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FINAL REPORT OF AN AUDIT

CARRIED OUT IN

BRAZIL

FROM 28 MAY 2018 TO 08 JUNE 2018

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 an audit carried out in Brazil from 28 May to 8 June 2018 as part of the European Commission's Directorate-General for Health and Food Safety planned work programme.

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

While the planning of residue monitoring follows principles of the Codex Alimentarius and Directive 96/23/EC, the reliability of the guarantees offered by the residue monitoring plan are partly weakened by the number of samples for aquaculture and honey not meeting the Codex approach, not testing for a number of substances nationally authorised for use in food producing animals and levels of action not always aligned with those applicable in the EU. The residue monitoring plan is implemented largely in line with planned arrangements and promptly carried out follow-up measures in case of non-compliant results contribute to the prevention of reoccurrence.

Samples under the residue monitoring programmes are tested with validated methods in ISO 17025 accredited governmental and private laboratories. Areas for improvement were identified in relation to inclusion of stability data in method validation, the correct use of CC-alpha, and the consistent application of control charts to monitor method performance.

Various national legal requirements governing the authorisation and use of veterinary medicinal products can support the adherence to the guarantees required by Article 29 of Directive 96/23/EC. However, there are some substances authorised in cattle which cannot be used in food-producing animals in the EU and which preclude certification requirements being met at present. The current veterinary medicine prescription system and limited requirements for maintenance of medicinal treatment records do not add much in the way of additional guarantees that veterinary medicinal products are used in line with label indications.

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

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ABBREVIATIONS & DEFINITIONS USED IN THIS REPORT

CGAL	*Coordenação-General de Laboratórios Agropecuários* - General Coordination of Agricultural Laboratories
CGIE	*Coordenação-General de Intelegencia e Estratégia* - General Coordination of Intelligence and Strategy
DFIP	*Departamento de Fiscalização de Insumos Pecuários* – Department of Livestock Inputs Inspection
DIPOA	*Departamento de Inspeção de Produtos de Origem Animal* - Department for Inspection of Products of Animal Origin
ELISA	Enzyme-linked immuno-sorbent assay
EU	European Union
EU RL	European Union Reference Laboratory
HACCP	Hazard analysis and critical control points
INMETRO	*Instituto Nacional de Metrologia, Normalização e Qualidade Industrial* – Brazilian National Accreditation Body
ISO	International Organisation for Standardisation
LANAGRO (-SP, -RS, -MG, -PE, -PA, -GO)	*Laboratório Nacional Agropecuário* – National Animal and Plant Laboratory (in the States of -São Paulo, -Rio Grande do Sul, -Minas Gerais, -Pernambuco, -Pará, -Goiás)
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
MAPA	*Ministério da Agricultura, Pecuária e Abastecimento* – Ministry of Agriculture, Livestock and Supply
ML	Maximum Level
MRL	Maximum Residue Limit
MRPL	Minimum Required Performance Limit
RASFF	Rapid Alert System for Food and Feed
SDA	*Secretaria de Defesa Agropecuária* – Secretariat of Animal and Plant Inspection
SEFIP	*Serviço de Fiscalização de Insumos Pecuários* - Inspection Services of Livestock Inputs (only in the States São Paulo and Minas Gerais)
SFA	State Superintendence (established in all 27 States, representing MAPA in all States)
SIF	*Serviço de Inspeção Federal* – Federal Inspection Service
SIPOA	*Serviço de Inspeção de Produtos de Origem Animal* –Inspection Service for Products of Animal Origin (10 regional units representing DIPOA in all States)
SISA	*Serviço de Fiscalização de Insumos e Serviços Pecuários e Saúde Animal* – Division of Livestock Inputs, Inspection and Animal Health (in State Superintendences other than São Paulo and Minas Gerais)
SISBOV	Brazilian System of Identification and Certification of Origin for Cattle and Buffalo
SISRES	*Sistema de Informações Gerencias de Resíduos* - electronic database for recording sampling under the residue monitoring plan
SSA	Authority with the responsibilities of SISA in the states São Paulo and Minas Gerais

1. INTRODUCTION

The audit took place in Brazil from 28 May to 8 June 2018 as part of the Directorate-General for Health and Food Safety work programme.

An opening meeting was held on 28 May with the relevant Departments of the Secretariat of Animal and Plant Protection (*Secretaria de Defesa Agropecuária* – SDA), under the Ministry of Agriculture, Livestock and Supply (*Ministério da Agricultura, Pecuária e Abastecimento* – MAPA). At this meeting, the objectives and the itinerary of the audit were confirmed and the control systems were described by the authorities. Representatives from the central competent authorities accompanied the audit team during the whole audit.

2. OBJECTIVES OF THE AUDIT AND AUDIT CRITERIA

The objective of the audit was to evaluate:

- implementation of the residue monitoring plan for animals and animal products for the commodities listed in the Annex to Commission Decision 2011/163/EU;
- the reliability of the guarantees in ensuring that the commodities eligible for export to the European Union (EU) do not contain residues of veterinary medicinal products, pesticides and contaminants exceeding EU maximum limits;
- the measures taken in response to the outcome of the last audits in which residue monitoring for the above commodities were evaluated.

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

The principal audit criteria against which fulfilment of the above objective was assessed comprised Regulation (EC) No 882/2004 of the European Parliament and of the Council, Council Directive 96/23/EC and Directive 2001/82/EC of the European Parliament and of the Council.

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

MEETINGS/VISITS		n	COMMENTS
COMPETENT AUTHORITIES	Central	2	Opening and closing meetings with the relevant department of SDA
	Regional	2	Regional authorities of the States São Paulo and Rio Grande do Sul
LABORATORIES		4	1 private and 3 governmental laboratories (LANAGRO SP, LANAGRO RS and LANAGRO MG)
FARMS		2	1 cattle farm and 1 turkey farm
ESTABLISHMENTS		3	1 honey processing establishment, 2 slaughterhouses (cattle, poultry)
OTHER SITES		2	1 wholesaler and 1 retailer of veterinary medicinal products

3. LEGAL BASIS FOR THE AUDIT

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

4. BACKGROUND

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

Brazil is listed in the Annex to Commission Decision 2011/163/EU with a residue monitoring plan approved in accordance with Directive 96/23/EC for bovines, poultry, *equidae*, aquaculture and honey. At the time of the audit, export of equine meat and aquaculture products to the EU was suspended following the outcome of two Commission audits in 2017 on the public health conditions for the production of fishery products (DG SANTE 2017-6278) and beef, horse and poultry meat (DG SANTE 2017-6261).

4.2. Summary of previous residues audits

Official controls on residues and contaminants and on the distribution and use of veterinary medicinal products were audited in 2008 and 2013. The 2008 report (DG(SANCO)/2008-7770 [1]) concluded that the residue monitoring plan covered all of the relevant substance groups required by Directive 96/23/EC and significant progress had been made in implementing the plan. Room for improvement was identified in relation to the scope of testing by the governmental laboratories, the supervision of implementation of the plan by the central competent authority, and effectiveness of the competent authority inspections on veterinary medicine wholesale and retail outlets.

The most recent audit report (DG(SANCO)/2013-6850 [2]) concluded that the residue monitoring plan was generally designed and implemented in line with Directive 96/23/EC and that the Brazilian authorities could have confidence in the performance of the laboratories and the reliability of analytical results produced by the laboratory network. Shortcomings were identified in relation to follow-up of non-compliant results and the absence of official controls concerning the use of veterinary medicinal products on farms.

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

In 2016 and 2017, there were several notifications made under the Rapid Alert System for Food and Feed (RASFF) for residues of veterinary medicinal products in food of animal origin: one for bovine meat (doramectin, 164 µg/kg), one for poultry meat (diclofenac, 59.8 µg/kg), three for horse meat, (salicylic acid, 340 µg/kg; 2 x naproxen, 19 µg/kg and 49 µg/kg).

4.4. Production, Trade Information and Specific Import Requirements

In 2017, Brazil exported 107,255 tonnes of bovine meat, 367,177 tonnes of poultry meat, 1,234 tonnes of equine meat, 73 tonnes of aquaculture products and 2458 tonnes of honey to the EU.

As of May 2018, around 1,440 cattle farms (located in seven States: ES - Espírito Santo, GO - Goiás, MG - Minas Gerais, MT - Mato Grosso, PR - Paraná, RS - Rio Grande do

[1] http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=2018

[2] http://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=3209

Sul and SP - São Paulo) were on the bovine holding list which allows them to deliver their cattle to the 50 EU-approved slaughterhouses for bovines. Similarly, as of May 2018, 30 poultry slaughterhouses and 30 aquaculture processing establishments were EU-approved. As stated previously, at the time of the audit, no slaughterhouses for *equidae* were EU-approved.

SDA informed the audit team that at the time of the audit, 35 out of 175 by Federal Inspection Service (*Serviço de Inspeção Federal* – SIF) registered honey processing plants were eligible to export honey to the EU.

5. FINDINGS AND CONCLUSIONS

5.1. Residue monitoring

5.1.1. Competent authorities

1. Within SDA, the General Coordination of Intelligence and Strategy (*Coordenação-General de Intelegencia e Estratégia* – CGIE), is responsible for the overall coordination of the residue monitoring programme which includes, *inter alia,* preparation of the annual sampling plans, distribution of collection orders, or reporting of non-compliant results.
2. The General Coordination of Agricultural Laboratories (*Coordenação-General de Laboratórios Agropecuários* – CGAL) within SDA is responsible for designating governmental and private laboratories for analysis of samples under the residue monitoring programme.
3. The Department for Inspection of Products of Animal Origin (*Departamento de Inspeção de Produtos de Origem Animal* – DIPOA) is responsible for supervising and providing guidance for the implementation of the residue monitoring programme to the 11 State Superintendences (SFAs), which represent MAPA in the 27 States of Brazil.
4. Within the SFAs, the Inspection Services for Products of Animal Origin (*Serviço de Inspeção de Produtos de Origem Animal* – SIPOA), via SIF, is responsible for the implementation, including follow-up activities, of the residue monitoring programme in the States with regard to bovines, poultry, equines, aquaculture and honey.
5. Also within the SFAs, the Services for Animal Health (SSAs) in the States Sao Paulo and Minais Gerais, or the Division of Livestock Inputs, Inspection and Animal Health (*Serviço de Fiscalização de Insumos e Serviços Pecuários e Saúde Animal* – SISAs), representing the Department of Animal Health (DSA) as well as the Department of Livestock Input Inspection (*Departamento de Fiscalização de Insumos Pecuários* – DFIP) within SDA, are responsible for taking urine samples of live bovines on farms under the residue monitoring programme. In some States, this sampling is done on behalf of SISA/SSA by officials of the State Veterinary Services.

5.1.2. Planning of residue monitoring

Legal Requirements

Article 29 of Directive 96/23/EC. References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

Findings

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

7. The number of samples to be taken is based on the principles of the Codex Alimentarius Guidance document CAC / GL 71-2009 [4], and 600 samples are planned to achieve a confidence level of 95% to detect at least one non-compliant result in a population with a non-compliance prevalence of 0.5%. In 2017, the number of samples planned for honey (285) and aquaculture (405 for finfish and 280 for crustaceans) was not sufficient to meet this goal. MAPA explained that this reduced number of samples had been decided based on the very low number of non-compliant results detected for these commodities in recent years.

8. For all commodities, the 2017 plan indicated sufficiently sensitive methods to meet the minimum required performance limits applicable in the EU [5] or the levels recommended by the European Union Reference Laboratories (EU RL).

9. In relation to residue monitoring plan for bovines:
   - The plan covered all of the required essential subgroups, similar to what is required in the EU [6], except for the testing of mycotoxins.
   - The plan included testing for stilbenes (A1), trenbolone (A3), zeranol (A4), beta-agonists (A4) in each of 600 urine samples, taken from live bovines on farm.
   - The plan indicated an action level for phenylbutazone of 5 µg/kg, although the limit of detection of the analytical method is 2.5 µg/kg, thus not addressing the fact that phenylbutazone in not authorised for use in food producing animals in the EU [7] and therefore any detection of residues of phenylbutazone in this species should be regarded as non-compliant for the purposes of export to the EU. This point also applies to *equidae*.
   - An action level of 2,000 µg/kg was indicated for eprinomectin (B2a) in bovine liver, which is higher than the maximum residue limit (MRL) of 1500 µg/kg applicable in the EU [8].
   - Although authorised for use in bovines, the plan did not include testing for numerous cephalosporins, (e.g. cephalexin, cephalothin, cephapirin, cefoperazone, cefquinome, ceftiofur). The cephalosporin cefazolin, which was included in the plan, is not included in the Brazilian list of pharmacologically active substances authorised for use in food-producing animals.

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3 Normative Instruction No 42, dated 20.12.1999 for implementation of the residue monitoring, Ordinance No 396, dated 23.11.2009 for follow-up measures in case of non-compliant results and Normative Instruction No 42 of 2008

4 Guidelines for the design and implementation of national regulatory food safety assurance programme associated with the use of veterinary drugs in food producing animals, adopted 2009, revised 2012 and 2014

5 Article 4 and Annex II to Decision 2002/657/EC

6 Annex II to Directive 96/23/EC

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

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

10. In relation to the residue monitoring plan for poultry:
    - The plan did not cover all of the required essential subgroups, as testing for subgroups A3 (steroids) and B2e (non-steroidal anti-inflammatory drugs) was not included, different to the situation in the EU [9].
    - The plan did not include testing for numerous pharmacologically active substances authorised for use in poultry in Brazil:
        - for subgroup B1 substances for which EU MRLs in poultry muscle has been established: amoxicillin (50 µg/kg), ceftiofur (1000 µg/kg), colistin (150 µg/kg), sulphadimidine (100 µg/kg), sulphasoxazole (100 µg/kg), sulphaguanidine (100 µg/kg), thiamphenicol (50 µg/kg), tiamulin (100 µg/kg), tilvalosin (50 µg/kg), tyvalosin (50 µg/kg for skin and fat, or liver), virginiamycin (10 µg/kg);
        - for subgroup B1 substances which are not authorised for use in poultry in the EU: avilamycin, bambermycin, cephalexin, enramycin, fosfomycin, josamycin/leucomycin, norfloxacin, phenoxymethyl-penicillin,
        - for subgroup B2a: fe(n)bendazole (EU MRL is 50 µg/kg), mebendazole, oxibendazole, praziquantel.
    - For some substances included in the plan, the level of action was higher than the respective EU MRL:
        - Chlortetracycline: EU MRL in poultry kidney is 600 µg/kg versus 1200 µg/kg in the plan, while the limit of detection of the analytical methods is 600 µg/kg;
        - For toltrazuril the level of action was 500 µg/kg in poultry muscle, while the limit of detection of the analytical methods is 12.5 µg/kg and the EU MRL is 100 µg/kg; in the Brazilian list of authorised pharmacologically active substances, toltrazuril is not authorised for use in poultry;
        - For clopidol, a coccidiostat no longer authorised in the EU, the level of action was 5,000 µg/kg in poultry muscle, while the limit of detection of the analytical methods is 12.5 µg/kg;
        - The level of action for the coccidiostat diaveridine was 50 µg/kg, which is not authorised in the EU as a feed additive or as a pharmacologically active substance for food-producing animals, while the limit of detection of the analytical methods is 12.5 µg/kg.

11. In relation to the residue monitoring plan for *equidae*:
    - The plan covered most of the required essential subgroups, similar to what is required in the EU [10]. Different to the situation in the EU the plan did not include testing for subgroups A2 (thyrostats), B2b (anticoccidials) and B3d (mycotoxins).

12. In relation to the residue monitoring plan for aquaculture fin fish and crustaceans:
    - Different to the situation in the EU [11], the plan did not cover all of the required essential subgroups, as testing for subgroup A3 (steroids) was not planned for finfish, although methyltestosterone is authorised in Brazil for sex inversion in finfish (tilapia), as would be possible in the EU [12]. In

[9] Annex II to Directive 96/23/EC
[10] Annex II to Directive 96/23/EC
[11] Annex II to Directive 96/23/EC

addition, the plan did not include testing for nitroimidazoles (subgroup A6), anthelmintics (subgroup B2a) in crustaceans, organochlorine compounds (subgroup B3a) in crustaceans and mycotoxins (subgroup B3d).

- The plan provided for an action level of 200 µg/kg for tetracyclines, which is higher than the MRL of 100 µg/kg applicable in the EU [13].

13. In relation to the residue monitoring plan for honey:
    - The plan covered all of the required essential subgroups, similar to what is required in the EU [14].
    - Although the analytical methods were sufficiently sensitive to meet detection limits as recommended by the EURLs and no pharmacologically active substances were authorised for use in honey bees in Brazil, the plan indicated for subgroup B1 substances higher levels of actions than the levels of detection of the analytical method (e.g. sulphonamides or tetracyclines), thus not addressing the fact, that also in the EU subgroup B1 substances are not authorised for use in honeybees [15] and therefore any detection of residues of subgroup B1 substances above the level of quantification of the analytical method would be non-compliant.
    - The plan indicated 300 µg/kg as level of action/decision limit for lead (B3c) thus exceeding the maximum level (ML) of 100 µg/kg in the EU [16].
14. The nationally required annual Normative Instruction [17] to implement the 2018 plan was not yet published at the time of the audit, but had been signed by the State Secretary.

Conclusions on planning of residue monitoring

15. While the planning of residue monitoring follows principles of the Codex Alimentarius and of Directive 96/23/EC and includes sampling of live bovine animals, the reliability of the guarantees offered by the plan is weakened by certain factors including the absence of analyses for various substances authorised for use in poultry and, levels of action not always aligned with those applicable in the EU.

5.1.3. Implementation of the residue monitoring plan

Legal Requirements

Article 29 of Directive 96/23/EC. References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

Findings

16. MAPA had issued instructions on how to implement the residue monitoring plan [18]. This Manual did not contain detailed instruction for selecting the most appropriate type of animal for certain analytes, e.g. no sampling of male bovines for steroids.

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12 Article 5 of Directive 96/22/EC
13 Table 1 of the Annex to Regulation (EU) No 37/2010
14 Annex II to Directive 96/23/EC
15 Table 1 of the Annex to Regulation (EU) No 37/2010
16 Article 1 and Annex to Regulation (EC) No 1881/2006
17 Normative Instruction No 16, dated 8 May 2018
18 Manual for sampling under the residue monitoring plan, dated 2011, updated 2014

17. Various electronic systems (SISRES, SEI, SIGLA) had been established to ensure timely implementation of the plan, reporting of laboratory results and to support CGIE in its supervising function, similar to the situation in the EU [19].

18. Similar to the situation in the EU [20, 21, 22]:

- Sampling was unforeseen and spread over the year;
- Allowed quick traceability to the farm of origin or to the bee-keeper, as sampling reports contained the relevant information;
- Ensured sample integrity and analytical validity as samples have to be transported sealed containers and within a deadline of seven days to the laboratory, to avoid being rejected for analysis. The audit team saw evidence for samples having been rejected due to broken seals or not respected deadlines in the sample rejection reports issued by the laboratory for such samples.

19. With regard to the implementation of the 2017 plan, the audit team noted that:
- Samples under the residue monitoring plan were taken in each of the EU-approved cattle and poultry slaughterhouses.
- Samples which had been rejected by the laboratory had not been rescheduled for sampling. In 2018, CGIE reacted to this issue and scheduled sampling orders for more samples than planned, aiming to ensure that the number of analyses will match the number of planned samples.
- The analysis of about 250 samples out of the 600 urine samples of live bovines, which are tested for anabolic substances (subgroup A3) and beta-agonists (subgroup A5), had to be finalised for the anabolic substances. This delay was caused by breakdown of the analytical instrument in 2017 (see finding 36).

20. With regard to the implementation of the 2018 plan the audit team noted that:
- Sampling had been either initiated or implemented for all commodities and all substances groups, except for sampling of urine in live bovines.
- On 25 May 2018, the state of implementation of the plan was as follows:
  - slaughtered bovines: 1017 samples analysed out of 3640 planned;
  - *equidae*: 54 samples analysed out of 126 planned;
  - poultry: 935 samples analysed out of 3090 planned
  - aquaculture (crustaceans): 40 samples analysed out of 240 planned;
  - aquaculture (finfish): 73 samples analysed out of 405 planned;
  - honey: 16 samples analysed out of 225 planned;

21. At the establishments visited, the audit team noted with regard to sampling under the residue monitoring plan that:

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19 Article 4 of Directive 96/23/EC
20 Point 2.1 of the Annex to Decision 98/179/EC
21 Point 2.7 of the Annex to Decision 98/179/EC
22 Points 2.6 and 2.9 of the Annex to Decision 98/179/EC

- At the cattle slaughterhouse visited, in 2017,
  - all 52 planned samples had been taken, of which 3 samples had been rejected by the laboratory and 1 sample arrived too late at the laboratory;
  - samples were taken from cattle of farms on the EU bovine holdings list as well as from other farms; from the latter ones, farms on the EU bovine holdings list can buy animals;
  - on 5 occasions, 2 samples were taken from the same animal, contrary to the national instruction that one sample should represent one farm or at least one lot of animals from a farm;
  - all sample reports were completely filled in. The sample report template did not require information on the sex or age of the animal nor the ear-tag number of animals from farms on the EU bovine holdings list. Such information could be useful for the interpretation of certain non-compliant results and follow-up activities;
  - the food business operator requested an affidavit from his suppliers to confirm the farmer had not used drugs which are prohibited by importing countries including ractopamine. Similar to the situation in the EU [23], farmers on the EU bovine holding list signed a declaration as requested in Model A of MAPA's food chain information template, stating that the animals had not been treated with prohibited drugs or hormones and when treated with authorised drugs, the withdrawal period had been respected.
- The poultry slaughterhouse visited, was part of an integrated system comprising also a hatchery, 243 poultry farms, a feed mill and veterinarians employed by the company. It:
  - had full information on the treatments applied to the poultry, as the use of veterinary medicinal products and coccidiostats used as feed additives were recorded in an electronic system on a daily basis; this information was also accessible to SIF officials;
  - could have confidence that applicable withdrawal periods had been respected as the company decides on the treatments to be applied as well as on the date of slaughter (see also finding 24);
  - SIF officials had implemented the 2017 residue sampling plan as requested by CGIE and had taken in October also an additional suspect sample based on *post mortem* findings in livers.
- At the honey processing establishment,
  - honey samples were taken from honey of individual bee-keepers;
  - in case a honey sample originated from an intermediary processing establishment, the establishment had records available which listed the individual bee-keepers who had delivered such honey for a specific lot, thus providing full traceability.

[23] Annex II, Section III, point 3(c) to Regulation (EC) No 853/2004 and Article 5 and Annex I, Section I, chapter IIA, point 1 of Regulation (EC) No 854/2004

Conclusions on implementation of residue monitoring

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

5.1.4. Other residue monitoring programmes

Legal Requirements

Article 29 of Directive 96/23/EC. References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

5.1.4.1. Other official residue monitoring programmes

Findings

23. There are no other official residue monitoring programmes.

5.1.4.2. Establishment own-checks

Findings

24. The integrated poultry meat production establishment visited had carried out own studies whether the withdrawal periods applied for the coccidiostats and pharmacologically active substances used in poultry allow to meet the maximum residue limits of the countries (which includes the EU) to which the company exports its products.

25. All 175 honey processing establishments have to have self-control systems in place according to national legislation. The honey processing establishment visited:
    - required an affidavit from each of its suppliers, confirming that antibiotics had not been used. To verify the correctness of these affidavits, the establishment occasionally sent honey samples from their suppliers to an accredited laboratory in the EU for analysis of various residues. The laboratory result reports of these analyses indicated methods which were suitable to detect residues at levels similar to those applicable in the EU [24]. These establishment own-checks were not mentioned in the "hazard analysis and critical control points" (HACCP) of the establishment;
    - carried out own-checks for residues prior to export, depending on the customer request. Official staff verified results under the residue monitoring plan and the outcome of official controls, which included checks on the required HACCP, before certifying an EU veterinary health certificate for honey [25].

Conclusions

26. The own-checks programme of the establishments visited support the guarantees offered under Article 29 of Directive 96/23/EC.

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

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

5.1.5. Follow-up of non-compliant results

Legal Requirements

Article 29 of Directive 96/23/EC. References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

Findings

27. In addition to the 5 RASFF notifications in 2016 and 2017 (see point 4.3. of this report), there had been
    - 35 non-compliant results for slaughtered bovines (23 x anthelmintics, 8 x cadmium, 3 x zeranol and 1 x ractopamine),
    - 13 non-compliant results for poultry (9 x coccidiostats, 3 x antibiotics and 1 x arsenic),
    - 4 non-compliant results for *equidae* (3 x cadmium and 1 x anthelmintics).
28. National legislation [26] on follow-up activities is similar to what would be expected in the EU [27].
29. The audit team evaluated eight follow-up files of non-compliant results in 2017 and noted:
    - For all these cases, the follow-up measures had been timely initiated, undertaken and reported (except for one case), similar to what is expected in the EU [28].
    - The measures comprised the investigation of the root cause for the non-compliance, restriction of animals and products until analytical results of follow-up are available and recall activities if the non-compliant products are still on the market.
    - The measures also included follow-up samples to be taken from the next five lots of animals of the farmer concerned.
    - All information and reports on follow-up activities were filed in an electronic system (SEI) and accessible to the officials of the competent authorities in charge.

Conclusions on follow-up of non-compliant results

30. Follow-up measures in the event of non-compliant results contribute to the prevention of reoccurrence, with prompt investigations, follow-up sampling and – if possible – measures to recall the affected products from the market.

5.1.6. Laboratories

Legal Requirements

Article 29 of Directive 96/23/EC. References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

Findings

[26] Ordinance No 396, dated 23 November 2006, and Decree No 9.013, dated 29 March 2017, for market recall activities

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

[28] Articles 16, 17 and 18 of Directive 96/23/EC

31. The laboratory network comprises a number of private laboratories subcontracted by MAPA/CGAL, and six governmental (LANAGRO) laboratories, the latter being responsible for analysing about 95 % of the samples under the 2018 residue monitoring plan.

32. Similar to what is expected in the EU [29], all these laboratories are ISO 17025 accredited by the national accreditation body, INMETRO which is a member of the International Laboratory Accreditation Cooperation. Those laboratories have most of their validated methods used for analysing samples under the residue monitoring plans within their currently valid scope of accreditation.

33. The audit team visited three governmental and one private laboratory and noted that:
    - Both INMETRO and GCAL have regularly carried out accreditation visits and internal audits and the laboratories had properly address all non-conformities identified during these visits or audits;
    - the laboratories visited were adequately equipped, and staff were adequately trained;
    - the sensitivity of the analytical methods used could meet standards similar to those in the EU [30];
    - the standard operating procedures (SOP) on validation of analytical methods addressed all steps similar to what would be required in the EU [31], except for the stability study;
    - as for data on analyte stability, the laboratories demonstrated the use of literature references related to stability. Nevertheless, there was no correspondence between the literature data shown to the audit team and routine procedures applied by the laboratories in terms of temperature regime and/or storage duration of standard solutions. There were no references available concerning the stability of the substances in the relevant matrices.
    - in the three LANAGRO laboratories, the decision limit (CC-alpha) was not exactly calculated as would be the case in the EU [32] which is likely to only have a minor effect on the CC-alpha calculated;
    - in the three LANAGRO laboratories, sample reception was in line with the SOPs and ensured integrity and suitability for analysis of samples. In the private laboratory, the temperature control of incoming samples had started after the most recent MAPA/CGAL audit;
    - the three LANAGRO laboratories had participated in relevant proficiency tests when available and, in case of an unsatisfactory result, appropriate corrective actions had been undertaken similar to what would be expected in the EU [33].

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

30 Maximum residue performance levels as listed in Annex II to Decision 2002/657/EC, concentrations recommended in the Guidance Document of the EURLs, and MRLs listed in the Annex I to Regulation (EC) No 37/2010

31 Decision 2002/657/EC

32 Decision 2002/657/EC

33 Point 1.2 of the Annex to Decision 98/179/EC

5.1.6.1. LANAGRO São Paulo

34. The laboratory was responsible for analysing:
    - with validated methods already within its scope of accreditation - beta-agonists (A5) and heavy metals (B3c) in different matrices and species, nitrofurans (A6) in equine muscle, chloramphenicol (A6) in honey and organochlorine compounds including PCBs (B3a) in fat of different species;
    - with validated methods soon to be included its scope of accreditation - stilbenes (A1), anabolic steroids (A3) and resorcylic acid lactones (A4) in bovine urine, thyrostats (A2) in bovine urine, nitrofurans (A6) in muscle other than equine muscle and heavy metals (B3c) in other matrices.

35. The audit team evaluated the validation files for most of these methods (see finding no 33, third to sixth bullet points).

36. Due to the termination of the contract with a private laboratory, LANAGRO/SP had to validate a method for anabolic steroids in bovine urine at short notice and to analyse 302 urine samples taken under the 2017 residue monitoring plan. The validation was finalised in October 2017 and some samples were analysed in November 2017. As the equipment then broke down and - despite a maintenance contract in place – the laboratory had to wait a long time for the reserve parts, the testing of the remaining samples only continued in April 2018. At the time of the audit, the analyses of 72 out of the 302 samples had to be finalised (see also finding 33 5th bullet point).

37. Control charts were based on recoveries obtained from testing of fortified samples included in every routine run similar to EU rules and ISO requirements [34]. Adequate quality control assessment criteria for the control charts were established and implemented.

38. Stock solutions of some analytes had been received from another LANAGRO laboratory and LANAGRO/SP had not verified the concentrations of these stock solutions. It was explained that the supplying LANAGRO laboratory (which had prepared these stock solutions) had similar quality assurance procedures and thus no further verification was justified. The validity of another stock solution had been prolonged based on a test performed by the manufacturer on the same lot produced two years ago. However, the storage conditions in LANAGRO/SP might differ from those of the manufacturer and thus the test results by the manufacturer might not be representative for LANAGRO/SP.

5.1.6.2. LANAGRO Rio Grande do Sul

39. The laboratory was responsible for analysing:
    - with validated methods already within its scope of accreditation - chloramphenicol (A6) in bovine muscle and fish, sulphonamides, tetracyclines, macrolides and lincosamides (B1) and avermectins (B2a) in muscle and liver of various species, quinolones in bovine, chicken and fish muscle, sedatives (B2d) and heavy metals (B3c) in organs of various species;

[34] Article 5 of Decision 2002/657/EC and ISO 17025 standard

- with validated methods to be included soon its scope of accreditation - coccidiostats (B2b) in poultry muscle.

40. The audit team assessed the LC-MS/MS methods for:
    a) cocciodiostats in poultry muscle,
    b) sulphonamides and tetracyclines (B1) in bovine and poultry muscle and
    c) avermectins in bovine muscle and bovine and poultry liver.

    In this respect,
    - the CC-alpha calculated during the validation of the method analysing coccidiostats in poultry muscle, and used in the method description differed by 10-times magnitude;
    - the control charts were based on recoveries (or trueness as in certain cases defined by the laboratory) obtained from testing of fortified samples included in every routine run. While an internal procedure how to assess the control charts was established, in six cases for the two multi-residue methods (coccidiostats and avermectins) examined by the audit team, negative performance trends in the control charts had not been identified and consequently no investigation and corrective action had been undertaken. This undermines the confidence in the analytical results for the methods concerned.

41. The laboratory had successfully participated in external proficiency tests.

5.1.6.3. LANAGRO Minas Gerais

42. The laboratory was responsible:
    - for analysing with validated methods already within its scope of accreditation - stilbenes (A1), anabolic steroids (A3) and resorcylic acid lactones (A4) in bovine, and equine urine, ractopamine (A5) in bovine muscle, chloramphenicol (A6) in muscle of various species, macrolides, lincosamides and other antibacterial substances (B1) in organs of various species, avermectins (B2a) in liver of various species, dioxins and PCBs (B3a) and heavy metals (B3c) in organs of various species;
    - for handling samples to be tested for dioxins and PCBs, which were forwarded to a private laboratory in an EU Member State. It regularly carried out on the spot visits and documentary checks to monitor the quality assurance of the contracted laboratory. A service agreement establishing satisfactory quality provisions and a 15 working days as turnaround time for the analysis of samples had been established.

43. The procedure for the selectivity study in the SOP on validation of analytical methods (performed on fortified samples without including also blank samples) differed from what would be applied in the EU [35].

44. The audit team assessed the LC-MS/MS methods for:
    a) stilbenes in bovine and equine urine,
    b) macrolides, lincosamides and ampicillin (B1) in organs of various species and
    c) ractopamine in bovine urine.

    In this respect,

[35] Decision 2002/657/EC

- selectivity studies were not carried out for new matrices which had been added to the current methods. This weakens the confidence in the analytical results obtained for those matrices not examined for selectivity;
- during the decision making, the CC-alpha was substituted by LOD/LOQ, resulting that in one case a result although above the CC-alpha had not been considered and reported as non-compliant and consequently, MAPA did not initiate follow-up investigations;
- with the exception of the method for macrolides and lincosamides for which no control charts were established, control charts for the other methods examined by the audit team were based on recoveries (or trueness as defined by the laboratory) obtained from testing of fortified samples. There was an internal procedure to assess the control charts,

5.1.6.4. Private Laboratory

45. In 2018, the laboratory was subcontracted to analyse samples:
    - with validated methods already within its scope of accreditation for - nitrofurans (A6) in bovine muscle and honey, chloramphenicol (A6) in honey and organochloride pesticides (B3a) in finfish.
46. The audit team assessed the method for nitrofurans in bovine muscle and chloramphenicol and noted that the control charts were based on recoveries obtained from testing of fortified samples included in every routine run. Adequate quality control assessment criteria for the control charts were established and implemented.
47. Some stock solutions for metabolites of nitrofurans had minor discrepancies in labelling on the vials versus what was registered in the corresponding quality control documentation.
48. The laboratory could not participate in any relevant proficiency test as it did not manage to get the ordered test material through the border controls due to presence of prohibited substances. MAPA/CGAL confirmed the ongoing difficulty to get the proficiency test material from outside Brazil.

Conclusions on laboratories

49. While the analysis of samples under the residue monitoring plan with validated methods in ISO 17025 accredited laboratories supports the guarantees offered under Article 29 of Directive 96/23/EC, the lack of data on analyte stability in the method validation phase and instances where control charts to monitor method performance where either not in place or where not acted upon, weaken the reliability of the analytical results obtained.

5.2. Veterinary medicinal products

5.2.1. Competent authorities

50. The DFIP within SDA under MAPA is responsible for issuing marketing authorisations for veterinary medicinal products.

51. The SISAs, or the Inspection Services of Livestock Inputs (*Serviço de Fiscalização de Insumos Pecuários* – SEFIPs) in the States São Paulo and Minais Gerais, are responsible for controls on manufacture, import, distribution and use of veterinary medicinal products.

5.2.2. Authorisation, distribution and use

Legal Requirements

Article 29 of Directive 96/23/EC. References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

Findings

52. Similar to what applies in the EU [36], the national legislation [37] describes the legal provisions and procedures for the authorisation and distribution of veterinary medicinal products.

53. Similar to the situation in the EU [38], national legislation provides for the prohibition of various pharmacologically active substances for:

    a) use in food producing animals: chloramphenicol and nitrofurans [39]; anabolic substances for cattle [40];

    b) use in feed for the purpose of growth promotion: avoparcin [41]; arsenic and antimony [42]; olaquindox [43]; carbadox [44]; crystal violet [45]; amphenicols, tetracyclines, beta-lactams, quinolones and sulphonamides [46]; spiramycin and erythromycin [47]; colistin [48]; hormones for poultry [49].

54. Different to the situation in the EU [50], the DFIP internal list of authorised pharmacologically active substances contains some substances which are not allowed for use in food-producing animals in the EU: e.g. 3-nitro-4-hydroxyphenyarsonic acid (roxarsone) for poultry, boldenone for horses (though the product seen at the retailer was limited to use in *equidae* not intended for human consumption), bovine somatropin for milking cows (not authorised in the EU for animal welfare reasons), oestradiol cypionate and valerate for bovines, phenylbutazone for bovines, equines and pigs, ractopamine for pigs.

55. The affidavits, nationally required at the time of the audit, did not allow the competent authorities to identify whether oestradiol 17-beta had ever been used in cattle meat from which is exported to the EU.

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36 Articles 30-40 of Regulation (EC) No 726/2004
37 Law 467, dated 13 February 1969 and the Decree No 5.053, dated 22 April 2004, amended in 2015 and 2016
38 Article 11 of Council Directive 96/22/EC and Table 2 of the Annex to Regulation (EU) No 37/2010
39 Normative Instruction No 9, dated 27 June 2003
40 Normative Instruction No 55, dated 1 December 2011
41 Official Circular No 47 of 1998
42 Ordinance No 31, dated 29 January 2002
43 Normative Instruction No 11, dated 24 November 2004
44 Normative Instruction No 35, dated 14 November 2005
45 Normative Instruction No 34, dated 13 September 2007
46 Normative Instruction No 26, dated 9 September 2007
47 Normative Instruction No 14, dated 17 May 2012
48 Normative Instruction No 45, dated 22 November 2016
49 Normative Instruction No 17, dated 18 June 2004
50 Article 11 of Council Directive 96/22/EC and Table 2 of the Annex to Regulation (EU) No 37/2010

56. At the time of the audit, the Brazilian list of authorised pharmacologically active substances did not contain any substances which were allowed for use in honey bees.

57. Methyltestosterone for sex inversion in tilapia was included in the list of authorised veterinary medicinal products in Brazil, as – under certain conditions – it would be possible in the EU [51].

58. Similar to the situation in the EU [52], [53], national legislation provides for:
    - the off-label use of veterinary medicinal products, albeit without any default minimum withdrawal periods to be respected;
    - specific requirements for labelling of veterinary medicinal products [54], which include, *inter alia*, the withdrawal period to be respected, even if zero days;
    - wholesalers and retailers to be licensed (annually by MAPA before they can distribute or sell veterinary medicinal products);
    - personnel [55], facilities and for products under veterinary prescription, record keeping requirements for wholesalers and retailers.

59. Different to the situation in the EU [56], farmers and bee-keepers do not need a veterinary prescription to purchase most of the veterinary medicinal products intended for use in food-producing animals. National legislation [57] requires a veterinary prescription e.g. for anaesthetics or psychotropic substances, or certain hormones and anabolic substances to be kept for two years.

60. Different to what would be required in the EU [58], farmers and bee-keepers do not need to record treatments. New national legislation [59], not yet fully in force, has been drafted, which will require farmers to keep records for the use of medicated feed.

61. With regard to the production and use of medicated feed, similar to the situation in the EU [60], national legislation provides for:
    - registration of feed mills before producing medicated feed;
    - a veterinary prescription for selling the medicated feed to a farmer;
    - cleaning and/or sequencing measures in place to prevent cross-contamination between medicated and non-medicated feed;
    - labelling requirements for medicated feed which includes the active ingredient, animal species, dosage, withdrawal period to be respected and other precaution measures.

Conclusions on authorisation, distribution and use of **veterinary medicinal**

51 Article 5 of Directive 96/22/EC
52 Article 11 of Directive 2001/82/EC
53 Article 58, 65 and 66 of Directive 2001/82/EC and Article 10 of Directive 96/23/EC
54 Article 39 of Decree 5053
55 Article 18 of Decree 5053
56 Article 67(aa) of Directive 2001/82/EC and Directive 2006/130/EC
57 Annex I to Normative Instruction No 35 of 2017
58 Article 10 of Directive 96/23/EC and Annex I, Part A III, point 8(b) to Regulation (EC) No 852/2004
59 Article 22 of Annex 1 to Normative Instruction No 14, dated 15 July 2016, which amends Normative Instruction No 65, dated 21 November 2006
60 Directive 90/167/EEC

products

62. The legal framework governing the authorisation of veterinary medicinal products generally supports the adherence to the guarantees required by Article 29 of Directive 96/23/EC. Nevertheless, animals can still be treated, for therapeutic or zootechnical purposes, with medicinal products containing oestradiol 17-beta and the absence of measures ensuring that these animals are excluded from export to the EU mean that the competent authorities are not in a position to reliably certify that the guarantees required by the relevant export certificates are complied with.

63. The current prescription and treatment record keeping system does not add assurances that the veterinary medicinal products are used appropriately.

5.2.3. Official controls

Legal Requirements

Article 29 of Directive 96/23/EC. References to the Union legislation applicable in the EU Member States are provided as footnotes for informative purposes.

Findings

64. In Rio Grande do Sul, the State in which the wholesaler and the retailer visited were located, the official of SEFIP planned to control manufacturers, once every year. In the last years, this frequency had not been achieved, due to other tasks.

65. Official controls on the use of veterinary medicinal products on farms or at bee keepers are carried in the event of identified non-compliances, e.g. in case of follow-up investigations of non-compliant results found under the residue monitoring programme.

66. The officials used templates for their official controls and to record the outcome.

67. The last official control of the wholesaler visited was in 2014, and had identified some shortcomings with regard to the temperature control of the storage of products, separation of expired products and products in stock which could not be sold at the time of the control. These shortcomings had been addressed and followed up by the competent authority. The audit team verified the correctness of the purchase, sales, and stock records for two products selected at random.

68. The range of products sold at the wholesaler and the retailer visited, were limited and most of the pharmacologically substances used in the products were included in the residue monitoring programme.

69. At the cattle farm visited, treatment records were kept, but did not include the withdrawal period to be respected for the various veterinary products being used.

Conclusions on official controls

70. Notwithstanding the limitations with regard to the frequency, the official control system in place to ensure compliance with the legal requirements for the distribution of veterinary medicinal products is implemented and largely effective.

5.3. Follow-up of relevant recommendations made in report DG(SANCO) 2008-7770 and DG(SANCO) 2013-6850

71. The table below summarises the follow-up to the relevant recommendations made in report DG(SANCO) 2008-7770:

3	Address the identified shortcomings in the supervision of implementation of the national residue control plan in order to ensure that the residues control system can offer guarantees on the residue status of exported food commodities which are at least equivalent to the standards set out in Community legislation (Article 29 of Council Directive 96/23/EC).	Addressed. *See finding 17 of the current report.*
4	Consider mechanisms to speed up the execution of follow-up investigations and improve communication between each of the parties involved (competent authorities and, where applicable, third party certification bodies) in this process to give an effect at least equivalent to that required by Article 4 (3) of Regulation (EC) No 882/2004 and ensure the effective application of measures equivalent to those described in Article 16 of Council Directive 96/23/EC.	Addressed. *See finding 29 and conclusion 30 of the current report.*
5	Continue with the process put in place to ensure that all analytical methods used in the national residue control plan are demonstrably 'fit for purpose' (i.e. appropriately validated) in order to provide reliable data on the residues status of commodities tested and guarantee that analytical testing meets standards which are at least equivalent to those required by Council Directive 96/23/EC and Commission Decision 2002/657/EC.	Addressed. *See finding 32 and conclusion 49 of the current report.*
6	Continue with the process put in place to ensure that appropriate quality control and quality assurance measures (including *inter alia* proficiency tests) are implemented across the entire laboratory network in order to increase confidence in the reliability of analytical results generated and provide guarantees with an effect equivalent to those described in Articles 3 and 5 of Commission Decision 2002/657/EC.	Not fully addressed, see also no 9. *See findings 40, 44 and 48, conclusion 49 and recommendation no 2 of the current report.*
7	Continue with the process put in place to ensure that the governmental laboratories involved in provision of analytical services for official residues controls are	Addressed. *See finding 32 and conclusion 49 of the*

	accredited to ISO 17025 in order to provide guarantees equivalent to those described in point 1.2. of the Annex to Commission Decision 98/179/EC and Article 12(2) of Regulation (EC) No 882/2004.	*current report.*
8	Ensure that in respect of the LANAGRO laboratories, the laboratory resources available (staff, equipment and expertise) are commensurate with the work load required in order to give guarantees equivalent to those provided for by Article 4(2)c of Regulation (EC) No 882/2004.	Addressed. *See finding 33 and conclusion 49 of the current report.*
9	Seek a resolution to problems with the importation of analytical standards and proficiency testing material in order to allow the laboratory network to perform to a standard equivalent to that laid down in point 1.2 of the Annex to Commission Decision 98/179/EC.	Not fully addressed. *See finding 48, conclusion 49 and recommendation no 2 of the current report.*

72. The table below summarises the follow-up to the relevant recommendations made in report DG(SANCO) 2013-6850:

1	Ensure that the follow-up of non-compliant results has an effect equivalent to those provided for by (Articles 13, 16-18, 23, 24, 27 and 28) of Council Directive 96/23/EC.	Addressed. *See finding 28 and 29, and conclusion 30 of the current report.*
2	Ensure that farmers are not made aware of non-conformities before the official follow-up investigations are carried out as required by Article 12 of Council Directive 96/23/EC.	Addressed. *See finding 29 and conclusion 30 of the current report.*
4	Ensure that medicines records are kept for all animal species from which products are exported to the EU, with an equivalent effect to the requirements laid down in Article 10 of Council Directive 96/23/EC.	Not fully addressed. *See finding 60 and conclusion 63.*
5	Ensure that controls on the distribution and use of veterinary medicinal products are carried out throughout the distribution chain – including farms - in order to support guarantees offered by the residue monitoring plan thus providing guarantees at least equivalent to those foreseen in Council Directive 96/23/EC.	Addressed. *See findings 64-67 conclusion 70 of the current report.*

6. OVERALL CONCLUSION

While the planning of residue monitoring follows principles of the Codex Alimentarius and Directive 96/23/EC, the reliability of the guarantees offered by the residue monitoring plan are partly weakened by the number of samples for aquaculture and honey not meeting the Codex approach, not testing for a number of substances nationally authorised for use in food producing animals and levels of action not always aligned with those applicable in the EU. The residue monitoring plan is implemented largely in line with planned arrangements and promptly carried out follow-up measures in case of non-compliant results contribute to the prevention of reoccurrence.

Samples under the residue monitoring programmes are tested with validated methods in ISO 17025 accredited governmental and private laboratories. Areas for improvement were identified in relation to inclusion of stability data in method validation, the correct use of CC-alpha, and the consistent application of control charts to monitor method performance.

Various national legal requirements governing the authorisation and use of veterinary medicinal products can support the adherence to the guarantees required by Article 29 of Directive 96/23/EC. However, there are some substances authorised in cattle which cannot be used in food-producing animals in the EU and which preclude certification requirements being met at present. The current veterinary medicine prescription system and limited requirements for maintenance of medicinal treatment records do not add much in the way of additional guarantees that veterinary medicinal products are used in line with label indications.

7. CLOSING MEETING

A closing meeting was held on 8 June 2018 with representatives of MAPA. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities offered some clarifications and provided supporting documentation as requested by the audit team.

8. RECOMMENDATIONS

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

No	Recommendation
1	To ensure that the commodities eligible for export do not contain residues of pharmacologically active substances in excess of EU MRLs where the corresponding national limits are greater, or where there is no established MRL in the EU, that residues are not present, thus allowing the guarantees provided under Article 29 of Directive 96/23/EC to remain effective. *Recommendation based on conclusion: 15.* *Associated findings: 9 (3rd and 4th bullet points), 10 (3rd bullet point), 11 and*

	12 (2nd bullet points) and 13 (2nd and 3rd bullet points).
2	To ensure that the designated laboratories fully implement quality assurance provisions (e.g. in relation to proper management of analytical standard stock solutions, creating, maintaining and analysing control charts) so that the guarantees provided under Article 29 of Directive 96/23/EC remain effective. *Recommendation based on conclusion 49.* *Associated findings 40 (2nd bullet point), 44 (3rd bullet point) and 48.*
3	To ensure that food derived from animals which have been treated with oestradiol 17-beta for therapeutic or zootechnical purposes is not exported to the EU, so that the certification requirements pertaining to Article 11 of Directive 96/22/EC are fulfilled. *Recommendation based on conclusion 62.* *Associated findings 54 and 55.*

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=2018-6349

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
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. 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
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
Dec. 97/747/EC	OJ L 303, 6.11.1997, p. 12-15	97/747/EC: Commission Decision of 27 October 1997 fixing the levels and frequencies of sampling provided for by Council Directive 96/23/EC for the monitoring of certain substances and residues thereof in certain animal products
Dec. 98/179/EC	OJ L 65, 5.3.1998, p. 31-34	98/179/EC: Commission Decision of 23 February 1998 laying down detailed rules on official sampling for the monitoring of certain substances and residues thereof in live animals and animal products
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. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin

Reg. 854/2004	OJ L 139, 30.4.2004, p. 206, Corrected and re-published in OJ L 226, 25.6.2004, p. 83	Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Reg. 726/2004	OJ L 136, 30.4.2004, p. 1-33	Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency
Reg. 882/2004	OJ L 165, 30.4.2004, p. 1, Corrected and re-published in OJ L 191, 28.5.2004, p. 1	Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Dir. 2006/130/EC	OJ L 349, 12.12.2006, p. 15-16	Commission Directive 2006/130/EC of 11 December 2006 implementing Directive 2001/82/EC of the European Parliament and of the Council as regards the establishment of criteria for exempting certain veterinary medicinal products for food-producing animals from the requirement of a veterinary prescription
Reg. 1881/2006	OJ L 364, 20.12.2006, p. 5-24	Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs
Reg. 470/2009	OJ L 152, 16.6.2009, p. 11-22	Regulation (EC) No 470/2009 of the European Parliament and of the Council of 6 May 2009 laying down Community procedures for the establishment of residue limits of pharmacologically active substances in foodstuffs of animal origin, repealing Council Regulation (EEC) No 2377/90 and amending Directive 2001/82/EC of the European Parliament and of the Council and Regulation (EC) No 726/2004 of the European Parliament and of the Council

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