivity of the methods checked, it is considered adequate, as detection limits of the methods in use are lower or equal to the respective MRPLs [25] and lower than respective MRLs [26] or MLs [27] applicable according to EU legislation.

43. As indicated in 2011 and 2014 reports, and similar to the arrangements existing in the EU [28], both the VGNKI and the Central Scientific and Methodical Veterinary Laboratory, Moscow (CSMVL) organise proficiency tests for the *Rosselkhoznador* network laboratories. Since 2015, the VGNKI has organised proficiency tests for

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21 Table 2 in the Manual on residue requirements for non-EU countries exporting to the EU.
22 Technical Regulation (TR EAEU 040/2016) on Safety of fish and fishery products (in force since 1 September 2017).
23 Article 5 of Decision 2002/657/EC and ISO 17025 standard.
24 Article 6 of Decision 2002/657/EC.
25 Annex II to Decision 2002/657/EC.
26 Annex to Regulation (EU) No 37/2010.
27 Regulation (EC) No 1881/2006, Regulation (EC) No 396/2005.
28 Article 14 of Directive 96/23/EC.

nitrofuran metabolites in poultry muscle and for tetracyclines, amphenicols/chloramphenicol in milk powder. The CSMVL organised inter-laboratory comparisons for chemical elements in water solutions and in milk powder, and for different mycotoxins in feed.

44. Similar to what would be expected in the EU [29], the laboratories visited – with the exception of the NCSFAP- have participated in inter-laboratory comparisons and proficiency tests organised by the VGNKI and CSMVL with satisfactory results. In addition, the Leningrad IOVL participated in some proficiency tests by commercial providers: for mycotoxins (B3d) in rice and feed, ractopamine (A5) in liver, nitrofuran metabolites (A6) and fluoroquinolones (B1) in honey. All results were satisfactory. Since 2015 the NCSFAP has not participated in proficiency tests relevant for the scope of the audit.

Conclusions on laboratories

45. Progress has been made, relative to the 2014 report, in the performance of residue laboratories to support the guarantees provided by the residue monitoring plan approved by the EU. Nevertheless, the confidence in the reliability of the results generated is still undermined by the fact that not all methods are adequately verified/validated in all of the matrices tested for, and for a number of methods there are no adequate quality controls in place. In particular, there are no verification/validation data concerning the performance of methods for residues of veterinary medicinal products in caviar and reindeer meat.

46. Although there are no veterinary medicinal products containing nitrofurans registered in the Russian Federation for use in food producing animals, testing for single compounds in different matrices risks not identifying the full extent of potential misuse of those substances, given the high number of non-compliant results detected even under this limited testing.

5.3. Veterinary medicinal products

5.3.1. Authorisation, distribution and use of veterinary medicinal products

Legal Requirements

Article 29 of Directive 96/23/EC.

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

Findings

47. *Rosselkhoznadzor* is responsible for the registration and circulation of veterinary medicinal products and maintenance of the State register of medicines. The *Rosselkhoznadzor* website lists, in a publicly accessible database, details of all veterinary medicines registered in the Russian Federation. Veterinary medicines registered in the other countries of the Eurasian Economic Union (Kazakhstan, Belarus, Kyrgyzstan and Armenia) can circulate freely in the Russian Federation. Lists of these veterinary medicines are also published on the internet.

[29] Point 1.2 of the Annex to Decision 98/179/EC.

48. The use of stilbenes, thyrostats and steroids for growth promotion purposes is prohibited, similar to the requirements in the EU [30]. Beta-agonists are not registered in the Russian Federation. In response to **Recommendation 8** of the 2014 audit report, the *Rosselkhoznadzor* described an ongoing process amongst the Eurasian Economic Union countries, considering the total ban of the use in food-producing animals of chloramphenicol, nitrofurans, nitroimidazoles, malachite green, crystal violet, carbadox, olaquindox, stilbenes, thyrostats, steroids, beta-agonists and resorcylic acid lactones. During the current audit, the *Rosselkhoznadzor* confirmed that this decision never entered into force so the actions proposed are still pending and the 2014 recommendation remains unaddressed. With regard to the above list, there are no veterinary medicinal products registered for use in food producing animals containing nitrofurans whereas chloramphenicol and metronidazole are included in veterinary medicinal products registered for use in food-producing animals (see finding 23).

49. Different to the situation in the EU [31], animal keepers buy the medicines directly from outlets. When the purchase is substantial, the wholesalers/retailers have proof of the sale and the buyer can be identified. During the visits, they confirmed that small amounts of medicines can be bought without recording the name of the customer.

50. Whilst animal keepers are required to keep records of the veterinary medicines bought for use on the farm, treatment records are not legally required. Still, in the dairy farm visited individual treatment records were maintained. Checking of whether withdrawal periods were observed was done by testing individually every animal treated. Only when the test was satisfactory were the animals put back into production (i.e. milk could enter the bulk tank).

51. In the reindeer holding, there were records of treatments for the different herds. Reproductive females were treated once per year with an avermectin. The farm buys gentamicin that, as explained by the animal keeper and the officials, was intended for the working animals (riding bucks). Testing for residues of this antibiotic was not included in the plan for 2017.

52. In the sturgeon farm visited, there were treatment records for the different ponds where fish were kept. The only veterinary medicine purchased was a quinolone antibiotic used as a preventive treatment in periods of stress.

53. In the feed mill visited, the production is done following a request for medicated feed by the farmer. The feed mill had in place a system to verify the homogeneity of mixing and absence of cross-contamination in medication-free or other medicated feed. As described in 2014, production of medicated feedingstuffs is not specifically regulated in the Russian Federation. Therefore, the competent authority had not verified if these measures were effective in achieving properly mixed medicated feed and uncontaminated medication-free feed respectively.

54. Detailed records of stocks and sales were available in the two veterinary medicinal product outlets visited. Batch numbers of veterinary medicinal products are not recorded, different to the situation in the EU [32].

55. Also different to the situation in the EU [33], there are no specific legal provisions governing the off-label use of veterinary medicinal products. Off-label use is left to the discretion of the animal keeper.

30 Directive 96/22/EC and Table 2 of the Annex to Regulation (EU) No 37/2010.
31 Article 67(aa) of Directive 2001/82/EC and Article 8 of Directive 90/167/EEC.
32 Article 66c of Directive 2001/82/EC.
33 Article 11 of Directive 2001/82/EC.

Conclusions on authorisation, distribution and use of veterinary medicinal products

56. The lack of a prescription system combined with the lack of requirements for keeping treatment records increase the risk of presence of residues over the maximum limits.

5.3.2. Official controls on the distribution and use of veterinary medicinal products

Legal Requirements

Article 29 of Directive 96/23/EC.

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

Findings

57. Veterinary medicinal product wholesalers and retailers, feed mills and farms can be subject to a scheduled (pre-notified) inspection no more frequently than once every three years. If a company changes its legal status within the three years, inspectors must wait for a further three years before they can perform a scheduled inspection. The inspections focus on the storage conditions and the labelling of products. Regional veterinary services confirmed that they only issue inspection reports when non-compliances are found.

58. Unplanned inspections can be performed if a specific complaint is received, in case of emergency, or if an instruction is received from the *Rosseklhoznadzor*.

59. Licences for the wholesalers and retailers of veterinary medicinal products are issued by the *Rosseklhoznadzor*. Licences are valid for an indefinite period rather than for five years (which is the situation in the EU).

60. Official controls on farms in relation to veterinary medicines verify the storage conditions of the medicines and expiry dates of the products in stock rather than on how the medicines have been used.

61. The feed mill visited held an approval from the revenue authority, but had not been inspected to date by the veterinary services. An inspection is planned for 2018, but the scope will not cover medicated feed as this production is not regulated under Russian law. This lack of regulatory framework for the production of medicated feed was already described in the 2014 audit report (see finding 53).

62. Certificates accompanying animals to slaughter detail recent vaccinations and anti-parasite treatments, but do not specifically refer to the administration of other veterinary medicines or relevant withdrawal periods. Under official rules inspectors verify these aspects on the farm of origin before certifying the animals for slaughter, but the information of individual treatments might not be available.

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

63. The system in place for official controls on the distribution and use of veterinary medicinal products has a very limited contribution to the guarantees on the compliance of animal products with EU maximum residue limits for pharmacologically active substances.

5.4. Follow-up of recommendations made in report DG(SANCO) 2014-7031

64. The table below summarises the follow-up to the relevant recommendations made in report DG(SANCO) 2014-7031.

N	Recommendation	Findings
1	In accordance with the provisions of Article 29 of Directive 96/23/EC, to ensure that the national residue monitoring plan presented to the Commission services includes only monitoring for residues and contaminants in unprocessed products, is based solely on domestic production, clearly specifying the matrices tested for each species, analytical limits of detection and the laboratories to be used (which should have suitable analytical methods in place).	Partially addressed. Testing in processed products is still included. See findings 3-5, conclusion 11 and Recommendation 1 in the present report..
2	To ensure 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, as laid down in Article 7 of Directive 96/23/EC.	Not addressed. See findings 8 and 51, conclusions 11 and 22 and Recommendation 1 in the present report.
3	To ensure that sampling is carried out without prior notice in order to provide guarantees with an effect equivalent to that required by Article 12 of Directive 96/23/EC.	Addressed See finding 14 and conclusion 32.
4	To ensure that the screening of positive results is subject to chemical confirmation to unambiguously identify and quantify the residue in question in order to have an effect equivalent to that required by Article 15.2 of Directive 96/23/EC.	Addressed. See findings 19 and 20 and conclusion 22.
5	To ensure that when non-compliant results are obtained, unannounced and effective follow-up investigations are performed which have an effect at least equivalent to that provided for by Articles 16-18 and 22-27 of Directive 96/23/EC.	Partially addressed. The effectiveness of the follow-up investigations remains limited. See findings 24-31, conclusion 32 and Recommendation 2 in the present report.
6	To ensure that all analytical methods used for the residue monitoring plan are validated to a standard equivalent to Article 3 of Decision 2002/657/EC and are demonstrably fit for purpose, as laid down in part 2 of Annex I to and Article 4 of this Decision.	Not addressed See findings 35, 37 and 40 (a, c, g, h and k), conclusion 45 and Recommendation 3 in the present report.
7	To ensure that appropriate quality control procedures are carried out in the laboratory network in line with Article 5 of Decision 2002/657/EC.	Not addressed See finding 41 (b, e and j), conclusion 45 and Recommendation 4 in the present report.
8	To ensure measures to guarantee that animals and products derived thereof, eligible for export to the EU, contain no detectable residues of substances	After the previous audit, on the basis of the guarantees provided by

	which are either prohibited in the EU or for which no EU MRL exists, as set out in Tables 2 and 1, respectively, of the Annex to Regulation (EU) No 37/2010.	*Rosselkhoznadzor* in its action plan, this recommendation was considered addressed. However, the proposed actions were never implemented and the recommendation remains unaddressed. See finding 48, conclusion 56 and Recommendation 5 in the present report.

6. OVERALL CONCLUSION

The Russian Federation's annual residue monitoring plan is developed in good time, allowing its timely implementation, with sampling spread throughout the year (where appropriate). Nevertheless, two factors weaken the effectiveness of the plan. The absence of testing for residues of some commonly used veterinary medicinal products and the policy of sampling and testing processed products. The latter reduces the likelihood of detecting misuse of veterinary medicinal products at farm level due to both processing factors and dilution of residue concentrations in the final product. Whilst this approach is appropriate for determining exposure assessment of consumers, it does not satisfy the requirements of Directive 96/23/EC.

Whilst follow-up of non-compliant results was done in a timely manner, the competent authority's ability to identify the reason for the non-compliance is weakened by both the aforesaid sampling policy and the lack of a legal obligation for farmers to record medicinal treatments. .

In relation to the performance of the laboratory network, whilst progress has been made, relative to the 2014 report, confidence in the reliability of the results generated under the residue monitoring plan is still undermined by the fact that (a) not all methods are adequately verified/validated in all of the matrices tested, and (b) for a number of methods there are no adequate quality control measures in place. In particular, for residues of veterinary medicinal products in caviar and reindeer meat, there were no verification/validation data available concerning the performance of methods in the laboratories visited, responsible for testing these commodities.

As regards the authorisation and use of veterinary medicinal products and official controls thereon, not much has changed relative to 2014. The official control system on the distribution and use of veterinary medicinal products makes a very limited contribution to the guarantees on animal products' compliance with EU MRLs for residues of pharmacologically active substances.

Undertakings previously given on banning the use of a range of substances in food producing animals (similar to the situation in the EU) did not eventually happen. Thus it remains the case that substances explicitly banned in the EU remain on the market in the Russian Federation and can be purchased over the counter without any legal requirement to record their use in animals.

Whilst improvements in the plan are noted since 2014, the shortcomings identified in its implementation, allied with the free availability of veterinary medicines, weaken the reliability of the guarantees provided by the plan.

7. CLOSING MEETING

A closing meeting was held on 20 October 2017 with representatives of the *Rosselkhoznadzor* and the laboratory network. At this meeting, the audit team received additional documents before presenting the main findings and preliminary conclusions of the audit. The authorities provided additional information, some clarifications and comments.

8. RECOMMENDATIONS

The competent authorities are invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below, within 25 working days of receipt of this audit report.

No	Recommendation
1	Ensure 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, and that samples are drawn from matrices where the concentration of detectable residues is not reduced due to processing or dilution, to ensure that the guarantees provided by the plan under Article 29 of Council Directive 96/23/EC are effective. *Recommendation based on conclusions 11, 22 and 46.* *Associated findings 3-5, 8, 18, 21, 41(f) and 51.*
2	Ensure that samples under the residue monitoring plan are drawn at a stage of production that allows traceability to a primary producer, in order to facilitate effective follow-up after a detection of residue violations, to ensure that the guarantees provided by the plan under Article 29 of Council Directive 96/23/EC are effective. *Recommendation based on conclusion 32.* *Associated findings 25-31.*
3	Ensure that all of the analytical methods used for the residue monitoring plan are verified/validated, so that the guarantees provided by the plan under Article 29 of Directive 96/23/EC are effective. *Recommendation based on conclusion: 45.* *Associated findings 35, 37 and 41 (a, c, g, h and k).*
4	Ensure that the national laboratories carrying out testing of samples under the residue monitoring plan have quality control measures in place, to ensure that the guarantees provided by the plan under Article 29 of Directive 96/23/EC are effective. *Recommendation based on conclusions: 45 and 46.* *Associated finding: 41 (b, e and j).*
5	Ensure that animals and products derived thereof, eligible for export to the EU, contain no detectable residues of substances which are either prohibited in the EU or for which no EU MRL exists to ensure that the guarantees provided by the plan under Article 29 of Council Directive 96/23/EC are

	effective. *Recommendation based on conclusions: 22, 46, 56.* *Associated finding: 18, 23, 41(f, h, i) and 48.*

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

http://ec.europa.eu/food/audits-analysis/rep_details_en.cfm?rep_inspection_ref=2017-6290

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 96/23/EC	OJ L 125, 23.5.1996, p. 10-32	Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products and repealing Directives 85/358/EEC and 86/469/EEC and Decisions 89/187/EEC and 91/664/EEC
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
Dec. 2002/657/EC	OJ L 221, 17.8.2002, p. 8-36	2002/657/EC: Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
Reg. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC
Reg. 333/2007	OJ L 88, 29.3.2007, p. 29-38	Commission Regulation (EC) No 333/2007 of 28 March 2007 laying down the methods of sampling and analysis for the official control of the levels of lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene in foodstuffs
Reg. 589/2014	OJ L 164, 3.6.2014, p. 18-40	Commission Regulation (EU) No 589/2014 of 2 June 2014 laying down methods of sampling and analysis for the control of levels of dioxins, dioxin-like PCBs and non-dioxin-like PCBs in certain foodstuffs and repealing Regulation (EU) No 252/2012
Reg. 37/2010	OJ L 15, 20.1.2010, p. 1-72	Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin

Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Dir. 2001/82/EC	OJ L 311, 28.11.2001, p. 1-66	Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products
Dir. 96/22/EC	OJ L 125, 23.5.1996, p. 3-9	Council Directive 96/22/EC of 29 April 1996 concerning the prohibition on the use in stockfarming of certain substances having a hormonal or thyrostatic action and of beta-agonists, and repealing Directives 81/602/EEC, 88/146/EEC and 88/299/EEC
Dir. 90/167/EEC	OJ L 92, 7.4.1990, p. 42-48	Council Directive 90/167/EEC of 26 March 1990 laying down the conditions governing the preparation, placing on the market and use of medicated feedingstuffs in the Community