EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and Food Audits and Analysis

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FINAL REPORT OF AN AUDIT

OF BRAZIL

CARRIED OUT FROM 27 MAY TO 14 JUNE 2024

TO EVALUATE CONTROLS ON

RESIDUES OF PHARMACOLOGICALLY ACTIVE SUBSTANCES,

PESTICIDES AND CONTAMINANTS

IN ANIMALS AND ANIMAL PRODUCTS

Executive Summary

This report describes the outcome of an audit of Brazil, carried out from 27 May to 14 June 2024 as part of the European Commission's Directorate-General for Health and Food Safety's planned work programme.

The objective of the audit was to evaluate the implementation of official controls on residues of pharmacologically active substances, pesticides and contaminants in animals and animal products, in accordance with the residue control plans for those species/commodities for which Brazil is listed in Annex -I to Commission Implementing Regulation (EU) 2021/405, the reliability of the guarantees offered by Brazil in ensuring that the commodities concerned when exported to the EU do not contain residues of pharmacologically active substances, pesticides and contaminants exceeding EU Maximum Residue Levels/Limits or Maximum Levels and whether Brazil continues to meet the requirements for listing as specified in Article 6(3) of Commission Delegated Regulation (EU) 2022/2292.

It is concluded that the implementation of the control plans for residues of pharmacologically active substances, pesticides and contaminants and the follow-up of non-compliant results are largely consistent with the principles laid down in EU legislation, underpinning the reliability of the guarantees offered by Brazil in ensuring that food of animal origin exported to the EU complies with EU requirements. Notwithstanding some shortcomings in the validation of analytical methods, and the room for improvement in the operation of the laboratories' internal quality control systems, the competent authority can have confidence in the reliability of the analytical results provided by the laboratory network.

Whilst national legislation on the authorisation of veterinary medicinal products and the prohibition of the use of hormones and beta-agonists for growth promotion purposes in bovine animals is broadly similar to EU legislation, the current arrangements in place to guarantee that cattle, meat from which is destined for the EU market, have never been treated with oestradiol 17β for zootechnical or therapeutic purposes, are ineffective. Consequently, the competent authority cannot guarantee the reliability of operators' sworn statements on non-use of oestradiol 17β in cattle and the Ministry of Agriculture, Livestock and Supply (MAPA) is not in a position to reliably attest to operator compliance with the corresponding section in the model EU health certificate for bovine meat exports to the EU, questioning the country's continued listing for bovine animals in Annex -I to Implementing Regulation (EU) 2021/405.

The report contains two recommendations addressed to the Brazilian authorities.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
CGAL	*Coordenação-Geral de Laboratórios Agropecuários* (General Coordination of Agricultural Laboratories)
CPV	*Coordenação de Fiscalização e Registro de Produtos de Uso Veterinário* (Coordination for the Oversight and Registration of Veterinary Products)
DICRC	*Divisão de Controle de Resíduos e Contaminantes (*Division of Residues and Contaminants Controls)
DIPOA	*Departamento de Inspeção de Produtos de Origem Animal* (Department for Inspection of Products of Animal Origin)
DSA	*Departamento de Saúde Animal e Insumos Pecuários (*Department of Animal Health and Livestock input)
ERAS	*Estabelecimentos Rurais Aprovados no SISBOV* (Livestock holdings approved in SISBOV)
EU	European Union
Group A, B	Categories of substances listed in Annex I to Regulation (EU) 2022/1644
ISO/IEC	International Organisation for Standardisation/International Electrotechnical Commission
LOQ	Limit of quantification
MAPA	*Ministério da Agricultura, Pecuária e Abastecimento* (Ministry of Agriculture, Livestock and Supply)
ML	Maximum Level
MRL	Maximum Residue Limit
NRCP	National Residue Control Plan
RASFF	Rapid Alert System for Food and Feed
RPA	Reference point for action
SDA	*Secretaria de Defesa Agropecuária* (Secretariat of Animal and Plant Inspection of MAPA)
SEI	*Sistema Eletrónico de Informações* (Electronic Information System)
SFA	*Superintendência Federal de Agricultura* (State Superintendence of Agriculture)
SIF	*Serviço de Inspeção Federal* (Federal Inspection Service)
SIPOA	*Serviço de Inspeção de Produtos de Origem Animal* (Inspection Service for Products of Animal Origin)
SISA	*Serviços de Fiscalização de Insumos e Saúde Animal* (Inspection Service for Animal inputs and Health)
SISBOV	*Sistema de identificação e certificação de bovinos e bubalinos* (Brazilian System of Identification and Certification of Origin for Cattle and Buffalo)
SISRES	*Sistema de Informações Gerências de Resíduos* (Electronic database for recording sampling under the residue monitoring plan)

1 INTRODUCTION

The audit took place from 27 May to 14 June 2024 as part of the European Commission's Directorate-General for Health and Food Safety 2024 work programme. The audit team comprised two auditors from the Commission. The audit was conducted in a hybrid format consisting of a remote (videoconference) meeting with the competent authorities and on-the-spot visits from 3 to 14 June to selected sites in the country. For the in-country component of the audit, the audit team was accompanied by one representative from the central competent authority, *Ministério da Agricultura, Pecuária e Abastecimento* – MAPA. The table below lists the meetings and visits held.

MEETING/VISIT		n	COMMENTS
COMPETENT AUTHORITIES	Central	2	Remote opening meeting with the representatives of MAPA and testing laboratories, relevant for the scope of the audit. Remote closing meeting with the representatives of the MAPA and testing laboratories, relevant for the scope of the audit.
LABORATORIES		3	Laboratories in three different states
FOOD ESTABLISHMENTS		1	Bovine slaughterhouse
REGIONAL AND LOCAL		3	Meetings with the competent authorities in three different states

2 OBJECTIVES AND SCOPE

The objective of the audit was to evaluate:

- the implementation of official controls on residues of pharmacologically active substances, pesticides and contaminants in animals and animal products, in accordance with the National Residue Control Plans (NRCPs) for bovine animals, poultry and honey for which Brazil is listed with an 'X' in Annex -I to Commission Implementing Regulation (EU) 2021/405;
- the reliability of the guarantees offered by Brazil in ensuring that commodities concerned when exported to the EU do not contain residues of pharmacologically active substances, pesticides and contaminants exceeding EU Maximum Residue Levels/Limits (MRLs) or Maximum Levels (MLs) ([1]); and
- whether Brazil continues to meet the requirements for listing as specified in Article 6(3) of Commission Delegated Regulation (EU) 2022/2292.

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation and in particular, Articles 120 and 122 of Regulation (EU) 2017/625 of the European Parliament and of the Council. A list of relevant European Union legislation is set out in Annex I to this report and

([1]) Commission Regulation (EU) No 37/2010, Regulation (EC) No 396/2005 of the European Parliament and of the Council, Commission Regulation (EU) 2023/915.

detailed provisions of those acts, pertinent to the chapters in the report are cited in Annex II. Legal acts quoted in this report refer, where applicable, to the last amended version.

4 BACKGROUND

Article 126(2)(a) of Regulation (EU) 2017/625 specifies that animals and goods shall only enter the Union from listed third countries. The conditions for listing are laid down in Article 127(3) of said Regulation and, regarding controls on residues of pharmacologically active substances, pesticides and contaminants in animals and food of animal origin, these conditions are supplemented by Delegated Regulation (EU) 2022/2292.

Third countries' control plans for residues of pharmacologically active substances, pesticides and contaminants must provide guarantees of compliance with the conditions laid down in Article 6(1) of Delegated Regulation (EU) 2022/2292 and Articles 9 to 12 thereof. Countries which meet these requirements are listed in Annex -I to Implementing Regulation (EU) 2021/405 for the species/commodities in question.

4.1 Country status in relation to EU-approval of control plans for residues of pharmacologically active substances, pesticides and contaminants

Brazil is listed with an 'X' in Annex -I to Implementing Regulation (EU) 2021/405 with approved control plans for residues of pharmacologically active substances, pesticides, and contaminants in the following species/commodities: bovine, equine, poultry, aquaculture, honey and casings. The country is also listed with an 'O' for milk and eggs, signifying that it may use processed dairy products and processed egg products sourced from another listed third country or an EU Member State for the manufacture of composite products.

4.2 Outcome of previous Commission audits

The Commission services last audited the implementation of official controls on residues of pharmacologically active substances, pesticides and contaminants in animals and food of animal origin in Brazil in 2018. The report of that audit (ref. DG (SANTE) 2018-6349 MR-Final) ([2]) concluded that the overall control system of residue controls was largely in line with EU requirements, with scope for improvement concerning compliance with EU MRLs, quality controls at laboratories and in the segregated production system in place to ensure that that food derived from animals which have been treated with oestradiol 17β for therapeutic or zootechnical purposes is not exported to the EU. Recommendations on these issues were made in the report. All were addressed satisfactorily based on commitments given by MAPA.

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

Since 2020, there have been four RASFF notifications for residues of pharmacologically active substances (chloramphenicol, doramectin and oxytetracycline) and a pesticide

([2]) Available at: Food Audits and Analysis | Food Safety (europa.eu).

(chlorate) in food of animal origin (two in beef and two in poultry) originating from Brazil (see finding 16).

4.4 Production, trade information and specific import requirements

According to MAPA, in 2023, Brazil exported approximately 41,000 tonnes of bovine meat, 59,000 tonnes of poultry meat and 2,800 tonnes of honey to the EU.

As of December 2023, around 1,220 bovine animal farms (located in nine States) were on the bovine holding list which allows them to deliver cattle to 53 EU-approved slaughterhouses. There are 26 poultry slaughterhouses and 346 local Federal Inspection Service (*Serviço de Inspeção Federal* – SIF) registered honey processing plants.

5 FINDINGS AND CONCLUSIONS

5.1 Implementation of the control plan for residues of pharmacologically active substances, pesticides and contaminants

1. Within the Secretariat of Animal and Plant Inspection (*Secretaria de Defesa Agropecuária* – SDA), under MAPA there are three departments involved in the implementation and supervision of the NRCP:

   1.1 The Department for Inspection of Products of Animal Origin (*Departamento de Inspeção de Produtos de Origem Animal* – DIPOA) with its:

   - Service of General Coordination of Special Programmes (*Coordenação Geral de Programas Especiais)* which is responsible for the overall coordination of the NRCP. This includes, *inter alia*, the preparation of the annual sampling plans, the creation of guidelines on how to collect samples, the distribution of sample collection orders to the regional and local SIFs, the reporting of non-compliant results and the consolidation, publication and evaluation of the NRCP results.
   - Risk Characterisation Coordination unit (*Coordenação Geral de Caracterização de Risco)* belonging to the Service of General Coordination of Special Programmes, which, *inter alia*, monitors the NRCP implementation. The Division of Residues and Contaminants Controls *(Divisão de Controle de Resíduos e Contaminantes* – DICRC) under the Risk Characterisation Coordination unit is responsible for reporting the results of any NRCP non-compliances immediately to the SDA, to the 11 Inspection Services for Products of Animal Origin (*Coordenação de Inspeção de Produtos de Origem Animal* – SIPOA*)*, and to the Department of Animal Health and Livestock input (*Departamento de Saúde Animal e Insumos Pecuários* - DSA) to enable them to conduct the required follow-up investigations.

- State Superintendencies of Agriculture (*Superintendência Federal de Agricultura* – SFAs), represent MAPA in the 26 States of Brazil. There are 11 SFAs and it is their SIPOAs which:

  a) coordinate and monitor the activities of the SIFs at the local level which take NRCP samples in slaughterhouses and establishments processing milk, eggs, honey and fish - if these are under federal oversight. The SIFs also conduct follow-up investigations with regards to NRCP non-compliances at these establishments.

  b) conduct follow-up investigations of NRCP non-compliances connected to feed at farms and feed-mills, as DIPOA is also responsible for rules and controls along the feed-chain in Brazil. They also conduct follow-up investigations of NRCP non-compliances of pesticides and contaminants.

1.2 The DSA through its state representations the Livestock Supplies and Animal Health Service (*Serviços de Fiscalização de Insumos e Saúde Animal* - SISAs) conduct follow-up investigations on farms where NRCP non-compliances related to the use of veterinary medicinal products have been detected. The DSA also collects urine samples from live cattle. In some states, bovine urine samples are taken by the Implementing Bodies for Agricultural Animal Health (*Órgãos Executores de Sanidade Agropecuária*). The Division for the Inspection and Oversight of Veterinary Products (*Divisão de Inspeção e Fiscalização de Produtos de Uso Veterinário*) belonging to the DSA also evaluates SISA´s technical investigation reports and forwards them to DIPOA. The DSA and its Coordination for the Oversight and Registration of Veterinary Products (*Coordenação de Fiscalização e Registro de Produtos de Uso Veterinário* — CPV), is also responsible for overseeing and registering establishments and veterinary products.

1.3 The Department for Technical Services (*Departamento de Serviços Técnico*s) and its General Coordination of Agricultural Laboratories (*Coordenação-Geral de Laboratórios Agropecuários* – CGAL) is responsible for the designation of governmental and private laboratories for analysis of samples under the NRCP, controlling the laboratories' accreditation status and analytical method validations and managing the allocation of samples to the laboratories.

2. Clear instructions for the implementation of the plan and for NRCP sampling are available to staff tasked with taking NRCP samples ([3]).

3. Provisions are in place that require that government employees when exercising their official control tasks, such as the implementation of the NRCP, conducting laboratory analysis or follow-up investigations, must be free from any conflict of interest ([4]).

4. All sampling for residues is performed without prior notice being given to the operator apart from taking urine samples on farm (by SISA) where such notice is given to ensure

([3]) National instructions: Manual instructivo do PNCRC (2019), Manual de coleta de amostras do PNCRC (2010).

([4]) National legislation: Ordinance (Portaria) No. 249, dated February 22, 2018 – MAPA.

that the required support staff and animals are available. Sampling is carried out at slaughterhouses and establishments processing honey by SIF officials.

5. Sample instructions for honey allow the pooling of honey from several producers in one sample. The same approach is permitted for bovine urine samples where the sample comprises urine from several animals. This is different to what is required in EU legislation ([5]). The competent authority amended the sampling instructions during the audit to rectify this shortcoming for honey and informed the audit team that they intend to amend those for urine as well.

6. Samples are taken in such way that it is always possible to trace them back to the farm of origin and the batch of animals or the individual animal, where relevant.

7. The validity and integrity of samples is ensured as each sample is identified and packed in an appropriate tamper-proof bag accompanied by a standardised sample report. Samples are to be transported frozen or refrigerated to ensure the stability of the analytes (see finding 26).

8. Weekly sampling plans, accompanied by sampling forms, are distributed from DIPOA via the electronic database for recording sampling under the residue plan - *Sistema de Informações Gerências de Resíduos* - SISRES. Through SISRES all sampling orders, sample records and sample results are managed and implementation is supervised. Sample orders for bovine animals and poultry need to be implemented by the respective SIF in 7 days; for honey it is three months.

9. The audit team found that in 2022 (apart from a negligible sampling shortfall of 1%, stated by MAPA to be caused by the diversion of resources to deal with avian influenza) and in 2023 (January to October), the NRCPs for bovine animals, poultry and honey were implemented as planned throughout the year.

Conclusions on implementation of control plans for residues of pharmacologically active substances, pesticides and contaminants

10. The residue control plans for bovine animals, poultry and honey are implemented in accordance with planned arrangements by competent staff in a timely manner, supporting guarantees offered by Brazil on the residue status of these commodities eligible for export to the EU.

5.2 Follow-up of non-compliant results and enforcement

11. DIPOA through its DICRC and the Division of Violations and Notifications (*Divisão de violações e notificações)* is responsible for initiating and coordinating follow-up actions of NRCP non-compliances for pharmacologically active substances at: (a) food business operator/establishment level (*e.g.*, slaughterhouses) in cooperation with its

([5]) Point 5 of Chapter C of Part II of Annex I to Delegated Regulation (EU) 2022/2292 and points 3 and 8 of Annex III to Commission Delegated Regulation (EU) 2022/1644.

representations at state level (SIPOA) and establishment level (SIFs) and (b) at farm level with cooperation from the DSA´s CPV/ Division for the Inspection and Oversight of Veterinary Products which coordinates and supports the investigations by the states' SISAs at farms. SISAs, if required, ask the states` Implementing Bodies for Agricultural Animal Health to impose animal movement bans on farms. SIPOA also is responsible for non-compliances related to feed and medicated feed, as well as for contaminants and pesticides. The Division of Violations and Notifications is responsible for coordinating any actions related to RASFF.

12. There are national procedures ([6]) on measures/actions to be taken in the event of non-compliant results. Such results are sent directly from the relevant laboratories via SISRES to DIPOA´s DICRC which opens a file in MAPA´s electronic information system (*Sistema Eletrónico de Informações - SEI*). Through SEI, all non-compliance-related communication to and from the involved competent authorities is recorded and supervised.

13. The audit team evaluated the follow-up investigations carried out for 14 recently identified non-compliant results. Ten of these were for bovine animals: two for Group A1b, one for Group A1c, two for Group A1d, one for Group A3d, one for Group B1a, two in Group B1b and one for Group B3d. One was for bovine milk (for which Brazil is not listed in Annex -I to Implementing Regulation (EU) 2021/405) - Group B1b. Two were for poultry - Group B1a and Group B3d and one was for honey - Group A2.

14. In two cases the first official control on the farm of origin took place three and nine months after the notification to the SISA concerned. In one case the second on-farm visit took place 46 months after the first one. Staff of the DSA´s CPV met by the audit team stated that they would in future more closely follow the timeliness of follow-up investigations for NRCP violations by SISAs at farm-level and added during the audit new criteria to their tracking tool to facilitate this.

15. In all but two cases the nationally applicable follow-up procedures were followed, the cause of the non-compliance comprehensively investigated and, in most cases, found. Furthermore, where required, deterrent measures on the farmer were imposed.

16. Regarding the three RASFF notifications concerning pharmacologically active substances referred to in section 4.3, the audit team noted that timely follow-up investigations were carried out and the cause of the non-compliance was identified in two cases with deterrent measures being imposed where required. Slaughterhouses or food processors concerned were tasked by the respective SIF to investigate and report the cause of the non-compliance as well as the actions taken to avoid re-occurrence of the non-compliance. These are subsequently assessed by the Division of Violations and Notifications.

([6]) Manual of procedures for investigating violations of residues of veterinary medicinal products, additives, and contaminants in products of animal origin (Version 2 of 2022), National legislation: Portaria 396 of 23 November 2009 and Decreto No 9.013 from 27 March 2017.

17. Results in excess of Brazilian maximum limits of residues of pharmacologically active substances. are followed up through official on-the-spot controls on farms or other relevant establishments with follow-up samples to be taken from five consecutive batches originating from the farm concerned, if the non-compliance was found in consignments originating from farms registered to supply animals for EU export and if the consignment concerned was intended for export to the EU.

18. Results exceeding EU MRLs/MLs but not the corresponding Brazilian limits/levels, are followed-up if the non-compliance is found at the moment of certification for EU export at the processing establishments. In this situation, SIF will require the processing establishment to investigate the reason for the non-compliance and to implement corrective actions. This report is then assessed by the SIF to see if the proposed measures are appropriate. Thus, it is largely ensured that such consignments are not authorised for the export to the EU. However, the audit team found that interviewed SIF staff involved in export certification were not always fully aware of the differences between EU and Brazilian residue limits.

19. Written records of the follow-up investigation included a description of the control methods applied at farm level and the outcome of the control.

20. Results which exceed EU levels/limits but comply with (higher) Brazilian levels/limits are not reported to the EU as required ([7]) with the annual submission of the NRCP results. MAPA informed the audit team that it would report such results to the EU with the submission of future NRCPs.

Conclusions on follow-up of non-compliant results

21. The application of appropriate procedures and comprehensive follow-up of non-compliant results positively contributes to the overall effectiveness of the NRCPs.

5.3 Laboratories, methods of analysis, method validation and internal quality control

22. The laboratory network consists of six national laboratories, five of which are within MAPA's network of official laboratories – Federal Agricultural Defence Laboratories (*Laboratórios Federais de Defesa Agropecuária*). The remaining laboratory is a third-party entity. The audit team visited three of the MAPA's laboratories.

23. Similar to EU requirements ([8]), all of the laboratories were accredited to ISO/IEC 17025 by the National Institute of Metrology, Standardisation, and Industrial Quality (*Instituto Nacional de Metrologia, Normalização e Qualidade Industrial*), which is a member of the International Laboratory Accreditation Cooperation. The vast majority of the analytical methods used were included in the laboratories' scope of accreditation.

([7]) Point B3 of Part III of Annex I to Delegated Regulation (EU) 2022/2292.
([8]) Article 37(4)(e)of Regulation (EU) 2017/625.

24. Similar to EU requirements ([9]), the laboratories visited, regularly participated in relevant proficiency tests and most of the results seen were satisfactory. When (rarely) unsatisfactory results were obtained, appropriate corrective measures had been implemented.

25. Similar to EU requirements ([10]), CGAL regularly evaluates the performance of the testing laboratories by audits.

26. In all of the laboratories visited, the audit team checked the acceptance/rejection system for incoming samples and saw that clear acceptance/rejection criteria were in place to ensure samples' legal, scientific and technical validity, similar to EU requirements ([11]). A check of the sample seal was always carried as part of the reception procedure and the temperature of incoming samples was measured. The audit team observed that while most of the samples (except honey and eggs) were frozen (at -20˚C in domestic refrigerators) by the samplers prior to dispatch to the laboratories, the temperature of the incoming samples was mostly around 0˚C, thus, the cold chain during the transportation had not been fully maintained (see finding 32). Maintenance of the required temperature during transport had not been requested from the contracted transportation companies. The target delivery time of 12 days from the place of sampling to the laboratories was for the vast majority of the samples seen by the audit team, achieved.

27. The audit team observed the general standard operating procedure on method validation for residues of pharmacologically active substances and observed that it was based on the requirements of partially out of date EU requirements ([12]). The CGAL representative stated that CGAL was aware about the current EU legislation ([13]), and that the validation standard operating procedure was being amended in light of the current EU requirements. For pesticides methods, European Commission guidelines ([14]) and for contaminants methods, EU legislation ([15]) were followed.

28. The audit team assessed in detail validation files for the following methods:

    a) Stilbenes (Group A1(a) as defined in EU legislation ([16])),
    b) Antithyroid agents (thyrostats) (Group A1(b)),
    c) Steroids (Group A1(c)),
    d) Resorcylic acid lactones, including zeranol (Group A1(d)),
    e) Beta-agonists (Group A1(e)),
    f) Chloramphenicol (Group A2(a)),
    g) Nitrofurans (Group A2(b)),
    h) Nitroimidazoles (Group A2(c)),

([9]) Article 38(2) of Regulation (EU) 2017/625.
([10]) Article 39 of Regulation (EU) 2017/625.
([11]) Article 34(5) of Regulation (EU) 2017/625.
([12]) Commission Decision 2002/657/EC.
([13]) Commission Implementing Regulation (EU) 2021/808.
([14]) Analytical quality control and method validation procedures for pesticide residues analysis in food and feed. SANTE 11312/2021.
([15]) Commission Regulation (EC) No 333/2007, Commission Regulation (EC) No 401/2006, Commission Implementing Regulation (EU) 2023/2782 and Commission Regulation (EU) 2017/644.
([16]) Annex I to Delegated Regulation (EU) 2022/1644.

i) Dyes (Group A3(a)),
j) Tetracyclines (Group B1(a)),
k) Abamectin (Group B1(b) for bovine and ovine tissues, Group A3(d) for all other commodities),
l) Emamectin (Group A3(d) in other than finfish commodities),
m) Monensin (Group B1(b) for bovine and poultry tissues, Group A3(d) for all other commodities), and
n) Pesticides (Group A3(b), *e.g.*, fipronil, aldicarb, tetramethrin, cyfluthrin, *etc.*).

For all of the methods, Liquid Chromatography – (Tandem) Mass Spectrometry was used. For some pesticides, Gas Chromatography – Mass Spectrometry was employed. The reference values used by the laboratories to assess methods' fitness-for-purpose were largely those established in EU legislation ([17]) and EU procedures ([18]).

29. With regard to method validation, the audit team observed that:

29.1. For the pesticides method, while initial attempts were made to validate the method for all analytes at 10 µg/kg, the validation outcome was unfavourable for a number of analytes and the limit of quantification (LOQ) was set at the next fortification level (50 µg/kg) resulting in the method's sensitivity being above current EU MRLs. For example, for disulfoton in muscle of terrestrial animals the EU MRL is 10 µg/kg and for poultry it is 20 µg/kg. Furthermore, said LOQ is inappropriately high for a number of analytes for which no EU MRLs have been set, for example, prothiofos in muscle of terrestrial animals, acephate, bromopropylate and cyphenotrin in fish, azinphos-ethyl, fenpropathrin, parathion-ethyl and tiomethon B in honey. Moreover, in one laboratory visited the LOQ for fipronil was 10 µg/kg while the EU MRLs range from 5 µg/kg for all commodities except bovine fat (30 µg/kg) and sheep fat (15 µg/kg).

29.2. In the multiresidue method for chloramphenicol, nitroimidazoles and dyes, one fortification level was used during the validation. The laboratory representative explained that said validation was an extension of the validation scope of a previously validated method. The use of a single fortification level differs from EU requirements - three different fortification levels are necessary ([19]).

29.3. In the nitrofurans method (for all relevant commodities), the lowest calibrated level *exceeded* the EU reference point for action (RPA) ([20]), contrary to EU validation requirements ([21]) and thus does not provide for sufficient assessment of the method performance at the (EU) level of interest ([22]).

([17]) Decision 2002/657/EC.
([18]) Analytical quality control and method validation procedures for pesticide residues analysis in food and feed. SANTE 11312/2021.
([19]) Chapter 4 of Annex I to Implementing Regulation (EU) 2021/808.
([20]) Commission Regulation (EU) 2019/1871.
([21]) Point 2.2. of Chapter 2 of Annex I to Implementing Regulation (EU) 2021/808.
([22]) As defined in Article 2(19) of Implementing Regulation (EU) 2021/808.

29.4. In the methods for stilbenes and steroids in urine, the lowest calibrated levels exceeded the minimum method performance requirements recommended by the EU reference laboratories ([23]). (Note that these guidelines are not binding for laboratories in third countries but can of course be used by those laboratories).

29.5. In all, but two methods scrutinised for unauthorised or prohibited pharmacologically active substances (beta-agonists and chloramphenicol + nitroimidazoles + dyes), the method of calculation of the decision limit for confirmation (CCα) was similar to the calibration curve procedure established in EU legislation ([24]). Verification of the value of CCα obtained with this approach (which was considerably lower than the lowest calibrated level) had been conducted for the stilbenes and steroids methods. It is an EU requirement ([24]) that such verification is conducted for all methods for unauthorised or prohibited pharmacologically active substances. The audit team reminded CGAL that the calculation of CCα made in accordance with previous EU legislation ([25]) is acceptable until 10 June 2026.

29.6. In relation to the stability of analytes in matrix ([26]), the audit team noted that two approaches were followed. The first was by conducting in-house experimental studies, and second by gathering available external data (*e.g.*, reports from proficiency test providers). In the case of in-house studies, those did not include an evaluation of the possible impact of prolonged (up to 12 days) transportation under varying temperatures (see finding 26). As for the external data, the audit team noted that in the materials seen, in most cases there was no detailed information on storage temperature and thus it was impossible to conclude whether the conditions in those reports had been identical to those adopted in the laboratory as required by EU legislation ([27]). The external data also covered a very limited number of analytes compared to the scope of the analytical methods concerned.

29.7. During sample preparation (both during validation and routine testing), skin was removed from finfish samples, and from porcine and poultry samples when testing fat. The audit team clarified that the MRLs for pharmacologically active substances in finfish muscle are set for "muscle and skin in natural proportions", and for "skin and fat in natural proportions" when analysing fat from porcine and poultry species ([28]).

30. With regard to internal quality control for the methods scrutinised (see finding 28), the audit team observed that while positive control samples were routinely included in

([23]) EU Reference Laboratory guidance on minimum method performance requirements for specific pharmacologically active substances in specific animal matrices, June 2022.
([24]) Point 2.6.1.(a) of Chapter 2 of Annex I to Implementing Regulation (EU) 2021/808.
([25]) Decision 2002/657/EC.
([26]) Point 2.5 of Chapter 2 of Annex I to Implementing Regulation (EU) 2021/808; Sections 17 and 18.4 of Guidelines for the design and implementation of national regulatory food safety assurance programme associated with the use of veterinary drugs in food-producing animals, CAC/GL 71-2009.
([27]) Point 2.5. of Chapter 2 of Annex I to Implementing Regulation (EU) 2021/808.
([28]) Regulation (EU) No 37/2010.

analytical sequences, the fortification levels were not always at the level of interest. For example, 1 µg/kg for nitrofurans in honey and finfish when the RPA is 0.5 µg/kg ([20]); 100 µg/kg for fipronil in bovine liver when the MRL is 5 µg/kg ([29]). Such an approach weakens ongoing method performance verification at the level(s) of interest ([30]). Quality control charts were created and maintained for all of the methods scrutinised. The audit team noted that, for the pesticides method, while there were three fortification levels (the lowest being largely at the level(s) of interest) used for the positive control samples, quality control charts were created and maintained only for the second fortification level which was well above the level(s) of interest for most of the analytes. This shortcoming should be easily addressed.

31. The audit team noted that there was no systematic, and documented, assessment whether the difference between parallel results of positive (fortified) control samples was acceptable. This did not allow for the verification whether the analytical runs were suitable for the purpose of internal quality control, including confirmation of non-compliant results.

32. In one laboratory visited, the audit team noted that during routine use of the method for antithyroid agents (thyrostats), consideration was given to analyte instability during freezing/thawing cycles and storage ([31]), and acidification of the urine (at the time of arrival to the laboratory) was applied. However, taking into account the prolonged transportation and partial thawing of the samples occurring during the shipment (see finding 26), the acidification applied after the sample(s) arrival to the laboratory might not be sufficient to ensure analyte stability and thus the possibility of detecting truly non-compliant samples could be hampered.

33. The audit team noted that, for all of the NRCP analyses, the target turnaround time was 21 calendar days from the time of acceptance of the sample. The turnaround times of a large number of samples randomly selected by the audit team for review adhered to that target. The audit team also saw that the analytical reports were promptly delivered to MAPA's relevant service by electronic means.

Conclusions on laboratories

34. Notwithstanding some shortcomings in analytical method validation and room for improvement in the operation of the internal quality control system, the facts that all of the testing laboratories are accredited to ISO 17025:2017, have the vast majority of the analytical methods included in their respective scopes of accreditation, largely successfully participate in regular proficiency tests and are regularly audited by the central competent authority, allow the competent authority to have confidence in the analytical results provided by the laboratory network.

([29]) Commission Regulation (EU) 2024/347.
([30]) Chapter 3 of Annex I to Implementing Regulation (EU) 2021/808.
([31]) EURL Refection paper 2014: Natural growth promoting substances in biological samples, Chapter 2, paragraph 2.2.

5.4 Veterinary medicinal products – legislative framework and controls thereon

35. At federal level the DSA´s CPV is responsible for market authorisation of veterinary products. At state level the SISAs are responsible for regular official controls on manufacturers, importers and distributors of veterinary medicinal products and as well of veterinarians that are registered to use and prescribe veterinary medicinal products under special control ([32]). There are no regular controls on the use of veterinary medicinal products on farms, unless in the context of follow-up investigations for NRCP non-compliances (see chapter 5.2).

36. Similar to what applies in the EU ([33]), national legislation ([34]) describes the legal provisions and procedures for the authorisation and distribution of veterinary medicinal products.

37. Similar to the EU ([35]), national legislation ([36]) prohibits the use of hormonal growth promotants in cattle.

38. The use of certain hormones for zootechnical purposes is allowed in national legislation ([37]), which is also the case in the EU ([38]). However, the list of hormones authorised for such use in Brazil, includes oestradiol 17β, which is prohibited from use in food-producing animals in the EU ([39]) for zootechnical purposes. There are 23 veterinary medicinal products containing oestradiol 17β authorised in Brazil for zootechnical purposes. None of their labels have any indication that the product should not be used for bovine animals, meat from which is intended for the EU market.

39. Brazil has several elements in place to ensure that bovine animals treated with oestradiol 17β for zootechnical purposes are not exported to the EU.

    39.1. There are two categories of bovine holdings – those approved in SISBOV (*Sistema de identificação e certificação de bovinos e bubalinos)* which are termed as ERAS (*Estabelecimentos Rurais Aprovados no SISBOV)* and those without such an approval (non-ERAS). ERAS holdings are allowed to produce and send bovine animals to slaughterhouses for export to the EU. Non-ERAS holdings can deliver bovine animals to ERAS farms but not *directly* to slaughterhouses for export to the EU.

    39.2. SISBOV requires individual identification of bovine animals on ERAS holdings and individual or batch identification on non-ERAS holdings.

    39.3. Animal movement permits (*Guia de Trânsito Animal*) are required for all transports of bovine animals between holdings or to slaughterhouses.

([32]) Normative Instruction No 35 of 11 September 2017.
([33]) Regulation (EU) 2019/6 of the European Parliament and of the Council.
([34]) Law 467, dated 13 February 1969 and the Decree No 5.053, dated 22 April 2004.
([35]) Article 11 of Council Directive 96/22/EC.
([36]) Normative Instruction No 55, dated 1 December 2011.
([37]) Article 2 of Normative Instruction No 55, dated 1 December 2011.
([38]) Article 5 of Directive 96/22/EC.
([39]) Article 5 and 11 of Directive 96/22/EC.

39.4. ERAS producers ([40]) and their (non-ERAS) supplying farms ([41])([42]) sign sworn declarations of non-treatment of bovine animals with oestradiol 17β. The use of oestradiol 17β in cows and heifers is permitted on both ERAS and non-ERAS farms provided that the meat of such animals is not destined for the EU. ERAS holdings sign the declaration when sending animals to slaughter if their meat is to be exported to the EU and non-ERAS holdings sign it when sending animals to ERAS farms.

40. The reliability of the information in the sworn declaration cannot be verified by MAPA. This is due to several factors.

40.1. Livestock farms in Brazil (including ERAS farms) are not legally required to keep on-farm-treatment records (though the competent authority has indicated its intention to adopt legislation mandating this) and, controls on the use of veterinary medicinal products on farms are not carried out (see finding 35).

40.2. While access to veterinary medicinal products containing oestradiol 17β requires a veterinary prescription ([43]), the information to be recorded in the prescription is not defined and moreover, the prescription does not need to be retained on the farm.

40.3. Non-ERAS farms that supply ERAS farms can buy cows and heifers from other non-ERAS farms and for such movements, there is no need to sign the sworn declaration on non-use of oestradiol 17β.

Conclusions on veterinary medicinal products – legislative framework and controls thereon

41. National legislation on the authorisation of veterinary medicinal products and the national prohibition of the use of hormones and beta-agonists for growth promotion purposes in bovine animals is broadly similar to EU legislation. However, in other respects, the Brazilian system differs substantially from that in the EU, for example in relation to the retention of veterinary prescriptions and the absence of a legal requirement to maintain medicinal treatment records. With regard to the use in cattle of oestradiol 17β for therapeutic and zootechnical purposes, current arrangements cannot guarantee the reliability of sworn statements on non-use in cattle, meat from which is destined for export to the EU. MAPA is therefore not in a position to reliably attest to operator compliance with the corresponding section in the model EU health certificate for bovine meat exports to the EU.

([40]) Appendix 1 of Joint Circular letter No.1 from March 14, 2024.
([41]) Manual - IN 51/2018 - Appendix III - Public Protocol for the European Union (Annex XXV).
([42]) Circular letter No6/2018/SAUD/CAMEO/CGIE/SDA/MAPA from 12 November 2018.
([43]) Normative Instruction 35 of 11 September 2017.

6 OVERALL CONCLUSION

The implementation of the control plans for residues of pharmacologically active substances, pesticides and contaminants and the follow-up of non-compliant results are largely consistent with the principles laid down in EU legislation, underpinning the reliability of the guarantees offered by Brazil in ensuring that food of animal origin exported to the EU complies with EU requirements. Notwithstanding some shortcomings in the validation of analytical methods and the room for improvement in the operation of the laboratories' internal quality control systems, the competent authority can have confidence in the reliability of the analytical results provided by the laboratory network.

Whilst national legislation on the authorisation of veterinary medicinal products and the prohibition of the use of hormones and beta-agonists for growth promotion purposes in bovine animals is broadly similar to EU legislation, the current arrangements in place to guarantee that cattle, meat from which is destined for the EU market, have never been treated with oestradiol 17β for zootechnical or therapeutic purposes, are ineffective. Consequently, the competent authority cannot guarantee the reliability of operators' sworn statements on non-use of oestradiol 17β in cattle and MAPA is not in a position to reliably attest to operator compliance with the corresponding section in the model EU health certificate for bovine meat exports to the EU, questioning the country's continued listing for bovine animals in Annex -I to Implementing Regulation (EU) 2021/405.

7 CLOSING MEETING

A closing meeting was held on 14 June 2024 with representatives of the competent authorities. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit, which were accepted by the competent authorities.

8 RECOMMENDATIONS

The competent authority is invited to provide details of the actions taken and planned, including deadlines for their completion ('action plan'), aimed at addressing the recommendations set out below. With regard to those non-compliances noted in the audit report which did not result in a recommendation being made, the competent authority is, nevertheless, requested to address these. The effectiveness of the actions taken to address such non-compliances will be assessed in future audits on this topic.

No	Recommendation
1	To ensure that the validation of analytical methods incorporates a sufficient number of fortification concentrations including the (EU) level(s) of interest. *Relevant EU legislation: Article 7 and point F(4) of Part II of Annex I to Delegated Regulation (EU) 2022/2292 in conjunction with Article 3 of Implementing Regulation (EU) 2021/808.* *Recommendation based on conclusion: 34.*

No	Recommendation
	Associated findings: 29.
2	To ensure that products from cattle that have been treated with oestradiol 17β for therapeutic or zootechnical purposes are not exported to the EU. *Relevant EU legislation: Article 7, 9 and 10 of Delegated Regulation (EU) 2022/2292 in conjunction with Article 11(2) of Directive 96/22/EC.* *Recommendation based on conclusion: 41.* *Associated findings: 38, 39 and 40.*

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=2024-8087

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Reg. 2017/625	OJ L 95, 7.4.2017, p. 1–142	Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC (Official Controls Regulation)
Reg. 2021/405	OJ L 114, 31.3.2021, p. 118-150	Commission Implementing Regulation (EU) 2021/405 of 24 March 2021 laying down the lists of third countries or regions thereof authorised for the entry into the Union of certain animals and goods intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council
Reg. 2022/2292	OJ L 304, 24.11.2022, p. 1–30	Commission Delegated Regulation (EU) 2022/2292 of 6 September 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with regard to requirements for the entry into the Union of consignments of food-producing animals and certain goods intended for human consumption

Legal Reference	Official Journal	Title
Reg. 2022/1644	OJ L 248, 26.9.2022, p. 3–17	Commission Delegated Regulation (EU) 2022/1644 of 7 July 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council with specific requirements for the performance of official controls on the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof
Reg. 37/2010	OJ L 15, 20.1.2010, p. 1-72	Commission Regulation (EU) No 37/2010 of 22 December 2009 on pharmacologically active substances and their classification regarding maximum residue limits in foodstuffs of animal origin
Dec. 2002/657/EC	OJ L 221, 17.8.2002, p. 8-36	2002/657/EC: Commission Decision of 12 August 2002 implementing Council Directive 96/23/EC concerning the performance of analytical methods and the interpretation of results
Reg. 2021/808	OJ L 180, 21.5.2021, p. 84–109	Commission Implementing Regulation (EU) 2021/808 of 22 March 2021 on the performance of analytical methods for residues of pharmacologically active substances used in food-producing animals and on the interpretation of results as well as on the methods to be used for sampling and repealing Decisions 2002/657/EC and 98/179/EC
Reg. 2019/1871	OJ L 289, 8.11.2019, p. 41–46	Commission Regulation (EU) 2019/1871 of 7 November 2019 on reference points for action for non-allowed pharmacologically active substances present in food of animal origin and repealing Decision 2005/34/EC
Reg. 2023/915	OJ L 119, 5.5.2023, p. 103–157	Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006
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

Legal Reference	Official Journal	Title
Reg. 2022/1646	OJ L 248, 26.9.2022, p. 32–45	Commission Implementing Regulation (EU) 2022/1646 of 23 September 2022 on uniform practical arrangements for the performance of official controls as regards the use of pharmacologically active substances authorised as veterinary medicinal products or as feed additives and of prohibited or unauthorised pharmacologically active substances and residues thereof, on specific content of multi-annual national control plans and specific arrangements for their preparation
Reg. 2021/1355	OJ L 291, 13.8.2021, p. 120–121	Commission Implementing Regulation (EU) 2021/1355 of 12 August 2021 on multiannual national control programmes for pesticides residues to be established by Member States
Reg. 2022/931	OJ L 162, 17.6.2022, p. 7–12	Commission Delegated Regulation (EU) 2022/931 of 23 March 2022 supplementing Regulation (EU) 2017/625 of the European Parliament and of the Council by laying down rules for the performance of official controls as regards contaminants in food
Reg. 2022/932	OJ L 162, 17.6.2022, p. 13–22	Commission Implementing Regulation (EU) 2022/932 of 9 June 2022 on uniform practical arrangements for the performance of official controls as regards contaminants in food, on specific additional content of multi-annual national control plans and specific additional arrangements for their preparation
Reg. 2019/2090	OJ L 317, 9.12.2019, p. 28–37	Commission Delegated Regulation (EU) 2019/2090 of 19 June 2019 supplementing Regulation (EU) 2017/625 of the European Parliament and Council regarding cases of suspected or established non-compliance with Union rules applicable to the use or residues of pharmacologically active substances authorised in veterinary medicinal products or as feed additives or with Union rules applicable to the use or residues of prohibited or unauthorised pharmacologically active substances
Reg. 401/2006	OJ L 70, 9.3.2006, p. 12-34	Commission Regulation (EC) No 401/2006 of 23 February 2006 laying down the methods of sampling and analysis for the official control of the levels of mycotoxins in foodstuffs

Legal Reference	Official Journal	Title
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 control of the levels of trace elements and processing contaminants in foodstuffs
Reg. 2017/644	OJ L 92, 6.4.2017, p. 9–34	Commission Regulation (EU) 2017/644 of 5 April 2017 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 589/2014
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
Reg. 2019/6	OJ L 4, 7.1.2019, p. 43–167	Regulation (EU) 2019/6 of the European Parliament and of the Council of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC

ANNEX 2 – LEGAL REQUIREMENTS RELATED TO SPECIFIC CHAPTERS IN THE REPORT

SECTION IN THE REPORT	REPORT HEADING	RELEVANT EU LEGISLATION – LEGAL REQUIREMENTS CORRESPONDING TO THE SPECIFIC PROVISIONS AND MEASURES	TOPIC
5.1.	Implementation of the control plan for residues of pharmacologically active substances, pesticides and contaminants	Regulation (EU) 2017/625	Conduct of official controls in general
		Commission Delegated Regulation (EU) 2022/1644	Specific rules for conduct of official controls on residues of **pharmacologically active substances** in animals and animal products.
		Commission Implementing Regulation (EU) 2022/1646	Practical arrangements for performance of official controls on residues of pharmacologically active substances in animals and animal products.
		Commission Implementing Regulation (EU) 2021/405	Annex -I – list of third countries with approved control plans for residues of pharmacologically active substances, pesticides and contaminants.
		Commission Implementing Regulation (EU) 2021/1355	Multiannual national control programmes for **pesticide** residues.
		Commission Delegated Regulation (EU) 2022/931	Specific rules for conduct of official controls on **contaminants** in food.
		Commission Implementing Regulation (EU) 2022/932	Practical arrangements for performance of official controls on **contaminants** in food.
5.2.	Follow-up of non-compliant results and enforcement	Commission Delegated Regulation (EU) 2019/2090	**Follow-up** of non-compliant results for residues of pharmacologically active substances.
		Art. 127(3)(c) of Regulation (EU) 2017/625	Performance of official controls in response to **RASFF** notifications.
		Articles 137, 138, 139 of Regulation (EU) 2017/625	**Enforcement** action.
		Commission Delegated Regulation (EU) 2022/2292	Annex I, Part III, Point B – **Follow-up investigations** by the competent authorities.
5.3.	Laboratories, methods of analysis, method validation and internal quality control	Art. 34, 37(4) and 37(5) of Regulation (EU) 2017/625	**Analytical methodology, accreditation**
		Commission Delegated Regulation (EU) 2022/2292	Annex I, Part II, Point F - Specific requirements for **analytical methods** and laboratories.
		Commission Decision 2002/657/EC	**Validation** of analytical methods for residues of pharmacologically active substances – repealed by Reg. (EU) 2021/808.

		Regulation (EU) 2021/808	**Methods of sampling** and **validation** of analytical methods for residues of pharmacologically active substances.
		Commission Regulation (EC) No 333/2007	**Methods of sampling and analysis** for certain **contaminants** in foodstuffs: lead, cadmium, mercury, inorganic tin, 3-MCPD and benzo(a)pyrene.
		Commission Regulation (EC) No 401/2006	**Methods of sampling and analysis** for certain **contaminants** in foodstuffs: mycotoxins.
		Commission Regulation (EU) 2017/644	**Methods of sampling and analysis** for certain **contaminants** in foodstuffs: dioxins, dioxin-like PCBs and non-dioxin-like PCBs.
		Commission Regulation (EU) No 37/2010	**Maximum Residue Limits** for residues of **pharmacologically active substances** in food of animal origin.
		Commission Regulation (EU) 2019/1871	**Reference points for action** for certain pharmacologically active substances.
		Commission Regulation (EC) No 396/2005	**Maximum Residue Levels** for residues of **pesticides** in food.
		Commission Regulation (EU) 2023/915	**Maximum Levels** for certain **contaminants** in food.
5.4	Veterinary medicinal products – legislative framework and controls thereon	Regulation (EU) 2019/6	**Authorisation** of veterinary medicinal products.
		Regulation (EU) 2019/4	**Authorisation** of medicated feedingstuffs.
		Directive 96/22/EC	**Ban** on the use of hormonal growth promotants, beta-agonists for growth promotion and certain hormonal substances for therapeutic and zootechnical use.
		Commission Delegated Regulation (EU) 2022/2292	Annex I, Part II, Point G – **Requirements** for pharmacologically active substances authorised in veterinary medicinal products or as feed additives, for use in food producing animals and prohibitions on use in such animals.