EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health and Food Audits and Analysis

DG(SANTE) 2023-7732

FINAL REPORT
OF AN AUDIT CARRIED OUT IN
GERMANY
FROM 05 NOVEMBER 2023 TO 24 NOVEMBER 2023
IN ORDER TO EVALUATE THE OFFICIAL CONTROLS
RELATED TO THE SAFETY OF MILK AND DAIRY 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

Executive Summary

The report describes the outcome of an audit of Germany carried out by the Directorate-General for Health and Food Safety of the European Commission from 6 to 24 November 2023. The objective of the audit was to evaluate the operation of controls over the production of dairy products for human consumption.

The national legislation and administrative provisions that have been issued at central and Länder level covering the audited sector are in line with the relevant EU legislation.

The structure and organisation of the Länder competent authorities (CAs) responsible for the implementation of official controls provide an adequate framework for the performance of these tasks. Structures are in place to facilitate co-ordination between the 16 Länder.

The autonomy of the districts and district-free cities cause some challenges regarding the internal supervision of the districts and district free cities by Land or regional authorities (Mittelbehörde) and the verification of the effectiveness and appropriateness of official controls and enforcement.

Procedures are in place and were implemented mostly correctly for the registration and approval of dairy operators. However, the CAs were not always aware of all activities requiring approval, so these were not covered by the approval or verified during inspections. Moreover, in some cases the food business operators failed in their duty to inform the CAs of changes in their production. In one Land the same approval number had been given to three separate units of a food business operator that we not on the same premises.

The verification of compliance of dairy holdings with hygiene regulatory requirements is carried out in line with the legal requirements and the annual control plans. The established frequencies vary between the Länder.

The quality control system in place regarding somatic cell count and plate count for raw cow milk upon collection is well established and enforced by the dairy industry and controlled adequately by the local CAs. Non-compliant cases were effectively dealt with and followed-up by the dairy industry and during CAs' official controls.

The official controls of dairy business operators are risk-based and implemented in line with the planned annual control plan and documented adequately. However, the controls did not cover HACCP and microbiological criteria with sufficient depth and did not identify some relevant shortcomings. This limits the effectiveness of the implementation of official controls.

The report contains recommendations to address the shortcomings identified.

Table of Contents

ABBREVIATIONS AND DEFINITIONS USED IN THIS REPORT

Abbreviation	Explanation
AFFL	LAV Working Group on meat and poultry meat hygiene and technical issues relating to foodstuffs of animal origin (*LAV Arbeitsgruppe Fleisch- und Geflügelfleischhygiene und fachspezifische Fragen von Lebensmitteln tierischer Herkunft*)
AG QM	Working Group Quality Management (*Arbeitsgruppe Qualitätsmanagement*)
ALS	Working group of the Food Chemistry Experts of the Länder and of the BVL (*Arbeitskreis Lebensmittelchemischer Sachverständiger der Länder und des BVLs*)
AVV	General administrative provisions (*Allgemeine Verwaltungsvorschriften*)
AVV-RÜb	Framework Control Regulation (*Allgemeine Verwaltungsvorschrift über Grundsatze zur Durchführung der amtlichen Überwachung der Einhaltung der Vorschriftendes Lebensmittelrechtes, des Rechts der tierischen Nebenprodukte, des Weinrechts, des Futtermittelrechts und des Tabakrechts* (*AVV Rahmen-Überwachung*))
BALVI iP	General Software system with technical modules for official controls in the food and veterinary sector
BMEL	Federal Ministry of Food and Agriculture (*Bundesministerium für Ernährung und Landwirtschaft*)
BVL	Federal Office of Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und Lebensmittelsicherheit)
CA	Competent authority
CCA	Central competent authority
CFU	Colony forming units
DG Health and Food Safety	Directorate-General for Health and Food Safety of the European Commission
EU	European Union
HACCP	Hazard Analysis and Critical Control Points
LAV	Länder Working Group for Consumer Protection (*Länder Arbeitsgemeinschaft für Verbraucherschutz*)
L-CCA	Central (supreme) competent authority of a Land
LFGB	Food, Consumer Goods and Feed Code (Lebensmittel, Bedarfsgegenstande und Futtermittelgesetzbuch)
LMHV	Ordinance on Food Hygiene (*Lebensmittelhygieneverordnung*)
OCR	Official Controls 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

Abbreviation	Explanation
	animal health and welfare, plant health and plant protection products
PC	Plate count
QM system	Quality Management System
RCA	Regional competent authority (*Mittelbehörde*)
SCC	Somatic cell count
Tier-LMHV	Ordinance on the hygiene requirements of the production, processing and placing on the market of certain foodstuffs of animal origin (*Verordnung über Anforderungen an die Hygiene beim Herstellen, Behandeln und Inverkehrbringen von bestimmten Lebensmitteln tierischen Ursprungs*)
Tier-LMÜV	Ordinance regulating certain aspects of official controls on production, processing and placing on the market of foodstuffs of animal origin (*Verordnung zur Regelung bestimmter Fragen der amtlichen Überwachung des Herstellens, Behandelns und Inverkehrbringens von Lebensmitteln tierischer Herkunft*)

1 INTRODUCTION

The audit took of Germany took place from 6 to 24 November 2023 as part of the planned audit programme of the Directorate-General for Health and Food Safety of the European Commission (DG Health and Food Safety) and included remote meetings via videoconference as well as on-site visits. The audit was conducted by two auditors from DG Health and Food Safety.

The auditors were accompanied during the audit by representatives from the central competent authority (CCA), the Federal Ministry of Food and Agriculture (*Bundesministerium für Ernährung und Landwirtschaft*, (*BMEL*), the Federal Office of Consumer Protection and Food Safety, *Bundesamt für Verbraucherschutz und Lebensmittelsicherheit* (BVL), and by Länder central competent authorities (L-CCA).This audit took place in Germany from 05 November 2023 to 24 November 2023.

2 OBJECTIVES AND SCOPE

The main objective of the audit was to assess the system in place for official controls related to the safety of milk and dairy products. In terms of scope, the audit focused on the organisation and performance of the CAs and on the official control system in place covering production, processing and distribution chains applicable to milk and dairy products.

In pursuit of this objective, the audit included the following meetings:

COMPETENT AUTHORITIES		
Central	3	Opening and closing meeting with the representatives of BMVL and BVL and representatives of the *Länder* Lower Saxony, Hessen and Saxony
L-CCA and regional CA *(Mittelbehörde)*, if existing	3	Meetings with *Länder* CAs of Lower Saxony, Hessen and Saxony.
Local CA (district and district-free cities)	9	Meetings with the local CAs of the districts involved in the audited
Dairy establishments	10	7 on-the-spot and 3 remotely
Dairy holdings	2	1 bovine and 1 ovine holding on-the-spot

3 LEGAL BASIS

The audit was carried out under the general provisions of European Union (EU) legislation and, in particular Articles 116, 117 and 119 of Regulation (EU) 2017/625 of the European Parliament and of the Council.

EU legislation relevant to the audit is listed in the Annex to this report and refers, where appropriate, to the last amended version.

4 BACKGROUND

The last audit to evaluate the official controls with regard to the safety of milk and dairy products in Germany was carried out in 2016 (ref. DG(SANTE)/2016-6884). The report of that audit can be found at https://ec.europa.eu/food/audits-analysis/audit-report/details/3836. The audit report did not contain any recommendations. Information on the control systems in place can be found in the country profile for Germany available at: https://ec.europa.eu/food/audits-analysis/country/profile/details/DE.

Commission Implementing Regulation (EU) 2021/620 recognises Germany as having a disease-free tuberculosis and brucellosis status.

The number of bovine and small ruminant dairy holdings in 2022 was 52 859 and approximately 500, respectively. The 2022 (January-November) production of raw cow milk comprised 31 022 000 tonnes and of raw sheep and goat milk 15 117 tonnes.

The following amounts of dairy commodities were produced in 2022: 4 797 244 tonnes of liquid milk and cream, 684 639 tonnes of milk and cream powders, 3 167 335 tonnes of fermented milk, 16 303 611 tonnes of whey and milk protein concentrates (calculated as liquid whey, containing also lactose and lactalbumins), 453 260 tonnes of butter and other milk fats, 2 438 726 tonnes of cheese and curd and 21 212 tonnes of ice cream (containing milk fats).

5 FINDINGS AND CONCLUSIONS

5.1 LEGISLATION AND IMPLEMENTING MEASURES

Legal requirements

Article 291(1) of the Treaty on the Functioning of the European Union.

Article 5(1)(g) and (h) of Regulation (EU) 2017/625.

1. Directive (EU) 2015/1535 of the European Parliament and the Council The audit team received the comprehensive legislation covering safety of milk and dairy products, comprising the framework law, Food, Consumer Goods and Feed Code (*Lebensmittel, Bedarfsgegenstande und Futtermittelgesetzbuch, LFGB*) and more detailed provisions laid down in several ordinances (*Verordnungen*) and general administrative provisions

(*Allgemeine Verwaltungsvorschriften, AVV*). The relevant legal provisions are referred to in the chapters below and most of them are also described in the previous audit report (report DG(SANTE/2016-8842).

2. As a consequence of the implementation of the OCR, the Articles 36, 137 and 138 of the OCR have been incorporated into the *LFGB*. The Articles 49 and 50 of the Implementing Regulation (EU) 2017/627 resulted in modification of the Control Ordinance of Food of Animal Origin (*Tierische Lebensmittel-Überwachungsverordnung, Tier-LMÜV*). The system of raw milk quality control is further regulated by the Raw milk Quality Ordinance (*Rohmilchgüteverordnung*) and a nationally adopted guideline of the Milk Industry Organisation.

3. No national rules have been established in relation to point 2(c) of Article 1 of Regulation (EC) No 852/2004 or point 3 (c) of Article 1 of Regulation (EC) No 853/2004.

4. Point 8 of Article 10 of Regulation (EC) No 853/2004 is transposed by Articles 17 to 19 of the Ordinance on the Requirements for Food of Animal Origin (*Tier-Lebensmittelhygieneverordnung, Tier-LMHV).*

5. The national legislation contains derogations for traditional dairy products (Articles 6, 6a and Annexes 3 and 3a of the Ordinance on Food Hygiene (*Lebensmittelhygiene-verordnung, LMHV*) in line with Annex II of Regulation (EC) No 852/2004.

6. The Articles 17, 18 and 21 and Annex 9 of the *LMHV* regulate the provision and sale of raw milk and cream to the final consumer. Based on the *LMHV*, it is, in general, prohibited, with the exception of *Vorzugsmilch* (raw milk that can be sold only in prefabricated packaging and can be consumed as such) and direct sale of raw milk from a holding (which must be heat-treated before human consumption). *Vorzugsmilch* must also fulfil stringent microbiological criteria and criteria for PC and SCC. Article 19 of the *LMHV* provides the CA with the option to allow the use of raw milk that does not fulfil the criteria for somatic cell count (SCC) and plate count (PC) of Chapter I.3 or Chapter II, Section IX of Annex III to Regulation (EC) No 853/2004.

7. Article 6 of the *Tier-LMHV* regulates the sale of products of animal origin from retail to another retail. This is possible within 100 km and the amount sold can be up to one third of the product produced by the seller.

8. The AVVs provide provisions on the principles on official controls covering criteria for risk-based controls, official sampling, the multi-annual control plan, implementation of official controls, exchange of information, enforcement actions, implementation of the rapid Alert system, etc. The Framework Control Regulation *(AVV Rahmen-Überwachung, AVV-RÜb*) lays down the general principles for official controls and includes the provisions for risk classification of different types of food establishments.

9. In addition to the national legislation the *Länder* have laid down their implementing provisions to complement the national rules and to take account the *Länder*-specific CA

structure and allocation of responsibilities. These include procedures for establishing risk-based control plans and documentation relevant to these controls. Most of these are incorporated in a Quality Management System (QM system).

Conclusions on legislation and implementing measures.

10. The national legislation and administrative provisions that have been issued at central and *Länder* level covering the audited sector are in line with the relevant EU legislation.

5.2 COMPETENT AUTHORITIES

Legal requirements

Articles 4 and 5 of, and Annex II to Regulation (EU) 2017/625.

Findings

11. An overview of how the control system is organised in Germany is available in the country profile and the multiannual controls plan 2022-2026 available at the following links: https://ec.europa.eu/food/audits-analysis/country/profile/details/de and mancp_2022-2026_en.pdf (bund.de). A short summary of the control system relevant to the current audit is set out below.

12. The *BMEL* is the CCA (supreme federal authority) and responsible for drafting legislation at federal level regarding food safety and consumer protection. Within *BMEL* Unit 312 and Unit 314 are responsible for food monitoring issues. The *BMEL* has under its umbrella several other federal bodies. These include, in particular; the Federal Office for Consumer Protection and Food Safety (*Bundesamt für Verbraucherschutz*) and the Federal Institute for Risk Assessment (*Bundesinstitut für Risikobewertung*). The *BVL*, in cooperation with the *BMEL* and the ministries of the *Länder*, is the CCA for the management of risks and crises, and the Federal Institute for Risk Assessment is responsible for assessing risks to public health in the food sector and it also supports national reference laboratories in their work. The *BVL* is also responsible, for communication and coordination of activities between the 16 *Länder*, the federal authorities and the European Commission and it contributes to drafting of national control plans and monitoring programmes. In addition, the *BVL* provides technical support for enforcement.

13. The overall responsibility for the implementation of official food control and enforcement, including the registration and approval of establishments, lies with the *Länder*. The *Länder* have either a 3-tier structure consisting of the *L-CCA* (Ministries of the *Länder*), the regional CAs and the local CAs at district or district-free city level; or a 2-tier structure (with no regional CAs.) The L-CCAs coordinate the performance of official controls in the respective *Land* and have transferred the control tasks to lower administrative authorities (food monitoring and veterinary authorities of the districts and

district-free cities). In the *Länder* visited by the audit team, Lower Saxony has a 2-tier structure whereas Hessen and Saxony have a 3-tier structure.

14. The CAs have established several working groups at federal level for cooperation and coordination of the implementation of EU legislative requirements. The *Länder* Working group on Consumer protection *(Länderarbeitsgemeinschaft Verbraucherschutz, LAV*) is the working group dealing with food and feed safety consumer protection, animal health, animal welfare, animal diseases, etc. It has 13 subgroups under its umbrella, of which the Working group on meat and poultry meat hygiene and technical issues relating to foodstuffs of animal origin *(LAV Arbeitsgruppe Fleisch- und Geflügelfleischhygiene und fachspezifische Fragen von Lebensmitteln tierischer Herkunft, (AFFFL*) and the Working group for Quality Management (*Arbeitsgruppe Qualitätsmanagement, AG QM*) are most relevant for the audit. The *LAV* and its subgroups meet at least twice annually.

15. The *AG QM* is developing and coordinating system-oriented quality management (QM) documents to be applied by the *Länder* after mutual agreement. The QM systems of the *Länder* must be comparable to each other. The basic structure of the QM systems and relevant documents (guidelines and instructions) are uniform at *Land* level (e.g. a QM document on internal audits was approved in March 2021 and the QM document for risk-based planning of audits is in its final stages to be adopted). The *AG QM* guidelines and instructions for the inspection personnel are incorporated into the *Länder* and district QM systems. The guidelines cover for example, inspections and official sampling.

16. The *Länder* and districts QMS are taking into account *Länder*-specific legislation and the local needs. This has resulted in slightly different QMS being implemented.

17. The IT tool BALVI iP and its offline version BALVI mobil are used to document and plan the control activities of the relevant CAs. All *Länder* use this software system for the management of official controls. However, the ownership of the data on official controls on operators belong to the relevant districts and district-free cities, which are authorities performing the official controls in the establishments and farms within their boundaries.

18. The audit team noted that in some *Länder*, the competent intermediate and supreme *Land* authorities do not have direct access to official controls records because the districts and district-free cities refuse to provide such access with the justification of data protection. In one *Land*, only the intermediate authority has permanent access to official control records of approved establishments. However, the supreme authority of the *Land* can request this information case-by case if needed to exercise technical supervision.

19. The BMEL and the *Länder* agreed in November 2022 to establish a central IT architecture for consumer health protection (ZITA gV) with the goal of increasing the efficiency of official controls as well as the planning and reporting thereof. A reporting and communications body (KKS) has been established to build and operate Zita gV. It

began to operate in the first half of 2023. Work on Zita gV is based on an IT framework plan.

20. The *Länder* have annual training plans which are established based on the needs and are part of the QM systems. Evidence was provided to the audit team that the *Länder* had organised regular training for their control staff that included relevant dairy topics. The *Länder* had also regularly sent their staff to participate in Better Training for Safer Food training sessions related to food safety controls.

Conclusions on Competent authorities

21. The structure and organisation of the *Länder* CAs responsible for the implementation of official controls provide an adequate framework for the performance of the controls. The regular meetings of the LAV and working groups under its umbrella contribute to an effective co-ordination between the 16 *Länder*.

22. The autonomy of the districts and district-free cities have resulted in some challenges regarding the internal supervision of the districts and district free cities by *Land* or intermediate authorities and the verification of the effectiveness and appropriateness of official controls and the enforcement. (see paragraphs 18 and 45).

5.3 REGISTRATION AND APPROVAL OF FOOD BUSINESS ESTABLISHMENTS

Legal requirements

Article 6 of Regulation (EC) No 852/2004.

Article 4 of Regulation (EC) No 853/2004.

Articles 10(2), 138(2)(j) and 148 of Regulation (EU) 2017/625.

Findings

23. The *Länder* CAs are responsible for approval of dairy establishments. Depending on the *Land* CA structure, the approval is granted either by the L-CCA or by the regional CA. At the time of the audit there were 22 approved milk collection centres and 1401 dairy processing plants in Germany. The registrations are dealt with by the local CAs (districts and district-free cities).

24. The approval procedures in place in two of the *Länder* reviewed were in line with the applicable EU legislation. The dairy establishments visited were approved and included in the list of approved establishments and the approvals were available. The milk production holdings visited were registered in the database BALVI iP with a unique identification number.

25. Regarding one *Land* the audit team checked the approvals of three establishments. One of the establishments comprised three facilities one of which was located in

approximately 1.5 km distance of the two other units (which were located on the opposite sides of a road). The CA had included all three units under one and the same approval number stating that the individual production steps in the three units of the food business operator (FBO) are inextricably linked. This contravenes, however, the definition of establishment in Article 2 of Regulation (EC) No 852/2004 to which the approval requirements of Article 148 of the OCR apply.

26. Furthermore, the audit team noted that in some cases, the FBOs had not kept the CAs updated of the product range or informed them correctly about changes in the production which made it difficult for the CA to check/verify that the approval is still in line with the actual production. For example, one FBO visited had produced for over year butter from non-pasteurised milk of which the CA had been unaware until recently (the product had been ticked off erroneously in the establishment description, which is a mandatory part of the approval application, as butter made from pasteurised milk). Also, a new product had been added to the production without informing the CA and without adequate product description. The product was not covered by HACCP, shelf-life studies had not been carried out and no samples of the product had been tested for food safety parameters.

27. The CA stated that the approval procedure will be integrated in the future in the national QM system.

Conclusions on registration and approval of food business establishments

28. Procedures are in place and were implemented mostly correctly for the registration and approval of dairy FBOs. However, the CAs were not always aware of all activities requiring approval, thus these were not covered by the approval and were not verified during inspections. Moreover, in some cases the FBOs failed in their duty to inform the CAs of changes in their production. In one *Land* the same approval number had been given to three separate units of a FBO that were not on the same premises.

5.4 CONTROLS OVER MILK PRODUCTION HOLDINGS

Legal requirements

Article 4 of Regulation (EC) No 852/2004.

Article 3 of, and Chapter I of Section IX, Annex III to Regulation (EC) No 853/2004.

Article 49 of Regulation (EU) 2019/627.

Findings

29. The planning and implementation of official controls on primary producers are carried out in accordance with the general criteria for risk-based controls of holdings laid down in Article 6 of the *AVV-RÜb*. The frequency of checks is determined by the responsible relevant local CA. In Hessen, alongside the lower veterinary authorities, a team of dairy

specialists (*Fachtierarzt für Milchhygiene*) within the intermediate authority is responsible for official controls of milk hygiene on dairy holdings. The CA provided data for the inspections carried out in the *Länder* reviewed. The frequency varied between one annual inspection to one inspection in ten years and covered also sheep and goat holdings. The inspections on milk hygiene were often combined with other inspections (e.g. cross-compliance, animal welfare or use of veterinary medicinal products). Holdings registered for direct sale of raw milk or dairy products made with raw milk were covered more frequently. The checklists seen contained relevant points of the legal requirements.

30. Evidence was available that dairy cattle and sheep on the milk production holdings visited by the audit team had been tested for tuberculosis and brucellosis in line with the national legislation. The national annual animal disease surveillance (monitoring) programmes are implemented to maintain the official freedom from *Mycobacterium tuberculosis* complex and B*rucella abortus* and *melitensis*.

31. The audit team visited two bovine and one ovine dairy milk production holdings. The animal health situation and the animal welfare conditions were adequate, and the holdings had been controlled by the veterinary services at regular intervals. The milk tank room at one bovine holding was not easy to clean and disinfect and the door was broken. The local CA took immediate action requested the shortcoming to be rectified.

Conclusion on controls over milk and colostrum production holdings

32. The verification of compliance with hygiene regulatory requirements is carried out in line with the legal requirements and the annual control plans. The established frequencies vary between the *Länder*.

5.5 CONTROLS OF RAW MILK UPON COLLECTION

Legal requirements

Article 4 of Regulation (EC) No 852/2004.

Article 3 of, and Chapter I, Part III, Section IX of Annex III to Regulation (EC) No 853/2004.

Article 50 of, and Annex III to Regulation (EU) 2019/627.

Findings

33. The system of bovine raw milk quality control produced by FBOs is laid down in the Raw Milk Quality Ordinance (*Rohmilchgüteverordnung*) and the nationally adopted guideline of the Milk Industry Association (*Verband der Deutschen Milchwirtschaft e.V.*). The Ordinance regulates bovine raw milk quality that is purchased from one or more producers with an average daily intake of 500 litres or more. The guideline deals with halting of raw cow milk delivery and restarting it in relation to SCC and PC. In addition, the *Länder*-specific legislation and guidance documents are in place. The raw

milk producers not covered by the above legislation must organise the testing of raw milk in line with legal requirements themselves (e.g., sheep and goat milk producers).

34. Laboratories testing raw milk for quality parameters (SC, PC, inhibitory substances, freezing point etc.) must be approved by the *Länder* or by the intermediate CA, depending on the administrative structure of the *Land*. The number of such laboratories varies between *Länder*.

35. The methods used are fixed in the legislation and must be accredited. The laboratories must participate regularly in proficiency test rounds. The results of the proficiency tests rounds seen were satisfactory.

36. The drivers of the raw milk collection trucks are responsible for the taking of the raw milk samples from the dairy production holdings must have passed a training regarding the sampling and the transport. In addition, the automatic milk samplers of the truck must undergo regular testing. The driver interviewed by the audit team had been trained and was aware of the relevant procedures and requirements.

37. The CCA does not compile national statistics of tests for PC and SCC, but these can be provided at *Länder* level. Such statistics was received by the audit team for Saxony and Hessen. In Saxony the percentage of compliance of bovine raw milk in 2022 was 99.3 for PC, 99.2 for SCC and 99.3 for the presence of inhibitory substances, whereas for Hessen the percentages were 96.4, 89.7 and 99.9, respectively. A similar statistic was not provided for Lower Saxony. The compliance level for goat and sheep raw milk based on the results available was high (e.g. 100 % in Hessen).

38. In two of the *Länder* visited, the results are sent by the laboratories to the purchasers of the raw milk, who inform the producers and in case of exceeding the limits for SCC, PC, or presence of inhibitory substances, also the relevant local CA. In this case, the producer's reporting obligation must be transferred to the inspection body. Evidence of such obligatory flow of information was provided to the audit team. In the third *Land* visited, the laboratory informed the CAs directly.

39. Regarding the raw milk delivered to the dairy establishments visited the samples for PC and SCC were taken from the holdings and dairy establishments (purchasers) in line with the requirements of the Regulation (EC) 853/2004 or more often. The dairy holdings exceeding the legal criteria for SCC, PC or tested positive for antibiotic residues received a deduction in the milk payment.

40. The quality of the bovine raw milk in the dairies visited was good, and the industry's system for SCC, PC and inhibitory substances sampling and testing was operating in line with the requirements of Regulation (EC) No 853/2004. The FBOs had taken the actions required in point 5 of Chapter I.III, Section IX, Annex III to Regulation (EC) No 853/2004 in cases of exceedance of the legal criteria for SCC and PC or the detection of inhibitory substances.

41. Raw milk tested positive for inhibitory substances was traced back to the producer – the individual dairy farm samples were tested at an approved accredited raw milk laboratory. The follow-up visits on the farm included root cause analysis and advice to farmers on more measures to be taken. The bigger dairies also sent their own consultant to the farm.

42. In the cases checked by the audit team the milk tested positive was sent to a biogas or composting plant and the farmer identified as the source had to pay for the destruction. In addition, the farmer was punished financially with reduction in the milk price.

43. The methods in place used by at the dairies for daily testing /screening of arriving bulk raw milk (truck tank loads) for antibiotic residues detects only a limited range of residues. However, based on the information received from the CCA, the antibiotics the industry is testing for comprise the antibiotic groups most commonly used in the dairy husbandry. The tests and methods used for regular random testing of raw milk at producers (holding) level milk tested randomly at producers' level cover a broad spectrum of antibiotics.

Conclusion on controls on raw milk upon collection

44. The quality control system in place regarding SCC and PC for raw cow milk upon collection is well established and enforced by the dairy industry and controlled adequately by the local CAs. Non-compliant cases were effectively dealt with and followed-up by the dairy industry and during CAs' official controls.

5.6 OFFICIAL CONTROLS OVER DAIRY OPERATORS' COMPLIANCE WITH HYGIENE RULES

Legal requirements

Articles 8, 9, 10, 11, 12, 13, 14, 15, 137, 138 and 139 of Regulation (EU) 2017/625.

Articles 3 and 4 of Regulation (EU) 2019/627.

Findings

5.6.1 General organisation of official controls

45. The controls of dairy establishments, including official sampling, are incorporated in the annual, national control plan which sets the framework for the work of the supervisory authorities in each *Land*. The *BMEL* coordinates the control and monitoring activities of the *Länder* whereas the L-CCA are responsible for ensuring implementation of the controls. Within the *Länder* the implementation of controls has been delegated to the district and district-free cities. The access of the L-CCA and regional CAs to the IT tool BALVI iP used for planning and documentation of official controls varies. For example, the L-CCA in Lower Saxony could not access BALVI IP data of official controls.

46. The local CAs apply the provisions of *AVV-RÜb* for establishing the risk-based inspection frequencies. The food processing establishments are classified in several basic risk classes which determines their basic control frequency.

47. Official controls in dairy establishments comprise the controls carried out by the inspectors of the local CA and the approval reviews carried out by the CAs responsible for the approval (L-CCA or regional CA depending on the administrative structure of the *Land*). The latter controls include checks by technical specialist of the CA together with the local CA inspector. The controls carried out by the local CAs are more frequent, and in the cases reviewed by the audit team, were carried out at least annually.

48. According to the 2022 annual report of the multiannual national control plan there were 843 approved establishments in the dairy sector in which the number of controls carried out was 1204. According to the statistics received, most shortcomings in relation to the production of milk and dairy products were in relation to microbiological criteria, labelling and composition.

49. The enforcement measures ranged from oral advice to written orders up to financial penalties.

50. The local CA of the *Länder* reviewed by the audit team were using BALVI iP and/or BALVI mobil for the planning and documentation of controls.

51. The inspection reports reviewed by the audit team had been generated in BALVI iP covered 11 control points (e.g. hygiene management, HACCP, cleaning/disinfection, traceability, staff training, pest control, general hygiene, documentation, composition, labelling) and the findings/shortcomings to the points checked, including deadlines for addressing them. The level of details included in the reports seen by the audit team was satisfactory. Evidence of corrective actions taken by the operator and follow-up actions was available.

5.6.2 General and specific hygiene requirements

Legal requirements

Article 4 of, and Annex II to Regulation (EC) No 852/2004.

Article 3 of, and Section IX of Annex III to Regulation (EC) No 853/2004.

Findings

52. The establishments visited by the audit team had in general adequate structures and equipment. The inspection reports of the establishments visited reflected, in general, the conditions of these establishments visited, except for some additional maintenance and hygiene shortcomings identified by the audit team. The officials accompanying the audit team took in these cases immediate action and instructed the FBOs to rectify the shortcomings found within specific deadlines.

53. When shortcomings were detected, a deadline for rectifying the shortcomings was given. The follow-up of the action taken was, in most cases, verified via documentation and photos (sent by the operator) or by a follow-up visit.

54. The animal by-products (ABPs) generated in the dairy plants visited were disposed of correctly and transported to biogas facilities (category 2 and/or category 3 ABP) or sold as feed (category 3 ABP). However, the containers used by some of the trucks seen by the audit team were not correctly identified.

5.6.3 Hazard Analysis and Critical Control Points based systems

Legal requirements

Article 5 of Regulation (EC) No 852/2004.

Findings

55. All establishments visited had in place procedures based on HACCP principles and verification of these was part of the official controls. Special attention was given to the compliance of the heat treatment. The equipment was checked regularly by a technical specialist of the CA as part of the approval inspection and subsequently as part of the regular controls for reviewing the approval.

56. The small-scale artisanal establishments visited were following the European Guide for Good Hygiene Practices in the Production of Artisanal cheeses and dairy products aimed at farmhouse and artisan producers.

57. The audit team noted that the official controls regarding HACCP were not sufficiently in-depth, especially regarding the small-scale producers visited. As a result, some shortcomings had not been identified. These concerned:

    a. In one establishment the time scale of the thermograph of the heat-treatment equipment did not allow a verification of the duration of the heat treatment.
    b. In one small establishment sampling of butter was not included in the HACCP (although it had been tested for the pathogen). In another establishment butter was not included in the FBOs profile (*Betriebsspiegel*) and no own control sample had been tested for *L. monocytogenes*.
    c. One establishment had put on the market a new product that was not included in the HACCP. No product specification was available for this product.
    d. One establishment had produced butter from non-pasteurised milk, but the CA had noted this only recently. The production has since then stopped.

58. Pest control programmes were in place and had been verified during official controls. One establishment with some older buildings had had a substantial problem with pests. The FBO had changed the company dealing with pest control and the situation had improved but it was not yet fully solved at the time of the audit. The CA is closely monitoring the case.

Legal requirements

Articles 3 and 4, and Annex I to Regulation (EC) No 2073/2005.

Findings

59. All establishments visited were implementing sampling and testing programmes for food safety and process hygiene criteria. The FBOs are obliged to report unsatisfactory results of food safety criteria to the CAs. The own checks, plans and controls and results were well documented by the operators in the establishments visited.

60. The audit team noted that the CAs met had checked, in line with the checklists used, several aspects of FBOs' compliance with Regulation (EC) No 2073/2005. However, certain aspects/shortcomings were overlooked:

    a. Some of the FBOs visited did not apply the number of sample units as laid down in Annex I to Regulation (EC) No 2073/2005 for food safety and process hygiene criteria, or the frequency was very low, or some products were not sampled at all.

    b. The environmental sampling was not fully in line with the EU Reference Laboratory guideline as the samples in some establishments were taken only after cleaning and in one establishment water samples from drains were analysed for *Listeria* instead of taking swabs. The EU guideline recommends sampling during processing and does not recommend sampling by rinsing surfaces.

    c. The quality controls in an own control laboratory of a FBO testing products for process hygiene criteria had some shortcomings.

Traceability, labelling and identification marking

Legal requirements

Article 18 of Regulation (EC) No 178/2002.

Article 5 of, and Chapter IV, Section IX, Annex III to Regulation (EC) No 853/2004.

Article 5 of Regulation (EU) 2019/627.

Findings

61. Official controls covered checks on traceability, labelling and identification marking of dairy products by FBO. In 2021, there was a special project to check the labelling which included smoked milk products.

62. The FBOs could provide full traceability for some random products chosen by the audit team. The officials interviewed stated that they did also carry out traceability exercises themselves.

63. The labels seen by the audit team were, in general, in line with the legislative requirements. However, one establishment was also selling sausages and meat produced

in another establishment from their own sheep (the FBO was planning to open a meat cutting plant in the future). The meat had the identification number of the dairy plant on the package and the sausages. The CA took immediate action and asked the FBO to correct the labelling. Another establishment was selling a cheese where the label included the nomination "Halloumi "which is a Cypriot product of designated origin (PDO). This is not in line with the provisions of Regulation (EU) No 1151/2012. The CA took immediate action and advised the FBO to correct the labels used.

Conclusions on official controls on food business operators' compliance with hygiene rules

64. The official controls of FBOs are risk-based and implemented in line with the planned annual control plan and documented adequately.

65. The official controls of the dairy sector did not cover HACCP and microbiological criteria with sufficient depth and did not identify all relevant shortcomings. The implementation of official controls did not always effectively enforce the FBOs' obligations in respect of these areas.

5.7 OFFICIAL SAMPLING PROGRAMMES AND LABORATORIES

Legal requirements

Articles 5(d), 14(g) and (h), 34,37,38,39, and 101 of Regulation (EU) 2017/625.

Part III of Chapter I, of Section IX, Annex III to Regulation (EC) No 853/2004.

Findings

66. The network of official laboratories is formed by the national reference laboratories (NRLs) and the official laboratories of the *Länder*.

67. The laboratories are accredited by the national accreditation body *Deutsche Akkreditierungsstelle GmBH*) to EN/IS 17025:201. Evidence was provided to the audit team that the NRLs and official laboratories participate regularly and with good results in proficiency test rounds.

68. The audit team received the lists of methods used by the official laboratories in the *Länder* reviewed. Most of the methods were ISO reference methods in line with Regulation (EC) No 2073/3005.

69. The National Monitoring Plan (*Bundesweiter Überwachungsplan*) is an annually established risk-oriented monitoring programme agreed between the *Länder* to verify compliance with food legislation. The requirements for risk-based official sampling are anchored in the *AVV-RÜb* (Articles 12,13 and Annex 6). The sampling is based on the cooperation between the official laboratory network and the relevant CA. The *Länder* decide independently in which *BÜp* programmes they participate in (dependent on the relevance of the programme for the *Land*) and how many samples they will take and

where. The programmes will only be implemented if at least two *Länder* commit to participate. The BVL draws up the *BÜp* on the basis of the selected programmes. In 2021, all *Länder* took part in a project on *Listeria spp*. and *Listeria monocytogenes* in specific types of cheeses. The total number of samples collected was 246. In four out of 231 samples examined (1.7 %), *Listeria monocytogenes* presence was found, while other *Listeria spp*. presence was found in nine out of 189 samples (4.8 %). None of the 88 samples tested quantitatively for *Listeria monocytogenes* exceeded 10 CFU/g.

70. Milk and milk products are included in the annual monitoring plans for undesirable substances such as residues of plant protection, pest control and veterinary medicinal products, heavy metals, mycotoxins and other contaminants in foodstuffs. The findings are continuously incorporated into health risk assessment. The sampling is carried out in accordance with the provisions of the *AVV Monitoring*. In 2020 and 2021, the population's representative basket of goods included Emmentaler cheese, butter, and feta cheese. The 2022 monitoring plan included full fat milk. Pesticide residues were detected in 12.6% of the 119 milk samples analysed but non exceeded the maximum residue limit.

71. The number of milk samples tested for non-steroidal anti-inflammatory drugs in 2021 as part of the national residue monitoring plan was 1646. Diclofenac and paracetamol were found in two samples.

Conclusions on official sampling programmes and laboratories

72. The official control system is supported by an adequate network of official laboratories, working with accredited methods. The regular participation in inter-laboratory proficiency test rounds ensures the reliability of the delivered results.

73. The official sampling programmes are, in general well designed and implemented and allow the district CAs to adopt them to their local circumstances.

5.8 RAPID ALERT SYSTEM FOR FOOD AND FEED (RASFF)

Legal requirements

Article 50 of Regulation (EC) No 178/2002 and Regulation (EU) 2019/1715.

Findings

74. The *AVV - Rapid Alert System* lays down uniform rules for rapid alerts which are implemented by *Länder* in their QM systems. The BVL is the Federal contact point for RASFF. The national portal www.lebensmittelwarnung.de is used by the *Länder* and BVL to publish public warnings and information pursuant to §§ 40(1) and (2) LFGB. The AVV – Rapid Alert System is implemented by the *Länder* in their systems.

75. The audit team followed up three RASFF notifications (plastic fragments in shredded cheese, *Listeria monocytogenes* in soft cheese and *Salmonella* in skim milk powder).

The cases were handled swiftly. The notification in relation to the skim milk powder was complicated as the contaminated lot had a large distribution and ended up in in many products that could be possible affected.

76. The CAs had handled the alerts adequately except that they had not required proof of the destruction of the returned lots. These documents were, however, made available to the audit team at its request.

Conclusion on rapid alert system for food and feed

77. The CAs had handled the alerts adequately except that they had not required proof of the destruction of the returned lots. These documents were, however, made available to the Based on the examples reviewed by the audit team the system in place to deal with RASFF notifications operates effectively.

5.9 SYSTEM OF SUPERVISION AND INTERNAL AUDITS

Legal requirements

Articles 5(1)(b) and 6 of Regulation (EU) 2017/625.

Findings

78. The procedures for verifying the effectiveness of official controls are designed according to the structure of the authorities and the respective supervisory principles of the *Länder*. The L-CCA or regional CAs of the *Länder* carry out technical supervision of the inspection personnel which is achieved through joint inspections (e.g. the pre-approval inspections and regular meetings of the staff with their superiors) and documentary checks.

79. At national level the CCA does not carry out any audits of the *Länder*, as its task is to deal with co-operation, not supervision.

80. Evidence was available of QM system based internal audits in the districts visited. At national level a plan for auditing the authorities and for independent scrutiny of audits (audit plan) has been adopted by the *LAV*. In addition to the independent scrutiny, the document provides for *Länder* observation. Observing parties of independent scrutiny are members of the AG QM. Such observations are generally carried out every five years in each *Land*.

Conclusion on system of supervision and internal audits

81. The QM systems based internal audits contribute towards a harmonised official control system.

6 OVERALL CONCLUSIONS

The national legislation and administrative provisions that have been issued at central and

Länder level covering the audited sector are in line with the relevant EU legislation.

The structure and organisation of the *Länder* competent authorities responsible for the implementation of official controls provide an adequate framework for the performance of these tasks. Structures are in place to facilitate an effective co-ordination between the 16 *Länder*.

The autonomy of the districts and district-free cities cause some challenges regarding the internal supervision of the districts and district free cities by *Land* or regional competent authorities (*Mittelbehörde*) and the verification of the effectiveness and appropriateness of official controls and enforcement.

Procedures are in place and were implemented mostly correctly for the registration and approval of dairy operators. However, the CAs were not always aware of all activities requiring approval, so these were not covered by the approval or verified during inspections. Moreover, in some cases the FBOs failed in their duty to inform the CAs of changes in their production. In one *Land* the same approval number had been given to three separate units of a food business operator that we not on the same premises.

The verification of compliance of dairy holdings with hygiene regulatory requirements is carried out in line with the legal requirements and the annual control plans. The established frequencies vary between the *Länder*.

The quality control system in place regarding SCC and PC for raw cow milk upon collection is well established and enforced by the dairy industry and controlled adequately by the local CAs. Non-compliant cases were effectively dealt with and followed-up by the dairy industry and during CAs' official controls.

The official controls of dairy operators are risk-based and implemented in line with the planned annual control plan and documented adequately. However, the controls did not cover HACCP, microbiological criteria with sufficient depth and did not identify some relevant shortcomings. This limits the effectiveness of the implementation of official controls.

7 CLOSING MEETING

A remote closing meeting was held on 24 November with the CCA and representatives of the *Länder*. At this meeting the audit team presented the findings and preliminary conclusions of the audit. During this meeting, the CAs acknowledged the findings and conclusions presented and offered some clarification.

8 RECOMMENDAITIONS

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

No.	Recommendation
1	To ensure that the approvals of dairy establishments are kept under review as laid down in Article 148 (5) of Regulation (EU) 2017/625. Recommendation based on conclusion No 28. Associated findings Nos 25 and 26.
2	To ensure that official controls of food business operators' compliance regarding procedures based on HACCP principles, as laid down in Regulations (EC) Nos 852/2004, 853/2004 and 2073/2005 (in particular in relation to microbiological criteria), are effective as required by Article 5.1 of Regulation (EU) 2017/625. Recommendation based on conclusion No 65. Associated findings Nos 57 and 60.

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=2023-7732

ANNEX 1 - LEGAL REFERENCES

Legal Reference	Official Journal	Title
Dir. 2020/2184	OJ L 435, 23.12.2020, p. 1–62	Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (recast)
Reg. 2074/2005	OJ L 338, 22.12.2005, p. 27-59	Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004
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)

Legal Reference	Official Journal	Title
Reg. 1151/2012	OJ L 343, 14.12.2012, p. 1-29	Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs
Reg. 1333/2008	OJ L 354, 31.12.2008, p. 16-33	Regulation (EC) No 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives
Reg. 2073/2005	OJ L 338, 22.12.2005, p. 1-26	Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs
Reg. 853/2004	OJ L 139, 30.4.2004, p. 55, Corrected and re-published in OJ L 226, 25.6.2004, p. 22	Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific hygiene rules for food of animal origin
Reg. 1334/2008	OJ L 354, 31.12.2008, p. 34-50	Regulation (EC) No 1334/2008 of the European Parliament and of the Council of 16 December 2008 on flavourings and certain food ingredients with flavouring properties for use in and on foods and amending Council Regulation (EEC) No 1601/91, Regulations (EC) No 2232/96 and (EC) No 110/2008 and Directive 2000/13/EC
Reg. 1169/2011	OJ L 304, 22.11.2011, p. 18-63	Regulation (EU) No 1169/2011 of the European Parliament and of the Council of 25 October 2011 on the provision of food information to consumers, amending Regulations (EC) No 1924/2006 and (EC) No 1925/2006 of the European Parliament and of the Council, and repealing Commission Directive 87/250/EEC, Council Directive 90/496/EEC, Commission Directive 1999/10/EC, Directive 2000/13/EC of the European Parliament and of the Council, Commission Directives 2002/67/EC and 2008/5/EC and Commission Regulation (EC) No 608/2004
Reg. 1935/2004	OJ L 338, 13.11.2004, p. 4-17	Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC

Legal Reference	Official Journal	Title
Reg. 2019/627	OJ L 131, 17.5.2019, p. 51–100	Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls
Reg. 178/2002	OJ L 31, 1.2.2002, p. 1-24	Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety
Reg. 852/2004	OJ L 139, 30.4.2004, p. 1, Corrected and re-published in OJ L 226, 25.6.2004, p. 3	Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs