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DG(SANTE) CT-2025-0241

FINAL REPORT OF AN AUDIT
OF BRAZIL
CARRIED OUT
FROM 14 TO 31 OCTOBER 2025
IN ORDER TO
FOLLOW-UP ON THE EFFECTIVENESS OF THE ACTIONS TAKEN IN RESPONSE
TO THE RECOMMENDATIONS OF AUDIT DG(SANTE) 2024-8087

Executive Summary

This report describes the outcome of an audit of Brazil, carried out from 14 to 31 October 2025 as a follow-up of the audit of Brazil carried out in 2024 (ref. DG(SANTE) 2024-8087) with the objective to evaluate controls on residues of pharmacologically active substances, pesticides and contaminants in animals and animal products.

The objective of the audit was to evaluate the effectiveness of corrective actions initiated or implemented by the Brazilian central competent authority (Ministry of Agriculture, Livestock and Food Supply, MAPA) in response to two recommendations made in the 2024 audit report.

The audit concluded that the actions proposed in relation to recommendation 1 on the performance of the laboratory network have been largely effectively implemented and the recommendation has been satisfactorily addressed.

Regarding the critical recommendation 2 to ensure that products from cattle that have been treated with oestradiol 17 β for therapeutic or zootechnical purposes are not exported to the EU, the action plan has not been implemented as proposed. Whilst MAPA has put in place a number of measures, which it has committed to in its action plan, these have not been fully effective in excluding from export to the EU the meat of female animals treated with oestradiol 17 β . As a consequence, this recommendation is considered to have not been addressed.

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ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
ABCAR	Association of Auditing and Traceability Certification Companies
EU	European Union
GTA	Animal Movement Permit
LFDA	Federal Agricultural Defence Laboratory
MAPA	Ministry of Agriculture, Livestock and Food Supply
MRL	Maximum Residue Limit (for pharmacologically active substances); Maximum Residue Level (for pesticides)
PEFB	Protocol for Export of Female Bovines
SIF	Federal Inspection Service

1. INTRODUCTION

The audit took place from 14 to 31 October 2025 as a follow-up of 2024 audit of Brazil with the objective to evaluate controls on residues of pharmacologically active substances, pesticides and contaminants in animals and animal products (DG(SANTE) 2024-8087 ⁽¹⁾). The audit team comprised two auditors from the European Commission. The audit was conducted in a hybrid format consisting of a remote (videoconference) opening meeting with the competent authority and an on-site component comprising visits to selected sites in Brazil and the closing meeting with the competent authorities. For the on-site component of the audit, the audit team was accompanied by three representatives from the central competent authority – Ministry of Agriculture, Livestock and Food Supply (MAPA). The table below lists the meetings and visits held.

Meeting/Visit	No	Comments
Opening meeting (remote)	1	With representatives of the central competent authority.
Slaughterhouse	4	In three different states.
Farm	5	In three different states.
Laboratory	2	In two different states. Both Federal Agricultural Defence Laboratories (LFDA). One laboratory was assessed remotely.
Closing meeting	1	With representatives of the central competent authority.

2. LEGAL BASIS FOR THE AUDIT

The audit was carried out under the general provisions of European Union (EU) legislation and, in particular, Articles 120 and 122 of Regulation (EU) 2017/625 of the European Parliament and of the Council. Full references to the EU acts relevant to the scope of this report are given in Annex I. Specific EU acts cited in Annex II are the criteria against which the fulfilment of the objectives of the audit is assessed. EU legal acts quoted in this report refer, where applicable, to the last amended version at the time of the audit.

3. OBJECTIVE OF THE AUDIT

The objective of the audit was to evaluate the effectiveness of corrective actions initiated or implemented in response to two recommendations made in the 2024 audit report (DG(SANTE)/2024-8087 ⁽¹⁾).

4. BACKGROUND

The 2024 audit report made two recommendations.

Recommendation 1: to ensure that the validation of analytical methods incorporates a sufficient number of fortification concentrations including the (EU) level(s) of interest.

Recommendation 2 (critical): to ensure that products from cattle that have been treated with oestradiol 17 β for therapeutic or zootechnical purposes are not exported to the EU.

⁽¹⁾ The audit report and the action plan submitted by MAPA are available at <https://ec.europa.eu/food/audits-analysis/audit-report/details/4804>.

In relation to recommendation 1, MAPA committed to take the actions necessary to ensure that all the methods in use for testing the samples within the residue control plans are adequately validated at the level(s) of EU interest ⁽²⁾.

In response to the recommendation 2, MAPA submitted an action plan ⁽¹⁾ committing to:

- (i) establish a private protocol – so-called Protocol for Export of Female Bovines (PEFB) – to ensure adequate traceability for female bovine animals treated with oestradiol 17 β with a proposed rollout timeframe of 12 months, and
- (ii) during the development and rollout of the protocol, to suspend all exports of products derived from female bovine animals to the EU (the male bovine animals are not treated with oestradiol 17 β).

On the basis of the above-mentioned commitments, the audit team assessed the actions proposed as satisfactory to address the deficiencies identified during the 2024 audit – subject to timely and effective implementation.

According to MAPA data provided at the time of the audit, there were 2 522 487 cattle farms in Brazil, of which 1 234 were approved for the export to the EU, this represents less than 0.05% of all cattle farms in Brazil.

5. FINDINGS AND CONCLUSIONS

5.1. Recommendation 1 of the 2024 Commission audit report

1. In the action plan, MAPA committed to (i) align the method validation approach with pertinent EU legislation ⁽³⁾, and (ii) ensure that the level(s) of (EU) interest was considered.
2. The audit team assessed the effectiveness of the actions taken by two LFDA laboratories and observed that sufficient actions in relation to the method validation had been taken or were in progress at the time of the audit.
3. In relation to level(s) of EU interest, the audit team noted that for the vast majority of the analyte/matrix combinations, the sensitivity of the methods was satisfactory. Notwithstanding this overall positive finding, in one laboratory, for 1.3% of the analyte/matrix combinations (pesticides only e.g. chlormequat chloride, disulfoton and prothiofos in muscle of bovine, porcine and equine animals, and poultry), the sensitivity of pertinent methods has still exceeded (up to five times) the relevant EU maximum residue levels (MRLs). The laboratory representative explained that this was most likely due to technical limitations of current (aged) analytical equipment, and that a public tender had been initiated to purchase a more suitable instrumentation.

Conclusion on the effectiveness of corrective actions in response to recommendation 1 of the 2024 Commission audit report

4. The actions proposed in relation to recommendation 1 have been largely effectively and timely implemented.

⁽²⁾ Article 2(19) of Commission Implementing Regulation (EU) 2021/808.

⁽³⁾ Chapter 2 of Annex I to Commission Implementing Regulation (EU) 2021/808.

5.2. Recommendation 2 of the 2024 Commission audit report

5. As a part of the actions proposed, the Association of Auditing and Traceability Certification Companies (ABCAR) designed the PEFB ⁽⁴⁾. The PEFB was ratified by MAPA Ordinance no. 1.228 of 16 January 2025. The main objective of the PEFB is to ensure adequate traceability of the female bovine animals treated with oestradiol 17 β at any time of their life and thus to ensure that only female bovine animals never treated with oestradiol 17 β are slaughtered for export to the EU.
6. MAPA stated that the dedicated ABCAR database (BD-ABCAR) had become fully operational in February 2025.
7. On 21 January 2025, MAPA issued Circular Letter no. 6/2025 establishing that only female bovine animals not treated with oestradiol 17 β , and male bovine animals would be eligible for export to the EU.
8. On 13 February 2025, MAPA issued Circular Letter no. 9/2025 imposing complete suspension of export to the EU of meat from female bovine animals – stating that the resumption of export to the EU of female bovine animal products could be possible only after complete implementation of the PEFB. The provisional timeframe for the rollout of the PEFB declared in the action plan was 12 months.
9. On 14 October 2025, during the opening meeting of the audit, MAPA informed the audit team that on 3 April 2025 MAPA issued Circular Letter no. 15/2025 recognising full operational status of the PEFB and thus resuming export of products from female bovine animals enrolled in the PEFB from that date. This decision, constituting a substantial deviation from the commitments made in the action plan, had not been communicated to the European Commission.
10. According to the PEFB, the farm interested in supplying female bovine animals for the EU market must first be listed in the PEFB BD-ABCAR database. The farm must apply for the listing with a certifying entity (accredited by the ABCAR) of their choice. Positive enrolment decision may be made only after a visit on farm by the certifying entity to verify compliance with all requirements of the PEFB. These certification inspections include verification of sanitary management plan, controls on oestradiol 17 β use, capacity to ensure segregation of female cattle based on oestradiol 17 β treatment status, controls on the movement of female cattle, and verification of age compliance for incoming female bovine animals.
11. By the time of the audit, there were 13 certifying entities accredited by the ABCAR and authorised to operate across all the States of Brazil.
12. Once listed in the PEFB, the farm must apply to the certifying entity every time the farm intends to send female bovine animals to slaughter, where meat of which is destined for export to the EU. The certifying entity must verify the correctness of the information provided and issue a Transaction Certificate when all of the PEFB requirements are complied with.

⁽⁴⁾ Available at <https://abcar.agr.br/protocolo-estradiol/>.

13. The receiving slaughterhouse must ensure that the Transaction Certificate accompanied the lot of the female animals and send a copy of the Transaction Certificate to the MAPA officials present at the slaughterhouse. These officials from the Federal Inspection Service (SIF) will scrutinise it by comparing the Transaction Certificate with the corresponding Animal Movement Permit (GTA) for at least 10% of the female bovine animals, where meat of which is destined for the EU. During slaughter 100% of the identities of the animals are assessed against the documentation submitted. In case of any discrepancies and/or ambiguities, the female bovine animals that presented the discrepancies and/or ambiguities will be disqualified from slaughter for the EU.
14. To verify the functioning of the PEFB on farm, MAPA, via Official Letter no. 11/2025, established an audit cycle for 2025 covering a sample of no less than 10% of the farms participating in the PEFB. In this context, MAPA prepared an Audit Procedure for Farms under the PEFB, accompanied by a checklist and corresponding guidelines, intended to guide MAPA auditors in evaluating the implementation of the system for certifying beef derived from female cattle that have never been treated with oestradiol 17 β .
15. MAPA informed the audit team that, at the time of the audit, there were 150 farms enrolled in the PEFB, thus eligible for supplying female bovine animals for slaughter for the EU. Of those 150 farms, seven declared that they used oestradiol 17 β .
16. The audit team visited five farms enrolled in the PEFB and scrutinised the records of certifying entities supervising the farms. The audit team saw that in all cases the initial inspections had been conducted as per the PEFB. When deficiencies were identified, those were promptly rectified by the farm.
17. MAPA stated that they routinely supervised the PEFB-related activities by the certifying entities. In two cases of such supervision, deficiencies were noted. As a result, one certifying entity and all farms PEFB-certified by that entity were suspended until the deficiencies were rectified. Another certifying entity got a notification letter from the ABCAR requesting corrective actions without suspending the certifying entity and the farms certified by it.
18. Of the five farms visited, three declared that they used oestradiol 17 β . The audit team noted that at all these three farms, there were comprehensive treatment records which is consistent with the requirements of the PEFB, and handling plans for the use of oestradiol 17 β endorsed by the supervising veterinarian. As required by the PEFB, the farms provided to the certifying entity a list of the female bovine animals treated with oestradiol 17 β , signed by the supervising veterinarian. The farms could not provide the audit team with prescriptions for the oestradiol 17 β -containing veterinary medicinal products observed during the audit, which is inconsistent with the action plan commitments ⁽⁵⁾. This was not noted as a deficiency either by the certifying entity or by the MAPA controls.
19. The first MAPA control on a farm was carried out on 17 July 2025. By the time of the audit, in total 17 farms were controlled by MAPA, and in four reports of those MAPA

⁽⁵⁾ In its response to the draft report, the competent authority informed the audit team that, as a corrective measure, the PEFB had been supplemented with a new Annex XIII 'Communication of Purchase of Oestradiol Esters'. This new annex strengthens control over the acquisition of oestradiol-based medications by requiring that the veterinary prescription be attached to all purchase notifications.

controls, deficiencies were noted (including one report from a farm that declared the use of oestradiol 17 β – see finding 23).

20. Of the five farms visited, four were controlled by MAPA prior to the audit. The audit team observed the MAPA control records and saw that they were consistent with the MAPA's procedure on pertinent controls.
21. By the time of the audit, MAPA had conducted controls on three farms (visited by the audit team) of the seven that declared using oestradiol 17 β . The audit team noted that the use of oestradiol 17 β was not a criterion for the selection of the farms for the MAPA controls ⁽⁶⁾.
22. The audit team noted that the first MAPA control on a farm to verify the functioning of the PEFB was conducted on 17 July 2025, thus 4.5 months after MAPA recognised the full operational status of the PEFB on 3 April 2025. This raises the question of whether the MAPA officials could reliably sign health certificates for export to the EU of products from female bovine animals over the period 3 April – 17 July 2025. MAPA informed the audit team that, during this period, 290 health certificates were signed by SIFs for consignments destined for the EU containing products from female bovine animals.
23. At one farm visited, which had declared use of oestradiol 17 β , the audit team noted that the MAPA control, carried out on-farm on 21 August 2025, had identified that 179 female bovine animals treated with oestradiol 17 β during autumn 2024 had been erroneously enrolled in the PEFB (due to an administrative mistake by the farm), and that for 174 of those animals the supervising certifying entity issued transaction certificates making the 174 animals eligible for slaughter for the EU in May and July 2025 (thus approximately nine months after the treatment). This is not in line with pertinent EU legal requirements on the functioning of the segregated production system ⁽⁷⁾. The certifying entity failed to identify this mistake when verifying the correctness of information submitted by the farm in the application for the transaction certificates (since the original treatment records had not been consulted by the certifying entity). MAPA did modify the PEFB aiming to prevent the recurrence of such a mistake; no attempts had nevertheless been made by MAPA to trace the products from the 174 animals concerned. The importers in the EU were not informed about the ineligible products included in the consignments for the EU, which is a breach of pertinent EU legal requirements ⁽⁸⁾. Upon request by the audit team, the traceability of the 174 animals was established during the audit and MAPA informed the audit team that in total 15 health certificates had been signed by the SIFs resulting in inclusion of products from animals treated with oestradiol 17 β in the EU consignments. At the time of the audit, MAPA did not provide any statements in relation to the further actions on the 15 tainted consignments. According to MAPA's data, the general inclusion rate of the products from female bovine animals in the EU consignments did not exceed 3%.
24. The audit team visited four slaughterhouses enrolled in the PEFB and requested a full traceability exercise for a significant number of health certificates (circa ten per

⁽⁶⁾ In its response to the draft report, the competent authority informed the audit team that the standard operating procedure "AUDITS OF HOLDINGS ADHERING TO PEFB" (48860214) had been amended as a corrective measure. The revised procedure establishes that holdings declaring use of oestradiol are now classified as higher risk, with a minimum audit rate of 20% annually (increased from the previous 10% rate applied to all holdings irrespective of oestradiol use).

⁽⁷⁾ Article 10(2)(a) of Commission Delegated Regulation (EU) 2022/2292.

⁽⁸⁾ Article 127(3)(d) of Regulation (EU) 2017/625.

slaughterhouse) randomly chosen by the audit team from TRACES NT ⁽⁹⁾. The audit team noted that between 13 February and 2 April 2025, the period during which MAPA committed to suspend export to the EU of products from *any* female bovine animals, a significant number of consignments did contain meat from female bovine animals. The audit team observed that while sufficient efforts were made to exclude female bovine animals from the slaughter for the EU, the certification procedures did not ensure that meat on stock from female bovine animals slaughtered before the start of the PEFB was excluded from the export to the EU. This is not consistent with the commitments made in the action plan.

25. At all of the slaughterhouses visited, the audit team observed that the SIFs exercised rigorous and comprehensive checks of the GTAs and Transaction Certificates for all of the arriving animal lots thus ensuring that, at the time of the audit, only products from female bovine animals enrolled in the PEFB were exported to the EU.

Conclusion on the effectiveness of corrective actions in response to recommendation 2 of the 2024 Commission audit report

26. While the private protocol for export of female bovines was devised and rolled out as committed to, its functioning at the initial stage of the rollout did not ensure that ineligible products from female bovine animals were excluded from certification for export to the EU. The competent authority failed to inform the Commission about ineligible products supplied to the EU. The actions proposed were not fully implemented as committed to. Cumulatively, these deficiencies undermine the trust in MAPA's ability to ensure adequate implementation of the commitments made in the action plan.

6. OVERALL CONCLUSION

The audit concluded that the actions proposed in relation to recommendation 1 on the performance of the laboratory network have been largely effectively implemented and the recommendation has been satisfactorily addressed.

Regarding the critical recommendation 2 to ensure that products from cattle that have been treated with oestradiol 17 β for therapeutic or zootechnical purposes are not exported to the EU, the action plan has not been implemented as proposed. Whilst MAPA has put in place a number of measures to which it has committed in its action plan, these have not been fully effective in excluding from export to the EU the meat of female animals treated with oestradiol 17 β . As a consequence, the corresponding recommendation is not considered to have been addressed.

⁽⁹⁾ Information system providing a web-based application and services for the sanitary and phytosanitary certification and the related border clearance process supporting the entry into the Union of animals and products, food and feed of non-animal origin and plants, plant products and other objects, as well as the sanitary certification of movements between Member States of animals and certain products, and the sanitary and phytosanitary certification of exports from the EU of animals and certain products, and plants, plant products and other objects, at the disposal of third parties, whether public or private, as appropriate.

7. CLOSING MEETING

A closing meeting was held on 31 October 2025 with representatives of the MAPA. At this meeting, the audit team presented its main preliminary findings and conclusions. The competent authority did not express disagreement and undertook to take the actions necessary to address the shortcomings identified.

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Regulation (EU) 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)
Regulation (EU) 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
Regulation (EU) 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

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

SECTION IN THE REPORT	SECTION HEADING	EU LEGAL REQUIREMENTS	TOPIC
5.1.	The effectiveness of corrective actions in response to recommendation 1 of the 2024 Commission audit report	Chapter 2 of Annex I to Commission Implementing Regulation (EU) 2021/808	Validation of analytical methods for residues of pharmacologically active substances.
5.2.	The effectiveness of corrective actions in response to recommendation 2 of the 2024 Commission audit report	Article 10(2)(a) of Commission Delegated Regulation (EU) 2022/2292	Requirements as regards the prohibition of certain substances .
		Article 127(3)(d) of Regulation (EU) 2017/625	Requirements for inclusion, and maintenance, in the list of third countries referred to in point (a) of Article 126(2) of Regulation (EU) 2017/625.