EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and food audits and analysis

DG(SANTE) 2022-7490

FINAL REPORT OF AN AUDIT
CARRIED OUT IN
INDIA
FROM 07 SEPTEMBER 2022 TO 29 SEPTEMBER 2022
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 of India, carried out from 7 to 29 September 2022 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 and for which India is seeking approval of its residues monitoring plans. The audit assessed the implementation of the residue monitoring plan for the commodities in question and the reliability of the guarantees offered by India in ensuring that the commodities concerned do not contain residues of veterinary medicinal products, pesticides and contaminants exceeding EU maximum limits. It also assessed the authorisation, distribution and use of veterinary medicinal products, given that these areas have an impact on the monitoring of residues.

Overall, this report concludes that the residue monitoring plan for aquaculture complies with the minimum requirements established in EU legislation and is implemented as planned. The implementation of the residue monitoring plan for milk, for which India is not approved, is weakened by the fact that the sampling and reporting strategy reduces the likelihood of non-compliances for certain substances being reported. Furthermore, a very high incidence of non-compliant results for aflatoxin M1 was noted for that programme.

With regard to follow-up of non-compliant results in aquaculture, investigations are undertaken quickly, but in many cases did not identify the origin of the non-compliance. The number of non-compliant results for residues of substances banned from use in food-producing animals in the EU and in Indian aquaculture, found in both the national residue monitoring plan and in the pre-export testing programme has not decreased in the last three years. In particular, there is a 20% noncompliance rate for such substances in samples taken in hatcheries and the over-the-counter availability of these substances on the Indian market is likely to contribute to the problem. The fact that the number of RASFF notifications for EU-banned substances in aquaculture products remains low, is more a reflection of the effectiveness of the mandatory pre-export testing programme in identifying and preventing the export of non-compliant consignments to the EU.

Concerning the laboratory network, there has been clear progress in their analytical performance since the previous Commission audit in 2018. Notwithstanding this, the effectiveness of testing in poultry is weakened by shortcomings in method validation as not all of the matrices tested have been validated to date.

With regard to veterinary medicinal products, there are few changes in comparison to the findings of previous Commission audit reports. Substances that are banned in the EU for use in food-producing animals remain on the market in India as over-the-counter medications (albeit not for aquaculture animals). Whilst there is a control system on the distribution and use of veterinary medicinal products, it contains many gaps in comparison to what is required in the EU and does not contribute to the guarantees on the residues status of food of animal origin provided by the various residue testing programmes in place.

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

TABLE OF CONTENTS

ABBREVIATIONS & DEFINITIONS USED IN THIS REPORT

Abbreviation	**Description**
AHD	1-aminohydantoin (Marker residue of the nitrofuran drug nitrofurantoin)
AMOZ	3-amino-5-morpholinomethyl-2-oxazolidone (Marker residue of the nitrofuran drug furaltadone)
AOZ	3-amino-2-oxazolidinone (Marker residue of the nitrofuran drug furazolidone)
CAA	Coastal Aquaculture Authority
EC	European Community
EIA	Export Inspection Agency
EIC	Export Inspection Council
ELISA	Enzyme-Linked Immuno-Sorbent Assay
EU	European Union
Group A, B	Categories of substances listed in Annex I to Council Directive 96/23/EC
ISO	International Organisation for Standardisation
LC-MS/MS	Liquid Chromatography-(Tandem) Mass Spectrometry
ML	Maximum Level
MPEDA	Marine Products Export Development Authority
MRL	Maximum Residue Limit
NABL	National Accreditation Board for Calibration and Testing Laboratories
PET	Pre-Export Testing
PHT	Pre-Harvest Testing
RASFF	Rapid Alert System for Food and Feed
SDLA	State Drug Licensing Authorities
SEM	Semicarbazide (Marker residue of the nitrofuran drug nitrofurazone)
SFA	State Fishery Authority

1 INTRODUCTION

The audit took place during the period from 7 to 29 September 2022 and was undertaken as part of the planned work programme of the Directorate-General for Health and Food Safety and following a request by the Indian competent authority to list additional commodities in the Annex to Commission Decision 2011/163/EU.

It covered India´s system of controls on residues and contaminants in live animals and animal products and the effectiveness of official controls on the use of veterinary medicinal products in food-producing animals. The audit team comprised three auditors from the Commission and one expert from a European Union (EU) Member State.

This audit was carried out by using a combination of remote meetings (by videoconference) and on-the-spot visits. Opening meetings were held on the 7th and 12th September 2022 with representatives of the Export Inspection Council (EIC), the Export Inspection Agencies (EIAs) from Delhi, Mumbai, Kochi, Kolkata and Chennai, the Marine Products Export Development Authority (MPEDA), the Coastal Aquaculture Authority (CAA), the Central Drugs Standard Control Organisation (CDSCO), the Department of Animal Husbandry and the Food Safety and Standards Authority of India (FSSAI).

At these meetings, the objectives of the audit were confirmed, and the control systems were described by the competent authorities. Representatives from the EIC and the central MPEDA accompanied the audit team during the on-the-spot part of the audit.

2 OBJECTIVES OF THE AUDIT

The objective of the audit was to verify the effectiveness of official controls on residues and contaminants in live animals and animal products eligible for export to the EU and for which India was seeking residue monitoring plan approval (and listing in the Annex to Decision 2011/163/EU ([1])). The audit team assessed:

- the adherence to the residue monitoring plans approved by the EU for aquaculture products;
- the guarantees provided by the residue monitoring plans implemented for milk and poultry, for which India has sought listing as mentioned above; and
- the reliability of the guarantees offered by India in ensuring that the commodities concerned do not contain residues of veterinary medicinal products, pesticides and contaminants exceeding EU maximum limits.

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

([1]) From 15 December 2022, this Decision is repealed and replaced by Annex -I to Regulation (EU) 2021/405.

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

MEETINGS/VISITS			COMMENTS
COMPETENT AUTHORITIES	**Central**	**2**	Opening and closing meetings with representatives of - Export Inspection Council - Export Inspections Agencies from Delhi, Mumbai, Kochi, Kolkata, Chennai and Kochi. - Marine Products Export Development Authority - Coastal Aquaculture Authority - Central Drugs Standard Control Organisation - Department of Animal Husbandry - Food Safety and Standards Authority of India
	Regional	**4**	Meetings at the States (Kerala, Odisha, Gujarat, and Tamil Nadu) visited and meetings with local authorities at establishments visited
LABORATORIES		**7**	- EIA Pilot Test House laboratory Mumbai (milk residue monitoring plan) - EIA laboratory Chennai (poultry residue monitoring plan) - MPEDA laboratory Kochi (aquaculture residue monitoring plan) - MPEDA laboratory Odisha -Bhubaneswar (aquaculture residue monitoring plan) - EIA laboratory Kochi (aquaculture pre-export testing) - EIA laboratory Chennai (aquaculture pre-export testing) - MPEDA Laboratory Odisha-Bhubaneswar (aquaculture pre-harvest testing)
OPERATORS		**22**	1 dairy plant, 2 milk collection centres and 2 dairy farms 2 poultry meat establishment and 2 poultry farms 3 aquaculture processing plants, 3 aquaculture farms, 2 hatcheries 3 veterinary medicines wholesaler/retailers, 2 aquaculture supply shops

3 LEGAL BASIS

The audit was carried out under the general provisions of EU legislation, and in particular Articles 120, 122 and 150 of Regulation (EU) 2017/625 of the European Parliament and of the Council.

Full legal references are provided in Annex I. Legal acts quoted in this report refer, where applicable, to the last amended version. Relevant provisions of the EU legal acts cited in Annex I are referred to in the individual findings.

4 BACKGROUND

4.1 COUNTRY STATUS IN RELATION TO EU-APPROVAL OF RESIDUE MONITORING PLANS

India is listed in the Annex to Decision 2011/163/EU with approved residue monitoring plans for aquaculture products (finfish and crustaceans), eggs, honey and casings.

India has requested to be listed in said Decision for poultry and milk. Given India's listing for dairy products required to undergo a specific risk-mitigating treatment against foot and mouth disease in Annex XVIII to Regulation (EU) 2021/404, residue plan approval is required for the country to be listed in Regulation (EU) 2021/405, pursuant to Article 16 thereof. For poultry, India is neither listed in Annex XIV to Regulation (EU) 2021/404 (animal health – fresh meat) nor in Annex XV to that

Regulation for meat products from poultry. Thus, residue plan approval for poultry would not in itself, permit exports of either fresh or processed poultry meat to the EU.

4.2 SUMMARY OF PREVIOUS COMMISSION AUDITS

The most recent audit during which residue controls in India were evaluated was carried out in 2018 (audit reference DG (SANTE) 2018-6345 MR-Final- hereafter: the 2018 audit ([2])). It concluded that the planning and implementation of residue monitoring for aquaculture products was largely in line with the legal requirements and supported by a functioning laboratory network and extensive additional pre-harvest testing and pre-export testing programmes which focussed on a limited range of substances. However, its effectiveness was weakened by a limited scope of analysis for certain pharmacologically active substances available on the market and weak follow-up of non-compliances that often did not identify their origin and lacked the legal tools to sanction producers.

The monitoring plans for milk and poultry were not deemed to provide guarantees equivalent to those foreseen in EU legislation with regard to the number of samples taken, the scope of testing (range of substances tested for) and laboratory performance. These issues militated against listing of either commodity in the Annex to Decision 2011/163/EU.

With regard to veterinary medicinal products, it found that labelling had improved relative to previous audits. In comparison to the EU, prescription requirements were limited and there was a lack of requirements for the maintenance of treatment records on farms. The availability of many substances not authorised for use in food-producing animals in the EU was also noted, a long-standing issue.

There were four recommendations made, three of which were addressed satisfactorily by the competent authorities. The one recommendation regarding validation of laboratory methods was followed up during this audit.

4.3 RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF) NOTIFICATIONS

Commission Decision 2010/381/EU ([3]), as last amended, requires that 50% of the aquaculture consignments of Indian origin arriving at EU borders are tested for residues of chloramphenicol, tetracycline, oxytetracycline, chlortetracycline and metabolites of nitrofurans 3-amino-2-oxazolidinone (AOZ), semicarbazide (SEM), 1-aminohydrantoin (AHD) and 3-amino-5-morpholinomethyl-2-oxazolidone (AMOZ). The same decision requires that all consignments are accompanied by a laboratory result from the place of origin (hereafter, the pre-export testing - PET) for the same substances. The data for 2020 to 2022 indicate (see below) that without the 100% PET obligation, the number of RASFFs in the EU would have been much higher.

([2]) https://ec.europa.eu/food/audits-analysis/audit_reports/details.cfm?rep_id=4055.

([3]) Commission Decision 2010/381/EU of 8 July 2010 on emergency measures applicable to consignments of aquaculture products imported from India and intended for human consumption (OJ L 174, 8.7.2010, p. 51).

The following table shows the implementation and results from 2020 to 2022:

Year	No of non-compliant PET results	No of non-compliant tests at EU border
2020	31(AOZ) - 0.9% of export consignments	4 (AOZ)
2021	24 (AOZ) – 0.47% of export consignments	3 (2x AOZ, 1 chloramphenicol)
2022 (Jan-Aug)	39 (AOZ) – 1.1% of export consignments	0

4.4 PRODUCTION AND TRADE INFORMATION

With regard to products either currently being exported to the EU (aquaculture finfish and crustaceans) or intended for export to the EU (poultry and milk), India applies a segregated market model whereby only this defined population of animals/products is eligible for the EU market. It is based on the annual production volume that theoretically *could* be exported to the EU in a given year. In 2021, for aquaculture, it covered 259 hatcheries and 73.872 farms registered for export, plus 393 processing plants approved for exports that produced in 2021 approximately 851,000 tonnes of crustaceans and 3,290 tonnes of finfish. In 2021 India exported 52,889 tonnes of aquacultured crustaceans and 637 tonnes of finfish to the EU.

For milk the model covers one dairy plant that receives milk from approximately 1,200 collection centres and 710,000 farms which produced, 962,314 tonnes of raw milk in 2020/21.

For poultry the model covers 4 processing establishments that received poultry from 958 farms and produced 77,107 tonnes of poultry meat in 2020/21.

5 FINDINGS AND CONCLUSIONS

5.1 RESIDUE MONITORING

5.1.1 Competent authorities

1. The central competent authority is the EIC under the Ministry of Commerce and Industry. The EIC and its five regional EIA offices are responsible for the planning, implementation, and supervision of the residue monitoring plan as well as for the approval, registration and execution of official controls on aquaculture, poultry and dairy production, processing, trading and export establishments, in line with national provisions ([4]). EIA officials also collect the residue monitoring samples for milk and poultry.

([4]) The Export (Quality Control and Inspection) Act, 1963, and amendments thereof, for the sound development of the export trade of India through quality control and inspection and for matters connected therewith for: a) aquaculture: Notification No S.O. 497 (E) of 10 March 2011 amended the Export of Fresh, Frozen and Processed Fish & Fishery Products (Quality Control and Inspection and Monitoring) Rules

2. As regards residue monitoring in samples drawn from aquaculture farms and processing establishments several other competent authorities are involved:

- MPEDA which is a statutory body under the same Ministry, implements the residue monitoring plan for aquaculture products under the guidance of the EIC. MPEDA's regional and subregional division offices are responsible for sampling at processing establishments, aquaculture farms, hatcheries and feed mills.

  Furthermore, MPEDA, in line with national legal provisions ([5]), has been appointed as one of the designated authorities for the enrolment of farms supplying aquaculture products for export, as well as of hatcheries and feed mills supplying feed to exporting aquaculture farms. MPEDA´s tasks include ensuring that enrolment numbers for farms are unique and not in conflict with any numbering system of other recognised registration authorities (e.g. the CAA and State Fishery Authorities (SFAs).

- The CAA has the responsibility for aquaculture farms and hatcheries in salt and brackish waters in coastal areas (i.e. within two kilometers of the high tide lines of the coast and rivers). Other aquaculture farms (e.g. inland freshwater farms) fall under the responsibility of the individual SFAs.

3. All aquaculture farms with an enrolment number provided by MPEDA can supply (farmed) finfish or shrimp to EIC-approved establishments for export to the EU, provided that they request and pass successfully a Pre-Harvest Test (PHT) showing that the products to be harvested do not contain nitrofurans and chloramphenicol.

5.1.2 Planning of residue monitoring

Findings

4. The EIC stated that the residue monitoring plans for aquaculture finfish and crustaceans, milk and poultry are based on the EU requirements ([6]) and the audit team could confirm that the residue monitoring plans largely follow these.

5. The planning process for residue monitoring begins early enough to ensure sufficient time for the implementation of the sampling plan for aquaculture from January to December and for milk and poultry from April to March the following year.

6. With regard to the 2021 residue monitoring plan, the planned sample numbers per commodity fulfil the overall minimum requirements indicated in EU legislation ([7]). For

---

from 1995; b) milk: S .O. 4031(E) dated 9th November, 2020 notifying Milk and Milk Products for quality control and inspection prior to export plus S .O. 4032(E) dated 9th November, 2020 called as the Export of Milk and Milk Products (Quality Control, Inspection and Monitoring) Rules, 2020; and c) poultry: Order No S.O. 1377(E) dated 30.12.2002 notifying Fresh Poultry Meat and Poultry Meat Products for quality control and inspection prior to export plus Notification No S.O. 1378(E) dated 30.12.2002 called as the Export of Fresh Poultry Meat and Poultry Meat Products (Quality Control and Inspection and Monitoring) Rules, 2002 and amendments thereof.

([5]) Order EIC/D(Q/C)/T-1/11-12.

([6]) Annexes II and IV to Directive 96/23/EC and the Annex to Commission Decision 97/747/EC.

([7]) Annex IV to Directive 96/23/EC, Article 1 and the Annex to Decision 97/747//EC.

aquaculture, they are based on the national production volume of all of the MPEDA-enrolled farms; for milk, on the production capacity of sole EIC-authorised dairy processing establishment and its associated farms and for poultry, on the production capacity of four EIC-approved processing establishments, which receive birds from those farms which aim to produce for the EU market. Sample numbers are distributed across the different states or regions according to the production volume of the commodity and the species concerned (see chapter 4.4).

7. In line with what is expected in the EU ([8]) all of the main aquaculture species (crustaceans and finfish) exported to the EU are covered by the residue monitoring plan. The residue monitoring plan for milk covers bovine milk, and the one for poultry, broilers.

8. During the elaboration of the residue monitoring plans two factors were taken into account, the production volume and the laboratories` analytical capacity. The audit team was not presented with evidence indicating whether other factors such as the availability or likelihood of use of particular veterinary medicinal products, or previously non-compliant results for a given analyte, were taken into account in the planning process.

9. The scope of testing for the residue monitoring plans for all three commodities includes all of the required substance groups and has been significantly expanded since the 2018 audit. Notwithstanding the expansion in scope, some pharmacologically active substances which are authorised and used in practice for the treatment of animals are not included in the plans.

- The scope for aquaculture has been, as agreed between the Commission and the EIC, widened since 2020 for a sub-set of 1% (459 samples) of all samples taken. The sub-set is analysed for an additional 18 substances in Group B1 (4 macrolides: erythromycin, tilmicosin, tylosin, spiramycin; 7 beta-lactams: amoxicillin, ampicillin, benzylpenicillin, dicloxacillin, oxcillin, cloxacillin, colistin; 2 aminoglycosides: spectinomycin, neomycin; 2 cephalosporins: cefalexin, cefapirin plus lincomycin, trimethoprim and doxycycline).
- The audit team noted that methyltestosterone (Group A3), which is used in India for sex-differentiation in some finfish species, has not yet been included in the scope of testing for finfish. ([9])
- The scope for poultry has been widened both for Group B1 with regard to macrolides, lincosamines and aminoglycosides and as well for Group B2a for which 5 anticoccidials (maduramicin, amprolium, salinomycin, monensin, nicarbazin and

([8]) Article 1 and Chapter 2 of the Annex to Commission Decision 97/747/EC.

([9]) In its response to the draft report the competent authority noted that methyl testosterone is used in the tilapia hatcheries for the production of all male tilapia. It is not used in the grow out stages. There is no evidence of its usage in other fin / shell fish species in aquaculture.

robenidine) have been added. Toltrazuril, which is authorised in India for use in poultry, has not yet been added.

- The scope for milk has been widened for Group B1 with regard to sulphonamides, beta-lactams and beta-lactam inhibitors such as taxobactam and sulbactam. It does not yet cover marbofloxacin and streptomycin, both of which were seen to be used on the dairy farms by the dairy plant`s veterinarians met by the audit team. It also does not cover certain substances in Group B2a such as triclabendazole and closantel which were seen to be used by the State Veterinary services during their annual anti-parasitic treatment campaigns at dairy farms. The scope of substances in Group B2e has been widened to include phenazone.

Furthermore, the audit team identified substances that are contained in veterinary medicinal products available on the Indian market, that are authorised use in food-producing animals in India, but not in the EU and which are not included in the respective residue monitoring plans. These concerned in Group B1, ceftizoxime and ceftriaxone, both of which are authorised in India for poultry and bovine animals plus ofloxacin, perfloxacin and ornidazole (in Group A6) which are authorised in India for bovine animals.

Notwithstanding the above, **recommendation No 1** of the 2018 audit report has been largely addressed.

10. In the 2021 and 2022 residue monitoring plans, the detection limits of the screening and confirmatory methods, as well as action levels for all analyte/matrix combinations were the same as those applicable in the EU ([10]).

Conclusions on planning of residue monitoring

11. For aquaculture for which India has an approved residue monitoring plan and for poultry and milk, for which it is seeking residue monitoring plan approval, the planning process is timely, sufficient sample numbers are planned, and the range of analytes included in the respective plans is much greater than was the case in the previous audit. Nevertheless, there is room for improvement in terms of the scope of testing, as evidenced by the fact that several substances on the Indian market were not included in the current residue monitoring plans and these were seen to be used in the relevant species.

5.1.3 Implementation of the residue monitoring plan

Findings

12. There are clear instructions ([11]) governing the implementation of the residue monitoring plans for aquaculture, milk and poultry. These are largely harmonised with the relevant

([10]) Table 1 of the Annex to Regulation (EU) 37/2010, Article 4 and Annex II to Decision 2002/657/EC or the levels recommended by the European Union Reference Laboratories.

([11]) India's residue monitoring plans for: a) poultry meat and poultry meat products, b) milk and c) aquaculture products.

EU requirements ([12]). In line with these instructions, sampling is unforeseen, spread throughout the year and covers the main production areas. Furthermore, residue monitoring samples are collected using adequate sampling material, sealed and transported ensuring their integrity, traceability and legal validity.

13. The 2021 residue monitoring plan for aquaculture (including samples at all hatcheries to be analysed for nitrofurans and chloramphenicol) and the 2021/22 plans for milk and poultry were implemented as planned.

14. For milk the EIC instruction on how to implement the residue monitoring plan reduces the likelihood of detecting substances included in Group A6 (banned antimicrobials) and Group B1 (antimicrobials) and in Group B2a (anthelmintics). This is due to the fact that the EIC instructed their laboratory to divide the total number of samples into 7 subsets that are each analysed with a multiresidue method, but where only certain substances included in the multi-residue method had to be reported in a given subset. Thus, if a non-compliance had been found for any of the *other* substances included in the subset´s multiresidue method it would not have been reported as a non-compliance. This is contrary to what would be expected in the EU ([13]).

15. Similar to EU rules, aquaculture samples to be analysed for Group A were taken at farm/hatchery level at all stages of farming ([14]). Milk samples were taken from individual farms when delivered to milk collection centres ([15]) and poultry samples to be analysed for substances in Group A were taken both at farm and at slaughterhouse level ([16]). There was a mechanism to avoid that samples were taken from the same farms, either at farm level or at processing establishment level. At one poultry processing plant visited by the audit team all 92 of the farms supplying it (and all of which intend to provide for the EU market, should India be successfully listed in the requisite EU Regulations for animal health, public health and residues) were eligible to be sampled. For the second processor visited, 723 out of the 1,937 farms supplying it were deemed to be able to supply to the EU market (as per the caveats above) and this second processor had specific days on which only poultry from those 723 farms would be processed and from which residue monitoring samples were taken.

16. The implementation of the aquaculture national residue monitoring plan is regularly monitored through an on-line data base by MPEDA which notifies all of the MPEDA offices/centres and the EIC about the plan's implementation status and the non-compliant results found. Monthly updates on the implementation of the poultry and milk residue monitoring plans are reported by the respective EIA offices to the EIC.

17. The residue monitoring plan for aquaculture specifies that samples have to be forwarded to the designated laboratory within three days and reach the laboratory after

([12]) Annex III to Directive 96/23/EC, Annex II to Regulation (EU) 2021/808.
([13]) Point 1(a) of Article 5 of Regulation (EU) 2017/625 (read in conjunction with Points 1 and 2 of the Annex III to Directive 96/23/EC and Point 1(B) of Chapter 1 of the Annex to Decision 97/747/EC).
([14]) Point 1 of Chapter III of the Annex IV to Directive 96/23/EC.
([15]) Point 3 of the Annex II to Regulation (EU) 2021/808.
([16]) Chapter 2 of the Annex IV to Directive 96/23/EC.

dispatch within 30 hours. The plans for milk and poultry specify that samples have to be delivered to the designated EIA laboratory within 48 hours of being taken.

Conclusions on the implementation of the residue monitoring plan

18. The residue monitoring plans for aquaculture animals, poultry and milk are implemented in a timely manner and in line with planned arrangements. Nevertheless, the sampling and reporting policy adopted for milk could impair the ability of the competent authority to identify non-compliant samples.

5.1.4 Other residues monitoring programmes

5.1.4.1 PHT for aquaculture

19. National legislation ([17]) requires that export establishments approved for export to the EU can source aquaculture products only from enrolled farms (see finding 3) that participate in the official PHT programme. This programme requires that all aquaculture batches harvested at farm are sampled and tested prior to harvest for the presence of chloramphenicol and four nitrofuran metabolites. Non-registered farms will, following a successful inspection, then be registered and subsequently will be able to participate in the PHT programme.

20. There is a process to ensure traceability of the PHT result to the specific farm and pond. Every pond is enrolled and identified with its Global Positioning System co-ordinates that define its exact surface area and location. Each pond is sampled by MPEDA staff and harvested separately and no aggregate samples are allowed. Furthermore, sampling forms have to include all of the required information to ensure traceability to the pond. However, on two farms visited in Odisha, the audit team found inconsistencies in the traceability records concerning stocking and harvesting data and the number of ponds compared to the data in the MPEDA database. In relation to the size of the sample, officials calculate the estimated size of the batch in the pond based on the size of the pond, the stocking density and the average size of the shrimp.

21. All samples are then sent to an MPEDA-run network of 15 laboratories performing enzyme-linked immunosorbent assays (ELISA). The cost of the ELISA tests is paid for by the farmer; MPEDA pays for the cost of any confirmatory tests required. Once the testing is done, the result reports have a validity of 20 days. If the pond is not harvested in that timeframe, sampling and testing needs to be repeated. When the pond is harvested, the system imposes a 3-month period until the next PHT sampling.

22. The three processing plants visited by the audit team had put in place mechanisms to minimise the risk of non-PHT tested product to be included in the batch, such as the crosschecking of amounts received with the production estimated for the pond. All the examples reviewed by the team during the audit of consignments of aquaculture

([17]) S.O. 497(E) of 10 March 2011.

products received at the processing plants, exported or subject to PET testing were accompanied by PHT results.

23. Since January 2020 until August 2022 there were 7 non-compliant PHT test results recorded by MPEDA.

5.1.4.2 PET scheme for aquaculture

24. European legislation ([18]) requires that all consignments of aquaculture products entering the Union from India are accompanied by the result of an analytical test for chloramphenicol, metabolites of nitrofurans, tetracycline, oxytetracycline and chlortetracycline, carried out at the place of origin.

25. To fulfill the above-mentioned requirements, the EIC has instructions in place which specify that:

- a composite sample is to be taken from each exported consignment that can contain products from a maximum of 4 daily production codes from the processing establishment. If the consignment includes products from more than 4 production codes, then a second composite sample needs to be taken from the additional production codes;
- composite samples of each exported consignment must be representative and include finished product from each code and pond;
- the samples must be analysed in an accredited EIA laboratory using validated methods (see finding 55). Each result of the (composite) PET sample applies to the whole consignment, consisting of a maximum of 4 production codes.

26. Between January 2020 and August 2022 there were 94 non-compliant PET test results reported. After a decrease in 2021 the percentage of non-compliant PETs increased in 2022 to levels seen in 2020 (see chapter 4.3).

27. In the three processing establishments visited by the audit team, PET tests were conducted by the EIA as required. In two cases, which were evaluated by the team and where prohibited substances had been found, the whole consignment had been destroyed and evidence from the rendering facility provided to the audit team.

28. With regard to the low number of non-compliances for the PHT (7) compared to the considerably higher number in the PET (94) in the period from January 2020 to August 2022, neither the EIC nor MPEDA had realised or could explain the reasons for the anomaly, albeit with different test types being employed in each programme. If anything, the PHT ELISA should have a *higher* false positive rate than the LC/MS/MS confirmatory methods in the PET programme. EIC had not analysed from where (establishments and states) the PET non-compliances had been found most frequently to help them improve their understanding of the origin of non-compliant results in the PET.

([18]) Decision 2010/381/EU amended by Commission Implementing Decisions (EU) 2012/690 and (EU) 2016/1774.

5.1.4.3 Official monitoring in EIC-approved export establishments (EIA monitoring scheme)

29. Establishments approved by the EIC for export are inspected by the EIA every one to three months depending on risk. Every six months samples are collected from all such establishments and are tested in an EIC-approved laboratory for the presence of antimicrobials including chloramphenicol, nitrofuran metabolites and tetracyclines.

5.1.4.4 Establishment own-checks

30. All three aquaculture processing establishments visited during the audit had, as part of their Hazard Analysis Critical Control Points system, a critical control point related to residues in raw material inputs. One conducted in-house ELISA tests for nitrofurans and had never found any non-compliant results. The other two processers sent samples to an accredited private laboratory for analysis for a range of antimicrobials (covering those banned and authorised in the EU), pesticides and heavy metals.

31. The dairy processing establishment visited had two own-check programmes in place for residues. In the first, each batch of raw milk received at the establishment is tested with a commercially available dipstick screening test for antimicrobials which covered certain penicillins, cephalosporins, tetracyclines and sulphonamides with national maximum residue limits (MRLs) in line with those applicable in the EU ([19]). Six antimicrobials (including two cephalosporins ceftriaxone and cefuroxime), two aminoglycosides (gentamycin and streptomycin) and two fluoroquinolones (enrofloxacin and marbofloxacin), all of which are on the list of antimicrobials for dispensation to dairy cows by the veterinarians of the same dairy processing establishment/cooperative, are not covered by the dipstick screening test. Neither ceftriaxone nor cefuroxime have a Maximum Residue Limit (MRL) established in the EU. The audit team was informed that the dipstick test had never been verified (i.e. shown to work) by the laboratory staff in the dairy processing establishment and they did not have access to 'positive control' samples or analytical standards. No non-compliances had been found from January 2020 to August 2022. In the second own-check programme, one sample was taken every two months from one of the 1,200 collection centres belonging to the dairy processing establishment to be analysed for aflatoxin M1. Staff from the dairy cooperative informed the audit team, that to date (and in marked contrast to the results found in the national residues plan – see finding 48), no non-compliances had been found for this contaminant.

32. The two poultry processors visited also operated self-monitoring programmes for residues and sent their samples to an ISO 17025-accredited EIA laboratory. The scope of substances largely mirrored that of the poultry residue monitoring plan. To date no non-compliances have been found but there are instructions to notify the EIA in the event of any non-compliances.

([19]) Regulation (EU) No 37/2010

Conclusions on other residue monitoring programmes

33. The PHT and PET schemes for aquaculture are implemented as planned by the competent authorities and they are useful in helping identify non-compliant batches and preventing their certification by the EIC and consequent export to the EU. Nevertheless, the difference in the non-compliance rates between the PHT and PET programmes is hard to explain and has not been investigated by the competent authorities. The additional testing of the products under establishments' own-control programmes has the potential to provide further assurances on the compliance of the commodities in question.

5.1.5 Follow-up of non-compliant results

Findings

5.1.5.1 Aquaculture

34. The EIC is responsible for coordinating the follow-up investigations of RASFF notifications. It calls on the concerned EIA to create an assessment panel comprising of experts from the EIA, MPEDA and the Central Institute of Fisheries Technology. The role of the panel is to carry out documentary and on-the-spot verification at the relevant processing establishments and farms.

35. The relevant EIA is responsible for coordinating the follow-up of non-compliant results found in the respective residue monitoring plans. After transmitting the alert notification along with the test results through an electronic system, a panel is created consisting of the EIA, MPEDA and the concerned CAA to jointly carry out documentary and on-the-spot verification in the processing establishments and farms, to take follow-up samples and to identify the origin of the contamination. A joint report is created and the EIAs are to take measures as required with regard to the processing establishments or farms concerned; the CAA does likewise for the hatcheries that fall under its jurisdiction.

36. The EIAs are also responsible for follow-up investigations of PET non-compliant results. There is no legal requirement for the non-compliant ELISA results in the MPEDA PHT programme to be followed up ([20]).

37. The residue monitoring plan contains documented procedures for the management of non-compliant results found in the residue monitoring plan and procedures are also described in the EIC executive instruction for aquaculture species ([21]). These procedures largely address key elements of follow-up of non-compliant results as

([20]) In its response to the draft report the competent authority noted that MPEDA on its own, has investigated all seven PHT positive cases to trace the root cause.

([21]) Chapter 13 in the "National residue control plan for aquaculture products" and chapter 10.2 of the "Executive instructions for approval and monitoring of fish and fishery products for export".

expected in the EU ([22]) and include measures such as an increase in the frequency of inspections, compulsory residue tests of subsequent consignments, temporary suspension, fines and revocation of the approval in the event of second time violations.

38. Based on information available on the EU RASFF portal and provided by the competent authority during the audit, the audit team reviewed 11 cases that occurred from 2019 to 2021. These concerned the RASFF notifications for nitrofurans (8 cases), chloramphenicol (2 cases) and dyes (1 case). In all cases follow-up investigations commenced promptly and involved both the processing establishment as well as the farms concerned. In nine cases a lack of product traceability was mentioned in the report as the potential reason for the non-compliance and it was speculated that contaminated products of unknown origin might have caused the non-compliance. In three cases it was mentioned in the report that farmers had sold to middlemen who might have mixed raw material from other farms, in the product that was then sent to the processing establishment.

39. Measures taken in the event of a RASFF notification, included in most cases the temporary suspension of the processing establishments, increase in the frequency of official controls and the establishments being officially instructed to be more vigilant during their procurement of raw materials. In three cases, letters were sent to: MPEDA requesting it to revoke the registration of the farm involved; the Commission of Fisheries of the state and the CAA, requesting them to take actions and to the Seafood Exporters Association requesting it to inform its members not to purchase raw materials from the farm concerned.

40. With regards to residue monitoring plan results, the non-compliance rate for Group A6 substances (chloramphenicol and nitrofurans) varied by year and by sampling site type. For samples drawn from *aquaculture farms and processing establishments* these were, by year: 2018: 7 cases – 0.37%; 2019: 18 cases - 0.81%, 2020: 6 cases – 0,29% and 2021: 23 cases – 0.9%. Regarding samples drawn from *aquaculture hatcheries*: 2018: 70 cases – 38%, 2019: 32 cases – 18%, 2020: 44 cases – 20% and 2021: 52 cases – 20%). Also, 2021 was the first year in which all 259 hatcheries were sampled for the presence of substances in Group A6. With regard to samples of *aquaculture feed* analysed for chloramphenicol and nitrofurans between 2018 to 2021, there were no non-compliant results in the 13 to 19 samples taken each year.

41. The above data demonstrate that, notwithstanding the ban on use of chloramphenicol and nitrofurans in Indian aquaculture ([23]) illegal use, particularly at hatchery level remains a sizable problem. In contrast, there were no non-compliant results for other antimicrobial substances in Group B1 from samples taken between 2018 and 2021 with around 2,500 samples being analysed each year (for a limited scope of substances) and since 2019 approximately 459 samples (1% of all samples) being analysed for an extended scope of substances.

([22]) Regulation (EU) 2019/2090.
([23]) Order S.O. 722 (E) of 10/07/2002.

42. The audit team reviewed 9 examples of follow-up investigations after the detection of residues of EU-banned substances (Group A6). Investigations both at the processing establishments and farms concerned took place immediately (with a few COVID-related exceptions), and the products or animals were detained, similar to what is required in the EU ([24]). Said investigations included a review of the documentation in the processing establishments such as production traceability records, reports of PHT and PET, reports of in-house pre-purchase testing etc. and follow-up sampling. On farms there was a review of the production cycle logbooks for each pond, the sourcing of larvae, feedingstuffs, disinfectants and other inputs, and follow-up samples from relevant ponds. These actions are similar to what is required in the EU ([25]).

43. Notwithstanding the actions that were taken, the source of the non-compliance was not identified in any of the 9 cases. The official reports concluded that the contamination came from unknown/unidentified inputs. In one case, where a follow-up sample had been taken from feed, which was non-compliant for chloramphenicol, no further action had been taken to trace the affected feed back to the distributor or producer of the feed. In a second case the official report highlighted that feed was suspected as a *potential* source, but this hypothesis was not backed up by any sampling of the feed.

44. Dissuasive measures taken by the EIC and EIA at processing establishments in which non-compliant results had been detected under the residues monitoring plan, consisted of the destruction of the affected product, in some cases the temporary suspension of the processing establishment, obligatory testing of five subsequent production batches intended for export to the EU and enhanced monitoring visits as per national requirements ([26]). At farm level, MPEDA informed the audit team, that no farm during the last three years, from which non-compliant product had originated, had been penalised in any way or had had their MPEDA enrolment suspended or withdrawn. The latter is different to the EU requirements ([27]). At hatchery level, the audit team was informed that in 2021/2022 the registration of 6 crustacean hatcheries, which had repeat non-compliances for banned antimicrobials, had been temporarily suspended.

45. According to EIC and MPEDA, the imposition of penalties on aquaculture farms, such as fines being levied or temporary or permanent closure, fall under the responsibility of the States` fishery and coastal aquaculture authorities. In the past, several states lacked a legal basis to take such measures though the audit team was provided with evidence that two states (Kerala and Andhra-Pradesh) now had such legislation ([28]) in place which allowed for the imposition of fines and revocation of licenses. Furthermore, in 2022, the main aquaculture-producing states had created district and task force committees, mandated to implemented stringent measures to curtail the use of banned

([24]) Point 2 of Article 6 of Regulation (EU) 2019/2090.
([25]) Point 4 of Article 6 of Regulation (EU) 2019/2090.
([26]) Chapter 10.2.2 and 16.1.4. of the "Executive instructions for approval and monitoring of fish and fishery products for export.
([27]) Article 8 of Regulation (EU) 2019/2090.
([28]) Kerala Fish Seed Act 2014, Kerala Inland Fisheries Aquaculture Act 2010 and Andhra Pradesh State Aquaculture Development Authority Act 2020.

antimicrobials in aquaculture ([29]). Committee members include district fisheries officers, food safety department officers, drug control authority officers, representatives of the revenue department, the police department, MPEDA and various stakeholders. The committees are empowered to conduct checks at aquaculture shops; manufacturing companies and suppliers of drugs, probiotics, chemicals, feeds and feed supplements; farms and hatcheries to verify and take action on the possession and use of unauthorised antimicrobials in aquaculture. Controls can include sampling, label checks, checks on veterinary medicinal products sales etc. Deterrent measures can be imposed such as fines (first offence = 25,000 rupees (€300); second offence 50,000 rupees (€600) or the revocation of licenses. The latter would be similar to what is required in the EU ([30]).

46. With regards to PET non-compliances for banned substances, the EIAs are required to do a documentary and on-the-spot control at the concerned processing establishment and to verify that it has developed a plan to avoid the reoccurrence of the non-compliance both at processing level and on the farms from which it had received the crustaceans. The EIAs do not conduct an on-the-spot follow-up investigation on the farms concerned to verify if the measures imposed by the processing establishment have actually been taken by the farmer. They also do not inform either MPEDA about the implicated processing establishments and farms or the Coastal Aquaculture Authorities about the farms.

5.1.5.2 Milk

47. The EIC and their EIA offices are responsible for the follow-up of non-compliances found in the milk residue monitoring plan. Furthermore, documented procedures for the management of non-compliant results are described in a specific EIC executive instruction for milk ([31]), that includes key elements as applicable in the EU ([32]).

48. A significant proportion of the residue monitoring samples analysed in the last three years for Group B3d (aflatoxin M1) were non-compliant ((2018/2019: 90 samples and 34 non-compliances (37%), 2019/2020: 90 samples and 10 non-compliances (11%), 2020/2021: 51 samples and 19 non-compliances (37%)). There were no residue monitoring plan non-compliances for any other substance group in the last three years, though that might be due to the fact that instructions were in place that clearly limited the effectiveness of detecting substances included in Group A6 (banned antimicrobials), Group B1 (antimicrobials) and Group B2a (anthelmintics) (see finding 14 and 67).

([29]) Andhra Pradesh order G.O. MS. No 2 dated 11.01.2017; Goa order No DF/AQUA/TFC-Antibiotics-misuse- 2022-23/2644, dated 03.08.2022; Gujarat resolution No: FDV-132017-GOI-24-T, dated 30.08.2022; Karnataka order G.O. AHF E-113 FSFS 2019, dated 28.02.2020; Kerala order G.O.(Rt) No 290/2022/F&P, dated 11 May 2022; Maharashtra resolution No: Matsyavi 1122/CR 118/ADF 14, dated 15.06.2022; Odisha order No 13871-6/FARD dated 23.11.2017, Tamil Nadu order T.O. (Ms). No 54, dated 13.06.2022 and West Bengal order No 1640-FI-999/28/2022, dated 25 July 2022.

([30]) Article 139 of Regulation (EU) 2017/625.

([31]) General procedure CODE: PG-12/01 "Actions taken in the case of non-compliant foodstuffs".

([32]) Regulation (EU) 2019/2090.

49. The audit team reviewed nine aflatoxin M1 results that were found between September 2020 and June 2022. In all cases the EIA quickly informed the processing establishment to seize the affected product, identify the source of the contamination, take corrective measures and requested a report summarising the outcome of actions to the EIA. The official follow-up investigation started promptly (in general within two days) and included measures that were largely equivalent to those foreseen in EU legislation ([33]) for example: identification of the source of contamination, taking follow-up samples, conducting on-the-spot visits, increasing the frequency of official controls etc. In two of the nine cases, the official follow-up investigation report did not describe the (final) outcome of the investigation. The competent authority informed the audit team that new legislation on animal feed is currently in the process of being developed and will include measures that aim to prevent the contamination of feed with aflatoxin B1.

50. The source of contamination was in all cases identified as feed that had been contaminated with aflatoxins. Feeds used at the dairy farms supplying milk to the dairy processing establishments, were largely treated with mycotoxin binders, but data seen by the audit team indicated that these are effective in about 70% of the treated feed. In one case seen by the audit team, follow-up samples taken from 339 batches of feed that had been treated with the mycotoxin binder revealed that 39 remained non-compliant for aflatoxins after the treatment.

5.1.5.3 Poultry

51. The EIC and their EIA offices are responsible for the follow-up of non-compliances found in the poultry residue monitoring plan. Furthermore, documented procedures for the management of non-compliant results are described in chapter 10 of the poultry EIC executive instruction and chapter 11 of the residue monitoring plan for poultry, these largely include key elements as applicable in the EU ([34]). There have been no non-compliances in poultry residue monitoring plan samples since 2020.

([33]) Articles 4 and 5 of Regulation (EU) 2019/2090.
([34]) Regulation (EU) 2019/2090.

Conclusions on follow-up of non-compliant results

52. Documented procedures for the follow-up of non-compliances found under the residue monitoring plans are largely equivalent to those foreseen in the EU and investigations are mostly implemented promptly. Nevertheless, the follow-up of the aquaculture non-compliances for banned substances and actions taken to prevent recurrence have not been effective as evidenced by the continuing high rate of non-compliant results in samples drawn from hatcheries and in the PET programme. Similarly, the continuing high incidence of aflatoxin M1 findings in raw milk suggest that measures to address and mitigate this problem are not particularly effective.

5.1.6 Laboratories

Findings

53. The laboratory network relevant for the scope of the audit consisted of:

a) laboratories involved in testing samples under the residue monitoring plans for:
   - aquaculture: 5 MPEDA laboratories (in Kochi, Bhimavaram, Nellore, Porbandar and Bhubaneswar and one EIA laboratory in Chennai (dioxins only);
   - milk: the EIA Pilot Test House laboratory in Mumbai;
   - poultry - the EIA laboratory in Chennai.

b) laboratories responsible for analysis under the PET programme for aquaculture products with regard to tetracycline, oxytetracycline, chlortetracycline chloramphenicol and nitrofuran metabolites: three EIA laboratories (in Chennai, Kochi, Mumbai and Kolkata);

c) laboratories responsible for screening analyses under the PHT programme for shrimp for chloramphenicol and nitrofuran metabolites: 15 MPEDA ELISA laboratories.

54. Similar to what is expected in the EU ([35]) all laboratories involved in testing residue monitoring samples and the PET programme are ISO/IEC 17025 accredited by the National Accreditation Board for Calibration and Testing Laboratories (NABL) which is a full member of International Laboratory Accreditation Cooperation. All EIA and MPEDA laboratories have a number of residue methods included in their respective scopes of accreditation. Of the 15 MPEDA ELISA laboratories involved in the PHT, 4 are accredited, each with residues methods listed in their scope of accreditation.

55. Similar to the EU requirements ([36]) and as described in the 2018 audit, all laboratories involved in official residues controls testing must hold an approval from the EIC. Under the EIC approval process, ISO 17025 accreditation audits are conducted as an integrated assessment by the NABL and the EIC in parallel, as described in the NABL document 127 ([37]). For the laboratories visited during the audit, EIA Chennai, EIA Kochi, EIA Mumbai, MPEDA Kochi and MPEDA Bhubaneswar, the integrated

([35]) Article 37(4)(e) of Regulation (EU) 2017/625.
([36]) Article 39(1) of Regulation (EU) 2017/625.
([37]) https://nabl-india.org/nabl/file_download.php?filename=202011170504-NABL-127-doc.pdf

assessment status was verified by the audit team and is reflected in each laboratory's scope of accreditation with the inclusion of the date of assessment and the official seal of the EIC on each page of the respective document describing the scope.

56. The laboratories visited were:

Laboratory	**Area of testing covered during the visit**
EIA Mumbai	milk – residue monitoring plan
EIA Kochi	aquaculture – PET
EIA Chennai	poultry – residue monitoring plan
	aquaculture – PET
MPEDA Kochi	aquaculture – residue monitoring plan
MPEDA Bhubaneswar	aquaculture – residue monitoring plan
	aquaculture – PHT

57. Similar to measures required in the EU ([38]), in all of the laboratories visited there were procedures and instructions for sample reception and handling and these were adhered to. In the sample reception areas, sample seals, temperature, quantity and sample submission forms are checked, and details recorded with evidence seen of the recording of sample deviations and follow-up communications to flag rejected samples and request additional sampling. Additionally, residue monitoring samples were stored in appropriate and adequately monitored conditions.

58. The EIA and MPEDA laboratories use electronic systems such as an in-house laboratory information management system used by the EIA and an electronic tool called "e-National Residue Control Plan" used by MPEDA to log and track sample analysis in the laboratory. Furthermore, seals for samples drawn under the residue monitoring plans, the PET and the PHT have a unique ID number which is checked against the details recorded on the sample form at the time of reception and sample login at the laboratory. These measures are similar to what is required in the EU with regard to sample traceability ([39]).

59. The laboratories visited indicated that they operated an agreed sample analysis turnaround time of 10 days (EIA laboratories Mumbai, Kochi, Chennai), 15 or 20 days (MPEDA Bhubaneswar, MPEDA Kochi) from the receipt of the samples. The documents inspected by the audit team indicated that these analysis turnaround times were largely achieved and in the case of the EIA, Mumbai, this was an improvement relative to the 2018 report.

60. The storage and management of reference standards was found to be adequate in all of the laboratories visited. Internal standards and matrix-matched calibration were used routinely for the Liquid Chromatography-(Tandem) Mass Spectrometry (LC-MS/MS) methods evaluated. In the case of ELISA for PHT, the test kits used are supplied with

([38]) Points 1, 5 and 7 of Annex II to Regulation (EU) 2021/808.
([39]) Point 3 of Annex II to Regulation (EU) 2021/808.

reference standards. At the time of the audit, all of the MPEDA ELISA laboratories were using test kits from the same manufacturer.

61. All of the laboratories visited had quality control procedures in place; these included the use of blank samples, reagent blanks, non-compliant controls spiked at appropriate concentrations in matrix, blind control check samples and duplicate samples. The audit team examined the method quality control charts in each laboratory and these were generally found to be adequate for monitoring longer term trends in method performance. In the case of the EIA laboratory in Chennai however, it was found that while the laboratory had quality control charts in place with data recorded over the past 2 years in the examples seen, trends in the control data were not evaluated routinely. The only prescribed control criteria considered by the laboratory were breaches of the calculated chart control limits or recovery levels outside the range of 80 to 120%. Trending patterns of data points were not considered by the laboratory; for example, a certain number of data points above or below the mean or a certain number of data points showing a continuous increase/decrease in recovery. This is not fully in line with ISO 17025 ([40]) standard or EU requirements ([41]).

62. Evidence was provided that all of the laboratories involved in testing under the residues monitoring plan had participated in proficiency testing. This is in line with expectations in the EU ([42]). With regard to the laboratories visited, the EIA Chennai laboratory had participated in one proficiency test for poultry since 2018 (lasalocid (Group B2b)) and the EIA Mumbai laboratory has participated in three proficiency tests for milk since 2019 (chloramphenicol (Group A6), sulphonamides (Group B1) and heavy metals (Group B3c)). The visited laboratories had recently participated in the following relevant proficiency with satisfactory results:

- EIA Mumbai: heavy metals (Group B3c) in milk powder;
- EIA Chennai: lasalocid (Group B2b) in poultry; nitrofurans (Group A6), quinolones (Group B1) and sulphonamides (Group B1) in shrimp; nitrofurans (Group A6), dyes (Group B3e) and heavy metal (Group B3c) in fish;
- EIA Kochi: quinolones (Group B1), chloramphenicol (Group A6), nitrofurans (Group A6), tetracyclines (Group B1) in shrimp; nitrofurans (Group A6) in fish;
- MPEDA Kochi: tetracyclines (Group B1), nitrofurans (Group A6) in shrimp; mycotoxins (Group B3d) in fish;
- MPEDA Bhubaneswar: tetracyclines (Group B1), nitrofurans (Group A6) in shrimp; nitrofurans (Group A6) sulphonamides (Group B1), dyes (Group B3e) in fish.

63. In those instances where the results of proficiency tests would be unsatisfactory, all of the laboratories visited had a root cause analysis procedure in place to identify the cause and implement appropriate corrective actions.

64. For testing under the residue monitoring plan, only chemical confirmatory methods are used, and all of the analytical methods reviewed by the audit team had decision limits

([40]) Chapter 7.7 of ISO/IEC 17025.
([41]) Chapter 3 of Annex I to Regulation (EU) 2021/808.
([42]) Article 38(2) of Regulation (EU) 2017/625 and Article 4 of Regulation (EU) 2021/808.

(CC-alpha) determined in line with the requirements for confirmatory methods, which is similar to what is required in the EU ([43]). In the case of the PHT the ELISA methods reviewed by the audit team determined the cut-off level in line with the approach recommend by the European Union Reference Laboratories ([44]). The sensitivity of all of the chemical confirmatory methods checked was seen to be adequate, as the detection limits of the methods in use were lower than or equal to the respective reference points for action ([45]) (where established) and were lower than EU MRLs ([46]), EU maximum levels ([47]) or the European Union Reference Laboratories' recommended minimum method performance requirements (MMPRs) ([48]).

65. Similar to what is required in the EU ([49]), in all of the laboratories visited, where non-compliant results are detected, they are reported promptly to the sampling officer and to the relevant authority.

5.1.6.1 EIA Pilot Test House Mumbai

66. Control of access to the sample reception area and laboratory is in line with the expected requirements ([50]), which is an improvement versus what was seen during the 2018 audit.

67. Regarding the laboratory's approach to analysis, described in Annex 3 to the residues control plan for milk in India, individual samples are tested on the basis of one of 7 "Sets" of substances. Each "Set" covers several compounds from different residue groups/subgroups and several analytical methods must be used to cover all substances in that set. The chemical confirmatory analytical methods used are mainly multi-residue methods which cover more than one analyte for a particular residues group (*i.e.,* for one analytical procedure for substances in Group B1, erythromycin A, spiramycin, tilmicosin and tylosin A can be determined in the same analysis run). Not all of these, even though they can be quantified, are included in the respective set, though, and if a non-compliant result is found for a substance not included in the respective set, it is not reported. This is contrary to what would be expected in the EU ([51]) (see finding 14 and 48).

68. The audit team assessed the validation files for the following methods in milk:

- nitroimidazoles (Group A6) metronidazole and ronidazole by LC-MS/MS;
- nitrofuran metabolites (Group A6), AOZ, AMOZ, AHD, SEM by LC-MS/MS;
- chloramphenicol (Group A6) by LC-MS/MS;

([43]) Point 2.6 of Chapter 2, Annex I to Regulation (EU) 2021/808.
([44]) CRL guidelines for the validation of screening methods for residues of veterinary medicines 2010.
([45]) Annex to Commission Regulation (EU) 2019/1871.
([46]) Annex to Regulation (EU) No 37/2010.
([47]) Regulation (EC) No 1881/2006, Regulation (EC) No 396/2005.
([48]) EURL guidance on minimum method performance requirements (MMPRs) for specific pharmacologically active substances in specific animal matrices.
([49]) Point 7 of Annex II to Regulation (EU) 2021/808
([50]) Point 6.3.4 of EN ISO/IEC 17025.
([51]) Points 1 and 2 of Annex III to Directive 96/23/EC and Point 2 of Chapter 1 of the Annex to Decision 97/747/EC.

- aflatoxin M1 (Group B3d) by LC-MS/MS;
- anthelmintics (Group B2a), ivermectin by LC-MS/MS;
- beta-lactams including cephalosporins (Group B1) by LC-MS/MS;
- lead (Group B3c) by inductively coupled plasma mass spectrometry.

All methods inspected were found to be adequately validated with appropriate validation criteria and concentration ranges applied in line with the EU regulations in force at the time of the validation ([52])([53]), although not fully in line with the additional validation criteria laid down in the most recent EU regulation ([54]). The laboratory indicated during the audit that it was aware of the latest validation requirements and inclusion in future validations has been flagged.

5.1.6.2 EIA Kochi

69. The audit team assessed the validation files for the following methods:

- chloramphenicol (Group A6) in shrimp and fish by LC-MS/MS;
- nitrofuran (Group A6) in shrimp and fish by LC-MS/MS;
- tetracyclines (Group B1) in shrimp and fish by LC-MS/MS.

All were found to be adequately validated with appropriate validation criteria and concentration ranges applied in line with the Regulation (EU) 2021/808.

5.1.6.3 EIA Chennai

70. The method for beta-agonists in poultry muscle is now validated at appropriate levels with appropriate decision limits, which is an improvement versus the 2018 audit.

71. The audit team assessed the validation files for the following methods:

- chloramphenicol (Group A6) in poultry muscle by LC-MS/MS;
- tetracyclines, quinolones and sulphonamides (Group B1) in poultry muscle by LC-MS/MS;
- anticoccidials (Group B2b) in poultry muscle by LC-MS/MS;
- chloramphenicol (Group A6) in shrimp and aquaculture feed by LC-MS/MS (PET);
- nitrofuran metabolites (Group A6) in shrimp by LC-MS/MS (PET).

For finfish muscle and shrimp, the validation reports reviewed, assessed all of the required criteria at appropriate concentration levels in line with the EU Decision (2002/657/EC) in force at the time of the validation but are not in fully line with the latest EU legislation on method validation, Regulation (EU) 2021/808. The laboratory indicated that it was aware of the introduction of the new requirements for method validation in said Regulation.

72. For the poultry methods above, the validation reports of other tissues and matrices included in the residue monitoring plan were requested. These included poultry liver,

([52]) Annex I to Commission Decision 2002/657/EC.
([53]) Annex to Commission Regulation (EC) No 333/2007.
([54]) Annex I to Regulation (EU) 2021/808.

kidney, fat & skin, body fluid (serum), farm water and feed. At the time of the visit, no validation had been performed for these other matrices. In this respect there has been no change to what was found during the 2018 audit and thus **Recommendation 3** of that audit report has not been addressed fully. The use of unvalidated methods for official controls testing is contrary to what would be required in the EU ([55]). Evidence was seen of the inclusion of a recovery check spiked matrix for non-validated matrices in recent analysis batches for anticoccidials (B2b) in liver. Whilst this is a sensible approach, there was no documented procedure indicating how the recovery data was applied to mitigate the non-validated status of these matrices and the laboratory had yet to analyse these recovery data with a view to validating matrices other than poultry muscle.

73. During the audit, the laboratory proposed to submit data for a two-day mini validation for the outstanding matrices. After the audit, validation results were submitted to the audit team for tetracyclines, quinolones and sulphonamides (Group B1) in kidney, liver and fat by LC-MS/MS. The files received did not include a comparison of the calculated validation parameters for the new matrices to poultry muscle. Thus the audit team could still not conclude that the method was fit for purpose for matrices other than muscle. No further validation details were received for any of the other laboratory methods in poultry matrices.

5.1.6.4 MPEDA Kochi

74. The audit team assessed the validation files for the following methods:

- nitrofurans and chloramphenicol (Group A6) in shrimp and fish by LC-MS/MS;
- malachite green (Group B3e) in shrimp and fish by LC-MS/MS;
- tetracyclines, sulphonamides and beta-lactams (Group B1) in shrimp and fish by LC-MS/MS.

All of these methods were found to be adequately validated with appropriate validation criteria and concentration ranges applied in line with Decision 2002/657/EC which was in force at the time of the validation. However, not all methods met the validation requirements laid down in the most recent EU legislation (Regulation (EU) 2021/808). The laboratory indicated that activities have already commenced to meet these more recent EU requirements.

5.1.6.5 MPEDA Bhubaneswar

75. The audit team assessed the validation files for the following methods:

- nitrofurans (Group A6) in shrimp and finfish by LC-MS/MS;
- dyes (Group B3e) in shrimp and finfish by LC-MS/MS;
- tetracyclines and quinolones (Group B1) in shrimp and finfish by LC-MS/MS;
- chloramphenicol (Group A6) screening in shrimp by ELISA (PHT);
- nitrofurans (Group A6) screening in shrimp by ELISA (PHT).

([55]) Article 3 of Regulation (EU) 2021/808.

In spite of the fact that the laboratory no longer tests finfish (in either the 2021 or 2022 residue monitoring plans), the majority of these methods were found to be adequately validated with appropriate validation criteria and concentration ranges applied in line with the EU Decision (2002/657/EC) in force at the time of the validation, though not all methods met the validation requirements laid down in Regulation (EU) 2021/808.

Conclusions on laboratories

76. Relative to the 2018 audit, improvements have been made in the performance of residue testing laboratories, particularly in respect of aquaculture products. Nevertheless, there is still a sizable number of analytical methods for residues in poultry matrices (other than muscle) which have yet to be validated, and in this respect there has been little progress since 2018.

5.2 VETERINARY MEDICINAL PRODUCTS

5.2.1 Authorisation, distribution and use of veterinary medicinal products

77. The manufacture, import, sale and distribution of drugs and drug products are regulated under the Drugs and Cosmetics Act (1940) and Rules (1945) both for human and veterinary medicinal products. It is implemented at national level by the Central Drugs Standard Control Organisation (CDSCO) (under the Directorate-General of Health Services of the Ministry of Health and Family Welfare) and at state level by their State Drug Licensing Authorities (SDLA). The CDSCO is responsible, *inter alia,* for the approval of new drugs (granted for 4 years), based on which the SDLA can approve the manufacturing of the drug in their state with a license validity of 5 years.

78. Drug manufacturers and wholesalers for veterinary medicinal products must be authorised (licensed) similar to what is required in the EU ([56]). Retail outlets also require a licence prior to being allowed to sell veterinary medical products. This is done by the SDLA in the state / state region in which they operate with licenses that are up for renewal every five years. The CDSCO stated that there are approximately 600,000 registered drug outlets/pharmacies registered in India. All of the wholesalers and pharmacies visited during the audit had valid licenses.

79. Drugs (for veterinary or human use) which include substances that require a prescription by a qualified practitioner (doctor or veterinarian) are listed in schedule H and H1 of the Drugs and Cosmetics Act and Rules. The most recent version of schedule H (31.12. 2016) lists 536 substances, of which only a few are relevant for use in food-producing animals. Schedule H1, includes 46 substances which include antimicrobials such as 3rd and 4th generation cephalosporins and some quinolones.

80. The list of schedule H substances includes the term “antibiotics” and lists furthermore several specific antimicrobial substances. The competent authority informed the audit

([56]) Articles 88 and 99 of Regulation (EU) 2019/6.

team that due to the mentioning of the term "antibiotics", all drugs containing antimicrobial substances are prescription drugs. Nitrofurans and chloramphenicol, banned in the EU for use in food-producing animals, are surprisingly, not included in either Schedule H and H1, and can legally be sold over-the-counter. The presence of nitrofurans on the market was confirmed by the audit team for furazolidone, nitrofurazone and furaltadone in several products for bovine animals and poultry. In aquaculture the use of nitrofurans, chloramphenicol, nitroimidazoles ([57]) as well as of stilbenes, steroids and dyes ([58]) is prohibited in India. This is similar to what is foreseen in the EU ([59]).

81. For the prescription-only schedule H and H1 drugs, the pharmacy is not required to keep a copy of the prescription. For schedule H drugs, a sales register is required with the name of the prescriber. This is different to what is required in the EU ([60]). For schedule H1 drugs, the pharmacy needs to keep the name and address of the prescriber, the name of the patient and the name of the drug and its quantity supplied ([61]) which is similar to what is required in the EU ([62]).

82. The CDSCO provided the audit team with the list of in India approved veterinary medicinal products. This list includes substances that are not authorised or explicitly prohibited for use in food-producing animals in the EU ([63]) such as dimetridazole, several nitrofurans, cefuroxime, buparvaquone and tolfenamic acid. The audit team identified that the list was incomplete as it did not include several veterinary medicinal products containing, *inter alia,* tetracycline, streptomycin, gentamycin, doxycycline, ceftriaxone (not allowed in the EU for food-producing animals), sulfadiazine, penicillin, fenvalerate, bromhexine and cloprostenol, which the audit team saw during their visits. Furthermore, the list does not mention the approval number of the product, nor in many cases product labelling or leaflet information such as the product name, the target species, nor the information on the required withdrawal periods per commodity, which is different than what is required in the EU ([64])

83. In two out of three states visited by the audit team, official staff from the respective SDLA provided the audit team with their state´s list of approved veterinary medicinal products. The third state did not do so when requested. The lists of the two states were largely identical to that of the CDSCO. SDLA staff therefore have little available information to determine whether a veterinary medicinal product found at a wholesaler, pharmacy or on a farm is approved and if the label information on target species or withdrawal periods are in line with those of the approval. This is different to the situation in the EU ([65]).

([57]) Points c and d of Order S.O. 722 (E) of 10/07/2002.
([58]) Point h of Order S.O. 1227(E) of 23/10/2003.
([59]) Regulation 37/2010 and Article 11 of Council Directive 96/22/EC.
([60]) Point 3(f) of Article 103 of Regulation (EU) 2019/6.
([61]) Point 3.1.g of Article 65 of the Drugs and Cosmetics Act and Rules.
([62]) Point 3(f) of Article 103 of Regulation (EU) 2019/6.
([63]) Table 1 and 2 of Regulation (EU) No 37/2010.
([64]) Articles 55 and 56 of Regulation (EU) 2019/6.
([65]) Point 32 of Article 4 and Points 1 and 2 of Article 123 of Regulation (EU) 2019/6.

84. Labelling requirements for veterinary medicinal products are laid down in Indian legislation ([66]) and are largely similar to those required in the EU ([67]). Containers of veterinary medicines have to be labelled with the words 'Not for human use; for animal treatment only', shall indicate "*inter alia*" the name of the drug, the pharmacologically active substances, the target species, the respective withdrawal periods, the expiry date, the batch number and as specific requirement for India, a symbol depicting the head of a domestic animal. All of the veterinary medicinal products checked by the audit team were correctly labelled.

85. The only two substances specifically prohibited for use in all food-producing animals in India are diclofenac since 2008 and colistin since 2019. Further to what was seen in the 2018 report, the competent authority informed the audit team that there are no longer any approved veterinary medicinal products containing diethylstilbestrol for use in cattle, sheep, goats and poultry. This is similar to the situation in the EU ([68]).

86. Certain antimicrobials are allowed to be used in aquaculture for therapeutic or zootechnical purposes when authorised by a qualified veterinary surgeon or fishery scientist ([69]). These include tetracycline, oxytetracline, trimethoprim and oxolinic acid which are also authorised for use in aquaculture in the EU. The use of other antimicrobials is prohibited in Indian aquaculture.

87. Compared to the EU, the audit team noted differences in the pharmacologically active substances authorised for different food-producing animal species. For example, in the EU where there may be a restriction on use (e.g. not for use in lactating animals), this was not the case in India (e.g. for doxycycline, ivermectin and doramectin). There were also substances on the market for use in various food-producing animal species for which no MRL has been established for said species in the EU (e.g. cefuroxime, ceftriaxone, ceftizoxime, tazobactam, ofloxacin, pefloxacin, ornidazole, phenylbutazone and paracetamol).

88. Different to the approach in the EU ([70]), national manufacturers of veterinary medicinal products indicated on the labelling information (for most of veterinary medicinal products to be used in dairy cows and other species) withdrawal periods which are not based on depletion studies but rather the withdrawal periods provided for in the EU for off-label use ([71]). National legislation ([72]) allows, when the withdrawal period has not been validated, the application of a default withdrawal period of 7 days for milk and 28 days for meat. At the retailers and wholesalers visited, most of the veterinary medicinal products for food dairy cows and other producing animals including those containing antimicrobials and anthelmintics had a 'standard' withdrawal period of 7 days for milk

([66]) Articles 96 and 97 of part IX of the Drugs and Cosmetics Act and Rules
([67]) Articles 10 and 11 of Regulation (EU) 2019/6.
([68]) Article 11 of Council Directive 96/22/EC
([69]) Point b of Order S.O. 722 (E) of 10/07/2002 read in conjunction with point h of Order S.O. 1227(E) of 23/10/2003.
([70]) Regulation (EC) No 470/2009.
([71]) Article 115 of Regulation (EU) 2019/6.
([72]) Point 3(a) of Article 97 of Part IX of the Drugs and Cosmetics Act and Rules.

and 28 days for meat. Even for poultry the withdrawal period was often 28 days for meat which, if followed would mean that broilers could not be legally treated after a week of age.

89. The competent authority informed the audit team that national legislation does not allow "off-label use", thus the use of human medicinal products for food-producing animals or veterinary medical products authorised for species other than the one indicated in the label instructions. However, in two pharmacies visited by the audit team, human medicines had been prescribed for food-producing animals. In one case this concerned the nitroimidazole tinidazole (not approved in the EU for food-producing animals). In another case, a product containing doxycycline (even though there are approved veterinary medicinal products containing doxycycline). The latter example is different to what is required in the EU ([73]).

90. Similar to the situation in the EU ([74]), national rules ([75]) require farmers to keep treatment records at dairy, poultry and aquaculture farms. The audit team found that with regards to dairy farms, there was a central electronic treatment record database at the dairy processing establishment visited, which recorded all treatments administered on its affiliated dairy farms by or under the supervision of the establishment's veterinarians. The audit team could verify at the processing establishment, the two milk collection centres and the two farms visited, that the recorded information was similar to what is required in the EU ([76]). Nevertheless, not all treatments were recorded. For example the annual deworming (using albendazole, fenbendazole, triclabendazole or closantel, the latter two of which are not included in the residue monitoring plan) or ectoparasitic treatment (using cypermethrin and amitraz) campaigns conducted by the state´s veterinary service. In the two collection centres visited, the audit team established that that milk from dairy cattle had been delivered to the processor within the withdrawal period of the substances used in the deworming campaigns.

91. For poultry, the on-farm treatment records on the two poultry farms visited included treatments with neomycin, chlortetracycline and the anticoccidial amprolium. The two processing establishments visited by the audit team had a process in place which required that treated poultry could not be delivered to the establishment but only sold on the local market after the expiration of a 28 day withdrawal period. The information provided in the on-farm record was largely in line with what would be expected in the EU ([77]). For aquaculture, there was a register of inputs on the farm visited but there had been no treatments with veterinary medicinal products in recent times. There are also national rules ([78]) applicable to aquaculture farms allowed to produce for the EU

([73]) Point 1(c) of Article 113 of Regulation (EU) 2019/6.
([74]) Article 108 of Regulation (EU) 2019/6.
([75]) Point 7.3 and points 2.3(j), 3.2(b) and 4.2 (d) of the Annex IC to Executive Instructions for Export of Milk and Milk Products (2022); Point II.6 (b) of the Annex IC to the Executive Instructions for Export of Fresh Poultry Meat and Poultry Meat Products (2015) and Appendix C (Traceability record) of the Executive Instructions for Approval and Monitoring of Fish and Fishery Products for Export.
([76]) Article 108 of Regulation (EU) 2019/6.
([77]) Article 108 of Regulation (EU) 2019/6.
([78]) Articles 6(5) and 13 of Notification S.O. 497 (E) dated 10th March 2011

market; they shall only source feed, or if authorised, medicated feed, from EIC-approved and registered feedmills.

92. There is no legislation in place for the labelling of premixes of medicated feeding stuffs, feed additives, medicated feed or feed. Thus, the producer is at liberty to decide what information is provided on labels of such products. The audit team saw at the visited pharmacies nutritional supplements for cattle which included no information on the ingredients. The EIC informed the audit team that legislation to establish such a system is currently under preparation by the Food Safety and Standards Authority of India.

Conclusions on authorisation, distribution and use of veterinary medicinal products

93. While there is a system in place for the authorisation, distribution and use of veterinary medicinal products it differs significantly from that in the EU and practices which are not foreseen in the EU are, consequently, permitted in India, such as "off-label use" of human medicinal products in food-producing animal species. Cumulatively these differences detract from whatever guarantees on the residues status of food are afforded by the various residue monitoring plans in place.

5.2.2 Official controls on distribution and use of veterinary medicinal products

Findings

94. According to national legislation ([79]) the manufacturers and retail outlets for veterinary medicinal products should be inspected regularly which is similar to what is required in the EU ([80]). The minimum yearly inspection frequency at wholesalers and pharmacies visited by the audit team in three states was complied with by the respective SDLAs.

95. Inspections of drug outlets covered the licensing, labelling (species logo, expiry dates, withdrawal periods), storage conditions, and presence of unauthorised substances. The SDLA inspectors also took occasionally samples to check if the content of pharmacologically active substances in the medicinal products is in line with label indications, which is similar to the EU requirements ([81]). Inspections at pharmacies and wholesalers visited by the audit team were well documented using a template provided for in national legislation ([82]) and the SDLA officers promptly informed a licensee in writing of any case of non-compliance identified, which is similar to the EU requirements ([83]).

96. Due to an incomplete CDSCO or SDLA list of approved veterinary medicinal products (see finding 83), SDLA inspectors were not in a position to verify if a veterinary medicinal product found at a wholesaler, pharmacy or on a farm was indeed approved

([79]) Articles 50, 51 and 52 of Part V of the Drugs and Cosmetics Act and Rules
([80]) Points 1 and 2 of Article 123 of Regulation (EU) 2019/6.
([81]) Point 6 of Article 123 of Regulation (EU) 2019/6.
([82]) Form 35 of Schedule A of the Drugs and Cosmetics Act and Rules
([83]) Point 2 of Article 123 of Regulation (EU) 2019/6

and if the label information on target species, pharmacologically active substances or withdrawal periods were in line with the approval. SDLA staff met by the audit team, stated that they have to trust the labelling information on the veterinary medicinal products, as the existing list of approved veterinary medicinal products was incomplete and as it was not practically feasible to access the Veterinary Monographs of the Indian Pharmacopoeia for such information.

97. In the two wholesalers and two of the three pharmacies visited by the audit team, there was a register of the products sold which contained the information required by national legislation ([84]). However, given the national requirements for retention of prescriptions (see finding 81), the SDLA inspectors met during the audit stated that it would only be possible to detect an illegal sale without prescription for a schedule H drug if it took place while the inspectors were present. Furthermore, the SDLA inspectors stated that they cannot check if the name entered under "prescribing doctor" on the sales receipt is a licensed veterinarian/doctor for schedule H drugs, as the prescriber's contact details do not need to be kept in a register at the pharmacy.

98. With regards to official controls on the use of veterinary medicinal products, SDLA officers met by the audit team stated that they do not conduct official controls on the use of veterinary medicinal products at feed mills or at farm-level. At aquaculture hatcheries and on aquaculture farms such controls take place during the approval of a farm and in the context of any follow-up investigation of residue monitoring plan non-compliances.

99. As regards dairy farms, the audit team was informed that 1 out of the 710,000 farms supplying the visited dairy processing establishment had been subject to such controls when it had been initially approved and at its quarterly monitoring visit. Controls on use also have to take place in the context of follow-up investigations of residue monitoring plan non-compliances.

100. As regards poultry farms, a minimum of three poultry farms that are identified by the processing establishment they supply need to be officially monitored each year to verify, *inter alia*, the use of veterinary medicinal products at the farm. Evidence was provided to the audit team, that such controls took place at 4 out of 723 farms delivering to one of the two processors visited and 4 out of 92 farms delivering to the second processor visited (see finding 15).

101. EIC-approved feed mills producing feed for aquaculture farms registered to produce for export to the EU, have to undergo regular official controls as per national legislation ([85]). EIC instructions state that after the approval of the feed mill and two initial monitoring visits at 6 and 12 months after approval, subsequent monitoring visits shall happen yearly. During these visits it is to be checked, *inter alia,* if traceability and labelling records of feed is proper and if the incorporation of feed additives and premixes, the storage, handling and use of medicated feeding stuffs are done as

([84]) Drugs and Cosmetics Act and Rules

([85]) Article 11 of S.O. 730 (E) dated 21st August 199 and amended by Notification S.O. 497 (E) dated 10th March 2011

required in the EIC instructions. However, there are no legal requirements for labelling of such products in India (see finding 92). The EIC informed the audit team that currently no feed mill is approved to produce medicated feed for aquaculture farms registered to produce for export to the EU.

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

102. Whilst there is a national control system on the distribution and use of veterinary medicinal products, it has, in comparison with the EU, a number of gaps and omissions and thus, adds little to guarantees on the residues status of food afforded by the various residue monitoring plans in place.

6 OVERALL CONCLUSIONS

It is concluded that the residue monitoring plan for aquaculture complies with the minimum requirements established in EU legislation and is implemented as planned. The implementation of the residue monitoring plan for milk, for which India is not approved, is weakened by the fact that the sampling and reporting strategy reduces the likelihood of non-compliances for certain substances being reported. Furthermore, a very high incidence of non-compliant results for aflatoxin M1 was noted for that programme.

With regard to follow-up of non-compliant results in aquaculture, investigations are undertaken quickly, but in many cases did not identify the origin of the non-compliance. The number of non-compliant results for residues of substances banned from use in food-producing animals in the EU and in Indian aquaculture, found in both the national residue monitoring plan and in the pre-export testing programme, has not decreased in the last three years. In particular, there is a 20% noncompliance rate for such substances in samples taken in hatcheries, and the over-the-counter availability of these substances on the Indian market is likely to contribute to the problem. The fact that the number of RASFF notifications for EU-banned substances in aquaculture products remains low, is more a reflection of the effectiveness of the mandatory pre-export testing programme in identifying and preventing the export of non-compliant consignments to the EU.

Concerning the laboratory network, there has been clear progress in their analytical performance since the previous Commission audit in 2018. Notwithstanding this, the effectiveness of testing in poultry is weakened by shortcomings in method validation as not all of the matrices tested have been validated to date.

With regard to veterinary medicinal products, there are few changes in comparison to the findings of previous Commission audit reports. Substances that are banned in the EU for use in food-producing animals remain on the market in India as over-the-counter medications (albeit not for aquaculture animals). Whilst there is a control system on the distribution and use of veterinary medicinal products, it contains many gaps in comparison to what is required in the EU and does not contribute to the guarantees on the residues status of food of animal origin provided by the various residue testing programmes in place.

7 CLOSING MEETING

A closing meeting was held on 29 October 2022 with representatives of the central competent authority. At this meeting, the audit team presented the main findings and preliminary conclusions of the audit. The authorities offered some clarifications and stated that they would take actions to address the shortcomings identified during the audit.

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, within 25 working days of receipt of this audit report.

No	Recommendation
1	To ensure that the planning of residue monitoring reflects the range of veterinary medicinal products on the market. *Legal basis: Article 29 (1) of Directive 96/23/EC (read in conjunction with Article 150(2) of Regulation (EU) 2017/625.* *Recommendation based on conclusion: 11.* *Associated finding: 9.*
2	To ensure that the testing and reporting arrangements in place for the residue monitoring plan for milk do not exclude the reporting of non-compliant results. *Legal basis: Point 1(a) of Article 5 of Regulation (EU) 2017/625 (read in conjunction with Points 1 and 2 of the Annex III to Directive 96/23/EC and Point 1(B) of Chapter 1 of the Annex to Decision 97/747/EC).* *Recommendation based on conclusion: 18.* *Associated finding: 14*
3	To ensure that follow-up investigations of non-compliant results reflect the provisions of applicable EU legislation and are effective in facilitating operators exporting (or wishing to export) to the EU, to comply with the conditions for entry of such animals and goods to the Union. *Legal basis: Article 138 of Regulation (EU) 2017/625; Article 4 of Regulation (EU) 2019/2090* *Recommendation based on conclusion: 52.* *Associated findings: 38, 40, 43, 44, 46, 48, 49, 50.*
4	To ensure that all analytical methods used for the residue monitoring programmes are appropriately validated to provide guarantees equivalent to those laid down in EU legislation and, in particular, that method performance characteristics are

	established for all matrices tested. *Legal basis: Article 3 of Regulation (EU) 2021/808.* *Recommendation based on conclusion: 76* *Associated finding: 61, 71, 72 and 73.*

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=2022-7490

ANNEX 1 – LEGAL REFERENCES

Legal Reference	Official Journal	Title
Controls by the Commission Services		
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)Text with EEA relevance.
Approval of residue monitoring plans submitted by non-EU countries		
Dec. 2011/163/EU	OJ L 70, 17.3.2011, p. 40-46	2011/163/EU: Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC
Reg. 2021/404	OJ L 114, 31.3.2021, p. 1–117	Commission Implementing Regulation (EU) 2021/404 of 24 March 2021 laying down the lists of third countries, territories or zones thereof from which the entry into the Union of animals, germinal products and products of animal origin is permitted in accordance with Regulation (EU) 2016/429 of the European Parliament and the Council

Reg. 2021/405	OJ L 114, 31.3.2021, p. 118-150	Commission Implementing Regulation (EU) 2021/405 of 31 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
Monitoring of residues and contaminants in food of animal origin and Maximum Residue Limits and Levels		
Dec. 2010/381/EU	OJ L 174, 9.7.2010, p. 51-53	2010/381/EU: Commission Decision of 8 July 2010 on emergency measures applicable to consignments of aquaculture products imported from India and intended for human consumption
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
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

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. 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
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. 396/2005	OJ L 70, 16.3.2005, p. 1-16	Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC

Reg. 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. 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
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. 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
Authorisation and use of veterinary medicinal products		
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