DG Health and Food Safety

COUNTRY PROFILE

Progress made in the implementation of audit recommendations

Health and Food Safety

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INTRODUCTION

The Directorate-General (DG) for Health and Food Safety of the European Commission carries out controls, primarily audits, aimed at verifying that EU legislation on food and feed, animal health and welfare, plant health and plant protection products, is properly implemented and enforced. This means EU citizens enjoy a high level of safety, and that goods are traded under safe conditions.

DG Health and Food Safety makes recommendations to Member States to deal with any shortcomings revealed during its audits. Member States are requested to present action plans on how they intend to address these shortcomings. Article 119(a) of Regulation (EU) 2017/625 requires that Member States take appropriate follow-up action in the light of recommendations resulting from EU controls.

DG Health and Food Safety evaluates these action plans and systematically monitors their implementation through a number of follow-up activities. Verification of the completion and effectiveness of corrective action is an integral part of this activity.

In 2005, DG Health and Food Safety introduced the instrument of general follow-up to review Member States' progress on the implementation of recommendations made. This general follow-up is carried out at regular intervals and provides an opportunity to discuss the full range of unresolved issues with the competent national authorities. In the period between general follow-ups, the competent national authorities may provide additional information on progress made in addressing recommendations and, following assessment by DG Health and Food Safety, this may result in some recommendations being closed.

The information in this part of the country profile has been compiled in the context of a general follow-up carried out by DG Health and Food Safety in March 2021. It provides a summary of progress made by Italy on the implementation of DG Health and Food Safety's recommendations.

This part of the country profile will be updated at regular intervals based on the results of future DG Health and Food Safety audits and other relevant information received by Commission services from the authorities in Italy.

SUMMARY OF THE PROGRESS MADE BY THE MEMBER STATE IN THE IMPLEMENTATION OF RECOMMENDATIONS MADE BY DG HEALTH AND FOOD SAFETY

The following table gives an overview of DG Health and Food Safety's audits in Italy and shows the Commission services' assessment of actions taken in response to the recommendations contained in the reports of those audits. This assessment is based on a review of the information and documentation provided by the competent authorities.

The basis for the assessment of actions in relation to individual recommendations is presented in Sections 2.A and 2.B.1 to 2.B.12. Recent published audit reports that are not yet ready for follow-up are listed in Section 3.

Overview of DG Health and Food Safety's audits in Italy 2009-2019

Control system	Total number of finalised audits	Recommendations				
		Total	Closed for Action taken	Closed for other reasons	In progress	Action Still Required
Horizontal	1	4	3	-	-	1
Animal Health	8	60	36	16	8	-
Food of animal origin	12	87	76	6	4	1
Import of animals and food of animal origin	9	27	17	8	2	-
Feedingstuffs and animal nutrition	5	25	22	3	-	-
TSE/ABP	1	6	4	-	2	-
Veterinary medicinal products and Residues	3	28	26	-	2	-
Foodstuffs and Food hygiene	4	18	13	2	2	1
Imports of food of plant origin	3	23	21	2	-	-
Plant Protection Products (Authorisation, Sustainable use and Residues)	3	23	17	3	3	-
Animal welfare	4	39	25	10	4	-
Plant health	16	117	56	54	2	5
Quality Labelling	2	18	12	4	2	-
Sub-total	**71**					
Audits without recommendations	**6**					
Total	**77**	**475**	**328**	**108**	**31**	**8**

General follow-ups/Administrative follow-ups: 6

The six audits without recommendations were: a general audit of control systems 2010-8741, Plant pest outbreaks (Kiwifruit canker) 2012-6314, Geographical indications scheme 2014-7108, Eggs and egg products 2016-8683 and two for approval of Border Control Posts, 2015-8761 and 2019-6829.

1. ISSUES ARISING FROM DG HEALTH AND FOOD SAFETY AUDITS

The issues identified in Italy through DG Health and Food Safety's audits that still need to be addressed by the authorities include:

1.1. Main issues covered in this country profile

1.1.1. Horizontal issues

The quality of controls carried out by the local level was found to be insufficient in several control areas: animal by-products (ABP), plant protection products (PPP) and animal welfare. The different control areas included in Regulation (EU) 625/2017 require specific competencies and the local level sometimes lack expertise or, in cases where they only have a few sites to control, carry out checks infrequently and never gain sufficient expertise in the control area. The central level have carried out internal audits to help address recommendations from the audits on ABP (2018-6336) and on PPP (2015-7468) and in both cases found similar issues to those identified by the DG SANTE audits. The regions audited have produced action plans to address these issues; however, evidence is still lacking that such actions have resulted in better quality controls throughout the country. The central level has made major changes in its approach to controls of animal welfare on farm since audit (2017-6257) see "*issues related to the Farm to Fork Strategy"* below.

Action is still required in relation to a recommendation concerning the system of internal audits, as the Ministry of Agriculture has failed to put in place arrangements to audit official controls of plant health (2018-6314_2).

1.1.2. Sector specific

Plant health is the control area with the highest number of recommendations where action is still required. The Ministry of Agriculture Foodstuff and Forestry Policies has not taken action to modify controls in this area, as promised in its commitment following an audit in 2016. The authorities have not yet addressed five recommendations from this audit, 2016-8796, on Thousand Canker Disease:

- To increase monitoring in all affected areas (2016-8796_1);
- Deploy disease suppression measures (2016-8796_2);
- Set buffer zones to ensure that infected material is not inadvertently moved to free areas (2016-8796_3);
- Prepare a specific contingency plan for the possible infection of commercial fruit plantations of J. regia (2016-8796_4);
- Take measures to prevent the possible dissemination of the disease via infected bark strippings from sawmills (2016-8796_5).

Three further recommendations in the plant health area remain in progress: import controls to ensure that wood packaging material is compliant with EU rules (2018-6551_1); to immediately fell infested Prunus plants and plants within a radius of 100m of infested plants where there is infestation with the red neck longhorn beetle *Aromia bungii* (2019-6733 recommendations 2 and 3).

For animal health, there are a number of long-standing recommendations still open from an audit on contingency plans (2015-7569):

- Regional and local authorities' contingency plans and manuals to be fully fit for purpose (2015-7569_2);
- Areas at risk of a major FMD outbreak identified and the feasibility of carrying out pre-emptive animal depopulation, carcass disposal and vaccination determined (2015-7569_3);
- To ensure that regional and local authorities are capable of preparing adequate action plans for depopulation (2015-7569_4) [a similar recommendation remains open from a more recent audit on Avian Inflenza (2019-6599_2)];
- Carry out real-time alert exercises for FMD (2015-7569_5).

Authorities have made major efforts to eradicate African Swine Fever (ASF) from Sardinia where it has been a long-standing problem for many years. Three recommendations from an audit on ASF from 2016 remain in progress (recommendations 1, 3 and 4 from audit 2016-8764) and were not followed up in this GFA, as these issues were to be covered in an audit planned for November 2021 (see section 3.B).

A database (Vetinfo) allows all levels of the CA to supervise measures to eradicate TB and Brucellosis in bovine and ovine animals. This development allowed the closing of two longstanding recommendations from audit 2013-6979 as authorities have better targeted actions to eradicate these zoonotic diseases.

One recommendation from an audit on nutrition and health claims of food labels (2018-6408) remains as 'action still required':

- National legislation and guidelines must be in line with EU rules (2018-6408-2).

The authorities are awaiting the adoption of a procedure at Union level to review and revise sampling plans to address two long-standing recommendations from 2012-6542 on controls of marine biotoxins in bivalve molluscs.

Concerning fish and fishery products, an audit on tuna fish production (2019-6747) which found shortcomings with regard to histamine testing and Hazard Analysis and Critical Control Points (HACCP) one recommendation remains 'action still required':

- Ensure adherence to the frequencies set in the official control plans for primary production fishing vessels (2019-6747_1);

Issues related to the Farm to Fork Strategy

Several control areas constitute essential elements for implementing the European Commission's Farm to Fork Strategy.[1] One of the goals of this strategy is to make Europe's food system the gold standard for sustainability, and official controls on the use of antimicrobials, animal welfare and pesticides help deliver the required standards.

Concerning pesticides, progress has been made in improving the exchange of information between the Ministries involved in controls on plant protection products, but there has

[1] https://ec.europa.eu/food/farm2fork_en

not yet been full implementation of the co-operation laid down in Ministerial Decrees 24/2021 and 27/2021, particularly with regards to the exchange of information with Customs (2015-7468_3). As highlighted in "horizontal issues" above, a main issue for controls continues to be that inspectors cover a wide range of control areas and operate in a small geographical area, and therefore have little opportunity to develop expertise for checks of plant protection products through their day-to-day work, and recommendation 2015-7468_8 remains in progress.

Concerning antimicrobials, Italy adopted a National Action Plan on antimicrobial resistance (2017-2020) that set clear targets most notably to reduce the consumption of antibiotics in the veterinary sector by at least 30% and the use of critically important antimicrobials by at least 10%. A DG SANTE fact-finding mission concluded that Italy invested considerable resources in this area, making an e-prescription system compulsory for veterinarians and raising awareness on antimicrobial resistance.

Concerning animal welfare, the central authorities has overhauled the approach to controls of animal welfare on farm following an audit on tail docking of pigs (2017-6257), with farm checks integrating animal welfare, medicinal products and biosecurity ("Classy farm" project). There has been good progress regarding the avoidance of tail docking of pigs, with, at the time of the March 2021 GFA, 11% of farms keeping only pigs with intact tails and a further 42% of farms having introduced groups of pigs with intact tails into their rearing systems. Four recommendations, nevertheless, remain in progress regarding the avoidance of tail docking:

- Provide inspectors with suitable compliance criteria for inspections (2017-6257_1);
- Guidance on how to assess evidence of tail and ear lesions on-farm and what constitutes sufficient changes to inadequate environmental conditions or management (2017-6257_2);
- Ensure veterinary declarations are based on evidence of tail biting and remedial actions already taken by the farmer (2017-6257_4);
- Monitoring of lesions in slaughterhouses to trigger actions on farms (2017-6257_5).

1.2. Issues arising from published audit reports not included in this country profile

An audit on plant health, Xylella fastidiosa (2019-6731), was not included in the current country profile as a follow up audit (2021-7280) was carried out in June 2021. The earlier audit (2019-6731) found that monitoring and controls were not as required and that many infected plants could remain undetected. In addition, there were delays in the confirmation of positive tests and in the felling of infected trees. The audit acknowledged that law No. 44, in effect since 22 May 2019, could facilitate better enforcement and management activities of harmful organism outbreaks on the Italian territory.

An audit on biosecurity measures for livestock vehicles entering the EU (2019-6627), was not included in the current country profile as the legal basis became obsolete and no new legislation dealing with this had been adopted at EU level.

Audit (2020-7047) Protected Designation of Origin (PDO) and Protected Geographical Indication (PGI) for products in the wine sector and audit 2021-7186 on controls of bovine meat, including traceability recommendations had not yet reached the follow-up stage for inclusion in the current country profile.

Chapter 3 lists the audit reports which are published but for which the follow-up status is not reflected in the current country profile, as well as a list of ongoing and planned audits.

The five most recent published reports are available at:
https://ec.europa.eu/food/audits-analysis/country_profiles/details.cfm?co_id=IT

2. FOLLOW-UP STATUS OF RECOMMENDATIONS

This part of the country profile gives the current status of actions undertaken in response to DG Health and Food Safety's recommendations. The aim is to provide a summary of progress by Italy on the implementation of our recommendations.

For the purpose of assessment, the terms: "Action taken," "In progress", "Closed for other reasons" and "Action still required" are defined as follows:

"Action taken": The competent authority has implemented appropriate measures to address the recommendation. The recommendation is therefore closed.

"In progress": The competent authority has initiated appropriate measures to address the recommendation but not all of the measures have been implemented. The recommendation therefore remains open.

"Closed for other reasons": For administrative, technical or legal reasons, follow-up of the recommendation is no longer appropriate. The recommendation is therefore closed.

"Action still required": Appropriate measures to address the recommendation have not been initiated by the competent authorities or are longstanding (i.e. not addressing the shortcomings in a timely fashion). The recommendation therefore remains open.

Given the nature and scope of the general follow-up, no verification through on-the-spot audits was carried out. The general follow-up is considered complementary to other follow-up actions and verifications that may be necessary and carried out as part of future sectoral audits by DG Health and Food Safety. Recommendations classified as “In progress" or "Action still required" are not necessarily considered to require immediate specific legal or administrative action on the part of the Commission services. These recommendations will remain the subject of monitoring by the Commission services to assess progress. If as a result of this monitoring the Commission services consider the situation in regard to any of these recommendations warrants additional action on its part, it will take the appropriate measures.

It should be noted that the number of recommendations in this overview does not represent, of itself, a measurement of the degree of responsiveness by the competent authorities or of the seriousness of the shortcomings. Some recommendations may be related to minor technical aspects while others may refer to more problematic, systemic, issues. Some may be resolved quickly, while others will require more complex and time-consuming action.

Acronyms are used throughout the following chapters for the sake of brevity. A list of acronyms, abbreviations and special terms is given in Annex I as a guide for the reader.

2.A HORIZONTAL RECOMMENDATIONS

Audit 2018-6314 of 11 April 2018 in order to evaluate the system put in place to implement article 4(6) of Regulation (EC) No 882/2004 (national audit system)	
Recommendation	Basis for assessment/Information Requested/CA response
2018-6314-1 Both the Ministry of Health and the Central Inspectorate for Quality Controls and Antifraud of Foodstuff and Agricultural Products should strengthen the systematic approach with respect to the development of audit programmes, so that the planning process can demonstrate that internal audits meet the objectives of Regulation (EC) No 882/2004, so as to ensure that there is no gap in audit coverage and that the planning and programming of official controls carried out at the central level are included in the process. Recommendation based on conclusion 74 and 75 Associated findings: 60 and 70	**Closed due to action taken** **Findings:** The activities of the (CCA) sectoral offices in relation to planning and development of programmes of official controls are not covered in the audit programme. ICQRF require an annual programme based on available documentation and new alerts. Audit programming is based on covering the full range of official control activities of each Territorial Office within a five-year cycle rather than on a risk-basis. In common with the situation for Ministry of Health, there is a gap in coverage of the planning and programming activities carried out at the central level. ***Assessment****: Both ICQRF and the Ministry of Health have improved their planning for audits by further taking into account the different risks for controls. The Ministry of Health provided a framework for the regions to support their planning of audits and evidence provided that* the regions follow this risk based planning. *ICQRF and Ministry of Health internal audits now include central level tasks.*

Audit 2018-6314 of 11 April 2018 in order to evaluate the system put in place to implement article 4(6) of Regulation (EC) No 882/2004 (national audit system)	
Recommendation	Basis for assessment/Information Requested/CA response
2018-6314-2 In relation to the plant health sector, the Ministry of Agriculture, Foodstuffs and Forestry Policies should ensure that a system of audit is introduced in line with previous commitments and as will be required under Article 6 of Regulation (EU) No 2017/628. Recommendation based on conclusion 18 Associated findings: 15 and 16	**Action Still required** **Findings:** The are no arrangements in place for audits of controls of plant health. This is required from 14 December 2019, but Italy had committed to introduce such a system in response to DG SANTE plant health audits in 2011 and 2013. ***Assessment*** *The Ministry of Agriculture did not respond to this recommendation despite reminders. This means this recommendation is classified as "action still required".*
2018-6314-3 The Central Inspectorate for Quality Controls and Antifraud of Foodstuff and Agricultural Products should ensure that arrangements for independent scrutiny are put into place in line with Article 4(6) of Regulation (EC) No 882/2004. Recommendation based on conclusion 41	**Closed due to action taken** **Findings:** ICQRF has no arrangements in place for independent scrutiny. ***Assessment*** *The MANCP permanent Evaluation Unit (Nucleo di Valutazione permanente del PNI) now provides independent scrutiny for ICQRF as well as for the Ministry of Health. Conclusions from the meetings of this body indicate that a suitable level of scrutiny is provided. Based on the evidence provided, this recommendation can be considered addressed.*

Audit 2018-6314 of 11 April 2018 in order to evaluate the system put in place to implement article 4(6) of Regulation (EC) No 882/2004 (national audit system)	
Recommendation	Basis for assessment/Information Requested/CA response
Associated findings: 39	
2018-6314-4 The Central Inspectorate for Quality Controls and Antifraud of Foodstuff and Agricultural Products should ensure that arrangements for transparency are put into place in line with Article 4(6) of Regulation (EC) No 882/2004. Recommendation based on conclusion 164 Associated findings: 161	**Closed due to action taken** **Findings:** ICQRF internal audit procedures do not set out measures to ensure transparency. ***Assessment:*** *ICQRF already practised internal transparency (transmission to the territorial offices) and the outcome of audits are now also included in published activity reports. Based on the evidence provided, this recommendation can be considered addressed.*

2.B SECTORAL RECOMMENDATIONS

2.B.1 Animal Health

Audit 2013-6979 of 07 October 2013 in order to evaluate the bovine, ovine and caprine brucellosis eradication programmes	
Recommendation	Basis for assessment/Information Requested/CA response
2013-6979-3	**Closed due to action taken**

Audit 2013-6979 of 07 October 2013 in order to evaluate the bovine, ovine and caprine brucellosis eradication programmes	
Recommendation	Basis for assessment/Information Requested/CA response
To approve and supervise dealers and dealers' premises in line with Article 13 of Directive 64/432/EEC and Article 13 of Directive 91/68/EEC. To ensure that the enforcement measures foreseen by the national legislation are applied.	**Findings:** The dealer premises are identified as such in the national registration database; however, the national legal requirements for their approval, structure, operation and official supervision of dealers, and movement rules from these premises, strengthened recently by specific enforcement rules for the Southern Regions, are not applied nor enforced. The CCA supervision of the eradication programme by the regions was limited which prevents them identifying regional deviations from the national eradication plan or national legislation. ***Assessment***: *The CA at all levels can access an IT tool, Vetinfo, already operational in 2018 and which allows supervision of official controls of animal dealers. Data provided for the four regions, Puglia, Calabria, Campania and Sicily for the last quarter of 2020 indicates that close to 100% of buffalo dealers were checked. The level of supervision of ovine/caprine dealers was less, but there are fewer dealers in this sector and at certain times of the year not all premises have animals. The functionality of Vetinfo allows the different levels of the CA to monitor the enforcement actions taken as well as any gaps in the coverage of controls by the local CAs. This means they can better identify the issues to focus on and effectively supervise dealers' premises. Based on the evidence provided, this recommendation can be considered addressed.*
2013-6979-7 To ensure that all summer fields and communal grazing fields are registered, and that movements to these places are registered, authorised only to brucellosis-free herds and flocks, and performed following a pre-movement test as required by the EU legislation or national legislation cited in the approved eradication programme.	**Closed due to action taken** **Findings:** To deal with frequent illegal movements, traceability has been greatly enhanced in Calabria by the compulsory introduction of electronic identification of all cattle, sheep and goats, going beyond the requirements of national legislation and eradication programme. This is in contrast to the region of Puglia, which only introduced the requirement for bovine electronic identification in one free ranging area of its territory, and did not enforce it. Completion of registration of summer grazing fields was performed in both regions, but not completed in Puglia. ***Assessment*** : *The vast majority of summer grazing was geo-referenced (100% in Puglia and 88.14% in Campania) and in 2020 96.84% of movements of animals were to geo-referenced grazing areas, with pre-movement testing taking place. With respect to the fencing of grazing areas in the Gargano area in Puglia, the Veterinary Service of the Foggia Local Health Unit confirmed that all infected grazing areas are fenced and it has been completed also in areas where they received a request to move livestock. Based on the evidence provided this addresses the*

Audit 2013-6979 of 07 October 2013 in order to evaluate the bovine, ovine and caprine brucellosis eradication programmes	
Recommendation	Basis for assessment/Information Requested/CA response
Article 11(1) of Decision 2009/470/EC.	*recommendation.*

Audit 2015-7569 of 13 October 2015 in order to evaluate the implementation of contingency plans in relation to animal health, including provisions on the protection of animals during depopulation for disease control	
Recommendation	Basis for assessment/Information Requested/CA response
2015-7569-2 To ensure that a swift and coordinated response could be given in the event of a widespread disease outbreak of FMD or AI affecting more than one region by having an overview of the level of preparedness available in all RVS and ASLs – i.e. that their plans and manuals are fully fit for purpose and applicable. Article 4 (2)(f) of Regulation (EC) No 882/2004; criteria for contingency planning listed in Appendix to this report. Based on conclusions (22) and (62), and associated findings (5), (39),	**In Progress** **Findings:** In case of large outbreaks of exotic animal diseases affecting several regions, in particular with regard to FMD, it is uncertain whether Italy could offer a swift and harmonised response, as there is no coordination of the development and no verification of the readiness of the animal health emergency preparedness systems at regional and local level. However, the animal health information management systems available to the CAs are largely adequate to facilitate the effective deployment of an early response to a disease outbreak and to speed its follow-up. ***Assessment****: The authorities have taken action regarding Avian Influenza, on the basis of lessons learned in dealing with outbreaks and exercises carried out. National level 'cascade' training for the management of an outbreak of FMD and biosecurity standards provides a certain level of preparation and central level are updating the National Contingency Plan to take account of Regulation 2016/429 and Regulation 2020/687, and surveying the regions and autonomous provinces to verify the adoption of regional emergency plans.* *To allow this recommendation to be closed, central level should provide an overview of the survey planned to be completed by end of October 2021 and indicate whether regional plans and manuals are fit for dealing with a multi-regional outbreak of FMD.*

Audit 2015-7569 of 13 October 2015 in order to evaluate the implementation of contingency plans in relation to animal health, including provisions on the protection of animals during depopulation for disease control	
Recommendation	Basis for assessment/Information Requested/CA response
(54) and (55).	
2015-7569-3 To identify and analyse the epidemiological factors and operational criteria (e.g. identification of risk areas with high density of susceptible animal populations, availability of sufficient carcass disposal capacity, clear vaccination strategy for FMD and AI) that would allow CAs to take a well-informed decision on the application of additional eradication measures – such as pre-emptive animal depopulation and emergency vaccination – in the event of a large outbreak of FMD, and to a lesser extent, of HPAI. Article 72 (3) of, and Annexes XVII (point 12) and X to Directive 2003/85/EC. Article 62 (2) of, and Annex X (point 9) to Directive 2005/94/EC. Based on conclusions (22) and (24)	**In Progress** **Findings:** The report states that the effective response to cope with the exceptional circumstances related to large outbreaks of exotic diseases, in particular FMD, is undermined by the limited specific arrangements that have been made to anticipate them (e.g. identification of risky densely populated livestock areas, additional arrangements related to depopulation, availability of sufficient carcass disposal capacity, clear vaccination strategies for FMD and AI). ***Assessment**: The authorities have taken action in relation to Avian Influenza. In relation to FMD, the central level together with the National Reference Center for Vesicular Diseases are mapping the areas at risk of introduction and spread of FMD and reviewing the National Contingency Plan in relation to the operational steps to implement emergency vaccination. To allow this recommendation to be closed, central level should provide, if available as planned by the end of 2021, the outcome of the mapping of risk areas and review of procedures for emergency vaccination and also indicate whether the capacity for carcass disposal in the event of a multi-regional FMD outbreak in northern Italy has been assessed.*

Audit 2015-7569 of 13 October 2015 in order to evaluate the implementation of contingency plans in relation to animal health, including provisions on the protection of animals during depopulation for disease control	
Recommendation	Basis for assessment/Information Requested/CA response
and associated findings (14), (15), (17), (18) and (58).	
2015-7569-4 To ensure that, on the basis of the various possible scenarios for the size and location of exotic disease outbreaks, staff at the RVS and ASLs are capable of preparing adequate action plans for depopulation operations in order to safeguard the welfare of the animals. Article 18 of Regulation (EC) No 1099/2009. Based on conclusions (23), and associated findings (14), (15) (53) and (55).	**In Progress** **Findings:** The CAs have the necessary information from the generic plan to make adequate arrangements in the event of a localised exotic disease outbreak to spare animals any unnecessary pain, suffering and distress during depopulation. However, the absence of details on how CAs would evaluate the circumstances of depopulation, and practical guidance is lacking with different levels of preparedness for carry out stunning. ***Assessment**: Training in 2019 and a general guideline on killing added to the national contingency plan represent progress; the central level has sent a procedure to the regions/local CAs which they could follow when creating an action plan for killing and this should be in place by January 2022. To allow this recommendation to be closed, central level should verify that the local veterinary services have a procedure and received training to support them in drawing up an action plan for depopulating a holding, also indicated as an action to address a recommendation in a more recent audit 2019-6599-2.*
2015-7569-5 To ensure that the requirements for real-time alert exercises for FMD (minimum frequency and scope) laid down in EU legislation are met. Thus, the real-time exercises could effectively contribute to: a) training	**In Progress** **Findings:** The the CAs have not taken sufficient action to organise adequate and frequent real-time exercises to test the contingency planning available for FMD at regional and national level. The central level do not have an adequate overview of exercises which were organised (number, scope and quality of the exercises). This limits the possibility for the CCA to coordinate, review and update the level of national animal health emergency preparedness. ***Assessment**: Real time exercises for ASF and AI meet the minimum frequency and scope required; however, the last*

Audit 2015-7569 of 13 October 2015 in order to evaluate the implementation of contingency plans in relation to animal health, including provisions on the protection of animals during depopulation for disease control	
Recommendation	Basis for assessment/Information Requested/CA response
personnel designated to be involved in an emergency situation, and b) testing, critically reviewing and up-dating contingency plans, emergency preparedness arrangements in general and disease eradication strategies at national, regional and local level. Article 73 and Annex XVII (point 11.2) to Directive 2003/85/EC. Based on conclusion (65), and associated findings (57) and (58).	*real time exercise on FMD took place in 2011. The work with the European Foot-and-Mouth Disease Spread model (EUFMDiS) is a good basis for future exercises to be planned and carried out. Such an exercise could also validate the preparedness of regional and local level as requested in recommendation 2015-7569-2 above. To allow this recommendation to be closed, central level should indicate the outcome of their review in relation to the organization of simulation exercises as referred to in Article 45 of Regulation 2016/429 and as planned to be completed in the first semester of 2022.*

Audit 2016-8764 of 11 October 2016 in order to evaluate the implementation of animal health controls in relation to African Swine Fever	
Recommendation	Basis for assessment/Information Requested/CA response
2016-8764-1 To ensure that all requirements on identification and registration of pigs laid down in Directive 2008/71/EC, are complied with and updated in the national pig database as required in Article 18(c) of Directive 1964/432/EEC, in particular as	**In Progress** **Findings:** The existence of unregistered pigs which are not subject to controls in some parts of Sardinia compromises the reliability of the pig population data and undermines the traceability of pig movements. Similarly the under-notification of movements of pigs weakens the reliability of the database, thus its data cannot fully support the planning and implementation of ASF eradication measures, nor the reliable/targeted planning of official controls when considering risks for example movements of pigs from infected to non-infected parts of the island. ***Assessment**: The information received from the Italian authorities, which was verified during the fact-finding mission in June 2019 (ref. 2019-6871), demonstrates a significant improvement in the implementation and*

Audit 2016-8764 of 11 October 2016 in order to evaluate the implementation of animal health controls in relation to African Swine Fever	
Recommendation	Basis for assessment/Information Requested/CA response
regards: registration of all pig holdings present in Sardinia to ensure an up-to-date list of all the holdings and keepers of pigs, in line with Article 3(1)(a) of Directive 2008/71/EC, adequate and timely individual identification of animals; notification to the competent authorities and adequate keeping of records in the holding registers of all movements of pigs, and effective enforcement of the prohibition to rear free-range pigs out of registered semi-enclosed or enclosed premises. To ensure that the national pig database contains timely information on all pig movements. Article 18(c) of Directive 1964/432/EEC. Recommendation based on conclusions No: 20, 22 Associated findings No.: 10, 14	*enforcement of pig identification, registration and movement control requirements since 2016. Commissioner Kyriakides replied to Minister Speranza on 10 February 2021 (under cover of a note from Head of Cabinet M. Giorgos Rossides to Ambassador Michele Quaroni) acknowledging the efforts made by Italy in relation to the eradication of ASF in Sardinia and proposing that, as soon as the current global situation will allow, DG SANTE will organise a specific audit to verify and evaluate the situation on the ground. This recommendation remains in progress until a specific follow-up audit is carried out (2021-7344 currently planned for November 2021).*
2016-8764-3 To carry out effective epidemiological investigation in the case of confirmation of ASF and to	**In Progress** **Findings:** The questionable quality of epidemiological investigations together with the unreliable information gained from the results of serological testing of pigs at the time of killing, reduces the confidence in implementing eradication measures including backward and forward tracing. It also reduces the reliability of overall understanding

Audit 2016-8764 of 11 October 2016 in order to evaluate the implementation of animal health controls in relation to African Swine Fever	
Recommendation	Basis for assessment/Information Requested/CA response
take required number of samples at the time of killing of pigs, so that they contribute effectively to provide accurate and timely information necessary to ascertain the origin of the disease, the length of its presence in the affected holding and all possible factors and contacts that could contribute to its spread beyond the investigated holding. Article 8 of Directive 2002/60/EC and Chapter IV(B)(2) of Decision 2003/422/EC. Recommendation based on conclusion No. 46 Associated findings No.: 34, 35	of the factors that contribute to the introduction, spread or persistence of ASF infection. ***Assessment****: Two epidemiological investigations provided (in December 2018) were consistent as they were based on completed check-lists. However, these did not provide information if a proper epidemiological investigation had been conducted. The two epidemiological investigations did not provide conclusions on the time frame the disease may have existed in the holding, and one of them did not provide conclusions on the origin of ASF. There have been no recent outbreaks to demonstrate the quality of epidemiological investigations. As indicated for recommendation 1 above DG SANTE plans to carry out a specific audit 2021-7344 in November 2021. This recommendation remains in progress until a specific follow-up audit is carried out.*
2016-8764-4 To ensure immediate establishment of protection and surveillance zones and associated measures in an occurrence of an ASF outbreak. Article 9 and Article 10(1)(a) of Directive 2002/60/EC. Recommendation based on conclusion No. 47	**In Progress** **Findings:** The frequent delays in establishing protection and surveillance zones and delays in checking holdings in the protection zone compromise the fast detection of other infected holdings and constrain the effectiveness of the measure in preventing further spread of the infection. ***Assessment****: The CA took action with regard to the immediate establishment of protection and surveillance zones after notification of outbreaks. As no ASF outbreaks involving domestic pigs have been notified since January 2019 it is difficult for the authorities to demonstrate the timely examination of pig holdings in the protection zone. The Veterinary intervention group (Gruppo di Intervento Veterinario - GIV) is routinely deployed to assist the local veterinary authorities to establish restrictive measures on and around confirmed outbreak holdings. An enforcement cell, comprised of GIV personnel and officials from the Forestry Corps, is established for each outbreak and is*

Audit 2016-8764 of 11 October 2016 in order to evaluate the implementation of animal health controls in relation to African Swine Fever	
Recommendation	Basis for assessment/Information Requested/CA response
Associated findings No.: 38, 39	*responsible for carrying out surveillance visits and patrols within the area to ensure that the restrictions are respected. No further information requested for following up this recommendation at this time. As indicated for recommendation 1 and 3 above DG SANTE plans to carry out a specific follow-up audit 2021-7344 in November 2021.*

Audit 2019-6599 of 11 November 2019 in order to evaluate the application of measures for the prevention and control of avian influenza	
Recommendation	Basis for assessment/Information Requested/CA response
2019-6599-2 To put in place measures / procedures to ensure that the regions effectively draw and use actions plans for the depopulation activities, which respect animal welfare requirements. Article 62 (2) of, and point 5 of Annex X to Directive 2005/94/EC; Article 18 of Regulation (EC) No 1099/2009. Based on conclusion (33), (34), (65) and (82), and associated findings (24), (71) and (72).	**In Progress** **Findings:** The main causes for delays in depopulation were the shortage of equipment to kill the animals, of staff to supervise those activities and, to a lesser extent, of transportation and disposal capacity for the carcasses resulting from them. As the authorities have not correctly anticipated the necessary resources to prioritise the quick depopulation of HPAI in periods of high incidence of the disease in areas with a high density of poultry, there were delays in the killing of infected flocks. This had a significant impact on the acceleration of the spread of infection during the last months of the second wave of the epidemic. The local units had rarely drafted actions plans for the depopulation activities, although this was required by national guidance on animal depopulation and Article 18 of Regulation (EC) No 1099/2009. None of the competent authorities met by the audit team could provide reports on the animal welfare issues evaluated during depopulation. ***Assessment**: Actions to address a similar recommendation 2015-7569_4 remain to be implemented. This recommendation remains in progress until the central level verifies (planned by January 2022 and also required by recommendation 2015-7569_4) that local CAs have procedures and training for drawing-up an action plan prior to any depopulation.*

2.B.2 Food of animal origin

Audit 2012-6542 of 16 October 2012 in order to evaluate the control systems in place governing the production and placing on the market of bivalve molluscs	
Recommendation	Basis for assessment/Information Requested/CA response
2012-6542-5 The CAs should ensure that, when monitoring classified production areas, the sampling plan to check for the presence of toxin-producing plankton in production water must take particular account of possible variations in the presence of plankton containing marine biotoxins and that when changes in the composition of plankton containing toxins suggest an accumulation of toxins in molluscan flesh, the sampling frequency of molluscs is to be increased, as established in Point B.4 and 7 of Chapter II of Annex II to Regulation (EC) No 854/2004	**In Progress** **Findings:** The clams from natural beds (in one region) were rarely monitored for the presence of biotoxins. The presence of biotoxins in clams was only monitored when toxic producing phytoplankton is detected in the production area, which is difficult to achieve as no monitoring frequency for phytoplankton has been established for these areas. The report states in addition that there is no defined action plan to implement, if algae values are high. Therefore it is not used to take further actions, such as intensification of sampling. Regulation (EC) 854/2004 has been repealed. The current requirements can be found on Article 61, 3 (a) & 7 of Commission Implementing Regulation (EU) 2019/627. ***Assessment**: There is a better definition of sampling plans, however, the approval of national guidance for phytoplankton sampling and monitoring is still to be adopted, pending the adoption of a procedure at Union level, which is still under discussion. According to the Competent Authority, once the European guidelines "Monitoring of Toxin-producing Phytoplankton in Bivalve Mollusc Harvesting Areas - Guide to Good Practice: Technical Application", are approved at EU level, the Ministry of Health, in collaboration with LNR-BM, will promptly inform the local CAs and LUs responsible for monitoring marine biotoxins and toxic phytoplankton. To allow this recommendation to be closed the CCA should provide an update (once EU guidelines are published) on the expected timescales for the publication and implementation steps for the national instructions. The Ministry also stated that the majority of the 11 official laboratories concerned already apply the quality assurance of analytical data to which a chapter of the European guidelines is dedicated. For the others, the NRL-BM will activate (for some laboratories it is already in progress) a specific assistance path for the accreditation of this procedure. Furthermore, again in the context of quality assurance, as required by European guidelines, the Italian LUs already regularly participate in*

Audit 2012-6542 of 16 October 2012 in order to evaluate the control systems in place governing the production and placing on the market of bivalve molluscs	
Recommendation	Basis for assessment/Information Requested/CA response
	proficiency testing schemes (ISO / IEC 17025 - ISO1704. *To allow this recommendation to be closed, the central level should (once EU guidelines are published) provide evidence of the implementation of the steps for introducing these in the national instructions.*
2012-6542-6 The CAs should ensure that, the sampling frequency for biotoxins analyses in all species of molluscs and marine gastropods is in line with Point B.5 of Chapter II of Annex II to Regulation (EC) No 854/2004	**In Progress** **Findings** The frequency of monitoring for biotoxins in live bivalve molluscs and marine gastropods was in several cases not carried out according to the criteria established in the national/regional guidelines or in EU legislation. Regulation (EC) 854/2004 has been repealed. The current requirements can be found on Article 61, 4 (a) & (b) & 5 of Commission Implementing Regulation (EU) 2019/627. ***Assessment****: Good progress has been made with regard to the implementation of sampling and evidence was provided of the risk assessment completed by the regions reducing the sampling frequency to fortnightly. However, there is currently no guidance or specific procedure in place to ensure consistency throughout the national territory on the completion of risk-assessments which would allow a reduction of sampling frequency. The national guidelines will include specific instructions on the process to follow to ensure a reduction of the weekly frequency is supported by a consistent risk-assessment and as stated for recommendation 2012-6542-5 above, are dependent on the adoption of guidelines at EU level. To allow this recommendation to be closed the CCA should clarify whether the risk-assessments used by the local CAs are adequate to allow for reduction of sampling frequency.*

Audit 2019-6747 of 29 January 2019 in order to evaluate the control systems in place governing the production of fishery products derived from tuna species	
Recommendation	Basis for assessment/Information Requested/CA response

Audit 2019-6747 of 29 January 2019 in order to evaluate the control systems in place governing the production of fishery products derived from tuna species	
Recommendation	Basis for assessment/Information Requested/CA response
2019-6747-1 While performing the official controls of primary production fishing vessels, the CA should ensure adherence to the frequencies set in the official control plans, drafted and adopted in accordance with the applicable EU rules, in particular Article 3(1) of Regulation (EC) No 882/2004. Recommendation based on conclusion No 48. Associated finding Nos 31 and 33.	**Action Still required** **Findings:** The frequency for the periodic inspection of vessels had not followed the set frequency. Article 3(1) of Regulation (EC) No 882/2004 has been replaced by Article 9(1) of Regulation (EU) 2017/625. ***Assessment:*** *Considering that the guidelines were implemented in 2018, we would expect that all fishing vessels should have been controlled by the end of 2022 and not 2023. The CA provided numbers of inspections from the two main regions (Sicilia and Puglia) which inspected 13 and 18% of vessels in 2020 respectively and Veneto did achieve the target with 20% of registered enterprises engaged in fishing checked in 2020. This was considered by the CA as a positive step, due to the limitations of the pandemic, overall 10% of vessels were inspected which is less than the expected 20%. The response does not provide guarantees that controls in all applicable regions will be completed in accordance with the frequency set, although the CA indicated that, once COVID-19 restrictions ease, the controls should be completed as planned. In order to progress this recommendation the CCA should provide evidence of a clear commitment by the regions to carry out the controls as planned and in accordance with the Italian guidelines pointing out the steps to reach the set target of all vessels inspected in a 5 year period as well as evidence of the completion of controls as planned.*
2019-6747-2 The CA should verify effectively that approved establishments comply with relevant requirements of Regulation (EC) No 852/2004 and Annex II of Regulation (EC) No 853/2004, in particular, cold stores equipped with temperature recording	**In Progress** **Findings:** The control system was not fully effective as certain non-compliances identified during the audit had not been noticed during inspections and/or had not been recorded. The findings explain these deficiencies were related to the unacceptable location of the ice machine in one fishing vessel and lack of a temperature recording device in a cold store together with cold room temperatures above the regulatory limits. The original best-before-dates of products packed in modified atmosphere was used for re-packed products in vacuum packages after opening and portioning. Shelf-life studies to support this practice had not been performed ***Assessment:*** *The CA provided e-learning with detailed information on official controls which was taken up by*

Audit 2019-6747 of 29 January 2019 in order to evaluate the control systems in place governing the production of fishery products derived from tuna species	
Recommendation	Basis for assessment/Information Requested/CA response
devices, hygienic ice production on board vessels and applicable microbiological criteria. Recommendation based on conclusion No 49. Associated findings Nos 34, 40 and 41.	*around 5000 staff. Following the GFA, the CCA sent a note to the regions asking them to ensure that warehouses storing frozen products are equipped with continuous temperature recording devices and for fishing vessels that the production of ice on board complies with hygiene requirements. A summary of actions taken following inspections in 2019 was provided where a total of 46 non-compliances resulted in 21 imposition of sanitation procedures 1 case restriction of the placing on the market and other measures in 11 cases.* They also provided data for 2020 controls where 70 *non-compliances included a* report of crime (Apulia) and a higher number of cases (13) of restriction of the placing on the market by Calabria. *To allow this recommendation to be closed the CCA should provide several examples of serious hygiene deficiencies identified during controls (including details of the case of* reported crime by Apulia and one of the cases of restriction of the placing on the market by Calabria*, as well as evidence of actions taken in these cases). Evidence should also be provided of the control verification procedures for checks on fishing vessels and actions taken where shortcomings were found in these controls (for example the results of the* audit of Emilia Romagna in 2021 and any follow up actions taken).
2019-6747-3 The CA should verify effectively that food business operators put in place appropriate permanent procedures based on the HACCP principles and that these are implemented and kept up-to-date in order to provide the guarantees specified in Article 5 to Regulation (EC) No 852/2004.	**Closed due to action taken** **Findings:** In half the establishments visited, the CA staff had not noted deficiencies in HACCP plans: did not describe the actual activities that took place, did not assess all relevant hazards, lacked documented procedures. ***Assessment*** *The CA confirmed that 5000 members of staff had completed online training of 50 hours which included detailed instructions on the checking of self-controls and HACCP application. This provides a good basis for staff to verify food business operators' HACCP programmes and based on the evidence provided, it is considered that this recommendation is addressed.*

Audit 2019-6747 of 29 January 2019 in order to evaluate the control systems in place governing the production of fishery products derived from tuna species	
Recommendation	Basis for assessment/Information Requested/CA response
Recommendation based on conclusion No 49. Associated finding No 42.	
2019-6747-4 The CA should verify effectively that food business operators demonstrate compliance with the health standard for fishery products, in particular with the requirement of Chapter V (B) of Section VIII of Annex III to Regulation 853/2004 and Regulation (EC) No 2073/2005 concerning the number of analyses performed and the maximum limits applied for histamine. Recommendation based on conclusion No 49. Associated finding No 45.	**In Progress** **Findings:** The food business operators did not apply EU rules for testing histamine and this had not been identified by the official controls. Often only one sample, instead of nine, was analysed for histamine and in one establishment nine samples were taken but the laboratory pooled all before the analysis. In another establishment, the maximum limit applied by the food business operator was 200mg/kg for raw material. None of these issues had been identified and/or recorded during official control*s*. ***Assessment*** *The CA did not provide a detailed explanation why the control system failed to detect that FBOs did not comply with the requirements in relation to health standards of fishery products (in particular, sampling and testing for histamine). The CA delivered a training programme to around 5000 staff, with detailed information on official controls; however no evidence was provided that this aspect of official controls (checks on histamine sampling) improved as a result. Added to that, verification activities had not been possible due to the interruption of internal audits in 2020 (COVID-19 restrictions). The note to the regions (2019-6747-2 2021 03 17 nota 10704 follow up country profile) asked them to ensure the sampling and analysis procedures to determine the maximum limits for histamine laid down in Regulation (EC) No 2073/2005, which provides for 9 sampling units per sample, are correctly applied. The note asks for evidence of official controls on establishments (audits — inspections), actions taken following significant findings and evidence of activities to verify controls. To allow this recommendation to be closed, the CCA should provide evidence of actions taken to ensure proper histamine sampling and appropriate measures applied where the maximum limits were exceeded (for example the relevant results from audits of Emilia Romagna regarding controls in the fishery sector and Sicily regarding histamine sampling by FBOs).*

2.B.3 Imports of animals and food of animal origin

Audit 2016-8874 of 14 November 2016 in order to evaluate the systems for enhanced import controls	
Recommendation	Basis for assessment/Information Requested/CA response
2016-8874-1 To ensure that the facilities and equipment at the DPEs/DPIs are adequate to undertake the necessary checks and to handle and store food of non-animal origin hygienically in line with the requirements set out in Article 4 of Commission Regulation (EC) No 669/2009 and Article 8 of Commission Implementing Regulation (EU) No 884/2014. Recommendation based on conclusion 20 Associated findings: 15, 16 and 17	**Closed due to action taken** **Findings:** The facilities at the Designated points of entry/ introduction (DPEs/DPIs) visited are not appropriate to undertake the necessary checks and to handle food of non-animal origin hygienically, leading to a risk of contamination or spoilage. ***Assessment:*** *A system is in place to verify that DPEs/DPIs comply with requirements. 15 out of 22 DPEs/DPIs were audited since 2017. Ravenna was included in the 2016 audit and has now rectified the identified non-compliances. Based on the evidence provided, this recommendation is considered addressed.*

Audit 2019-6640 of 26 November 2019 in order to evaluate the system of official controls on imports of animals and goods	
Recommendation	Basis for assessment/Information Requested/CA response

Audit 2019-6640 of 26 November 2019 in order to evaluate the system of official controls on imports of animals and goods	
Recommendation	Basis for assessment/Information Requested/CA response
2019-6640-1 To ensure that a) the facilities and equipment to carry out official controls on imports of animals, products of animal origin, and products of non-animal origin subject to special import conditions comply with the requirements laid down in Article 6(3) and Annex A to Directive 91/496/EC (animals), Article 4 and Annex to Decision 2001/812/EC (products of animal origin) and Article 4 of Regulation (EC) 669/2009 and Article 8 of Regulation (EU) 884/2014 (food of non-animal origin subject to special import conditions), and b) that an updated list of designated points of entry and imports is made publicly available in line with Article 5 of Regulation (EC) 669/2009 and Article 8 of Regulation (EU) 884/2014. Recommendation based on conclusions: 85 and 86 Associated findings: 77 – 80, 82, and	**In Progress** **Findings:** Milano-Malpensa Airport BIP facilities for ungulates (category U) had a roof leaking in different places. In addition, BIP staff did not identify damaged floor surfaces and the absence of restraining equipment for animals. At Gioia Tauro Port BIP plans have been approved, but construction has not yet begun for new border control facilities in 2020. The facilities and equipment for products for human consumption and other products at Civitavecchia Port BIP did not meet the standards for approval (e.g. damaged floors, walls and ceiling, entry doors, non-functioning cooling systems in the storage rooms and rusty equipment). No plan to upgrade the substandard facilities and equipment at Civitavecchia Port BIP. At "SPRESS" at Rome-Fiumicino airport BIP was built in line with the plans for the categories: chilled and frozen packed products for human consumption (which need to be kept at specific temperatures) and the necessary equipment was in place. However, the facilities were not appropriately cleaned and the walls in both storage rooms need some repair. Palermo Port, new border control facilities under construction. ***Assessment*** *The CA took action in relation to Civitavecchia, Milan Malpensa and Palermo; further action required for Gioia Tauro and Venice. Civitavecchia – given the visible overall improvement the situation is not comparable with what is described in the findings, together with the compliance statement form the Italian authorities, this addresses the recommendation for Civitavecchia. Milan Malpensa - The Italian authorities suspended control activities for live animals, categories U and E. this addresses the recommendation for ALHA Airport MXP SpA. Palermo – DG SANTE listed the new BCP Palermo for the categories of product of animal origin. Following this, the Italian authorities notified that the new facilities will be used for products of non-animal origin, categories PNAO-HC(food), PNAO-NHC(feed) and PNAO(NHC)(other) (NT) Ares(2021)2677550. This leads to an extension of the scope of designation with the category PNAO-HC-T(FR). The facilities for products of animal origin and non-animal origin are separated. The facilities for POA have been completed in August 2020 and the facilities for PNAO in March 2021. Gioia Tauro - evidence of documented system of cleaning and disinfection of the BCP facilities carried out by the external company. The Italian authorities stated (GFA 19 March 2021) that work is underway on the new border control facilities will be completed in March 2022 and in the meantime, non-conformities have been removed at the current BCP facility. At Venice port it was decided to reorganize the current structure of the BCP for*

Audit 2019-6640 of 26 November 2019 in order to evaluate the system of official controls on imports of animals and goods	
Recommendation	Basis for assessment/Information Requested/CA response
84	*products of animal origin (POA) and to dedicate the POA-NHC sector to the official controls of products of non animal origin. The project will be sent by September 2021 with all the information required by the Commission. A national law (Legislative Decree n. 24 of 2 February 2021) allows the CCA to have more power in requests for intervention on problems that affect the structures of all BCPs without having more situations managed in a different way by various port and airport management companies.* *In order to allow this recommendation to be closed, the CA should provide evidence that the facilities at both port BCPs (Gioia Tauro and Venice) have been adapted appropriately.*
2019-6640-3 To ensure that official control staff enter the required data into TRACES on consignments which require confirmation of receipt at destination, in particular related to transit, supplying sea transport and re-importation of products of animal origin in line with the requirements laid down in Article 3(2) of Decision 2004/292/EC. Recommendation based on conclusion:67 Associated findings: 39, 40 and 54	**In Progress** **Findings:** For certain records of supplies of goods from the customs warehouse to cross border means of sea transport, operators had not provided the BIP staff with the completed certificate confirming the delivery of goods on board the vessel within the deadline of 30 days. The BIP staff issued a similar document for delivery of goods from the warehouse to NATO/US army bases, and validated thereafter the CVEDs in TRACES. The proportion of cases where confirmation of arrival at NATO/US army bases within the deadline of 30 days varies significantly between bases, ranging from 99,6% to as little as 13.4 % confirmed. Consignments of animal origin channelled to their destination: the local veterinary units had been informed of the dispatch and had reported the arrival of such consignments at destination. However, local veterinary units did not enter in TRACES the completion of part III of the CVEDs in 16 of the 50 cases, but used instead other means to report the arrival e.g. by email. The guarantees in response to recommendation 1 of a previous audit report in relation to entering required data into TRACES by the local veterinary units, confirming the arrival of consignments at destination have not been effectively implemented. ***Assessment*** *The CCA wrote to the regions 3/3/2021 and provided legislation (Legislative DECREE No 24 of 2 February 2021) to confirm the arrangements for the use of TRACES for entering data regarding the Common Health Entry Document (CHED) for transits and that audits are planned with a specific sectoral audit in 2021 (to take place in autumn to include also aspects concerning products of non-animal origin, with the BCP that will be subjected to the audit identified in the monitoring checks carried out by central level every 6 months). To allow this*

Audit 2019-6640 of 26 November 2019 in order to evaluate the system of official controls on imports of animals and goods	
Recommendation	Basis for assessment/Information Requested/CA response
	recommendation to be closed the CCA needs to provide evidence (e.g. an audit report) that it monitors the use of TRACES and acts in cases where there has been a lack of notifications for transiting consignments.

2.B.4 Feedingstuffs and animal nutrition

There are no recommendations currently open for follow-up.

2.B.5 TSE\ABP

Audit 2018-6336 of 20 March 2018 in order to evaluate the implementation of hygiene, traceability and trade requirements of processed animal proteins, including exports, imports and intra-union trade	
Recommendation	Basis for assessment/Information Requested/CA response
2018-6336-1 To ensure the accuracy of the lists of plants in the chain of production and use of feed containing PAP derived from non-ruminants for aquaculture, as laid down in Section A, Chapter V of Annex IV to Regulation (EC) No 999/2001. Recommendation based on conclusion: 26	**In Progress** **Findings:** The report states the lists of plants in the chain of production and use of non-ruminant PAP for the aquaculture sector are not sufficiently accurate. This weakness hampers the competent authority's overview and has resource implications for officials who have to investigate each case when a decision on the presence of ruminant protein in a given consignment of PAP has to be taken. Moreover, certain inaccuracies identified in the approval and registration of some ABP plants and operators partly undermine the overall effectiveness of official controls. ***Assessment*** *The CCA provided a guideline to the regions on listing operators approved under Regulation (EC) No 999/2001 (which includes plants in the chain of production of aquaculture feed). The CCA asked the regions to verify and update the list for slaughterhouses and cutting plants and the list for processing plants. In order to allow this recommendation to be closed the CCA should provide evidence that the list of processing plants has been updated (and highlight plants approved under Regulation (EC) No 1069/2009 which also appear in the list approved*

Audit 2018-6336 of 20 March 2018 in order to evaluate the implementation of hygiene, traceability and trade requirements of processed animal proteins, including exports, imports and intra-union trade	
Recommendation	Basis for assessment/Information Requested/CA response
Associated findings: 15 and 16	*under Regulation (EC) No 999/2001).*
2018-6336-2 To ensure that the approval and registration of ABP plants and operators accurately reflect the products manufactured and the nature of the operations performed, based on information provided by the operator as laid down in Article 23 of Regulation (EC) No 1069/2009. Recommendation based on conclusion: 26 Associated findings: 12, 13 and 14	**Closed due to action taken** **Findings:** Approval and registration certificates issued by the RVS did not reflect the current products manufactured/handled and the nature of the operations performed. A producer of OF/SI visited, initially approved as a Category 2 OF/SI plant and using manure, acting as a storage plant. Risk of cross-contamination between Category 2 and 3 ABP due to transporter using trucks in both categories for category 3. ***Assessment*** *The CCA have carried out audits to further assess compliance at local level. The three audit reports indicate controls were not effective in detecting discrepancies and in response the regions provided action plans to train staff. The CCA provided a checklist for approving ABP operators which highlights that the operator must have the necessary infrastructure and procedures in place to match the approval given and an instruction making clear to the other levels that they should ensure training/competence and only approve a plant in relation to its operational capacities. Based on the evidence provided, this recommendation is considered addressed.*
2018-6336-3 To ensure that planned official controls on operators along the chain of production of ABP are actually carried out following the planned arrangements, as required by Article 3 of Regulation (EC) No 882/2004.	**Closed due to action taken** **Findings:** The inspections on approved operators were generally in line with the planned frequencies, in one region those concerning traders and transporters were not carried out as scheduled, thereby missing an important link in the ABP chain. ***Assessment*** *The CA sent a reminder to the regions/ASLs (doc "nota trader e trasportatori 2018-6336-3.1") and refer to the audits and action plans as above. The reports of internal audits indicate the planning is satisfactory regarding checks of traders and transporters, which is sufficient to address this recommendation (the inaccuracies*

Audit 2018-6336 of 20 March 2018 in order to evaluate the implementation of hygiene, traceability and trade requirements of processed animal proteins, including exports, imports and intra-union trade	
Recommendation	Basis for assessment/Information Requested/CA response
Recommendation based on conclusion: 44 Associated findings: 27 and 28	*detected by the audits are more linked to recommendation 2018-6336-2 above which remains open). Based on the evidence provided, this recommendation is considered addressed.*
2018-6336-4 To put in place measures aimed at ensuring that the departure of consignments of organic fertilisers and soil improvers (OF/SI) containing PAP or Category 2 MBM is notified in the TRACES system as laid down by Article 48(3) of Regulation (EC) No 1069/2009. Recommendation based on conclusion: 46 Associated findings: 37	**In Progress** **Findings:** The arrival of a significant number of consignments of PAP traded from other Member States is not notified in TRACES to the competent authority of the Member State of origin, and consignments of OF/SI containing PAP dispatched from Italy have not been considered as requiring notification in TRACES. ***Assessment*** *The CA has made better use of TRACES to notify consignments of soil improvers containing Processed Animal Proteins (PAPs) traded to other Member States. Four of the 12 regions where operators are approved under Article 24 (f) of Regulation (EC) No 1069/2009 are using TRACES and the CCA requested the 8 who have not notified any dispatch to verify if this situation is correct. In order to allow this recommendation to be closed, the CCA needs to provide the control verification procedure in place to ensure that the dispatch of consignments of Organic Fertilizers/Soil Improvers to other Member States is notified in TRACES.*
2018-6336-5 To put in place measures aimed at ensuring that information about the arrival of consignments of PAP is notified to the Member State of origin, by means of the TRACES system, as required by Article 48(3) of Regulation (EC) No 1069/2009.	**Closed due to action taken** **Findings:** The arrival of consignments containing Processed Animal Proteins (PAPs) is not always notified to the Member State of origin in TRACES. ***Assessment*** *Regular central level supervision of TRACES has assured that the arrival of consignments containing Processed Animal Proteins has been notified to the Member State of dispatch. Data provided indicates that 95.67% of consignments were notified as required over a two and a half year period. Based on the evidence provided, this recommendation is considered addressed.*

Audit 2018-6336 of 20 March 2018 in order to evaluate the implementation of hygiene, traceability and trade requirements of processed animal proteins, including exports, imports and intra-union trade	
Recommendation	Basis for assessment/Information Requested/CA response
Recommendation based on conclusion: 46 Associated findings: 38	
2018-6336-6 To put in place measures aimed at ensuring that all obligations concerning the export of PAP containing proteins of ruminant origin, in particular the verification of the seals of the consignments by the competent authority at the point of exit, are implemented as laid down by Article 7 and Section E, Chapter V of Annex IV to Regulation (EC) No 999/2001. Recommendation based on conclusion: 47 Associated finding: 40	**Closed due to action taken** **Findings:** The measures put in place by the competent authorities to control the export of PAP containing proteins of ruminant origin, in particular the verification of the seal of consignments, are not yet sufficient to ensure that all relevant legal requirements are fulfilled. ***Assessment*** *The CCA instruction to the regional CAs and data provided, which indicates that all consignments of Processed Animal Proteins from ruminants was verified at exit points, satisfactorily addresses the recommendation.*

2.B.6 Veterinary medicines and residues

Audit 2017-6191 of 24 January 2017 in order to evaluate the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria in certain food-producing animal populations and food	
Recommendation	Basis for assessment/Information Requested/CA response
2017-6191-2 To ensure that the coordination and cooperation between competent authorities and the gathering of isolates from food business operators allow that the available Salmonella isolates, from the populations specified in point 1 (a) of Part A of the Annex to Decision 2013/652/EU, are gathered and subject to antimicrobial susceptibility testing, in order to achieve the minimum number required by point 2.2 and comply with Article 2(2)(a) of the said Decision. Recommendation based on conclusions No 12 and 45. Associated findings No 6, 27, 28, 29, 32 and 33.	**Closed due to action taken** **Findings:** The minimum target of 170 Salmonella isolates had not been achieved for the relevant bacteria/species combinations since the introduction of Decision 2013/652/EU. ***Assessment*** *The minimum number of 170 salmonella isolates has been achieved in pigs since 2017. An operational procedure for private laboratories to send samples from food business operator´s own control programmes for poultry to the NRL has been sucessfully implemented and the numbers of isolates achieved (both by FBOs and as part of official controls) has increased in the last years and it generally reaches the target numbers for poultry populations. Based on the evidence provided, this recommendation is considered addressed.*

Audit 2018-6343 of 06 February 2018 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products	
Recommendation	Basis for assessment/Information Requested/CA response
2018-6343-3 To ensure that the NRL for residues of veterinary medicinal products fully meets its obligations as an NRL in accordance with the requirements laid down by Article 33 of Regulation (EC) No 882/2004 and by Article 14 of Directive 96/23/EC. Recommendation based on conclusions: 48. Associated findings: 31, 37 to 39 and 45.	**Closed due to action taken** **Findings:** The report states that the competent authority can largely have confidence in the laboratory performance and the reliability of analytical results as all laboratories are accredited, methods are generally appropriately validated and staff well-trained. However, a few factors weaken the system, such as the long sample analysis turnaround times, the not fully adequate validation of a few rare matrices/species combinations and the fact that the NRL for residues of veterinary medicinal products does not completely meet its NRL obligations and has deficiencies in its quality assurance procedures. [Regulation (EC) 882/2004 has been repealed. The current requirements can be found on Article 101 of Regulation (EU) 2019/625]. ***Assessment:*** *The CCA has taken action to ensure the validation of the required matrices and supervised these activities. There were delays due to the pandemic in completing proficiency tests for Chloramphenicol in Honey and Sulfonamides in bovine muscle. The CCA provided a report (12/05/2021) on the proficiency tests for Chloramphenicol in Honey and procedures for planning future proficiency tests including the involvement of the National reference laboratory in planning proficiency tests. Based on the evidence provided, the recommendation is considered addressed.*
2018-6343-5 To ensure that the provisions of Regulation (EU) 2015/262 are implemented. Recommendation based on conclusion: 78. Associated findings: 66 - 68, 71, 74	**In Progress** **Findings:** The current EU rules governing the equine passport system have not yet been implemented and the control system based on previous EU rules demonstrates several weaknesses with regards to controls on equine identification requirements. Notwithstanding this, documented guidance on how to assess equine passport and food chain information in slaughterhouses decreases the risk that equines, ineligible for human consumption, enter the food chai*n.* ***Assessment****: Implementing Regulation (EU) 2021/963 was published on 10 June 2021 and according to the CCA this*

Audit 2018-6343 of 06 February 2018 in order to evaluate the control of residues and contaminants in live animals and animal products including controls on veterinary medicinal products	
Recommendation	Basis for assessment/Information Requested/CA response
and 75.	*has involved a total amendment of the scheme of the national Decree, the transmission of which to the inter-regional coordination and to the State-Regions Conference has been extended. To close this recommendation the CCA should confirm the decree on the management and operation of the equine database is in force and provide evidence of communications to the regions requesting the implementation of this decree and information on audits planned to verify its implementation.*
2018-6343-6 To ensure that equine passport issuing bodies fulfil their obligations in line with the requirements laid down in Article 3(4) of Regulation (EU) 2015/262 and that when shortcomings with regards to equine identification and registration at such bodies are found, corrective actions are taken, as required by Article 5(3) of Regulation (EU) 2015/262. Recommendation based on conclusion: 78. Associated findings: 72.	**In Progress** **Findings:** The MIPPAF audited three equine passport issuing bodies for the correct implementation of equine identification and registration requirements and found several deficiencies. The audit team was informed that no follow-up had been implemented to see if corrective action had been taken. Since 2012, no other such audits at issuing bodies had been conducted by MIPAAF, neither did the MIPAAF verified if issuing bodies: a) issued identification documents in line with requirements laid down in Article 7 of Regulation (EU) 2015/262 or have a system in place to verify that identification documents are unique, genuine and authentic and have a unique serial number or b) enter identification information of all equines for which they issued a passport into one of the databases. ***Assessment**: Implementing Regulation (EU) 2021/963 was published on 10 June 2021 and according to the CCA this has involved a total amendment of the scheme of the national Decree, the CA confirmed that preparatory work had been completed to ensure that, once the Ministerial Decree specifying the procedures for the management and operation of the equine registry is approved, the requirements can be implemented. To allow this recommendation to be closed the CA should provide information on the planning of audits and inspections of the equine passport issuing bodies by the Ministry of Health, the Regions, the Local Health Authorities and MIPAAF to verify implementation of the requirements of Article 5 of Regulation (EU) No 2015/262.*

2.B.7 Foodstuffs and food hygiene

Audit 2018-6408 of 27 November 2018 in order to evaluate the official control systems in place governing food information to consumers and nutrition and health claims made on foods	
Recommendation	Basis for assessment/Information Requested/CA response
2018-6408-1 To ensure that official controls are implemented in the areas contained in Regulation (EC) No 1924/2006 covering all foodstuffs in accordance with documented procedures and by appropriately trained staff as required by Point 1 of Article 8 and Article 6 of Regulation (EC) No 882/2004, and that the verification of the effectiveness of these controls is carried out and coordination and cooperation is assured as required by Point 3 (a) of Article 8 and Point 5 of Article 4 of Regulation (EC) No 882/2004. Recommendation based on conclusions set out in paragraphs Nos 9, 33, 34, 62 and 102. Associated findings set out in paragraphs Nos 5, 22, 24, 27, 41, 46, 49, 50, 66, 71, 78, 80, 81, 83, 84, 85,	**In Progress** **Findings:** The national guidelines to carry out controls on nutrition and health claims were inadequate. Effective coordination and cooperation was not in place within the Ministry of Health and between the CAs involved, there were misunderstandings within/between the different competent authorities in relation to their responsibilities. Training did not ensure that official staff could perform official controls competently especially related to controls on health claims. There were gaps in risk basis for controls especially related to controls on health claims, and there were no procedures to verify the effectiveness of control activities. Official controls focused on food safety aspects and were limited in scope regarding food information especially at production level and in relation to food supplements and foods for specific groups. The official controls by the Ministry of Health did not include controls on heath claims at any level of food chain and few on nutrition claims. Note the legislation referred to in the recommendation has been replaced as follows: Point 1 of Article 8 of Regulation (EC) No 882/2004 to be replaced by Article 12 (1) of Regulation (EU) No 2017/625; Article 6 of Regulation (EC) No 882/2004 to be replaced by Article 5 (4) of Regulation (EU) No 2017/625; Point 3 (a) of Article 8 of Regulation (EC) No 882/2004 to be replaced by Article 12(2) of Regulation (EU) No 2017/625; Point 5 of Article 4 of Regulation (EC) No 882/2004 to be replaced by Article 4(2)(a) of Regulation (EU) No 2017/625. ***Assessment*** *The CCA has written to the regions and set up a working group as first steps to address this recommendation. To allow this recommendation to be closed the CCA should assess the replies from the regions and provide a control verification procedure for controls of health and nutrition claims.*

Audit 2018-6408 of 27 November 2018 in order to evaluate the official control systems in place governing food information to consumers and nutrition and health claims made on foods	
Recommendation	Basis for assessment/Information Requested/CA response
89 and 90.	
2018-6408-2 To ensure that national legislation and guidelines are in line with EU rules. Recommendation based on conclusion set out in paragraph: No 10. Associated findings set out in paragraphs: Nos 3, 4 and 6.	**Action Still required** The report states that there are national legal requirements and guidance documents not in compliance with EU rules. In particular the requirement to include the name of the production or packing facility on the label of all foods. This cannot be made mandatory as set out in Article 9(1) of Regulation (EU) No 1169/2011. Claims of effect can be made in food supplements, again on a voluntary basis, not mandatory as requested by Decree 169/2004. The (national) guideline on probiotics and prebiotics, revised in March 2018, allows a label (on botanicals) to indicate: "*It promotes the intestinal flora balance*"; however, this health claim is not permitted by Regulation (EC) No 1924/2006. ***Assessment*** *The Italian CA have not taken action to address this recommendation as they disagree with the Commission service's view that the statement on probiotics "It promotes the intestinal flora balance" constitutes a health claim. The Commission service's maintain the view that this implies a health benefit and may be understood as such by consumers, therefore it is not permitted by Regulation (EC) No 1924/2006. Commission guidance has already confirmed that the reference to probiotic/prebiotic implies a health benefit (see p. 11 https://ec.europa.eu/food/system/files/2016-10/labelling_nutrition_claim_reg-2006-124_guidance_en.pdf).* *To address this recommendation the CCA should reconsider its position in relation to health claims for probiotics and subsequently ensure that the labelling of these products follows the aim of the legislation in protecting consumers from misunderstandings regarding the labelling and health claims.*

Audit 2019-6662 of 04 July 2019 in order to evaluate the official control system in place governing food improvement agents	
Recommendation	Basis for assessment/Information Requested/CA response
2019-6662-1	**In Progress**

Audit 2019-6662 of 04 July 2019 in order to evaluate the official control system in place governing food improvement agents	
Recommendation	Basis for assessment/Information Requested/CA response
The CCA should provide the necessary guidance and tools to regional and local authorities to ensure that controls over compliance with the applicable EU legislation on FIA at the level of the FBOs, and with particular attention to the FIA users, are carried out in a consistent manner at all levels, in accordance with article 4, point 4 of Regulation (EC) No 882/2004. Recommendation based on conclusion: 77 Associated findings: 44, 46, 49, 50, 51	**Findings:** states that official controls are incomplete and lack depth resulting in insufficient verification of the compliance with at the (food improvement agent) legislation. The absence of specific guidance or instructions, and the limited hands-on experience of the inspectors, leads to omissions to check the recipe of the product being examined, to define the product category and examine the specifications of all the raw materials used in production of food containing food improvement agents. [The corresponding legal references to the new legislation (OCR) covering consistency of official controls are Articles 1(2) and 4(2) (a) of Regulation 2017/625]. ***Assessment*** *The CA confirmed that the guidance document had been approved and recently circulated to the regional and local authorities. Verification of its implementation will be possible only after June 2022, through the examination of the annual report that regions / provinces prepare under the national plan 2020-2024. Pending this, the Office urged the same regional / provincial authorities to specify the measures implemented at the territorial level to ensure more uniform and structured controls at the users of food improvement agents. To allow this recommendation to be closed the CCA should provide evidence that the regions have implemented the procedures on food additives, aromas and enzymes.*

2.B.8 Imports of food of plant origin

Audit 2019-6640 of 26 November 2019 in order to evaluate the system of official controls on imports of animals and goods	
Recommendation	Basis for assessment/Information Requested/CA response
2019-6640-2 To ensure that official controls on food of non-animal origin subject to special import conditions are	**Closed due to action taken** **Findings:** DGISAN does not ensure that documentary checks are done at the DPE and that physical checks, including sampling, are carried out at the DPE/DPIs. At Venice port, documentary checks on food of non-animal origin subject to special import conditions took place at the local USMAF-SASN office instead of in the port of entry

Audit 2019-6640 of 26 November 2019 in order to evaluate the system of official controls on imports of animals and goods	
Recommendation	Basis for assessment/Information Requested/CA response
performed at appropriate facilities (designated points of entry and/or designated points of import) in line with the requirements laid down in Articles 8(1)(a) and 8(1)(b) of Regulation (EC) 669/2009, Articles 9(1) and 9(2) of Regulation (EU) 884/2014 and Articles 8(1) and 8(2) of Regulation (EU) 2015/175. Recommendation based on conclusions: 68 and 86 Associated findings: 47 - 51 and 83	where physical facilities are in place. USMAF-SASN staff carry out documentary controls based on copies of original certificates and/or laboratory test results. This hinders the verification of the authenticity of the health certificates, declarations and the laboratory results due to the reliance on copies. USMAF-SASN do not check the originals of certificates or other relevant documents and therefore are not in a position to ascertain their authenticity. Furthermore, the way in which the system for documentary checks on consignments of food of non-animal origin subject to special import conditions has been set up at the designated point of entry in Venice Port (checks are being carried out at local office level instead of at the entry point at the border) is contrary to EU requirements. Physical checks and sampling takes also place in customs warehouses, which are not designated by DGISAN as DPIs. ***Assessment*** *Following the reorganization of the competent authorities, Decree No 24/2021 was adopted which provides a strong basis, with accompanying sanctions, to ensure that management bodies and operators provide appropriate facilities for the authorities to carry out controls of food of non animal origin. Responsibilities of controls of such goods are transferred by means of this Decree from the Ministry of Health to the Ministry of Health border post department. The guidance to implement this Decree provides the practical steps and actions for controls of food of non-animal origin. Based on the evidence provided, this recommendation is considered addressed.*

2.B.9 Plant protection products

Audit 2015-7468 of 26 January 2015 in order to evaluate controls on the marketing and use of plant protection products	
Recommendation	Basis for assessment/Information Requested/CA response
2015-7468-3 Ensure efficient and effective coordination between all the	**In Progress** **Findings:** There is limited co-operation and co-ordination between and within CAs. This extends to critical areas such as the designation of CAs at central level, and as such, this lack of cooperation and co-ordination undermines

Audit 2015-7468 of 26 January 2015 in order to evaluate controls on the marketing and use of plant protection products	
Recommendation	Basis for assessment/Information Requested/CA response
competent authorities involved in the official controls on the marketing and use of PPPs as required by Article 4 of Regulation (EC) No 882/2004 Conclusions upon which this recommendation is based: 34 Associated findings upon which this recommendation is based: 26, 27	the effectiveness of controls. [Note: Regulation (EC) 882/2004 has been repealed. The current requirements can be found on Article 4 (2) (a) of Regulation (EU) 2019/627]. ***Assessment*** *The Ministry of Health provided evidence of progress in improving the exchange of information between all the relevant CAs (meetings, e-mails with exchange of information, guidelines for planning of control activities) as well as a project outline aimed at improving the co-operation and information exchange with Customs. The current version of Italy's MANCP provides a description of the areas of responsibility of the different authorities but does not enter into detail regarding the co-ordination activities between the different authorities. Although co-operation and co-ordination has been improved and two recent Ministerial Decrees (24/2021 and 27/2021, February 2021) have clarified the division of responsibilities. Following the indications in the Ministerial Decrees 24/2021 the Ministry of health is working on a Ministerial decree for import controls of PPP that involves also the Custom Agency, planned to be issued in September 2021.* *To allow this recommendation to be closed, The Ministry of Agriculture should provide evidence that the co-operation project with Customs is implemented (operational IT system and required information is exchanged between Customs, the Ministry of Health and other relevant CAs and evidence of Customs' participation in controls).*
2015-7468-8 Review the overall planning of controls, and allocation of competencies between CAs, so that inspectors conducting controls on PPP marketing and use have sufficient experience and knowledge of this specialist area to ensure that controls are effective as required by	**In Progress** **Findings:** PPP controls comprise a very small part of a large work programme and ICQRF and ASL staff met had limited experience in PPP controls and very limited knowledge of the area. [Note: Regulation (EC) 882/2004 has been repealed. The current requirements can be found on Article 5 (1) (a) and (b) of Regulation (EU) 2019/627]. ***Assessment:*** *The main issue continues to be that inspectors cover a wide range of areas, and therefore have little opportunity to develop expertise for checks of plant protection products during their day to day work. The Ministry of Health provided evidence of the progress made on the training and instructions provided to the inspectors. The Ministry of Health planned audits of Piedmont & Apulia may provide evidence of the effectiveness of this training. In*

Audit 2015-7468 of 26 January 2015 in order to evaluate controls on the marketing and use of plant protection products	
Recommendation	Basis for assessment/Information Requested/CA response
Article 4(2) of Regulation (EC) No 882/2004. Conclusions upon which this recommendation is based: 77 Associated findings upon which this recommendation is based: 72, 73	*order to close this recommendation, The Ministry of Agriculture should provide evidence of the success of training (evaluation of tests at the end of training courses) as well as findings from their planned 2021 internal audits of PPP controls regarding knowledge and expertise of inspectors (planned for* October and November 2021)

Audit 2019-6723 of 21 October 2019 in order to evaluate the control system for pesticide residues	
Recommendation	Basis for assessment/Information Requested/CA response
2019-6723-1 When delegating tasks, the CA designating the official laboratories should include clear and mandatory instructions as to the methodology, time span and scope of laboratory analysis, and ensure that the instructions are implemented, so that official controls can be carried out efficiently and effectively, in line with Article 4(2)(c) of Regulation (EC) No 882/2004. Conclusions upon which this recommendation is based: 25;	**Closed due to action taken** **Findings:** The CAs have not established or agreed specific requirements for laboratories to comply with, such as maximum turn-around time for the analyses, the capacity to analyse all analytes included in the coordinated control plan of the European Union, or mandatory participation in EURL proficiency tests. ***Assessment*** *The Ministry of Health confirmed that the pesticides residues control plans now contain an indication of turn-around time for results. This aspect is verified centrally with regards to the level of compliance, achieving an average of 35 days in 2019 . The laboratories have participated in proficiency tests, as expected, and this is also checked by the accrediting body, providing an acceptable level of assurance. A target has also been set for the capacity to analyse all analytes. This target was communicated as 80% of 175 substances in 2019 and between 80-100% in 2020. The setting of targets has not resulted in all participating laboratories achieving the expected capacity but this will be followed-up through recommendation 2019-6723-2. The Ministry of Health evaluates yearly the performance of all laboratories and the level reached for the capacity target. As the competent authority has established specific requirements for the laboratories and there are systems in place to verify compliance with these*

Audit 2019-6723 of 21 October 2019 in order to evaluate the control system for pesticide residues	
Recommendation	Basis for assessment/Information Requested/CA response
Associated findings upon which this recommendation is based: 13	*requirements, this addresses the recommendation.*
2019-6723-2 To ensure that designated laboratories carrying out analyses of pesticide residues for official controls do include within their scope of analyses the required analytes as established by Articles 1 and 2(2) of Implementing Commission Regulations concerning the coordinated multiannual control programme to ensure compliance with maximum residue levels of pesticides, such as Regulation (EU) 2018/555. Conclusions upon which this recommendation is based: 26, 37 and 50 Associated findings upon which this recommendation is based: 16, 31, 42, 43, 45, 48	**In Progress** **Findings:** There is a lack of capacity for analysing all required analytes. The designation of laboratories which do not have the necessary capability to complete the requested analyses has a negative impact on the effectiveness of the official control plan. ***Assessment*** *Progress has been observed in the two regions previously visited and the laboratories there have increased the number of analytes within their capacity; however, the national data shows that many laboratories are still not able to analyse the national target number of analytes for 2019, which was set at 80% of 175 substances. The Ministry of Health monitors annually the performance of the laboratories and a report is forwarded to the regions, requesting an explanation for the lack of progress. To allow this recommendation to be closed The Ministry of Health should provide the 2020 verification report and indicate any further steps to be taken to ensure that the capacity of the designated laboratories meets the requirements of the control plan.*
2019-6723-3 To ensure that designated laboratories carrying out analyses of pesticide residues for official	**Closed due to action taken** **Findings:** The failure of official laboratories to participate in EURL proficiency tests limits their capacity to detect problems in pesticide residue analysis**.** ***Assessment*** *The CA provided Accredia (accrediting body) reports which conclude laboratories participate in inter-*

Audit 2019-6723 of 21 October 2019 in order to evaluate the control system for pesticide residues	
Recommendation	Basis for assessment/Information Requested/CA response
controls participates in proficiency test organised by the Commission as required by Article 28(3) of Regulation (EC) No 396/2005. Conclusions upon which this recommendation is based: 51 Associated findings upon which this recommendation is based: 44	*laboratory proficiency testing. Verification checks by the accrediting body now include checks on the participation in the proficiency tests. Based on the evidence provided this recommendation is considered addressed.*

2.B.10 Animal welfare

Audit 2017-6257 of 13 November 2017 in order to evaluate Member State activities to prevent tail-biting and avoid routine tail-docking of pigs	
Recommendation	Basis for assessment/Information Requested/CA response
2017-6257-1 The competent authority should provide inspectors with suitable compliance criteria to enable them to effectively enforce legal requirements of Council Directive 2008/120/EC and Council Directive 98/58/EC that are associated with risk factors for tail-biting. Conclusions 17, 38 and 39. Findings	**In Progress** **Findings:** There is an ongoing project (Istituto Zooprofilattico Sperimentale - IZS, of Lombardia and Emilia Romagna) that aims to revise national checklists (IZSLER checklists) for animal welfare inspections to include animal-based indicators as well as to develop a national database for the recording of animal-based indicators on farm and at slaughter. However, as inspection checklists have not yet been finalised and animal-based indicators on-farm and at slaughter are not yet assessed, the current controls are not moving the pig industry toward compliance. Also the IZSLER checklists did not set sufficiently clear criteria to improve compliance with the Pig Directive with regard to several legal requirements associated with tail-biting risks, including the requirement on enrichment materials nor did they enable inspectors to consistently and effectively enforce the provisions of the Pig Directive concerning whether effective changes to management or environmental systems had been made on farms prior to routine tail-docking. IZSLER checklist contains guidance for trough length, for adequacy of staff numbers and

Audit 2017-6257 of 13 November 2017 in order to evaluate Member State activities to prevent tail-biting and avoid routine tail-docking of pigs	
Recommendation	Basis for assessment/Information Requested/CA response
4, 26, 27, 28, 34 and Annex II.	training and provides acceptable levels for gas concentrations. It indicates an option for the provision of water "all animals…..must be able to meet their needs for liquids in other ways" which is not in compliance. ***Assessment***: *The revised checklists provide assessment criteria for enrichment material, harmful gases, provision of water. Although the guidance indicates that compliance with minimum weaning age is an important risk factor it does not provide a method to verify this. In order to allow this recommendation to be closed the CCA should ensure that the Italian regions and local health units have guidance on how to assess the age of weaning when inspecting a large reproductive pig unit.*
2017-6257-2 The competent authority should provide inspectors with suitable instructions and guidance (compliance criteria) to enable them to effectively enforce the provision on the prevention of tail-biting and avoidance of routine tail-docking, as laid down in the second paragraph of point 8 of Chapter I of Annex I of Council Directive 2008/120/EC, including how they should assess evidence of tail and ear lesions on-farm and what constitutes sufficient measures by farmers to change inadequate environmental conditions or management systems before	**In Progress** **Findings:** There is no proper assessment of the incidence of tail-biting and improvement measures taken on-farm before allowing tail-docking. ***Assessment***: *The checklist requires official vets (OVs) to directly evaluate injuries to tails and ears. The CCA note (0015220-22/06/2021-DGSAF-MDS-P) asks officials to check completion of farmers' self-assessments (risk assessment) changes made and progress in keeping at least a minimum % of pigs with intact tails, with officials required to take different actions depending on the state of progress. This provides a good basis for using official controls to help bring about the changes needed to avoid routine tail docking. Requests for a derogation include assessment of tail biting prevalence (as well as improvements carried out) and the documents for veterinary certification require a statement on prevalence of lesions. The evidence that injuries to other pigs' ears or tails have occurred is therefore a point prevalence at the time of inspection, and does not give a full picture of such injuries throughout the year. Such injuries may occur in certain pens, in certain houses, at certain times of year, and it is important that officials have such detailed evidence when assessing whether risks have been properly assessed and that improvements were made. The manual for OVs Chapter II, Point 3 (Page 25) states that it is positive if the farm assistant, in the daily inspection(s), writes and records injuries. The CCA also indicated (July 2021) that monitoring relevant slaughterhouse findings is still being worked on and should be functioning very soon. In order to allow this recommendation to be closed, guidelines for officials should indicate all the relevant evidence that should be*

Audit 2017-6257 of 13 November 2017 in order to evaluate Member State activities to prevent tail-biting and avoid routine tail-docking of pigs	
Recommendation	Basis for assessment/Information Requested/CA response
resorting to tail-docking of pigs, including the situation where tail-docked pigs are purchased from rearing farms which have shown no evidence of tail-biting. This entails the development of measurable criteria to enable inspectors to properly assess progress with regard to the risk factors listed in the Recommendation. Conclusions 17, 38 and 39. Findings 4, 26, 27, 28, 34 and Annex II.	*considered when assessing evidence of tail biting and that necessary improvements are made.*
2017-6257-4 As required in Article 5(1)(a) of Regulation (EU) 2017/625 The competent authority should assess the incidence of tail-biting and the effectiveness of improvement measures taken on-farm as required in point 8 of Chapter I, of Annex I to Directive 2008/120/EC, including when piglets are going to be sent to rearing farms for further fattening, instead of relying on veterinary statements.	**In Progress** **Findings:** Effective actions to enforce the provisions of the Directive hampered by the misinterpretation of the word "evidence" in point 8 of Chapter I, of Annex I to Directive 2008/120/EC with the word "compravata" justifying the need for documentation to support the need to tail dock. ***Assessment****: The CA revised the national action plan to clarify the role of the farm veterinarian and veterinary certification in any decision to tail dock. Guidelines help ensure certification follows a standard format and that the necessary elements are considered. To allow this recommendation to be closed the CCA should ensure that farmers and their veterinarian use all available evidence when assessing, and making declarations on, the prevalence of tail biting.*

Audit 2017-6257 of 13 November 2017 in order to evaluate Member State activities to prevent tail-biting and avoid routine tail-docking of pigs	
Recommendation	Basis for assessment/Information Requested/CA response
Conclusion 19, 20 and 38. Findings 13, 14, 15 and 34.	
2017-6257-5 The competent authority should ensure that the level of tail-damage and associated lesions in slaughterhouses is monitored and that high levels trigger actions on the respective farms, as required in Article 39 of Commission Implementing Regulation (EU) 2019/627. Conclusion 41. Findings 35 and 36.	**In Progress** **Findings:** There is information available to the authorities at slaughterhouses for follow-up actions on farms, but it is not used. In region 1 the results of ante-mortem inspections are recorded in a regional database. According to the records, official veterinarians reported that tail injuries were very infrequently seen at ante-mortem inspection. Official veterinarians recorded information on the incidence of a wide range of post-mortem conditions leading to part or full condemnation in the official database. Data on lesions linked to tail-biting is entered into the system but is only collated on a farm basis. The authorities indicated that the system could be modified to provide collated information on the categorisation of abscesses (spinal, limb etc), to give useful feedback on the levels of sub-clinical lesions and the economic cost of tail-biting. Farmers will receive information from slaughterhouses on carcase condemnations resulting from abscessation but there is no link made to the presence (or not) of tail lesions. ***Assessment*** *The CCA is still considering how best authorities can implement this recommendation in the context of Article 39 of Commission Implementing Regulation (EU) 2019/627 so that the officials responsible for slaughterhouses transmit the relevant data to the authorities responsible for the relevant farms. To allow this recommendation to be closed the CCA should confirm the system in place so that relevant information available at slaughterhouses is made available to officials responsible for controls of farms.*
2017-6257-6 The competent authority should consider liaising with other Government Agencies centrally and at Regional level responsible for funding new buildings where pigs	**Closed due to action taken** **Findings:** The (EU) co-financed incentives for improving welfare conditions for pigs are not used in any coordinated way to reduce tail-biting and avoid routine tail-docking of pigs and the competent authority has no overview of their implementation. ***Assessment*** *The CA has had discussions with Ministry of Agriculture on promoting farming methods that go beyond*

Audit 2017-6257 of 13 November 2017 in order to evaluate Member State activities to prevent tail-biting and avoid routine tail-docking of pigs	
Recommendation	Basis for assessment/Information Requested/CA response
are to be kept and renovating existing ones with the assistance of European funding under Article 17 of Regulation (EU) No 1305/2013 to ensure not only that the relevant animal welfare payments related to such facilities are suitable to commitments going beyond the relevant mandatory standards but that in addition the facilities, as a minimum, comply with relevant mandatory requirements (of Directives 2008/120/EC and 98/58/EC) including the avoidance of routine tail-docking e.g. slurry systems that can handle optimal enrichment materials, different temperature zones, suitable flooring, feeding, space allowances etc. Conclusion 23. Finding 21.	*the mandatory standards through rural development funding and on developing a national animal welfare accreditation system, to improve cooperation between services so that the objective of reducing tail biting risks and avoiding tail docking is considered in such schemes. Based on the evidence provided, this recommendation is considered addressed.*

2.B.11 Plant health

Audit 2016-8796 of 12 September 2016 in order to evaluate the situation and control for Thousand Canker disease

Recommendation	Basis for assessment/Information Requested/CA response
2016-8796-1 In line with the application of protective measures under Article 16(2) of Directive 2000/29/EC, a more reliable and accurate delimitation of the presence of Thousand canker disease, should be conducted via increased monitoring intensity in all regions. Recommendation based on conclusions 55, 56 and 57 Associated findings 39, 40, 41, 43, 44, 45, 47, 49, and 52	**Action Still required** **Findings:** The relative low level presence of the host, particularly in Piedmont and Lombardy, where outbreaks have occurred, the variation in susceptibility, as well as the issue of latency with respect to delayed symptom expression, the current level of monitoring intensity of timber producing trees is inadequate to reliably delimit for the presence of Thousand canker disease. Similarly, in Veneto, despite a higher presence of host trees, predominantly plantations of J. nigra, and based on the same issues with respect to susceptibility and latency, the current level of monitoring intensity there is also inadequate to reliably delimit the disease. The report stated further that insufficient monitoring is carried out for mono-cultures of J. regia in commercial walnut fruit production in all of the regions, and for which no contingency plan exists. Such absences pose particular potential challenges with respect to disease management and further control should Thousand canker disease enter the fruit production industry. [Directive 2000/29/EC has been replaced by Commission Implementing Regulation (EU) 2019/2072]. ***Assessment:*** *The CA confirmed that Official Controls in the area of plant health will be significantly modified in the coming years. The CA provided evidence of the CREA report, the regional plans and the current monitoring activity in all areas. Although monitoring in the areas with recent outbreaks was increased, the levels of monitoring in the areas previously affected, particularly Veneto and Piedmont, had not been significantly increased. Monitoring should be enhanced even in areas where eradication has been considered unrealistic and where the current plans concentrate on containment. Increased monitoring has not been implemented in all affected areas and thus this recommendation has not yet been addressed. To progress this recommendation, the Ministry of Agriculture should provide an updated action plan indicating the measures taken to increase the monitoring, in particular, any increase in monitoring intensity, the deployment of specific traps and the number of assessment areas and monitoring sites.*
2016-8796-2 Disease suppression measures should be deployed within the DAs in the Veneto region, in line with	**Action Still required** **Findings:** Veneto has adopted an approach of containment. Trees are not felled nor destroyed and no other disease suppression measures are applied within the DAs. This means that the risk of natural spread is not prevented. Given the absence of suppressive measures in Veneto, and the potential dissemination distance of the vector, the width of

Audit 2016-8796 of 12 September 2016 in order to evaluate the situation and control for Thousand Canker disease	
Article 16(2) of Directive 2000/29/EC. Recommendation based on conclusions 81 and 82 Associated findings 61, 62, 63, 71 and 72	the current buffer zone is most likely too narrow to prevent the long distance natural spread of the disease with wood or planting material from areas that are infected, but not yet recognised as such. [Directive 2000/29/EC has been replaced by Commission Implementing Regulation (EU) 2019/2072]. *Assessment Disease suppression measures have not yet been deployed in the Veneto and Piedmont regions and there are no plans to change this approach. The CA confirmed that the measures taken in these areas aim only for containment (as eradication has been considered unrealistic) and therefore, felling of trees is recommended but not mandatory. This recommendation has not yet been addressed. To make progress in addressing this recommendation the Ministry of Agriculture should reconsider its approach of containment and instead implement disease suppression measures in all affected areas and provide details of these plans.*
2016-8796-3 Ensure that buffer zones are wide enough to ensure that infected material are not inadvertently moved to free areas, including other Member States, as required by Article 16(2) of Directive 2000/29/EC. Recommendation based on conclusion 82 Associated findings 60 and 64	**Action Still required** **Findings:** The absence of suppressive measures in Veneto, and the potential dissemination distance of the vector, the width of the current buffer zone is most likely to be too narrow to prevent the long distance natural spread of the disease with wood or planting material from areas that are infected, but not yet recognised as such.[Directive 2000/29/EC has been replaced by Commission Implementing Regulation (EU) 2019/2072]. ***Assessment** The CA considered its expert (CREA) report and the regional action plans and believes that the long latency period of the disease and the long distance flight capacity of the vector make it unfeasible to establish buffer zones. This recommendation is not yet addressed. To make progress in addressing this recommendation the Ministry of Agriculture should reconsider its approach and review the implementation of buffer zones for all affected areas and provide an update on implementation (Commission Implementing Regulation (EU) 2019/2072).*
2016-8796-4 A contingency plan for the possible	**Action Still required** **Findings:** Insufficient monitoring was carried out for monocultures of J. regia in commercial walnut fruit production

infection of commercial fruit plantations of J. regia, in particular with respect to preventing such plantation contributing to further spread, should be elaborated between relevant RPSs and industry associations in line with Article 16(2) of Directive 2000/29/EC. Recommendation based on conclusion 57 Associated findings 86, 21, 22, 39, 43, 45 and 52	in all of the regions, and no contingency plan exists. Such absences pose particular potential challenges with respect to disease management and further control should Thousand canker disease enter the fruit production industry. ***Assessment*** *The CA actions have focused on raising awareness and supporting the technical experts working for the operators, as well as monitoring activities in adjacent areas. No specific contingency plan for the possible infection of commercial fruit plantations of J. regia has been developed and put in place, thus this recommendation has not been addressed. To make progress in addressing this recommendation the Ministry of Agriculture should provide information on the relationship established with producers to assist in the creation of contingency plans (or any alternative plans) for the potential infection of commercial plantations in the regions where these exist (e.g. Veneto) and highlight the key elements in the plans: where they need to be taken, when they need to be started, by when they need to be completed. The Ministry of Agriculture should provide a detailed overview of the number of commercial plantations indicating the number of trees, number trees monitored/checked and number of traps installed (or planned number of checks and traps).*
2016-8796-5 Measures to address the possible dissemination of the disease via infected bark strippings from sawmills from within DAs to other areas outside, should be taken, in line with Article 16(2) of Directive 2000/29/EC, to eliminate this potential source of regional and wider spread. Recommendation based on	**Action Still required** **Findings:** The absence of controls on untreated stripped bark from sawmills within the DA to outside the DA may represent an inadvertent source of dissemination of Thousand canker disease and/or its vector. ***Assessment:*** *The CA confirmed that the 12 sawmills in Veneto are compliant with the provisions and authorised for plant passports, however no specific details were provided with regards to the number of movements and the official controls completed at sawmills. This recommendation has not been addressed. To make progress in addressing this recommendation the Ministry of Agriculture should provide a) a list of sawmills dealing with j. regia/ j.nigra trees, in particular for furniture production b) the number of registered movements for j. regia/ j.nigra trees and c) a description of official controls conducted at these sawmills (including findings and actions taken). Furthermore industry guidance would be useful on how to deal with j. regia/ j.nigra strippings to ensure that they do not leave the designated area .*

Audit 2016-8796 of 12 September 2016 in order to evaluate the situation and control for Thousand Canker disease	
conclusion 83 Associated finding 78	

Audit 2018-6551 of 15 October 2018 in order to evaluate the system of import controls for plant health	
Recommendation	Basis for assessment/Information Requested/CA response
2018-6551-3 Ensure that plant health checks of wood packaging material under Decision 2018/1137/EU, are capable of confirming its compliance with the requirements laid down in point 2 of Section 1 of Part A of Annex IV to Directive 2000/29/EC, in line with Article 4 of the Decision. The recommendation is based on conclusion No. 81. Associated findings Nos. 78 and 80.	**In Progress** **Findings:** The inspection of wood packaging material (WPM) carried out by the Customs service demonstrated that the Customs officer was only looking for the presence of an ISPM 15 mark, and not any signs or symptoms of the presence of harmful organisms. The officer had little if any knowledge of the different harmful organisms likely to be associated with WPM or the different signs and symptoms which might indicate their presence. Half of the pallets were unloaded from the container so that the Customs officer could check for the presence of an ISPM 15 mark, although the officer stated that this would not be necessary if the marks were visible from the rear doors of the container. The emptied containers were not checked for any evidence of pest activity, such as frass. The pallets were not checked for the presence of bark. Checks of WPM under Decision 2018/1137/EU, carried out by the Customs service, are not capable of confirming that such high risk material is compliant with EU import requirements. ***Assessment*** *The competent authority (CA) stated that since 1 March 2021, the checks carried out of wood packaging material comply with the necessary requirements; however, no evidence was provided to demonstrate this. The CA confirmed that the agreement with Customs in order to provide specific training had not been finalised due to the reorganisation of official controls currently on-going. To make progress in addressing this recommendation the Ministry of Agriculture should provide the agreement with Customs to provide training on the detection of pests and examples of checks of wood packaging material with a summary of the number of checks and the non-compliances recorded.*

Audit 2019-6733 of 14 May 2019 in order to evaluate the situation and control of red neck longhorn beetle (Aromia bungii)	
Recommendation	Basis for assessment/Information Requested/CA response
2019-6733-2 Immediately fell infested Prunus plants and plants with symptoms caused by A. bungii. In particular, felling should include complete destruction of the trunk of the trees and where necessary complete removal of their roots in demarcated areas where eradication or containment measures are in place in line with points 1(a) and 2(a) of Article 6 of Decision (EU) 2018/1503. Recommendation based on conclusion 58 Associated finding 52 bullet point 4	**Closed due to action taken** **Findings:** The intensive surveillance applied after new findings of A. bungii, instead of the required but non-enforced complementary clear cut of Prunus plants has not achieved eradication of the insect. Early stages of infestation, such as oviposition, may remain latent without visual signs and symptoms and cannot always be detected. In Campania, the approach of carrying out intensive surveillance alone without preventive felling of non-symptomatic plants has led to the gradual increase of the demarcated areas. ***Assessment*** *The competent authority provided evidence of the new procedures in place which require the verification of the felling and destruction activities in order to confirm the completion of the required interventions. Based on the evidence provided, this recommendation is considered addressed.*
2019-6733-3 Fell all Prunus plants within a radius of 100m around infested plants in demarcated areas where eradication measures are in place in line with point 1(b) of Article 6 of Decision (EU) 2018/1503.	**In Progress** **Findings:** The eradication measures, where these were stated to be applied in Lombardy, do not involve the compulsory felling of all Prunus plants within 100m radius around infested plants required by the Decision. The same applies in Campania, where eradication measures do not involve the timely and complete destruction and removal of all infested plants, nor the compulsory felling and destruction of Prunus plants in their immediate vicinity. The intensive surveillance applied after new findings of A. bungii, instead of the required but non-enforced complementary clear cut of Prunus plants has not achieved eradication of the insect. Early stages of infestation, such as oviposition, may remain latent without visual signs and

Audit 2019-6733 of 14 May 2019 in order to evaluate the situation and control of red neck longhorn beetle (Aromia bungii)	
Recommendation	Basis for assessment/Information Requested/CA response
Recommendation based on conclusions 57 and 58 Associated findings 43 bullet point 2 and 52 bullet point 5	symptoms and cannot always be detected. In Campania, the approach of carrying out intensive surveillance alone without preventive felling of non-symptomatic plants has led to the gradual increase of the demarcated areas. ***Assessment*** *The CA confirmed that plans were in place for the felling of all affected plants. The two infected plants identified in Lazio had been felled and sent for laboratory examination but no documentary evidence was provided of this (or other details for the Lazio outbreak) at the time of the GFA. Out of the 231 affected plants in Campania, 173 had been felled and there were plans in place to fell the remaining plants before the start of the flying season of the insect. Actions to fully address this recommendation have not yet been completed.* *To allow this recommendation to be closed the Ministry of Agriculture should provide the outcome of the eradication and laboratory examination of the affected plants in the Lazio outbreak within the area of 100m radius from the focal point(s), before start of the flight period of the pest in this region and any further available relevant details for this outbreak, including the results of the surveillance that has to be carried out in the rest of the 2km radius demarcated area. The Ministry of Agriculture should also provide evidence of the felling of all affected plants in Campania within the area of 100m radius from the focal point(s) before the start of the flight season of the insect.*
2019-6733-4 Ban the planting of new specified plants in the open air in the infested zone in line with point 2(e) of Article 6 of Decision (EU) 2018/1503. Recommendation based on conclusion 59 Associated finding 52 bullet point 4	**In Progress** **Findings:** Replanting of Prunus plants or plant material in the infested zone is tolerated indicating that, in practice, no eradication or effective containment measures are in place in Campania *Assessment The CA provided evidence of a ban in Campania regarding the planting of specified plants in the infested zone. No documentary evidence was provided for the Lazio outbreak so once this is provided the recommendation can be considered as addressed. To allow this recommendation to be closed the Ministry of Agriculture should provide evidence of the prohibition of planting specified plants in the open air of the infested zone in Lazio and in case of infringement how many follow up measures were taken to destroy any planted material.*

2.B.12 Quality Labelling

Audit 2018-6401 of 05 June 2018 in order to evaluate the system of official controls for organic production and labelling of organic products	
Recommendation	Basis for assessment/Information Requested/CA response
2018-6401-2 Ensure that: checks carried out by CBs cover the verification of records kept by operators, in particular at reception of organic goods, as required by Article 66(2) of Regulation (EC) No 889/2008; inspection reports issued by CBs provide details of such verification having taken place, in line with Article 9 of Regulation (EC) No 882/2004. Recommendation is based upon conclusion No 42 Associated findings No 41	**Closed due to action taken** **Findings:** The CBs require supporting documents (such as updated documentary evidence of the supplier) are present at the time of inspection, but there is no control measure in place to ensure that these are verified at the time goods are received. Verification made by operators at reception of goods was not capable to detect that the incoming products were not organic. ***Assessment*** *The CA submitted evidence demonstrating that the CBs had adapted their procedures and the checklists used during inspections to ensure that the operators' checks on organic goods at the point of reception were verified. The CA also provided supervision reports confirming the CBs were carrying out the verification of this activity, as required. Based on the evidence provided, this recommendation can be considered addressed.*
2018-6401-3 Ensure that sampling is adequately planned and implemented and its results followed-up by CBs, and in	**In Progress** **Findings:** Samples are not necessarily planned at the most suitable time to detect the use of unauthorised substances, and not all detections of such substances lead to further investigation by CBs or to decertification of the products involved. In addition, CBs are not always in the position to assess the analytical results as relevant information on

Audit 2018-6401 of 05 June 2018 in order to evaluate the system of official controls for organic production and labelling of organic products	
Recommendation	Basis for assessment/Information Requested/CA response
particular that: samples are taken by CBs at the most suitable time to detect the use of unauthorised substances and at all stages of the food chain, in line with Article 65(2) of Regulation (EC) No 889/2008; harmonised rules are followed by the CA and CBs when deciding when analytical results are to be considered as being false positives; CBs take actions in all cases where the analytical results show the presence of unauthorised PPPs to confirm that operators are compliant with Article 12(1)(h) of Regulation (EC) No 834/2007; Sample sheets used by CBs contain valuable information on the circumstances of collection of samples, to allow the CBs to assess the analytical results obtained. Recommendation is based upon conclusion No 56 Associated findings No 52, 53, 54 and 55	the circumstances of sampling is generally missing on the samples sheets. ***Assessment*** *The CA demonstrated that action was taken in relation to the sampling of foodstuffs and other matrices (such as leaves and soil), with samples taken at the most suitable time to detect unauthorised substances. The investigations triggered when unauthorised substances are detected is also evidence of action taken to address this recommendation. However, a negative retest which contradicts the first test result should not be considered as the definitive result without further investigation of the conditions/circumstances of sampling. The CA is considering its approach in light of the provisions introduced by EU Reg. 625/2017 and EU Reg. 848/2018 (and Implementing Regulation (EU) 2021/279). This does not require a third test but rather emphasises that the results of laboratory analysis is only one element that the control body/control authority/competent authority should take into account when deciding if there is a non-compliance.* *The sample forms now indicate the location where the sample was taken but do not contain all the required information (e.g. full details of neighbouring crops) which would allow an informed assessment of analytical results.* *To allow this recommendation to be closed the Ministry of Agriculture should clarify its procedures regarding these two issues. The results of laboratory analysis would be only one element that the control body/control authority/competent authority should take into account when deciding how to resolve contradictory tests. It will also be necessary to ensure sampling forms provide the necessary details for a full assessment of field sampling results.*
2018-6401-5 Ensure that: physical checks for the verification	**In Progress** **Findings:** The report states that Customs may carry out physical checks, although no specific assessment is made for organic products based on the countries of origin or type of products received. In addition samples taken by CBs

Audit 2018-6401 of 05 June 2018 in order to evaluate the system of official controls for organic production and labelling of organic products	
Recommendation	Basis for assessment/Information Requested/CA response
of organic consignments required by Article 13(1)(b) of Regulation (EC) No 1235/2008 are carried out based on risk assessment, in line with Article 2(5) of the same Regulation; samples are taken from all consignments originating from Ukraine, Russian Federation and Kazakhstan, as required by the increased control measures decided by the European Commission for these countries. Recommendation is based upon conclusion No 70 Associated findings No 67, 68 and 69	from imported consignments and the Ministerial Decree 8283/2018 allocated responsibilities to CBs in the framework of import controls. Article 6 requires CBs to take samples from the consignments based on the results of specific risk assessment which must take into account several criteria defined in the same Article. The CA could not provide statistics on the total number of consignments imported from the higher-risk countries, and therefore it could not be demonstrated that samples are taken from the consignments in all cases. ***Assessment*** *Ministerial Decree 221907 was published 13 May 2021 and this provides modified risk criteria for importers as well as the rules on mandatory sampling of batches of organic products from Third Countries (following the categories indicated annually in the guidelines of the European Commission). The CCA requested the Control Bodies (Note no. 139824 of 24 March 2021) to adapt the standard control procedure. The CCA indicated that results of controls related to the sampling and analysis of imported organic products (indicated in the guidelines of the European Commission) can be sent by 2022. To allow this recommendation to be closed the CCA should provide statistics which demonstrate adequate targeting of sampling for higher-risk countries (the total number of consignments imported from the higher-risk countries, samples taken distinguishing between regular controls carried out by CB at importers and import checks to be carried out before the release for free circulation of the consignments).*

3. OVERVIEW OF MORE RECENT AUDITS NOT COVERED IN THIS COUNTRY PROFILE

3.A PUBLISHED REPORTS

In addition to the recommendations dealt with in chapters 2.B.1 to 2.B.12, the reports of a further four audits carried out by DG Health and Food Safety in Italy have now been published. The follow-up of the recommendations in these reports will be published in future country profile updates. The recommendations from the audit on Xylella fastidiosa (2019-6731) will be linked to the more recent audit on this topic indicated in table 3.B (2021-7280).

Audit number	***Topic***	***Date***
2019-6731	To evaluate the situation regarding Xylella fastidiosa	January 2019
2019-6627	To evaluate checks on animal transporters entering at European Union borders	December 2019
2020-7047	Protected Designation of Origin (PDO) and Protected Geographical Indication (PGI) for products in the wine sector	September 2020
2021-7186	Bovine meat, including traceability	January 2021

3.B ONGOING AND PLANNED AUDITS

In addition to the published reports, there are a further eight audits ongoing or planned:

Audit number	Topic	Date
2021-7278	Plant Health - Plant pest outbreaks (Tomato Brown Rugose Fruit Virus)	February 2021
2021-7298	Food of Non-Animal Origin - Sustainable use of pesticides	March 2021
2021-7250	Animal welfare - Laying hens	April 2021
2021-7280	Plant Health - Plant pest outbreaks (Xylella fastidiosa)	June 2021
2021-7283	Plant Health - Plant pest outbreaks (Anoplophora glabripennis, Anoplophora chinensis, Popillia japonica)	September 2021
2021-7175	Food of Non-Animal Origin - Microbiological contamination of ready to eat products	September 2021
2021-7210	Feed Safety - General feed hygiene	October 2021
2021-8764	Animal Health – African Swine Fever	November 2021

ANNEX I – ACRONYMS, ABBREVIATIONS, SPECIAL TERMS

ACRONYM	DESCRIPTION
ABP	Animal By-Products
ASF	African Swine Fever
BCPs	Border Control Posts (replaced BIPs as from 14 December 2019)
BIPs	Border Inspection Posts
BSE	Bovine Spongiform Encephalopathy
CA	Competent authority
CCA	Central competent authority
CSF	Classical Swine Fever
EFSA	European Food Safety Authority
FMD	Foot and Mouth Disease
GMOs	Genetically Modified Organisms
FVO	Food and Veterinary Office (Directorate F – Health and Food Audits and Analysis - of DG Health and Food Safety, with effect from 1 February 2016)
HACCP	Hazard Analysis and Critical Control Points
MANCP	Multi Annual National Control Plan
MRL	Maximum Residue Level
NRL	National Reference Laboratory
OF/SI	Organic fertilizers and soil improvers
PAP	Processed animal proteins
PPP	Plant Protection Products
RASFF	Rapid Alert System for Food and Feed
SRM	Specified Risk Materials
SUD	Directive on the Sustainable Use of Pesticides
TRACES	Trade Control and Expert System
TSEs	Transmissible Spongiform Encephalopathies
VMPs	Veterinary Medical Products