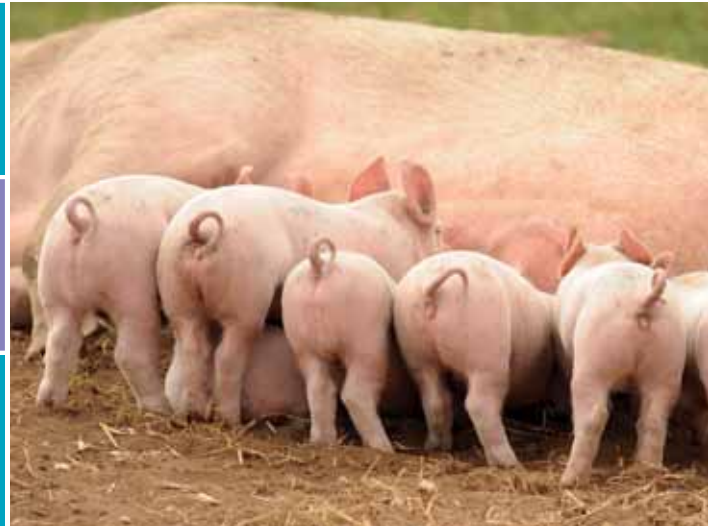




European
Commission



DG Health and
Food Safety

Health and Food Audits and Analysis Programme 2019

Further information on the Health and Food Safety Directorate-General is available on the internet at:
http://ec.europa.eu/dgs/health_food-safety/index_en.htm

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1.

Executive Summary

The European Commission's Directorate-General (DG) for Health and Food Safety, and, in particular, its Directorate 'Health and Food Audits and Analysis', carries out audits to verify that EU legislation on food safety, animal health, animal welfare, plant health and some areas of human health is properly implemented and enforced.

Food safety is one of the key concerns of citizens and safe food is essential to public health and long-term economic development. The effective enforcement of EU requirements in the above areas within the EU, and in non-EU countries exporting animals, plants and products to the EU, is key to maintaining high levels of food safety, animal health and welfare and plant health in the EU. Strict enforcement also means that the food industry, Europe's largest manufacturing sector and a leading employer, can operate in a stable and predictable regulatory environment.

The EU's high standards both facilitate intra-EU trade and create opportunities for European businesses to compete on the global market. High levels of safety are fundamental to stable markets and consumer confidence and also protect Europe from the economic and human costs of disease outbreaks.

DG Health and Food Safety establishes a multi-annual audit and analysis programme in line with key Commission strategic priorities. A particular focus of the 2019 audit and analysis programme will be on

- tackling antimicrobial resistance (AMR);
- better preparedness, prevention and response to human, animal and plant health threats;

- safe and sustainable food and feed production systems;
- ensuring effective implementation of EU food legislation;
- ensuring a sustainable food production that improves the welfare of animals;
- effective, efficient and reliable controls;
- contributing to harmonisation in the pharmaceutical sector and patients' access to safe medicines.

Chapter 3 presents an overview of the projects and activities DG Health and Food Safety plans to perform in 2019, with a summary of their objectives, methodology and outputs. As shown in Annex 1, some of these projects already started in 2018, others will be carried forward into 2020 or 2021. While some work is desk-based (for example, the assessment of countries' residue monitoring plans or the operation of Europhyt¹), the majority of projects involve audits, fact-finding missions or other on-the-spot visits to Member States, candidate countries and countries outside the EU.

In the areas food and feed safety, food quality, animal health and welfare and plant health, DG Health and Food Safety plans 163 audits in Member States, candidate countries and countries outside the EU (see Annexes 2 – 4).

1. *The European Commission's rapid alert and notification system for plant health*

In the area of human health protection, the DG will carry out approximately 40 joint assessments, together with designating authorities in Member States of the performance and designation of notified bodies in the medical devices sector. It will also perform up to six visits on AMR together with the ECDC². In addition, two audits are planned on active pharmaceutical ingredients for medicinal products for human use (see [Annex 5](#)).

Many projects will result in overview reports summarising the findings on the ground. The Commission will also

organise exchanges with Member States experts, in the framework of the Better Training for Safer Food programme, to discuss common problems and share good practices identified.

The 2019 audit and analysis work programme also contains a summary of the audits performed in 2017 (chapter 4).

The programme can be found on the Commission's website:

http://ec.europa.eu/food/audits_analysis/audit_programmes_en

2. *European Centre for Disease Prevention and Control*



DG Health and Food Safety: Priorities for Audit and Analysis for 2019 – 2021

The results of the audit and analysis work performed by the European Commission's Directorate-General for Health and Food Safety support the development of evidence-based policies. A solid, evidence-based regulatory framework is essential to sustain high levels of health protection that support growth, investment and competitiveness.

The European Commission's Directorate-General (DG) for Health and Food Safety, and, in particular, its Directorate 'Health and Food Audits and Analysis', works to ensure the effective and correct implementation and enforcement of EU legislation, to maintain high standards and safety levels and to provide a level playing field for business operators in relation to food safety, animal health, animal welfare, plant health and some areas of human health. It does this mainly by carrying out audits in Member States and non-EU countries exporting to the EU. The results support the development of evidence-based policies and contribute to a regulatory environment which facilitates jobs, growth and investment.

The work programme of audits and analysis is developed in consultation with other Commission services and with Member States, taking into consideration risk as well as trade and regulatory factors. It builds on a multi-annual plan that is reviewed annually to make sure it is up to date and focusses on the areas of highest risk (see [Annex 1](#)).

The work on audits and analysis contributes to several key priorities of the Commission, notably:

- A regulatory environment which facilitates jobs, growth and competitiveness by ensuring high levels of safety supported by sound control and enforcement systems.
- A deeper and fairer internal market by providing a level playing field where citizens and businesses can be confident of uniform and high levels of safety.
- A strong EU presence on international markets through the promotion of EU values and the EU regulatory approach on food safety and in its trading relations with countries outside the EU.

The aim of the audit and analysis strategy for the 2019 to 2021 period is to achieve a high level of coverage of the priority areas identified by DG Health and Food Safety requiring scrutiny as to the level and effectiveness of control and enforcement measures. This in turn allows weaknesses and the preventative or corresponding corrective measures to be identified and taken up with the relevant authorities.

A particular focus of the planned audit and analysis work will be on the following Commission and DG Health and Food Safety objectives:

• Tackling antimicrobial resistance

Antimicrobial resistance (AMR) remains a major global challenge with serious implications for the economy and human health unless tough action is taken to address it. The EU is a global leader in the fight against AMR, and, in 2019, DG Health and Food Safety will continue to implement the 2017 European “One Health” Action Plan against AMR to promote swift and effective actions across the human health, animal health and environmental sectors.

• Better preparedness, prevention and response to human, animal and plant health threats

Food borne emergencies, animal and plant health crises not only have serious implications for public health but can also have high economic losses as a consequence. “Prevention is better than cure” and therefore a more cost-effective crisis preparedness, prevention and response capacity in the field of human, animal and plant health remain a key priority for DG Health and Food Safety in 2019.

Animal health is often directly linked to public health as some animal diseases are transmissible to humans. The recent outbreaks of African swine fever, highly pathogenic avian influenza, lumpy skin disease or *peste des petits ruminants* all manifest the important risks confronting the EU in the area of animal diseases. If not quickly detected and effectively treated, such animal diseases can expand uncontrollably and cause substantial damage and economic loss. The work in animal health therefore aims at ensuring that Member States have the capability to react to, isolate and eradicate outbreaks of major animal diseases.

Crisis preparedness and response capability are equally important in the **plant health** area. The globalisation of plant trade has substantially increased the risk of infestation by plant pests - Member States currently notify over 200 plant health outbreaks every year. The outbreaks of the Pine Wood Nematode in Portugal and of *Xylella fastidiosa* in Italy, France and Spain have shown that the introduction of harmful organisms into the flora of the EU can have devastating effects for the agricultural economy, public budgets and the environment. With this work programme the Commission aims at enhancing its

own crisis preparedness and response capability and that of Member States.

• Safe and sustainable food and feed production systems

DG Health and Food Safety contributes to the establishment and maintenance of safe and sustainable food and feed production systems; by working towards strong control systems for pesticides with an increase of the sustainable use of pesticides, market access for safe products and control/removal of those which are not; and controls over organic production to ensure effective product flows as well as a level playing field in this growing market.

• Ensuring effective implementation of EU food legislation

The audit and analysis work carried out by DG Health and Food Safety provides continued and credible assurance that key EU standards are implemented, controlled and enforced in Member States and non-EU countries exporting animals, plants and food products to the EU. Furthermore, it contributes to the development of evidence-based policies, in particular, through the increased country knowledge available. The knowledge built is presented in “country profiles” on each Member State outlining the state-of-play of their performance and providing transparent country-specific knowledge.

This work also provides a valuable input into the Commission’s “Better Regulation initiative”. Better Regulation is about designing EU policies and laws so that they achieve their objectives in the most efficient and effective way possible. The audit and analysis results provide the Commission with important feedback on the effectiveness and impact of EU legislation on-the-ground and in that way contribute to the process of legislative review.

• Ensuring a sustainable food production that improves the welfare of animals

Good treatment of animals is an integral part of a sustainable food production. European citizens are

increasingly concerned that the welfare of animals is threatened or affected by the way they are kept and treated. Activities in 2019 continue to focus on improving the implementation and enforcement of existing legislation and on the identification and exchange of information on best welfare and husbandry practices, with priority given to the welfare of pigs and the improvement of the reporting on animal welfare on farms by Member States.

- **Effective, efficient and reliable controls**

A number of projects in DG Health and Food Safety's audit and analysis programme 2019 aim specifically at ensuring that Member States' control systems are effective, efficient and reliable. Activities include the systematic follow-up of

audit recommendations to ensure that Member States and countries outside the EU implement the actions necessary to correct identified shortcomings. In addition, the Better Training for Safer Food (BTSF) programme and the Multi-Annual National Control Plan and National Audit Systems Networks provide the opportunity to discuss common problems identified during the assessment work, and to exchange good practices between countries.

- **Contributing to harmonisation in the pharmaceutical sector and patients' access to safe medicines**

Finally, DG Health and Food Safety carries out work in the area of medical devices and active pharmaceutical ingredients for human use.



Audit and Analysis Work Programme 2019

DG Health and Food Safety's audit and analysis programme for 2019 comprises 47 projects and up to 211 audits and other on-the-spot visits in the EU Member States and countries outside the EU.

3.1. Overview of projects



Project approach

The work programme is mainly organised in projects with defined objectives, scope, outputs and timeframes. Many projects are prepared through

desk analyses to gain a thorough overview of the topic, identify potentially problematic areas and prioritise audits, followed by a targeted series of audits or other on-the-spot visits such as fact-finding missions. Fact-finding missions are organised in areas where the Commission needs to complete its knowledge about the operation of legislation on the ground; and the results of these missions provide input into the review or development of legislation.

In addition to individual audit reports, the Commission prepares overview reports which identify what is working, or not, in relation to the enforcement of controls (and the interpretation of legislation). They also form the basis for

exchanges with Member State experts in the framework of the Better Training for Safer Food (BTSF) programme to discuss common problems identified and to share best practice.

In addition, desk-based control activities and activities to promote sound regulatory practices in the implementation of controls make up a large amount of the work programme alongside the traditional audit work.

Number and distribution of projects

The following subchapters describe the 47 projects on audit and analysis that DG Health and Food Safety carries out in 2019, by area and sector.

As shown in Chart 1, 6% of projects are planned in the area of human health protection. The majority of projects, 26%, will be in the area of food safety, 15% of projects each will take place on animal and plant health and 4% on animal welfare. One project is planned on food quality, while four projects deal with feed safety. Projects on import controls make up 17% of the work programme and, finally,

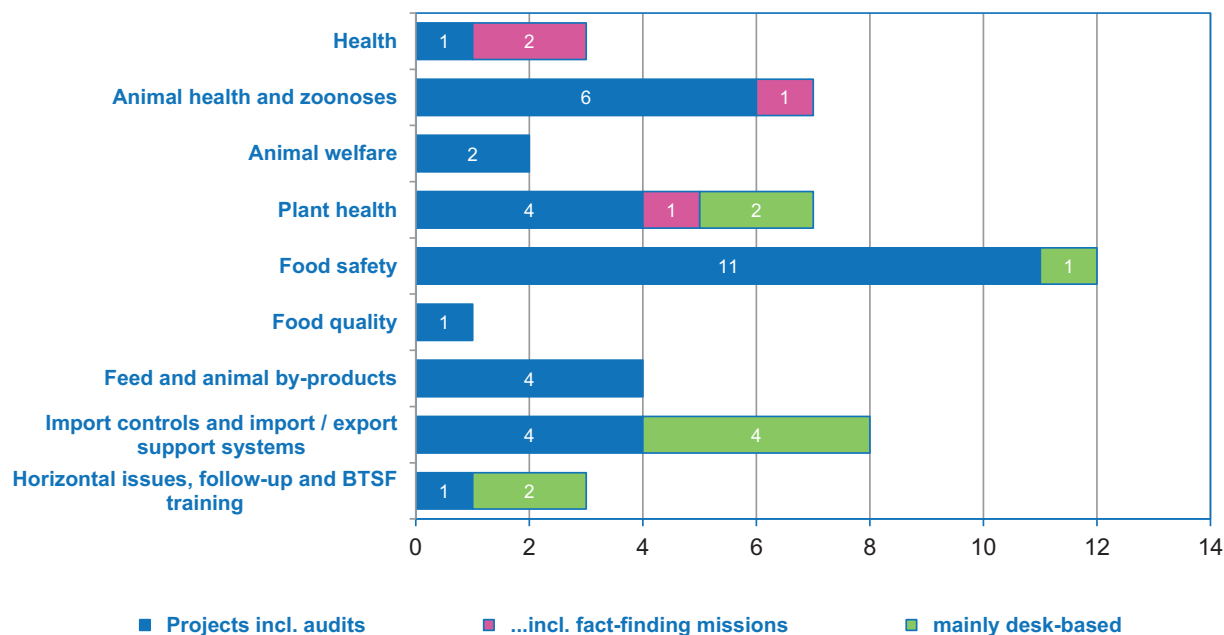
6% of projects cover horizontal issues, follow-up and BTSF training.

Chart 1 also shows the proportion of projects including audits (blue bars), fact-finding missions or other on-the-spot visits (pink bars) and desk-based work (green bars). 72% of all projects include audit series, and 9% other on-

the-spot visits. 19% of projects are mainly desk-based.

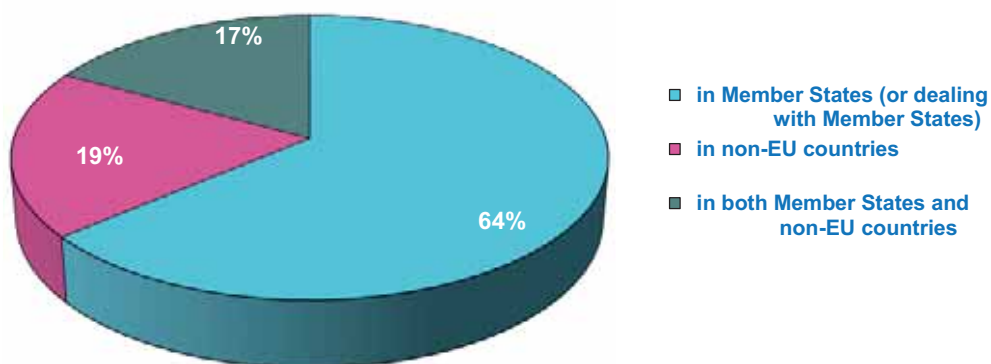
These include desk analyses to support audit planning and prioritisation or projects with only a small number of audits that will be carried out based on the results of a desk analysis. Finally, some projects involve support activities, or describe follow-up and networking or training activities.

Chart 1: Number of projects on audit and analysis in 2019, by main area



As shown in Chart 2, 64% of all projects are in Member States (or deal with Member States). 19% of projects are dealing with countries outside the EU while 17% deal with both Member States and non-EU countries.

Chart 2: Breakdown of projects in 2019 by region

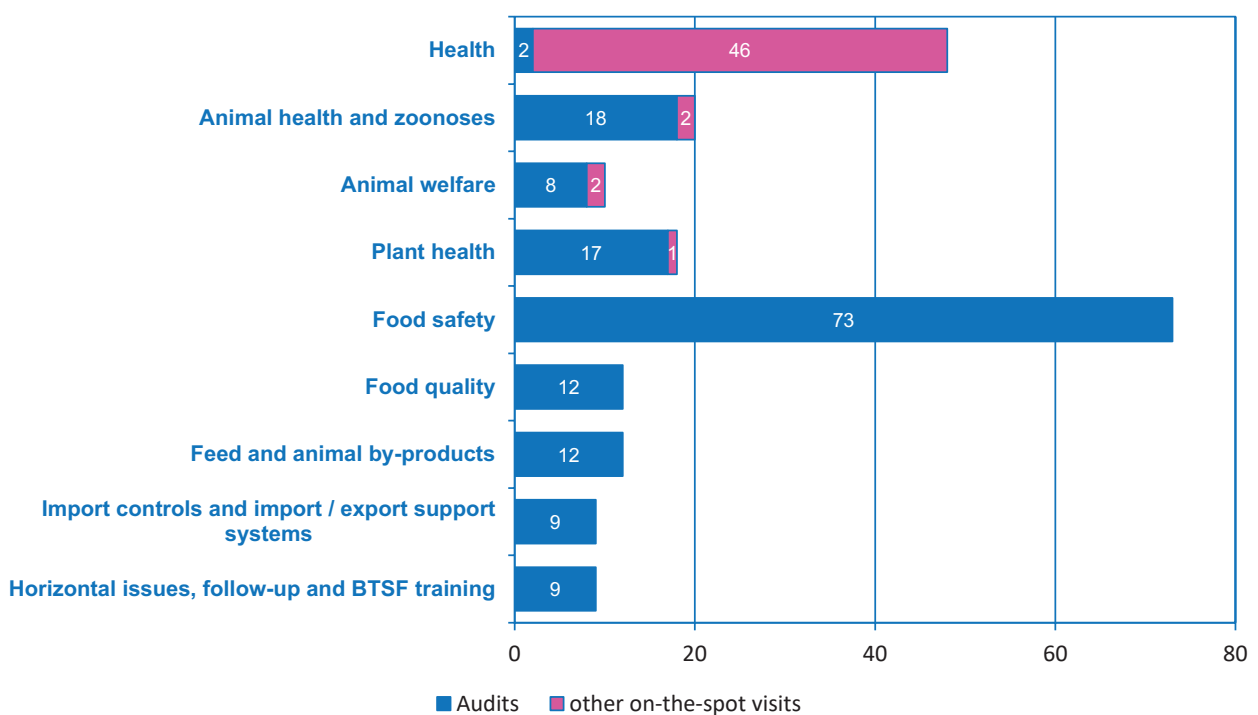


The 47 projects comprise up to 211 audits and other on-the-spot visits, corresponding to roughly 4,400 auditor days on the ground (travel time excluded). The figure takes account of the national experts from Member States who accompany more than 50% of Commission audits each year.

other on-the-spot visits (24% of visits) by main area. 23% of visits are planned in the health area, dealing with medical devices, antimicrobial resistance and active pharmaceutical ingredients. 34% of audits and fact-finding missions deal with food safety, 14% with animal health and welfare, and 9% with plant health. 6% of audits each will be carried out in the areas of food quality and feed safety, while 4% of audits each concern import controls and follow-up.

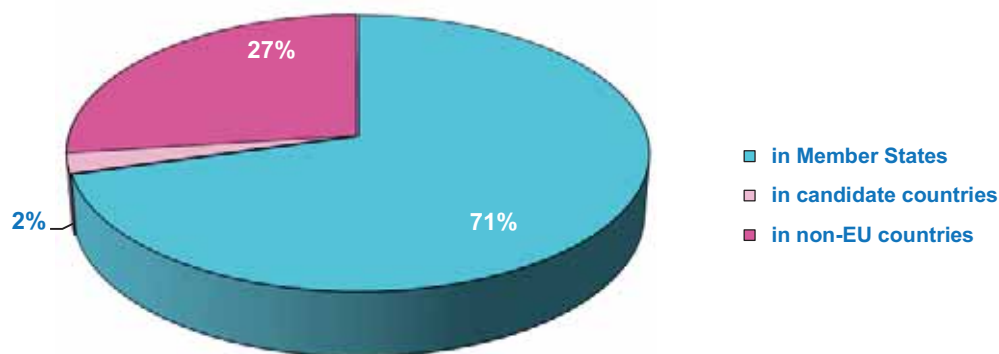
Chart 3 shows the number of audits (76% of all visits) and

Chart 3: Number of audits and other on-the-spot visits in 2019, by main area



Of the 211 audits and other on-the-spot visits, 149 are planned in Member States, 5 in candidate countries and 57 in countries outside the EU (see also chart 4).

Chart 4: Breakdown of audits and other on-the-spot visits in 2019 by region



The following subchapters provide summaries of each project planned for 2019.

[Annex 1](#) shows an overview of all projects, together with the number of the page on which they appear in this chapter.

[Annexes 2 - 4](#) list all audits and other on-the-spot visits in Member States, candidate countries and non-EU countries

in the areas of food safety and quality, animal health and welfare, and plant health.

[Annex 5](#) provides an overview of on-the-spot visits in the area of human health protection.

3.2. Health



Antimicrobial resistance (AMR) – the ability of microorganisms to resist antimicrobial treatments, especially antibiotics – has a direct impact on human and

animal health and is high on the agenda of the European Commission, Member States, EU agencies (European Medicines Agency, European Centre for Disease Prevention and Control, European Food Safety Agency), countries outside the EU and international organisations. In June 2017 the Commission adopted the EU One Health Action Plan against AMR. It builds on the EU's 2011 five year Action Plan which is viewed as a precursor to a number of global initiatives. Its overarching goal is to preserve the possibility of effective treatment of infections in humans and animals.

Together with the European Centre for Disease Prevention and Control, the Commission is supporting Member States in the adoption and implementation of their national action plans relating to AMR.

The projects on AMR monitoring in food producing animals and food, and on the prudent use of antimicrobials in animals will conclude in 2019, with final overview reports.

The Commission also contributes to the safety of, and a well-functioning internal market for, medical devices and human medicinal products by

- coordinating joint assessments of notified bodies in the medical devices sector and
- assessing the regulatory framework, and its implementation, for the production of active pharmaceutical ingredients (APIs) imported into the EU for use in human medicines.

AMR – One Health country visits

Objective	To support Member States in the adoption and implementation of their national One Health Action Plans relating to AMR.
Project summary	<p>This project is organised together with the European Centre for Disease Prevention and Control and covers AMR holistically from a "One Health" perspective, i.e. recognising the role played by and interactions between human, veterinary and environmental factors.</p> <p>Visits are organised on invitation by the Member States. After three visits in 2017 and two in 2018, further visits, depending on requests received, are envisaged for 2019.</p>
Outputs 2019	Up to six country visits, together with the European Centre for Disease Prevention and Control.

Joint assessments of notified bodies for medical devices

Objective	To ensure that only appropriately resourced and adequately performing and reliable notified bodies are designated in the field of medical devices.
Project summary	<p>The Directorate has been carrying out, together with national designating authorities from the Member States, joint assessments of notified bodies in the medical devices sector since 2013. These notified bodies are responsible for assessing that medical devices are in conformity with the relevant legal requirements. The field is very wide, with tens of thousands of devices ranging from plasters to pacemakers. The assessments were first carried out in the framework of the voluntary joint action plan following the PIP breast implant scandal and are mandatory since October 2013.</p> <p>The project entails the continuation of assessments under Commission Implementing Regulation (EU) No 920/2013³ and assessments under the new Regulations on medical devices and <i>in vitro</i> diagnostic medical devices (Regulations (EU) 2017/745⁴ and 2017/746⁵). They expand the scope of the joint assessments to cover <i>in vitro</i> devices.</p>
Outputs 2019	It is estimated that approximately 40 joint assessments will be performed in 2019 under both Regulation (EU) No 920/2013 and Regulations (EU) 2017/745 and 2017/746.

3. Commission Implementing Regulation (EU) No 920/2013 of 24 September 2013 on the designation and the supervision of notified bodies under Council Directive 90/385/EEC on active implantable medical devices and Council Directive 93/42/EEC on medical devices Text with EEA relevance, OJ L 253, 25.9.2013, p. 8–19

4. Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance.), OJ L 117, 5.5.2017, p. 1–175

5. Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices and repealing Directive 98/79/EC and Commission Decision 2010/227/EU (Text with EEA relevance.), OJ L 117, 5.5.2017, p. 176–332

APIs for human medicines: Equivalence determination in countries outside the EU

Objective	<p>To contribute to the health protection of EU citizens in relation to the active substances (APIs) exported to the EU from non-EU countries. These APIs are used for the manufacturing of human medicines in the EU.</p>
Project summary	<p>The Commission assesses applications received from countries outside the EU to determine whether their regulatory framework and the control and enforcement activities on the manufacturing of APIs intended for export to the EU are equivalent to the system in the EU or not. The Commission also has to re-assess every three years those non-EU countries already listed as equivalent.</p> <p>The assessments include desk evaluations and/or on-site audits.</p>
Outputs 2019	<ul style="list-style-type: none"> • Audits to two non-EU countries; • contribution to the evaluation of new applications.

3.3. Animal health and zoonoses



The projects in the area of animal health aim at providing continued support to the objective of managing and isolating outbreaks of major animal diseases. Two separate projects deal with African swine fever – one in Member States and EU neighbouring countries with recent outbreaks and one in Member States not yet affected by the disease. Another project looks at improving the preparedness, early detection and rapid response to avian influenza, learning from actions taken

in response to the last epidemics.

Zoonoses are diseases or infections that are naturally transmissible from vertebrate animals to people. Two projects are ongoing in 2019 to support the continued eradication of rabies in wildlife and to further reduce the number of human salmonellosis outbreaks in the EU.

DG Health and Food Safety also evaluates requests by countries outside the EU for approval of exports of live animals or food of animal origin to the EU and reviews animal health controls of countries outside the EU already exporting to the EU.

A small project looks at Chronic Wasting Disease monitoring.

African swine fever – affected Member States

Objective	Improve the early detection, rapid response and effectiveness of control measures in Member States affected by African swine fever.
Project summary	Through audits the Commission is verifying, amongst others, national surveillance programmes, their capacity for, and effectiveness of vaccination campaigns – when relevant-, movement controls and containment measures, laboratory support, eradication measures and regionalisation. The audits also aim to identify good practices.
Outputs 2019	Audits to Hungary, Lithuania and Poland.

African swine fever preparedness

Objective	Increase preparedness by Member States against African swine fever in wild boar by strengthening controls on hunting grounds and wild boar populations.
Project summary	<p>This project takes place in Member States not yet affected by the disease. It specifically aims at increasing the number of Member States that have</p> <ul style="list-style-type: none"> operational arrangements between the veterinary services and forest/hunting services for the control of wild boar habitats; good control of wild boar populations and biosecurity in wild boar habitats; surveillance programmes for African swine fever in wild boar capable of detecting the disease promptly. <p>Following a desk-based phase with questionnaires to Member States (not affected by the disease) and fact-finding missions (Slovakia and Spain in 2018), the project should result in agreed codes of practice and a platform to facilitate information exchange and decision making.</p>
Outputs 2019	<ul style="list-style-type: none"> Fact-finding missions to Austria and Germany (Slovakia and Spain in 2018); agreed operational codes of practice for the management by competent authorities of wild boar habitats and populations, including African swine fever surveillance and emergency response (to be published as a Commission Recommendation); collaborative platform established to improve information sharing and decision making involving competent authorities, hunters and pig producers at all levels (EU, national and local); overview report and presentation of results at the Standing Committee for Plants, Animals, Food and Feed.

Avian influenza

Objective	Evaluate the implementation of EU measures on the control and eradication of avian influenza in Member States affected by the disease, mainly in the domestic waterfowl production sector.
Project summary	The project entails further audits on avian influenza following the current unstable situation with worldwide spread of the disease involving different virus subtypes and increased risk for continuous outbreaks in the EU relevant to animal but also human health.
Outputs 2019	Audits to Bulgaria, Czech Republic, France, Italy and Romania.

Chronic Wasting Disease

Objective	Assess the surveillance of Chronic Wasting Disease and the implementation of related safeguard measures.
Project summary	Chronic Wasting Disease is a transmissible spongiform encephalopathy in cervids, with zoonosis potential. Following the detection of the disease in reindeer in Norway and in a moose in Finland, two audits are planned to Finland and Sweden. The audits will assess the surveillance system for farmed and wild or semi-domesticated cervids and also cover the measures implemented to minimise the risk of introducing or spreading the disease.
Outputs 2019	Audits to Finland and Sweden.

Salmonella Control Programmes

Objective	<ul style="list-style-type: none"> • Further reduce the number of foodborne outbreaks in the EU by improving the effectiveness of control programmes in live poultry. • Obtain information, on-the-spot, to support a well-informed evaluation of Member States' co-financing requests.
Project summary	Eggs remain the main cause of human salmonellosis. For instance, the 2016-2017 outbreak of Salmonellosis with its origin in Polish eggs accounted for more than 500 reported human cases alone. The Commission will audit the correct implementation of <i>Salmonella</i> control programs for poultry populations in Member States.
Outputs 2019	Audits to Greece and Spain.

Rabies eradication in the EU

Objective	Support Member States in achieving the Commission targets of reducing the number of rabies cases in wildlife (excluding bats) and eradicating wildlife rabies in the EU by 2020.
Project summary	The project will verify the effectiveness of the rabies eradication programmes in Member States. Following audits to Poland and Greece in 2017 and Croatia and Slovakia in 2018, the project concludes in 2019 with an audit to Bulgaria.
Outputs 2019	Audit to Bulgaria.

Animal health – countries outside the EU

Objective	<ul style="list-style-type: none"> • Evaluate requests by non-EU countries for approval of exports of live animals or food of animal origin to the EU; • review animal health controls by non-EU countries already exporting to the EU.
Project summary	<p>Countries outside the EU wishing to export live animals, germinal products or a category of food of animal origin must be in the list of approved countries for that specific commodity. Before a country – or a new region in a country – is approved, DG Health and Food Safety carries out an evaluation of its competent authority and its control system to ensure they provide the necessary guarantees. An audit will be carried out, once the DG has received satisfactory replies to its questionnaire on various elements of the country's control system, disease situation and more.</p> <p>The DG also regularly reviews animal health controls in countries already exporting to the EU.</p>
Outputs 2019	<p><u>Listing requests:</u></p> <ul style="list-style-type: none"> • Audits to Belarus (live fish, FMD status), the former Yugoslav Republic of Macedonia (live fish), Mauritania (oysters), Mexico (beef). <p><u>Reviews:</u></p> <ul style="list-style-type: none"> • Audit to Paraguay (beef).

3.4. Animal welfare



The audit and analysis programme on animal welfare supports DG Health and Food Safety's animal welfare strategy. There are two main projects related to better implementation of

existing legislation: one is focussing on reducing the tail-docking of piglets, the other one on the enforcement of

animal welfare on farms. This work will involve a wide range of activities such as audits, data analysis, meetings with main stakeholders, and the creation of a team of technical experts to help Member States.

DG Health and Food Safety also leads the subgroup of the EU Animal Welfare Platform which will work on transport of animals.

The project on animal welfare during export to countries outside the EU concludes in 2019 with an overview report and BTSF training.

Reducing the systematic tail-docking of piglets

<p>Objective</p>	<p>Reduce animal suffering during the rearing of piglets by improving the application of Council Directive 2008/120/EC⁶ over a three year period. The project focusses specifically on the rules on the avoidance of routine tail-docking of piglets and the provision of manipulable material.</p>
<p>Project summary</p>	<p>The focus will be on improving management practices which impact on animal welfare, on pig farms.</p> <p>The project includes providing support to national authorities to assess the current situation in pig farms and improving communication within and between stakeholders, including farmers and private veterinarians.</p> <p>It comprises political and technical meetings, targeted audits, request of action plans from all Member States and administrative follow-up. It also includes forming a group of technical experts ("task force") to support Member States in implementing the relevant legislation.</p>
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • Audits to Austria, France, Hungary and Portugal; • task force visits to the Netherlands and Spain; • follow-up, assessment of implementation, final meeting with Member States and communication activities.

Quality controls and indicators for animal welfare

<p>Objective</p>	<p>Determine whether</p> <ul style="list-style-type: none"> • Member States have a strategic approach to enforcement of EU requirements for animal welfare on farm,
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6. Council Directive 2008/120/EC of 18 December 2008 laying down minimum standards for the protection of pigs (Codified version), OJ L 47, 18.2.2009, p. 5-13

Objective	<ul style="list-style-type: none"> controls are carried out following “quality management” principles and animal welfare indicators are used to measure the severity, extent and permanence of animal welfare problems.
Project summary	<p>The project targets in particular farming of pigs and broilers and will focus on commercial farms and different points of the production chain, including slaughterhouses. The project will analyse the competent authorities' systems for inspection and reporting and also the use of indicators by the agri-food sector (e.g. private quality assurance schemes), as well as by research bodies and private veterinarians.</p> <p>Following a desk-based preparatory phase including questionnaires to all Member States and the sectors above on policy and use of indicators, the Commission will carry out audits to gather more in-depth information in 2019 and 2020. In addition, it will organise meetings with the groups concerned and with Member States authorities to agree a methodology for reporting on farm inspections.</p>
Outputs 2019	<ul style="list-style-type: none"> Audits to Finland, Germany, the Netherlands and Sweden; report on stakeholder meetings presented at the Standing Committee for Animals, Food and Feed.

3.5. Plant health



With the increase in trade over the last decades, the risk of introducing new pests and diseases into the EU has increased substantially. Given favourable weather conditions and a lack of natural

enemies, they can spread and lead to environmental damage, destruction of native plant species, substantial economic losses in agricultural production and an increase in the use of pesticides.

The main aim of the audit and analysis activities of DG Health and Food Safety in the plant health area,

therefore, is to prevent the introduction into and spread of harmful organisms within the EU and at the same time, maintain a dynamic trade environment within the EU single market and in our trade relations with our non-EU trading partners. Its work will cover phytosanitary controls of the trade in plants and plant products both by countries outside the EU and Member States and the eradication and control of harmful organisms on EU territory by Member States.

The projects presented below include audits in Member States (in particular rapid responses to outbreaks) and in targeted non-EU countries exporting to the EU (to follow up on non-compliant imports to the EU) as well as the further development of EUROPHYT (the rapid alert system for plant health interceptions and outbreaks of harmful organisms) and other tools for alerts and analysis.

Plant pest outbreaks

Objective	<p>To contribute, as part of the Commission crisis preparedness, to the proper handling of outbreaks of harmful organisms on the EU territory (their eradication or containment), including timely EU level involvement where needed.</p>
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<p>Project summary</p>	<p>This will be achieved by audits, the number and scope of which will be regularly reviewed in light of the developments concerning plant pests. There will be follow-up of existing outbreaks and audits of the measures taken by Member States in response to new ones. The outcome will be used for review and enforcement, as appropriate, of EU legislation, including emergency measures.</p>
<p>Outputs 2019</p>	<p>7 audits in 2019:</p> <ul style="list-style-type: none"> • <i>Xylella fastidiosa</i>: France, Italy and Spain • <i>Bursaphelenchus xylophilus</i>: Spain • <i>Aromia</i>: Italy • <i>Epitrix</i>: Spain • One further audit to be confirmed <p>The results of the audits will be presented to the Member States. In addition, and for those Member States that are not audited, the Commission will evaluate the action plans submitted to deal with key harmful organisms.</p>

Plant health import controls

<p>Objective</p>	<p>To prevent the introduction of harmful organisms into the EU whilst maintaining a dynamic trade environment.</p>
<p>Project summary</p>	<p>Import controls operated by Member States of the EU should be applied uniformly; however, previous audits of import control systems have revealed differences between Member States in the knowledge of EU requirements as well as their approach and level of controls for imports of various plants and plant products. The audit series, therefore, assesses the capacity and performance of Member States' plant health import controls, focussing on the inspection methodology employed with regard to plant health checks and on the policy and capacities of Member States to diagnose harmful organisms.</p> <p>Following a desk analysis and five audits in 2017, six audits were completed in 2018. The project concludes in 2019 with one further audit and an overview report.</p>
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • Audit to Spain; • overview report; • BTSF training.

Plant health audits in countries outside the EU

<p>Objective</p>	<p>To improve compliance of the exports from the countries audited with EU requirements for freedom of regulated harmful organisms.</p>
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Project summary	The project aims to cover the most important plant health issues in non-EU countries, chosen based on the risk from their imports to the EU. Audits cover selected countries that appear on the published non-EU trade alert list with most EUROPHYT notifications and the certification programmes for export of wood. In addition, one audit each is planned in relation to the EU recognition of freedom from potato ring rot and on wood packaging material.
Outputs 2019	<p>8 audits in 2019:</p> <ul style="list-style-type: none"> • Alert list countries: Dominican Republic, Malaysia, Suriname and Uganda; • export certification of wood: United States (softwood and hardwood); • wood packaging material: Belarus; • potatoes: Montenegro. <p>The Commission will present the results of the project to the Member States.</p>

Seeds and propagating material

Objective	To evaluate non-EU countries' system of official controls and certification of seed and their equivalence with EU requirements.
Project summary	Seed produced in countries outside the EU must offer the same guarantee of quality as EU seed. Desk evaluations and audits are carried out based on requests by non-EU countries to obtain seed equivalence.
Outputs 2019	One audit to India.

Fruit plants

Objective	<p>To contribute to ensuring that</p> <ul style="list-style-type: none"> • appropriate controls for the certification of fruit plants are applied uniformly across the Union and • only planting material that is healthy and of the required quality is marketed in the EU.
Project summary	The EU legislation provides for official controls during production and marketing of propagating material and fruit plants. This new project will start with an exploratory visit. Based on its results further fact-finding missions or audits will be organised.
Outputs 2019	One fact-finding mission to Hungary.

EUROPHYT

<p>Objective</p>	<p>To operate and develop the IT systems EUROPHYT-<i>Interceptions</i> and EUROPHYT-<i>Outbreaks</i>: and provide the necessary data for Member States and Commission for policy development and for the targeting of controls. The operation of EUROPHYT-<i>Interceptions</i> and EUROPHYT-<i>Outbreaks</i>: significantly contributes to the successful handling of new risks and to the management of crises.</p>
<p>Project summary</p>	<p>EUROPHYT is the European Commission notification and rapid alert system for plant health interceptions of imported and traded consignments and outbreaks of organisms harmful to plants on the EU territory. EUROPHYT provides an essential support for the implementation of preventative measures by ensuring that the data on risks to plant health from trade in plants and plant products and from outbreaks are up-to-date and accurate.</p> <p>EUROPHYT-<i>Interceptions</i>, in addition to its function as a rapid alert system, is an effective policy support tool for risk assessment and risk management. Based on EUROPHYT data, a non-EU trade alert list is published each month on the website of DG Health and Food Safety.</p> <p>All Member States are using the EUROPHYT-<i>Outbreaks</i> system to notify outbreaks and provide updates about outbreaks.</p>
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • Main outputs EUROPHYT-<i>Interceptions</i>: Weekly Commission internal interception reports, monthly and annual statistics as well as an annual report and monthly non-EU trade Alert Lists published on DG Health and Food Safety's website⁷. • Main outputs EUROPHYT-<i>Outbreaks</i>: Monthly outbreak reports produced for the Standing Committee on Plants, Animals, Food and Feed. Annual report published on the website and in print.

Plant health surveys

<p>Objective</p>	<p>To analyse and report on the results of the harmful organism surveys the Member States must carry out under emergency Decisions and control Directives (currently 12 organisms).</p>
<p>Project summary</p>	<p>The Commission has launched a "Plant Health Surveys" module under the EUROPHYT portal and extracts and analyses data for the production of reports for presentation to the Standing Committee on Plants, Animals, Food and Feed. In addition, it evaluates Member States' action plans for at least the most important harmful organisms.</p>
<p>Outputs 2019</p>	<p>Presentations to the Standing Committee on Plants, Animals, Food and Feed.</p>

⁷ http://ec.europa.eu/food/plant/plant_health_biosecurity/europhyt/interceptions_en

3.6. Food safety



Contributing to the effective implementation of food legislation continues to be a core element of DG Health and Food Safety's work programme of audit and analysis.

- ready-to-eat food;
- food improvement agents package.

For the following projects the main work is already completed; their results will be summarised in overview reports and/or discussed in workshops or BTSF trainings:

- Aquaculture in non-EU countries;
- food information to consumers and nutrition and health claims;
- food waste;
- food contact materials;
- biocides;
- flexibility and derogations for micro and small and medium-sized enterprises.

The projects described in this chapter deal with food control systems in Member States and non-EU countries exporting food to the EU.

While many activities in relation to food (of both animal and non-animal origin), residues of veterinary medicines in products of animal origin, contaminants and pesticides are of a more regular nature, the following three projects will conclude in 2019:

- Tuna imports from countries outside the EU and tuna from the EU;

An exploratory desk study is planned during 2019 on a future project on cross-sectoral emergency preparedness.

Food of animal origin – controls in Member States

<p>Objective</p>	<ul style="list-style-type: none"> • To verify that official controls on the food production chain are in compliance with EU food law and to contribute to a better and harmonised implementation by Member States. • To contribute to the Better Regulation⁸ initiative by providing input into the review of legislation.
<p>Project summary</p>	<p>The scope of this multi-annual project includes:</p> <ul style="list-style-type: none"> • Food of animal origin (FAO), excluding primary production; • food business operators producing and handling FAO; • competent authorities at the different levels involved in the organisation and performance of the official controls; • general and specific legal requirements related to FAO.

8. Better regulation is about ensuring that EU policies and laws achieve their objectives at minimum cost. It is a way of working to ensure that policy is prepared, implemented and reviewed in an open, transparent manner, informed by the best available evidence and backed up by the comprehensive involvement of stakeholders.

<p>Project summary</p>	<p>The selection of commodities and countries to be audited is based on risk. Various sources including findings from previous audits, country profiles, type and volume of production, the rapid alert system for feed and food (RASFF) and TRACES⁹ inform this process.</p> <p>A special focus in 2019 will be on countries with important horse meat production or imports and countries with a high number of Salmonella outbreaks. Two audits will follow up on the short series on tuna and recent related foodborne outbreaks.</p>
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • <u>Horse meat</u>: Belgium, Ireland, Poland and Romania • <u>Products from mammals and poultry</u>: France • <u>Products from poultry</u>: Poland and Czech Republic • <u>Tuna</u>: Italy and Spain • <u>Fishery products</u>: Cyprus, Denmark and Malta

Food of animal origin – controls in countries outside the EU

<p>Objective</p>	<p>To verify the compliance or equivalence of legislation and of the control systems of non-EU countries with EU food law.</p>
<p>Project summary</p>	<p>The scope of this multi-annual project includes:</p> <ul style="list-style-type: none"> • FAO excluding primary production (such as aquaculture); • organisation and performance of competent authorities; • official control system in place covering production, processing and distribution stages. <p>Based on a risk-based methodology which takes account of, amongst others, export volumes and compliance records (e.g. rapid alert notifications, information from previous audits, foodborne outbreaks), trade partners from outside the EU are selected for audits.</p> <p>Audits will also be planned to countries outside the EU which have requested approval of exports of various commodities, and for which the Commission has received satisfactory replies to its questionnaire on the control systems in place.</p>
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • <u>Live bivalve molluscs</u>: South Korea • <u>Products from mammals</u>: Australia, Canada, Paraguay and Serbia • <u>Products from mammals and poultry</u>: Brazil, Israel and Taiwan • <u>Products from poultry</u>: Thailand and Ukraine • <u>Products from mammals</u>: Belarus (<i>combined with small exporters of fish project</i>) • <u>Fishery products</u>: Brazil, Ghana, Mauritania, Namibia, Russian Federation and Tunisia • <u>Export approvals</u>, based on requests and satisfactory replies received: approximately four audits

9. The TRAdE Control and Expert System (TRACES) is a single central database to track the movement of animals and certain types of products both within the EU and from outside the EU.

Microbiological risks in food of non-animal origin

Objective	To evaluate the system of official controls in the area of microbiological risks of food of non-animal origin, such as fresh fruit and vegetables eaten raw, and soft berries, including frozen produce.
Project summary	<p>This project is ongoing. Food of non-animal origin has proven an important source of foodborne outbreaks with berries lately involved in several of these outbreaks. Seeds for sprouting will also be covered. Volume of exports and rapid alert notifications are the main selection criteria for audits in countries outside the EU.</p> <p>In the EU, countries will be selected based on recent outbreaks and audit history; the focus will be on fresh fruit and vegetables.</p>
Outputs 2019	<ul style="list-style-type: none"> • Audits to non-EU countries: Egypt, Serbia, United States; • audits to Member States: Hungary, Lithuania, Poland.

Tuna imports from countries outside the EU

Objective	To verify that the official control systems in place in non-EU countries exporting tuna to the EU are capable of ensuring that tuna imported to the EU meets the applicable requirements concerning public health, fish policy and customs rules.
Project summary	<p>Tuna is a high value and high volume product, therefore traceability, labelling, identity (species), harvesting/catching (hygiene, temperature) and transport (conditions, reefer vessels) are important elements covered by the project, as well as sustainability.</p> <p>The project started in 2016 with a desk analysis to assess the worldwide tuna catch, identify representative exporting countries located within the regional tuna fishing centres and overall obtain a clearer picture of the industry. This was followed by a short series of targeted audits of the most important tuna exporters in 2017 and 2018. Two follow-up audits will take place in 2019. The results will be presented to Member States in a BTSF workshop and at the Standing Committee on Plants, Animals, Feed and Food.</p>
Outputs 2019	<ul style="list-style-type: none"> • Two audits: Colombia and Ecuador; • overview report.

Small exporters of fishery products

Objective	To evaluate the effectiveness of the measures implemented by the competent authorities of non-EU country trading partners exporting small amounts of fishery products to the EU.
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Project summary	This multi-annual project involves the desk-based assessment of the written assurances provided by non-EU countries exporting small volumes (less than 5,000 tons) of fishery products. Pre-audit questionnaires are sent to the competent authorities in selected non-EU countries. Around 10 countries (out of 50) are assessed each year. Based on an assessment of the responses to these questionnaires, one or two countries are selected for an on-the-spot audit.
Outputs 2019	<ul style="list-style-type: none"> • One audit to Belarus (<i>combined with audit on food of animal origin</i>); • a further non-EU country to be determined based on the results of the desk analysis.

Ready-to-eat food

Objective	To provide an overview of the measures Member States have in place to comply with EU requirements on ready-to-eat (RTE) food and identify any difficulties in their implementation and/or any good practices that could support the Commission's policy of reducing the number of foodborne outbreaks caused by the consumption of this category of food.
Project summary	<p>RTE food is food that will not be cooked or reheated before consumption (e.g. salads, smoked fish, desserts, sandwiches, sushi, and food that has been cooked in advance to serve cold). The project focusses on RTE products that represent the highest risk according to scientific data currently available and RTE foods that are increasingly common on the market (e.g. RTE containing food of animal origin, fresh RTE food with ingredients not subject to thermal treatment, such as prepared salads, sushi, pre-cut fruits, and smoothies).</p> <p>Following a desk analysis, a pilot (fact-finding) mission was organised at the end of 2017. A short audit series took place in 2018 and two further audits will be organised in 2019. The results will be summarised in an overview report and possible difficulties in the implementation and any best practices identified will be discussed with Member States.</p>
Outputs 2019	<ul style="list-style-type: none"> • Two audits: Belgium and Spain; • overview report.

Food improvement agents package

Objective	To assess whether legislation on food improvement agents is fit for purpose and official controls work as intended.
Project summary	Food additives, food enzymes and food flavourings are known as food improvement agents. These products are added intentionally to foodstuffs to perform certain technological functions. Examples are colourings, sweeteners or preservatives. Serious health risks could arise from the use (or misuse) of non-authorized products in foodstuffs.

<p>Project summary</p>	<p>The project follows on from a series of fact-finding missions, in 2015, on food additives and smoke flavourings. This identified that whilst most of the Member States visited have systems in place to control food additives and smoke flavourings at various levels in the production and distribution chain, few have assigned a high priority to controlling this area. Thus, it is important to establish that foodstuffs containing food improvement agents placed on the EU market are safe.</p> <p>Following on from a pilot mission in 2017 and four audits in 2018, further audits are planned in 2019.</p>
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • Audits to Bulgaria, Greece and Italy; • overview report.

Controls of contaminants in food

<p>Objective</p>	<ul style="list-style-type: none"> • To assist the enhancement of controls on contaminants in food by competent authorities and industry. • To provide input into the establishment of new legal limits and import conditions.
<p>Project summary</p>	<p>Contaminants - unwanted substances that have not been intentionally added to food and feed - can occur at various stages of production, processing and distribution. They can occur in products from the EU or in products that are imported from countries outside the EU. As they mostly occur naturally and cannot be removed, they are regulated with the establishment of a maximum level, acceptable from a public and animal health point of view. This level can normally be achieved by applying good agricultural and manufacturing practices combined with controls on the processing and exporting stages.</p> <p>The project involves</p> <ul style="list-style-type: none"> • regular monitoring of rapid alert notifications and analysis of relevant product volumes and imported commodities, respectively, to identify Member States or countries exporting to the EU with a high level of risk for certain products and contaminants; • audits in Member States and countries outside the EU.
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • Audits to Argentina, Iran and the United States; • in Member States, contaminants (heavy metals) will be covered in the audit series on tuna (Italy and Spain) and fishery products (Cyprus, Denmark and Malta).

Assessment of residue monitoring plans

<p>Objective</p>	<p>To contribute to the effectiveness of official controls on residues of veterinary medicines and contaminants in live animals and animal products.</p>
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<p>Project summary</p>	<p>Member States have the legal obligation to present to the Commission their annual residue monitoring plans for assessment and approval. The same applies to the (currently) 85 non-EU countries which are eligible to export animals and food of animal origin to the EU and who have to annually present their plans for the commodities they are listed for in the Annex to Decision 2011/163/EU¹⁰. The activities of DG Health and Food Safety in this regard are as follows:</p> <ul style="list-style-type: none"> • It assesses Member States' residue monitoring plans, taking into consideration the comments provided by the EU Reference Laboratories. The outcome of the evaluations is presented to the Standing Committee on Plants, Animals, Food and Feed for approval. • It also verifies whether the listed non-EU countries have provided their annual residue monitoring plans for all the commodities for which they are listed, and also whether any non-EU country wishes to be listed for any new commodity, for which a residue monitoring plan is required to be submitted and assessed. Non-EU countries' residue monitoring plans are selected on a risk basis for detailed assessment starting with those for which new commodities have been proposed and where previous audit reports have made recommendations on this matter. The result of the assessment will either lead to a new listing, continuation of the current listing or de-listing from the above Decision. The aim is to cover all non-EU countries in a 5-year cycle.
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • Assessment of all Member States' residue monitoring plans; • assessment of a risk-based selection of non-EU country residue monitoring plans which results in (continuation of) listing or de-listing of these non-EU countries in the Annex to Decision 2011/163/EU for the respective commodities.

Residue audits

<p>Objective</p>	<p>To contribute to the effectiveness of official controls on residues of veterinary medicines and contaminants in live animals and animal products.</p>
<p>Project summary</p>	<p>Residue audits in Member States in 2019 have been planned based on the assessment of their residue monitoring plans and the audit history in this area. The results of these audits will help inform the discussions on the new legislation on residue monitoring which is being developed under the Official Controls Regulation (EU) 2017/625¹¹.</p> <p>The programme of residue audits in countries outside the EU is established on a risk basis which takes into account information obtained from the assessment of residue monitoring plans, export volumes, rapid alert notifications, audit history or requests for new listing in Decision 2011/163/EU.</p>
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • Five audits to Member States: Austria, Cyprus, Czech Republic, Denmark and France; • seven audits to non-EU countries: Australia, Belarus, Israel, Paraguay, Russian Federation, Switzerland and Thailand (combined with other food safety audits, where appropriate); • the results of these audits will be shared with the Commission-chaired working group of Member States' residues experts and the import controls working group with regard to those pharmacologically active substances which could be selected for targeted testing in imported products of animal origin at Member States' border inspection posts.

10. 2011/163/EU: Commission Decision of 16 March 2011 on the approval of plans submitted by third countries in accordance with Article 29 of Council Directive 96/23/EC (notified under document C(2011) 1630) Text with EEA relevance, OJ L 70, 17.3.2011, p. 40–46

11. Regulation (EU) 2017/625 of the European Parliament and of the Council of 15 March 2017 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products, amending Regulations (EC) No 999/2001, (EC) No 396/2005, (EC) No 1069/2009, (EC) No 1107/2009, (EU) No 1151/2012, (EU) No 652/2014, (EU) 2016/429 and (EU) 2016/2031 of the European Parliament and of the Council, Council Regulations (EC) No 1/2005 and (EC) No 1099/2009 and Council Directives 98/58/EC, 1999/74/EC, 2007/43/EC, 2008/119/EC and 2008/120/EC, and repealing Regulations (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council, Council Directives 89/608/EEC, 89/662/EEC, 90/425/EEC, 91/496/EEC, 96/23/EC, 96/93/EC and 97/78/EC and Council Decision 92/438/EEC, OJ L 95, 7.4.2017, p. 1–142

Controls of pesticide residues

<p>Objective</p>	<p>To contribute to the improvement of pesticide residue controls</p> <ul style="list-style-type: none"> • in Member States by identifying root causes for weaknesses in the control systems for pesticide residues in foodstuffs of plant origin as well as weaknesses in the laboratory network; • in non-EU countries exporting produce to the EU; with a focus on countries with the highest non-compliance rate with EU Maximum Residue Limits.
<p>Project summary</p>	<p>A new audit series in Member States commenced in the second half of 2017 and will be conducted over a two-year period. Its results will be compiled in an overview report in 2019 and presented to the Standing Committee on Plants, Animals, Feed and Food (PAFF), the European Pesticide Residue Workshop (EPRW), at European Reference Laboratory workshops and the EFSA Pesticide Monitoring Network.</p> <p>Audits in countries outside the EU will be targeted on the basis of pesticide residue control data, Rapid Alert notifications and export volumes. The results will also be disseminated at the PAFF, the EPRW, and the Commission working group on import controls under Commission Regulation (EC) 669/2009¹².</p>
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • Two audits to Member States: Italy and Spain; • three audits to non-EU countries: China, Colombia and Turkey; • overview report; • presentations to the PAFF, EPRW, EFSA Pesticide Monitoring Network and Commission working group on import controls under Commission Regulation (EC) 669/2009.

Sustainable Use of Pesticides Directive (SUD)

<p>Objective</p>	<p>To contribute to achieving a sustainable use of pesticides by reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of integrated pest management and of alternative approaches or techniques such as non-chemical alternatives to pesticides.</p>
<p>Project summary</p>	<p>New activities for 2017-2019 will focus on assessing the achievements and impact of the overall process and improving information exchange through the following actions:</p> <ul style="list-style-type: none"> • Six fact-finding missions on the ground and desk analysis in 2017 on the implementation by Member States of the SUD including national targets, and production of a report to the European Parliament and the Council (October 2017); • adoption of a strategic guidance document on monitoring and surveying impacts of pesticide use (October 2017); • development of a new web portal for information sharing, including links to national technical guidelines, national indicators and any revised National Action Plans after 2017 (October 2017); • audits (four in 2018, six each in 2019 and 2020);

¹² Commission Regulation (EC) No 669/2009 of 24 July 2009 implementing Regulation (EC) No 882/2004 of the European Parliament and of the Council as regards the increased level of official controls on imports of certain feed and food of non-animal origin and amending Decision 2006/504/EC (Text with EEA relevance), OJ L 194, 25.7.2009, p. 11–21

<p>Project summary</p>	<ul style="list-style-type: none"> • engagement with Eurostat¹³ and the OECD¹⁴ on the development of harmonised risk indicators (2018); • adoption of harmonised indicators to measure the reduction in risks from pesticide use (2019); • launch of a new BTSF programme on integrated pest management (IPM); • evaluation of revised National Action Plans (2018-2019); • report to the European Parliament and the Council (2019); • commencing evaluation process for the SUD. <p>In addition, the European Court of Auditors will publish a special report on its audit of EU actions for the sustainable use of pesticides programmed for 2019.</p>
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • Six audits to Austria, Cyprus, Greece, Ireland, Lithuania and Portugal; • 12 BTSF courses; • adoption of harmonised risk indicators; • IPM workshop with Member States and stakeholders; • Second report to the European Parliament and the Council.

¹³ Eurostat is the statistical office of the European Union

¹⁴ Organisation for Economic Cooperation and Development

3.7. Food quality



The markets for organic production and geographical indications in the EU are growing in value

and contribute to the economic sustainability of rural communities. Growth in consumer demand for these products in recent years is remarkable. Ensuring the integrity of these products is, therefore, important.

Organic production and geographical indications

Objective	To ensure that products labelled as being of organic production or designated as geographical indications or guaranteed traditional specialities are in compliance with EU legislation.
Project summary	Official controls on organic production and on geographical indications (protected designations of origin, protected geographical indications) as well as on traditional specialties guaranteed in Member States, and on organic production in countries outside the EU are verified through audits. In countries outside the EU, the Commission is also assessing private Control Bodies which are recognised for certifying/providing guarantees in relation to export of organic products to the EU.
Outputs 2019	<ul style="list-style-type: none">• 6 audits to Control Bodies operating in countries outside the EU;• 3 audits on geographical indications and guaranteed traditional specialities: Cyprus, Ireland and Sweden;• 3 audits on organic production: Croatia, the Netherlands and Spain.

3.8. Feed safety, animal by-products and TSEs¹⁵



In the area of feed safety, the Commission is continuing its work on:

- feed additives and critical ingredients,

- traceability and trade of processed animal proteins and
- the use of insects as feed.

A small new project will be organised in 2019 on the feed ban and other TSE-related issues.

Feed additives and critical ingredients

<p>Objective</p>	<ul style="list-style-type: none"> • To verify the implementation of Member States' official controls on the manufacturing and trade of (premixtures of) feed additives, including certain critical ingredients for the production of premixtures of feed additives. • To inform the evaluation and fitness check of Regulation (EC) No 1831/2003 on additives for use in animal nutrition¹⁶.
<p>Project summary</p>	<p>Following a preparatory phase and five audits in 2018, further audits will be carried out in 2019. Their results will be summarised in an overview report and discussed with Member States.</p> <p>A particular emphasis of the project will be on traceability. In light of recent cases of biomass by-product from amino acid production using genetically modified organisms illegally placed on the EU market (as feed material), this particular aspect of traceability will be looked at, where possible, in the remaining audits to be carried out.</p>
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • Five audits to France, Ireland, Lithuania, Poland and Portugal; • overview report in the second half of 2019.

Traceability and trade of processed animal proteins

<p>Objective</p>	<p>To evaluate the implementation of hygiene, traceability and trade requirements for processed animal proteins (PAP).</p>
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15. Transmissible Spongiform Encephalopathies

16. Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition (Text with EEA relevance), OJ L 268, 18.10.2003, p. 29-43

<p>Project summary</p>	<p>This project follows up on a previous audit series carried out between 2014 and 2015 which had identified shortcomings in the traceability of PAP during export, import and intra-EU trade of such materials to prevent the risk of infringement of some of the main feed ban rules. The project will also establish whether the recent relaxation, in 2017, of the requirements for export of PAP has had any impact on the level of control of imports, exports and intra-EU trade of PAP.</p> <p>Following five audits in 2018, further audits will be organised in 2019. The results will be summarised in an overview report and discussed with Member States.</p>
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • Three audits to Germany, the Netherlands and Spain; • overview report in late 2019 or early 2020 and presentation to Member States at the Standing Committee on Plants, Animals, Food and Feed or at an Animal By-Products or TSE working group.

Use of insects as feed

<p>Objective</p>	<p>To verify how Member States perform official controls on the production, trade and use of insects in feed and insect proteins in feed for aquaculture.</p>
<p>Project summary</p>	<p>The project is mainly focussed on the last amendment of Regulation (EC) No 999/2001¹⁷ and Commission Regulation (EU) No 142/2011¹⁸ which entered into force on 1 January 2018. In addition, the project will also assess controls on the placing on the market of insects as feed for pet and farmed animals (see Art 15 of Regulation (EC) No 178/2002)¹⁹.</p> <p>Following a desk study and one audit in 2018, two further audits are planned in 2019. The project will conclude with an overview report and discussion with the Member States in 2020. At this stage it is not envisaged that there will be further audits, however, as this is a dynamic and growing sector, there may be a need to do so, depending on the outcome of the scheduled audits and possible changes in feed legislation.</p>
<p>Outputs 2019</p>	<p>Two audits to France and Germany.</p>

17. Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, OJ L 147, 31.5.2001, p. 1–40

18. Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive Text with EEA relevance, OJ L 54, 26.2.2011, p. 1–254

19. Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24

Feed ban / BSE²⁰

Objective	To evaluate official controls on ensuring that food and feed business operators observe the rules on the feed ban and other TSE-related issues.
Project summary	This small project comprises two audits to Bulgaria and Romania in relation to their surveillance programmes for BSE.
Outputs 2019	Two audits to Bulgaria and Romania.

3.9. Import controls and trade-related activities

Imports from countries outside the EU



Member States' official controls on imports of animals and goods to verify their compliance with EU import requirements are an important element of the overall system which underpins

food and feed safety and animal and plant health. Such controls are one way to verify that the official control systems put in place in non-EU countries are effective. They are also important in helping to prevent illegal trade. In turn, Commission audits of Member States' import control systems are crucial to maintain and improve the effectiveness of such controls and to provide confidence to EU citizens and other stakeholders on the safety of imported animals and goods.

In 2019, the Commission will continue its project on import controls on animals and goods. In addition new projects will evaluate

- the performance of small Border Inspection Posts (BIPs) with a limited throughput of live animals and goods;

- the implementation of checks on cleansing and disinfection of livestock vehicles entering the EU from countries affected by epizootic animal diseases and
- the performance of remote BIPs located in the outermost regions that form part of the territory of Member States of the European Union.

Technical evaluations of new BIPs or modified facilities in existing BIPs complement this work.

Trade-related support activities

In relation to imports from non-EU countries, DG Health and Food Safety manages the lists of approved non-EU country establishments for the production of food of animal origin.

It also facilitates and processes requests from non-EU countries seeking market access to the EU for exports of food and animals. To the extent possible under EU law, it also undertakes a number of activities to support Member States in their efforts to export food and animals to non-EU countries (for example, on request of individual Member States to support them when they are subject to audits by a non-EU country).

²⁰ Bovine Spongiform Encephalopathy

Import controls on live animals, food and feed

Objective	To evaluate how Member States implement official controls on imports of animals and goods.
Project summary	<p>Effective implementation of controls on imports is important for the protection of the Single Market and the prevention of introduction of diseases into the EU as well as illegal trade.</p> <p>The project will also cover official controls on travellers' luggage in airports.</p> <p>A series of seven audits was carried out in 2018; further audits and an overview report are planned for 2019. The results will also be discussed with Member States.</p>
Outputs 2019	<ul style="list-style-type: none"> • Seven audits: Belgium, Denmark, Finland, France, Greece, Italy and Slovakia; • overview report and communication activities.

Compliance of BIP facilities

Objective	To ensure that new and modified BIPs are constructed in compliance with legislative requirements and are able to perform official controls efficiently and effectively.
Project summary	<p>EU legislation places the responsibility for approval of BIPs on the Commission services and this includes a requirement for an on-the-spot inspection of newly constructed or modified BIPs.</p> <p>Before the Commission can propose a BIP facility for listing in Commission Decision 2009/821/EC²¹, the competent authorities must consult the Commission which assesses the proposals for new BIPs or modifications to existing facilities to ensure correctness, coherence and completeness. Once the proposal is confirmed to be satisfactory (on paper) and the works are finished, the Commission visits the new BIP to verify that the structure and layout of the facility complies with EU legislative requirements.</p>
Outputs 2019	<ul style="list-style-type: none"> • Up to 25 assessments of files; • approximately two to four visits of facilities, based on submission of proposals by Member States.

21. 2009/821/EC: Commission Decision of 28 September 2009 drawing up a list of approved border inspection posts, laying down certain rules on the inspections carried out by Commission veterinary experts and laying down the veterinary units in Traces (notified under document C(2009) 7030) (Text with EEA relevance), OJ L 296, 12.11.2009, p. 1–58

Smaller BIPs with limited throughput

Objective	To evaluate the performance of small BIPs with a limited throughput of animals, food and feed which have not been audited by DG Health and Food Safety in recent years.
Project summary	<p>It is important that both the size and throughput of a BIP do not compromise the implementation of official controls on imported animals and goods. Such facilities should be suitably equipped, in a position to function properly and manned by staff who are knowledgeable on the correct procedures.</p> <p>The import control audits above will be extended by one or two days to include visits to such smaller BIPs, which will be selected on the basis of a prior desk study.</p>
Outputs 2019	Seven audits: Belgium, Denmark, Finland, France, Greece, Italy and Slovakia.

Checks on animal transporters on the EU borders

Objective	To verify the implementation of checks on cleansing and disinfection of livestock vehicles entering the EU from countries affected by Foot-and-Mouth Disease (FMD) or African Swine Fever (ASF).
Project summary	<p>The introduction of epizootic animal diseases, for example FMD and ASF, from affected countries neighbouring the EU via fomites such as contaminated livestock vehicles represents a risk to animal health in the EU. Legislation has therefore been established to prevent the introduction of these diseases into the EU; it requires that such cleansing and disinfection is properly documented.</p> <p>The project includes a desk analysis, audits to two Member States in 2019 which trade with Northern African countries and if warranted, further audits in 2020 or beyond.</p> <p>The audits will focus on a selected number of important road or port crossing points (e.g. ports where roll on/roll off traffic takes place or empty livestock vehicles return from non-EU countries with a potential risk of the introduction of epizootic animal diseases).</p>
Outputs 2019	Audits to Italy and Spain.

Remote BIPs

Objective	<p>To verify the extent and appropriateness of competent authorities' official controls carried out in remote BIPs (located in Outermost Regions that form part of the territory of Member States of the EU), which have not been visited by DG Health and Food Safety in recent years. Such controls are necessary to ensure compliance of animals and goods imported under EU rules or applicable national provisions. The BIP facilities should also comply with EU legislative requirements, enabling official controls to be carried out effectively.</p>
Project summary	<p>A desk analysis will be conducted to identify remote BIPs in three Member States (France, Spain and Portugal) and a strategy to assess their performance will be elaborated. This desk-based activity will be based on a questionnaire.</p>
Outputs 2019	<ul style="list-style-type: none"> • Assessment reports on the evaluation of the remote BIPs; • overview report (if deemed appropriate) presented during a session of the working group on import controls.

Market access

Objective	<ul style="list-style-type: none"> • To assist Member States in their efforts to secure market access for food and feed in non-EU countries (e.g. assisting Member States on request during controls carried out by non-EU countries). • To facilitate and process requests from non-EU countries seeking market access to the EU for exports of food and animals.
Project summary	<ul style="list-style-type: none"> • Member States' access to non-EU country markets <ul style="list-style-type: none"> - Provision of information on the EU regulatory policies and control systems to visiting delegations of competent authority representatives from non-EU countries considering import of food or animals from the EU; - At the request of Member States, accompanying non-EU country auditors during their inspections in the EU. • Non-EU countries' access to the EU <ul style="list-style-type: none"> - Elaboration and management of Commission questionnaires on animal health and veterinary public health, issued to non-EU countries seeking approval to export the animals or commodities in question to the EU; - management of non-EU country responses to Commission questionnaires.
Outputs 2019	<ul style="list-style-type: none"> • Member States' access to non-EU country markets <ul style="list-style-type: none"> - Present the EU regulatory framework and overview of Member States' and the Commission's role in official controls governing food safety and animal health in the Union; - on request of the affected Member States, accompany non-EU audit teams during their audits of those Member States. • Non-EU countries' access to the EU market <ul style="list-style-type: none"> - Drawing up and sending product-specific questionnaires to non-EU countries wishing to export to the EU, coordinating the assessment of the responses to those questionnaires, and making recommendations to other Commission services on whether the responses justify listing of those non-EU countries and thus their eligibility to export food of animal origin to the EU.

Listing of non-EU country food-producing establishments

Objective	To ensure the accuracy and validity of all non-EU country requests for amendment to establishment lists and update of TRACES within the deadlines laid down in Union legislation.
Project summary	The management of lists of approved establishments in non-EU countries for the production of food of animal origin is an essential prerequisite for EU import controls and entails validating the content of requests, entry of requests into TRACES and compilation of new lists. Approximately 500 requests for amendments of these lists are received each year.
Outputs 2019	Up-to-date lists of approved non-EU country establishments for existing commodities and new lists for previously non-harmonised commodities.

Review of rarely visited non-EU country establishments

Objective	To gather information on the compliance history of approved non-EU establishments producing food of animal origin in those non-EU countries where security or other considerations prevent periodic audits being conducted by DG Health and Food Safety.
Project summary	There are non-EU countries which have rarely been audited by DG Health and Food safety. Reasons could include negligible export volumes to the EU or security concerns. It is therefore appropriate that additional guarantees are sought from the competent authorities in those countries as a prerequisite for either the continued listing of already-listed establishments or the addition of new establishments. These guarantees should provide assurances on the consistent and effective performance of official controls on listed establishments.
Outputs 2019	Questionnaires to a minimum of six non-EU countries, selected according to risk-criteria. For each country, a number of establishments will be selected by the Commission and for each establishment, the two most recent inspection reports and supporting documentation (i.e. results of follow-up visits, evidence of closure of non-conformities etc.) will be sought and evaluated by DG Health and Food Safety to determine whether continued listing is justified.

3.10. Horizontal control issues, follow-up and BTSF training



DG Health and Food Safety’s general follow-up audits and administrative updates of country profiles are intended to ensure that progress made by Member States in addressing

recommendations of previous audits is systematically followed up and to encourage Member States’ commitment

to continuous improvement. The “country profiles²²” on each Member State provide the Commission’s assessment of the actions taken by the Member States in response to its audits.

Main work on the projects “national audit systems” and “risk-based planning of official controls” is completed and overview reports of these projects will be published in 2019.

The Commission continues to engage with Member States in network meetings and training activities under the BTSF initiative.

General follow-up audits and administrative updates of country profiles for Member States

<p>Objective</p>	<ul style="list-style-type: none"> • To provide assurance to stakeholders, including Member States, consumers and trading partners, regarding the performance of Member States’ official control systems and • to provide up-to-date information to stakeholders and the Commission on the structure and organisation of competent authority official control systems.
<p>Project summary</p>	<p>The Commission systematically and transparently follows up on the actions taken by the Member States in addressing recommendations of specific audits, either administratively/ desk-based or in general follow-up audits.</p> <p>Good country-specific knowledge to inform policy-making is important. DG Health and Food Safety maintains and publishes country profiles which include information on the structure and organisation of official control systems in each Member State as well as information on the state of progress with the implementation of actions to address audit recommendations²³.</p>
<p>Outputs 2019</p>	<ul style="list-style-type: none"> • 9 general follow-up audits: Bulgaria, France, Germany, Greece, Hungary, Portugal, Slovakia, Slovenia and Spain; • one administrative/desk-based follow-up for Luxembourg.

22. http://ec.europa.eu/food/audits-analysis/country_profiles/index.cfm

23. *Audit reports on specific topics may make recommendations to assist the competent authorities in taking corrective measures.*

Multi-Annual National Control Plan (MANCP) and National audit systems (NAS) Networks

<p>Objective</p>	<p>To enhance Member States' official control systems in the areas of food and feed safety, plant health, animal health and welfare, thus contributing to maintaining EU consumers' confidence in the EU's high standards.</p>
<p>Project summary</p>	<p>The networks are comprised of Member States and EFTA (CH, NO, IS) experts from national competent authorities responsible for (a) the MANCPs and Annual Reports and (b) the performance of audits of official control systems. The networks meet regularly, under the chairmanship of DG Health and Food Safety, to</p> <ul style="list-style-type: none"> • exchange experiences in implementing MANCPs and national audit systems on official control activities; • discuss better ways to address common problem areas and on the identification of good principles and practices; and • to consolidate agreed principles and good practices into reference documents. <p>In 2017 and 2018, work of the MANCP network was dedicated to the development of the Implementing Act in respect of establishing standard model forms for annual reports as mentioned in Article 113(2) of Regulation (EU) 2017/625. This work will be finalised in 2019.</p> <p>In addition, the MANCP network is (a) developing guidelines on how to fill the standard model forms for annual reports and (b) reviewing the guidelines to assist Member States in preparing the single integrated multi-annual national control plan.</p> <p>The NAS network reviewed the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004²⁴ during 2018 along with guidance on audit reporting. This work will be combined and finalised in 2019.</p> <p>The network will also update the existing network reference documents, namely the one on "Auditing Effectiveness of Official Control Systems".</p>
<p>Outputs 2019</p>	<p><u>MANCP network</u></p> <ul style="list-style-type: none"> • Three plenary meetings are planned with the main focus on finalising the guidelines on how to fill the standard model forms for annual reports. • Two subgroup meetings are planned on the review of the guidelines contained in Commission Decision 2007/363/EC²⁵ to assist Member States in preparing the single integrated multi-annual national control plan.

24. Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules, OJ L 165, 30.4.2004, p. 1–141

25. 2007/363/EC: Commission Decision of 21 May 2007 on guidelines to assist Member States in preparing the single integrated multi-annual national control plan provided for in Regulation (EC) No 882/2004 of the European Parliament and of the Council (notified under document number C(2007) 2099) (Text with EEA relevance), OJ L 138, 30.5.2007, p. 24–49

Outputs 2019	<p><u>Audit network</u></p> <ul style="list-style-type: none"> • Two plenary meetings are planned. The first meeting will host a BTSF workshop to discuss the outcome, and overview report, of the project on the Evaluation of the National Audit Systems. • Two subgroup meetings are planned on the review of Commission Decision 2006/677/EC²⁶ setting out guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004. <p>The documents are shared by the Commission with the Network members via CIRCABC²⁷ dedicated interest groups.</p>
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Contribution to the Better Training for Safer Food Programme

Objective	To optimise the use of the BTSF programme to address training requirements identified in the course of DG Health and Food Safety's audit and analysis activities and to disseminate and promote good practices for official controls with a view to enhancing official controls and other official activities by the Member State competent authorities.
Project summary	<p>The Directorate for Health and Food Audits and Analysis provides input into the development of the BTSF programme (e.g. by identifying training requirements and good practices to be disseminated and promoted) and participates as tutors or quality controllers in the programme.</p> <p>It organises specific training activities (e.g. workshops) for Member States, to discuss common problems and good practice identified in audit series and projects.</p>
Outputs 2019	<ul style="list-style-type: none"> • Proposals for 2019/2020 BTSF training programmes (incl. evaluation of tenders and training materials); • trainings for officials of Member States' competent authorities who are selected to be national experts on DG Health and Food Safety's audits; • provision of training and quality assessments of training provided by independent contractors.

26. 2006/677/EC: Commission Decision of 29 September 2006 setting out the guidelines laying down criteria for the conduct of audits under Regulation (EC) No 882/2004 of the European Parliament and of the Council on official controls to verify compliance with feed and food law, animal health and animal welfare rules (notified under document number C(2006) 4026) (Text with EEA relevance), OJ L 278, 10.10.2006, p. 15–23

27. Circabc is a European Commission application to create collaborative workspaces where communities of users can work together over the web and share information and resources.



4.

Report on the Audit Programme 2017²⁸

In 2017, the Commission carried out 199 audits and fact-finding missions in the areas of food safety and quality, animal health and welfare, and plant health. In addition, it performed three country visits on AMR, together with the ECDC, and 15 joint assessments of notified bodies in the medical devices sector, together with designating authorities from the Member States.

4.1. Audits in the areas of food safety and quality, animal health and welfare, and plant health



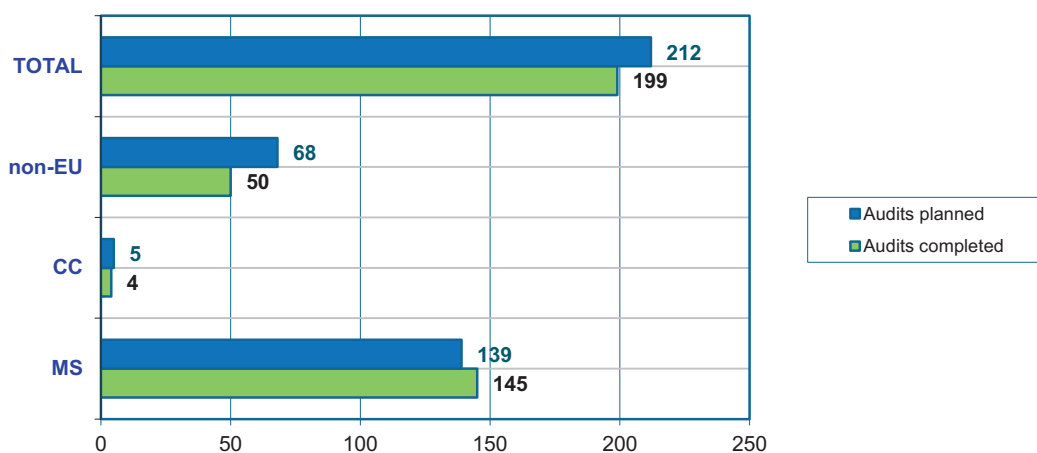
In 2017, the Commission carried out 199 audits and fact-finding missions in the areas of food safety and quality, animal health and welfare and plant health,

compared to 208 audits, fact-finding missions and study visits in 2016.

145 audits and missions took place in Member States and 54 in candidate countries and countries outside the EU.

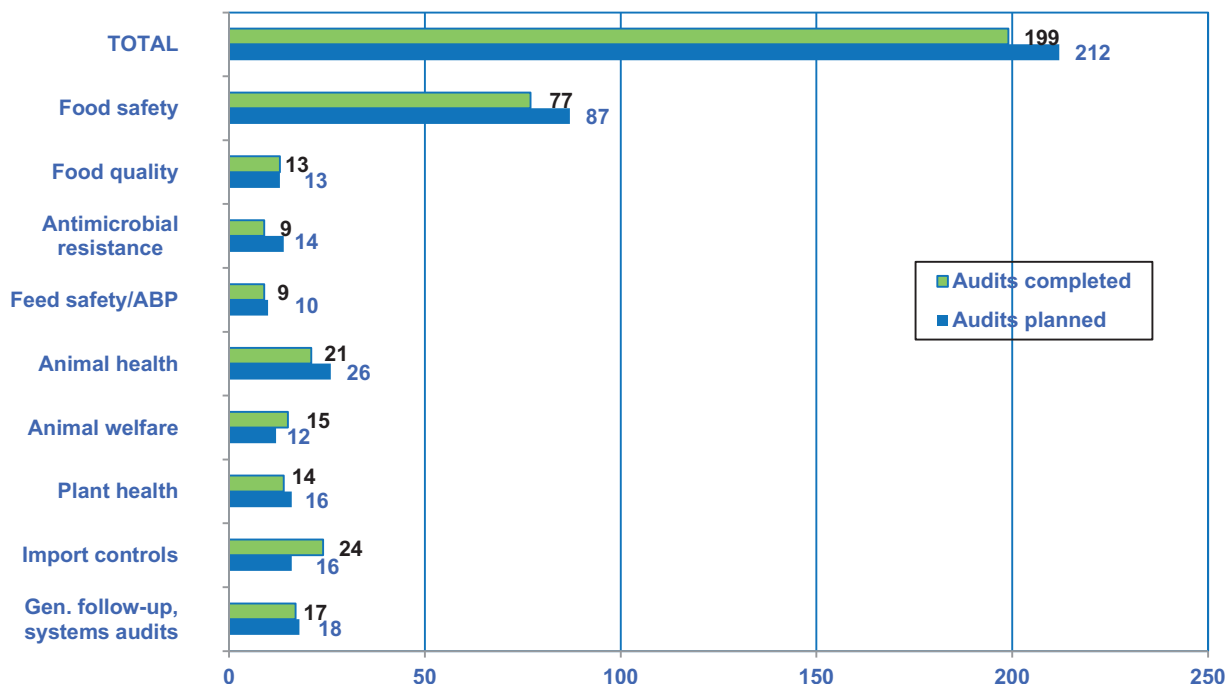
Chart 5 compares the number of planned and completed audits and missions by region.

Chart 5: Number of planned and completed audits in 2017 by region



28. Alongside the traditional audit work, the Commission carries out desk-based control activities and activities to further promote sound regulatory practices in the implementation of controls. This report focusses on audit activities.

Chart 6: Number of planned and completed audits in 2017 by main area



The breakdown by area of activity (chart 6) shows that 9 audits and missions (5%) dealt with antimicrobial resistance while 77 (or 39%) and 13 (7%) of audits were performed in the fields of food safety and quality, respectively. 9 audits (5%) dealt with feed safety and 36 (18%) with animal health and welfare. 14 audits (7%) took place in the area of plant health and 24 (12%) in the area of import controls. Finally, 17 audits (9%) were general follow-up or systems audits.

Out of the 199 completed on-the-spot visits, 130 were audits and 69 fact-finding missions, to gather information about the operation of legislation on the ground and to provide input into the review or development of legislation. Amongst those were fact-finding missions on

- the prudent use of antimicrobials in animals;
- animal welfare of rabbits and of animals transported to countries outside the EU;
- aquatic animal diseases;
- avian influenza;
- fipronil contamination of eggs and egg products;
- measures at the EU borders to prevent the introduction of African swine fever;
- internet sales of food;
- flexibility provisions for SMEs;
- food contact materials;
- risk-based controls in the feed and food sectors;
- synergies of official controls with food business operators' own checks and
- the sustainable use of pesticides.

The following two charts provide overviews on sectors and commodities covered by the audit programme 2017 in Member States (chart 7) and candidate countries and countries outside the EU (chart 8).

Chart 7: Audits in Member States 2017 by sector

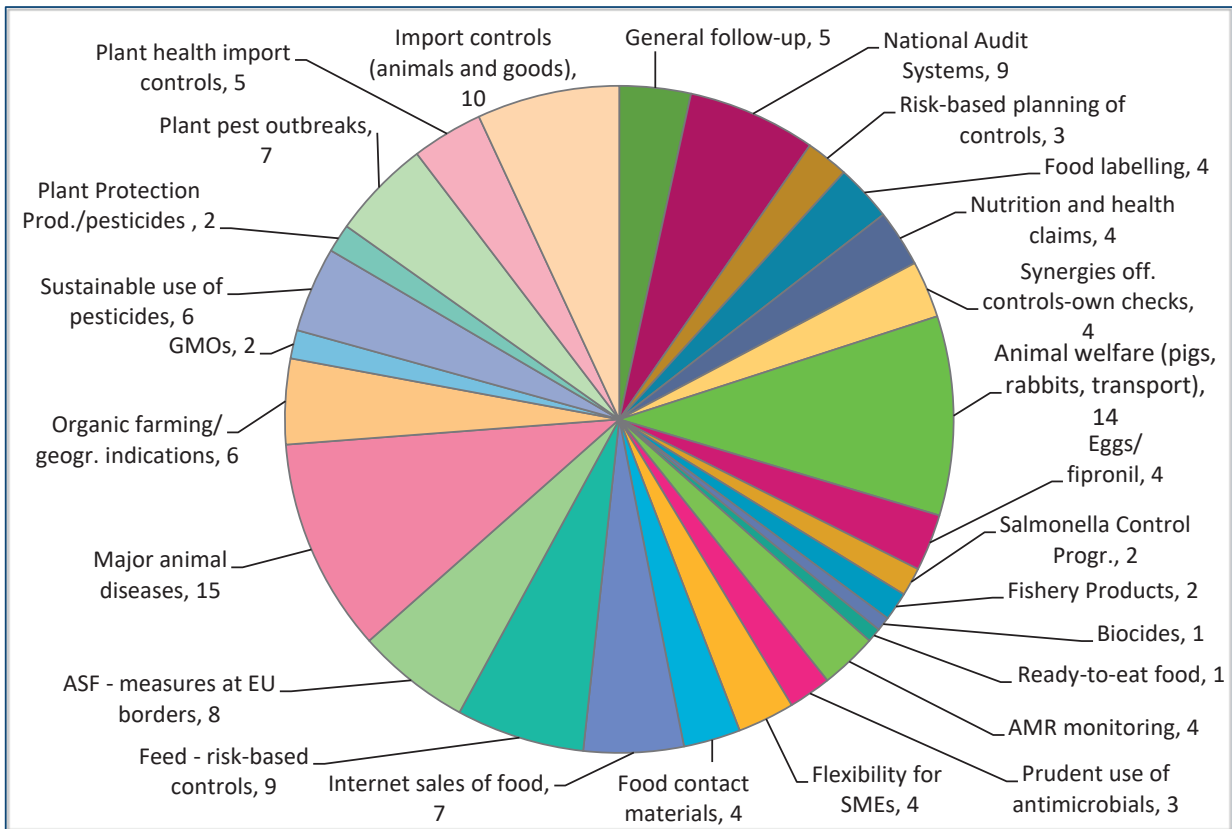
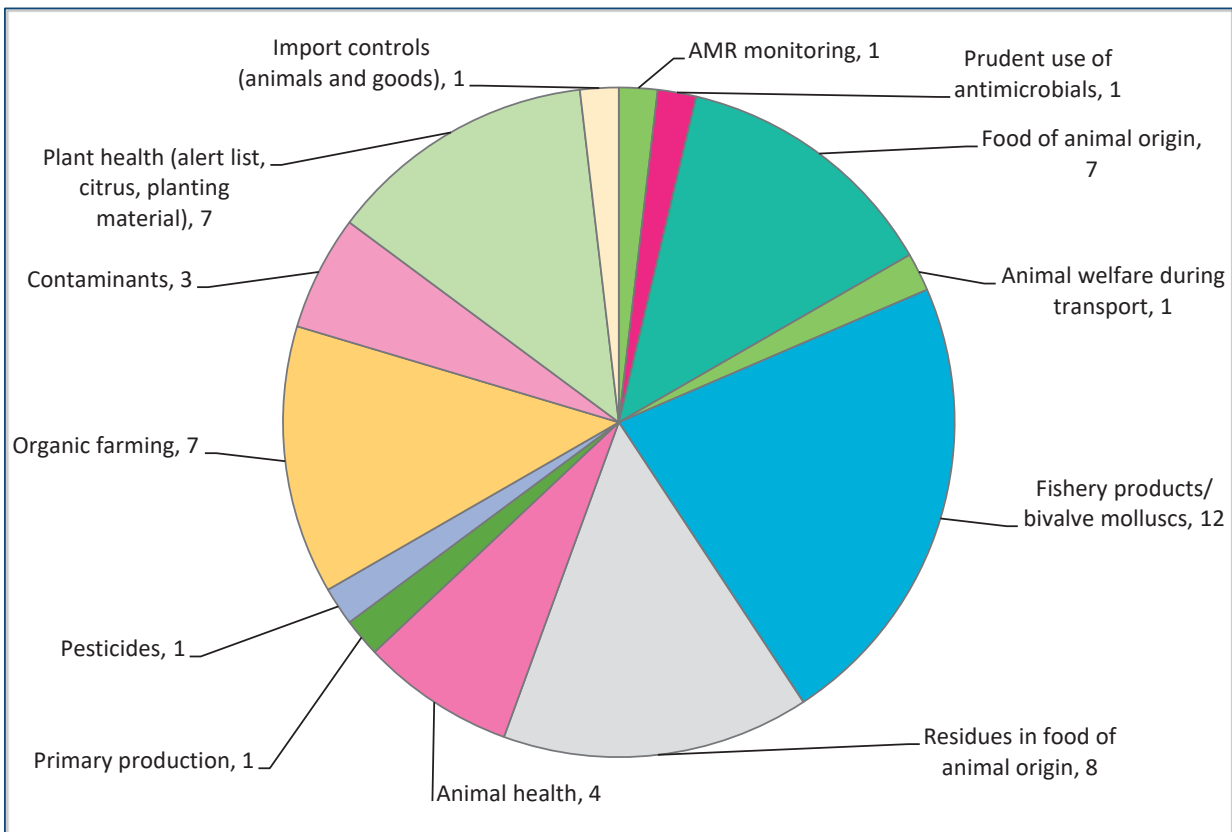


Chart 8: Audits in Candidate Countries and non-EU Countries 2017 by sector



Apart from the audits specifically targeted at animal welfare, there were animal welfare components to audits in Member States and countries outside the EU on meat or milk.

• Auditor days on the ground and participation of national experts

Commission auditors, together with national experts of the Member States, spent 4,050 auditor days on the ground (excluding travel time) in 2017. These figures do not include the preparation of audits, reporting and follow-up work. 99 national experts participated in 107 audits and missions.

• Indicator achievement and programme changes

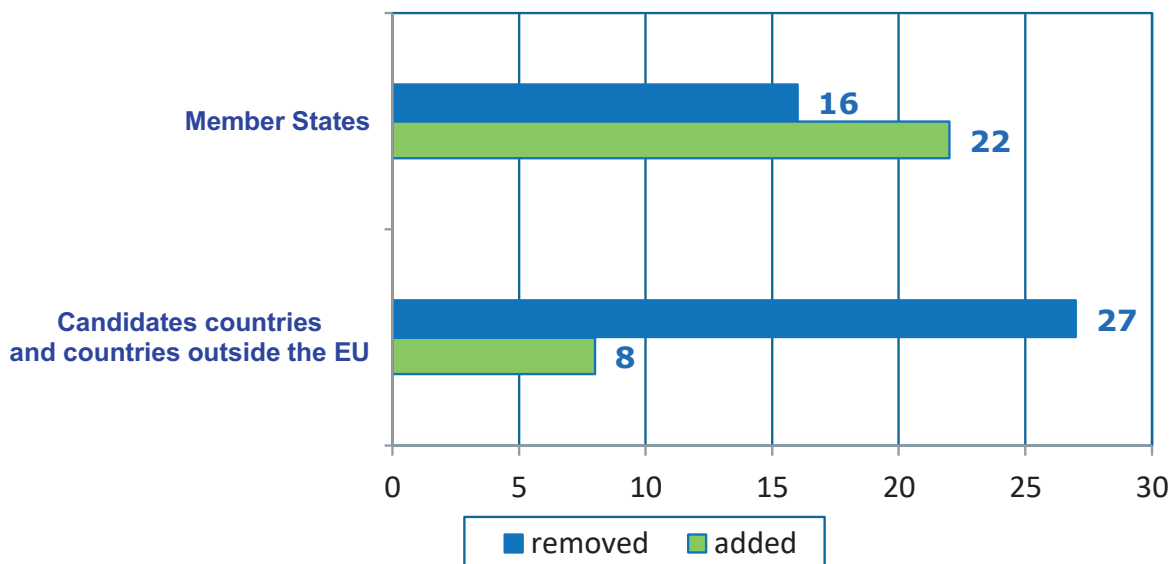
In 2017, the indicator target of performing 80% of all programmed audits and fact-finding missions was achieved. The total number of audits and fact-finding

missions completed (including audits added during the year) compared to the number of programmed audits was 94%, exceeding the target of 90% for this indicator measuring use of audit capacity.

43 audits were postponed or removed from the programme. The reasons for this were, for example, security concerns or a lack of preparedness of competent authorities (action plans from previous audits not yet fully implemented or replies to pre-audit questionnaires not yet received by the Commission). Where possible, these audits were replaced by audits from the reserve list.

Other audits had to be replaced as new priorities emerged during the year, incl. outbreaks of plant pests (*Candidatus Liberibacter solanacearum*) or animal diseases (African swine fever), or in response to Rapid Alert Notifications (for example of fipronil contamination of eggs and poultry meat or the presence of histamine above regulatory limits in fishery products). In total, 30 audits were added in 2017 (compare chart 9).

Chart 9: Overview on programme changes in 2016



• Overview reports

In 2017, the Commission published 21 overview and annual reports on its audit and non-audit activities in the areas of food safety and quality, animal health and welfare, and plant health:

- Use of slaughterhouse data to monitor welfare of broilers on farm
- Educating professionals on animal welfare
- Study visits on rearing pigs with intact tails
- Hazards and management of risks in the feed sector
- Rabies eradication in the EU
- Pesticide residue control in organic production
- Animal health controls in zoos and laboratories
- Audits of official controls in EU-Member States
- Authorisation of plant protection products
- Antimicrobial resistance monitoring in zoonotic and commensal bacteria
- Marketing and use of plant protection products
- Europhyt interceptions 2016
- Identification and response to new plant health risks
- Sustainable use of pesticides
- Longhorn beetles surveys in the EU 2016/2017
- Official control systems in place for food additives and smoke flavourings
- Welfare of dairy cattle
- Private assurance schemes in the feed sector
- Harmful organisms in the EU: Member State reporting 2015/16
- Potato ring rot and brown rot surveys in the EU 2015-2016
- Mitigation measures in place for *Campylobacter spp.* in poultry.

4.2. Activities in the health protection area



In 2017, the Commission carried out 15 joint assessments, together with designating authorities from the Member States on the performance and designation of

notified bodies in the medical devices sector.

It also performed three “AMR One Health” country visits in Member States, together with the ECDC, to support them in the adoption and implementation of their national AMR action plans.

46 national experts participated in these activities.

One overview report was published on medical devices.

The Commission publishes its audit reports and overview reports summarising the findings on the ground on the DG Health and Food Safety’s website:

http://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm

http://ec.europa.eu/food/audits-analysis/overview_reports/index.cfm

Annex 1. Strategic Multi-Annual Outline 2019-2021

The aim of the audit and analysis strategy for the period 2019 to 2021 is to achieve a high level of coverage of the priority areas identified by DG Health and Food Safety requiring scrutiny as to the level and effectiveness of control and enforcement measures. This in turn allows weaknesses and the corresponding corrective measures to be identified and taken up with the relevant authorities. The multi-annual programme is reviewed annually to make sure it is up to date and focusses on the areas of highest risk.

AREA	2018	2019	2020	2021
Human health protection	Antimicrobial resistance (AMR) monitoring			
	AMR - prudent use of antimicrobials in animals			
		AMR - One-Health country visits (jointly with the ECDC) (page 13)		
				Clinical trials
	Medical devices - joint assessments of notified bodies (page 13)			
	Active pharmaceutical ingredients for human medicines (page 14)			
Cross-sectoral	Veterinary preparedness for natural disasters		Cross-sectoral emergency preparedness (page 14)	
Zoonoses		Salmonella control programmes (page 16)		
		Rabies eradication in the EU (page 17)		

Annex 1. Strategic Multi-Annual Outline 2019-2021

AREA	2018	2019	2020	2021
Animal health	Categorisation of non-EU countries exporting to the EU			
	Live bivalve molluscs	Chronic Wasting Disease <i>(page 16)</i>		
		Animal health - major diseases		
	African swine fever (preparedness and affected Member States) <i>(page 15)</i> , avian influenza <i>(page 16)</i>			
Animal welfare		Animal health - countries outside the EU (review of animal health controls/requests for approval of exports) <i>(page 17)</i>		
	Animal welfare during export to countries outside the EU <i>(page 18)</i>			
	Reducing the systematic tail-docking of piglets <i>(page 18)</i>			
	Animal welfare of farmed rabbits (overview report)	Quality controls and indicators for animal welfare <i>(page 18)</i>		
Plant health		Plant pest outbreaks <i>(page 19)</i>		Plant health import controls
	Plant health import controls <i>(page 20)</i>			National plant health reference laboratories
	Seeds and propagating material <i>(page 21)</i>			
	Plant health surveys <i>(page 22)</i>			
	Euromphyl-Interceptions <i>(page 21)</i>			
	Euromphyl-Outbreaks <i>(page 22)</i>			
	Plant health audits in countries outside the EU <i>(page 20)</i>			
		Fruit plants <i>(page 21)</i>		

Annex 1. Strategic Multi-Annual Outline 2019-2021

Projects in both Member States and countries outside the EU

Projects in Member States

Projects in countries outside the EU

AREA	2018	2019	2020	2021
Food safety			Food of animal origin - controls in Member States (page 23)	
		Food of animal origin - controls in countries outside the EU (page 24)		
		Microbiological risks in food of non-animal origin (page 25)		
		Tuna imports from countries outside the EU (page 25)		
		Small exporters of fishery products (page 25)		
	Aquaculture primary production in non-EU countries			
	Flexibility and derogations in micro-, small and medium sized enterprises			
	Ready-to-eat food (page 26)			
	Controls of internet sales of food			
	Synergies of official controls with food business operators' self controls and private certification schemes			
	Food information for consumers and nutrition and health claims			
	Food improvement agents package (page 26)			
	Food waste			
	Food contact materials			
			Controls of contaminants in food (page 27)	
		Assessments of residue monitoring plans (page 27)		
		Residue audits (page 28)		
		Controls of pesticide residues (page 29)		

Annex 1. Strategic Multi-Annual Outline 2019-2021

AREA	2018	2019	2020	2021
Food safety			Sustainable use of pesticides Directive <i>(page 29)</i>	
		Biocides		
Food quality			Organic production and geographical indications <i>(page 31)</i>	
Feed safety/ animal by-products/ TSEs		Feed additives and critical ingredients <i>(page 32)</i>		
		Traceability and trade of processed animal proteins <i>(page 32)</i>		
		Use of insects as feed <i>(page 33)</i>		
		Feed ban/BSE <i>(page 34)</i>		
Import controls		Import controls on animals, food and feed <i>(page 35)</i>		Import controls
		Consignments in transit	Smaller Border Inspection Posts (BIPs) with limited throughput <i>(page 36)</i>	
		Compliance of BIP facilities <i>(page 35)</i>		Border Control Posts
			Checks on animal transporters at the EU borders <i>(page 36)</i>	
			Remote BIPs <i>(page 37)</i>	
			Market access <i>(page 37)</i>	
Horizontal issues, follow-up & BTSF training			Listing of non-EU country food-producing establishments <i>(page 38)</i>	
			Review of rarely visited non-EU country establishments <i>(page 38)</i>	
		General follow-up audits and administrative updates of country profiles <i>(page 39)</i>		
		Member States' audit systems		
		Multi-annual national control plan and national audit systems networks <i>(page 40)</i>		Contribution to the Better Training for Safer Food (BTSF) Programme <i>(page 41)</i>

Annexes 2 - 4 List audits, fact-finding missions and other visits planned in Member States, candidate countries and countries outside the EU in the areas of food safety and quality, animal health and welfare, and plant health.

Annex 5 Lists on-the-spot activities in the area of health protection.

Annex 2. Audits in Member States 2019, by country in alphabetical order²⁹

MEMBER STATE	THEME	TYPE OF VISIT	REFERENCE NUMBER
Belgique/België (Belgium)	Horse meat	audit	2019-6666
	Ready-to-eat food	audit	2019-6676
	Import controls – animals and goods	audit	2019-6636
България (Bulgaria)	Food improvement agents	audit	2019-6660
	Rabies	audit	2019-6595
	Avian influenza	audit	2019-6600
	Feed ban - BSE	audit	2019-6634
	General follow-up	follow-up	2019-6585
Česká republika (Czech Republic)	Products from poultry	audit	2019-6667
	Avian influenza	audit	2019-6601
	Residues in food	audit	2019-6649
Danmark (Denmark)	Fishery products	audit	2019-6664
	Import controls – animals and goods	audit	2019-6637
	Residues in food	audit	2019-6650
Deutschland (Germany)	Animal welfare reporting	audit	2019-6591
	African swine fever preparedness	fact-finding	2019-6612
	Processed animal proteins	audit	2019-6643
	Feed – use of insects	audit	2019-6646
	General follow-up	follow-up	2019-6543
Eesti (Estonia)	-	-	-
Éire/Ireland	Horse meat	audit	2019-6669
	Geographical indications (PDO, PGI, TSG)	audit	2019-6703
	Sustainable use of pesticides	audit	2019-6720
	Feed additives and ingredients	audit	2019-6630

29. This programme is drawn up on the basis of the assumption that the EU-UK withdrawal agreement, which provides for a transition period, enters into force and applies before the withdrawal date (30 March 2019)

MEMBER STATE	THEME	TYPE OF VISIT	REFERENCE NUMBER
Ελλάδα (Greece)	Food improvement agents	audit	2019-6661
	<i>Salmonella</i> control programmes - poultry	audit	2019-6598
	Sustainable use of pesticides	audit	2019-6717
	Import controls – animals and goods	audit	2019-6639
	General follow-up	follow-up	2019-6587
España (Spain)	Ready-to-eat food	audit	2019-6677
	Tuna	audit	2019-6678
	<i>Salmonella</i> control programmes - poultry	audit	2019-6597
	Animal welfare – tail docking of pigs (<i>task force</i>)	country visit	2019-6752
	Organic farming	audit	2019-6711
	Pesticides	audit	2019-6724
	Plant health – Import controls	audit	2019-6728
	Plant pest outbreaks (<i>Xylella fastidiosa</i>)	audit	2019-6730
	Plant pest outbreaks (<i>Epitrix</i>)	audit	2019-6732
	Plant pest outbreaks (<i>Bursaphelenchus xylophilus</i>)	audit	2019-6734
	Animal transporters	audit	2019-6628
	Processed animal proteins	audit	2019-6645
	General follow-up	follow-up	2019-6586
France	Products from mammals and poultry	audit	2019-6668
	Animal welfare – tail docking of pigs	audit	2019-6603
	Avian influenza	audit	2019-6757
	Plant pest outbreaks (<i>Xylella fastidiosa</i>)	audit	2019-6729
	Feed additives and ingredients	audit	2019-6629
	Import controls – animals and goods	audit	2019-6638
	Feed – use of insects	audit	2019-6647
	Residues in food	audit	2019-6651
	General follow-up	follow-up	2019-6578
Hrvatska (Croatia)	Organic farming	audit	2019-6710

MEMBER STATE	THEME	TYPE OF VISIT	REFERENCE NUMBER
Italia (Italy)	Food improvements agents	audit	2019-6662
	Tuna	audit	2019-6747
	Avian influenza	audit	2019-6599
	Pesticides	audit	2019-6723
	Plant pest outbreaks (<i>Xylella fastidiosa</i>)	audit	2019-6731
	Plant pest outbreaks (<i>Aromia</i>)	audit	2019-6733
	Animal transporters	audit	2019-6627
	Import controls – animals and goods	audit	2019-6640
Κύπρος (Kypros)/Kıbrıs (Cyprus)	Residues in food	audit	2019-6652
	Fishery products	audit	2019-6663
	Geographical indications (PDO, PGI, TSG)	audit	2019-6701
	Sustainable use of pesticides	audit	2019-6718
Latvija (Latvia)	-	-	-
Lietuva (Lithuania)	Microbiological contamination	audit	2019-6674
	African swine fever (affected Member States)	audit	2019-6609
	Sustainable use of pesticides	audit	2019-6722
	Feed additives and ingredients	audit	2019-6631
Luxembourg	-	-	-
Magyarország (Hungary)	Microbiological contamination	audit	2019-6673
	Animal welfare – tail docking of pigs	audit	2019-6604
	African swine fever (affected Member States)	audit	2019-6608
	Fruit plants	fact-finding	2019-6736
	General follow-up	follow-up	2019-6583
Malta	Fishery products	audit	2019-6665
Nederland (Netherlands)	Animal welfare reporting	audit	2019-6592
	Animal welfare – tail docking of pigs (<i>task force</i>)	country visit	2019-6751
	Organic farming	audit	2019-6712
	Processed animal proteins	audit	2019-6644
Österreich (Austria)	African swine fever preparedness	fact-finding	2019-6611
	Animal welfare – tail docking of pigs	audit	2019-6749
	Sustainable use of pesticides	audit	2019-6721
	Residues in food	audit	2019-6648

MEMBER STATE	THEME	TYPE OF VISIT	REFERENCE NUMBER
Polska (Poland)	Horse meat	audit	2019-6670
	Products from poultry	audit	2019-6671
	Microbiological contamination	audit	2019-6675
	African swine fever (affected Member States)	audit	2019-6607
	Feed additives and ingredients	audit	2019-6632
Portugal	Animal welfare – tail docking of pigs	audit	2019-6750
	Sustainable use of pesticides	audit	2019-6719
	Feed additives and ingredients	audit	2019-6633
	General follow-up	follow-up	2019-6580
România (Romania)	Horse meat	audit	2019-6672
	Avian influenza	audit	2019-6602
	Feed ban - BSE	audit	2019-6635
Slovenija (Slovenia)	General follow-up	follow-up	2019-6582
Slovensko (Slovakia)	Import controls – animals and goods	audit	2019-6641
	General follow-up	follow-up	2019-6584
Suomi/Finland	Animal welfare reporting	audit	2019-6590
	Chronic wasting disease	audit	2019-6777
	Import controls – animals and goods	audit	2019-6642
Sverige (Sweden)	Animal welfare reporting	audit	2019-6593
	Chronic wasting disease	audit	2019-6776
	Geographical indications (PDO, PGI, TSG)	audit	2019-6702
United Kingdom	-	-	-

In addition, one further audit is planned on plant pest outbreaks (Member State to be confirmed).

Some audits will be combined into one visit.

Annex 3. Audits in Candidate Countries 2019, by country in alphabetical order

Audits in countries negotiating to join the EU will be targeted at exports of products.

CANDIDATE COUNTRY	THEME	TYPE OF VISIT	REFERENCE NUMBER
поранешна југословенска Република Македонија (former Yugoslav Republic of Macedonia, the)	Listing request (fish)	audit	2019-6618
Црна Гора (Montenegro)	Plant health – derogations (potatoes)	audit	2019-6741
Србија (Serbia)	Products from mammals	audit	2019-6684
	Microbiological contamination	audit	2019-6698
Türkiye (Turkey)	Pesticides	audit	2019-6727

Annex 4. Audits in Countries outside the EU in 2019³⁰, by country in alphabetical order

The readiness of application files (such as timely replies by competent authorities to pre-audit questionnaires) and also certain specific regional circumstances (e.g. security considerations) are always major conditions for the completion of the audit programme. Therefore, a number of non-EU country audits can only be programmed provisionally.

NON-EU COUNTRY	THEME	TYPE OF VISIT	REFERENCE NUMBER
AR – Argentina	Contaminants	audit	2019-6713
AU – Australia	Products from mammals	audit	2019-6679
	Residues in food	audit	2019-6653
BR – Brazil	Products from mammals and poultry	audit	2019-6680
	Fishery products	audit	2019-6689
BY – Belarus	Mammals and fishery products	audit	2019-6688
	Listing request (live fish, FMD status)	audit	2019-6616
	Wood packaging material	audit	2019-6746
	Residues in food	audit	2019-6654
CA – Canada	Products from mammals	audit	2019-6681
CH – Switzerland	Residues in food	audit	2019-6658
CN – China	Pesticides	audit	2019-6725
CO – Colombia	Tuna	audit	2019-6695
	Pesticides	audit	2019-6726
DO – Dominican Republic	Plant health – alert list	audit	2019-6739
EC – Ecuador	Tuna	audit	2019-6696
EG – Egypt	Microbiological contamination	audit	2019-6697
GH – Ghana	Fishery products	audit	2019-6690
IL – Israel	Products from mammals and poultry	audit	2019-6682
	Residues in food	audit	2019-6655
IN – India	Seed equivalency	audit	2019-6745
IR – Iran, Islamic Republic of	Contaminants	audit	2019-6715
KR – Korea, Republic of	Live bivalve molluscs	audit	2019-6620

³⁰. Including EFTA countries

NON-EU COUNTRY	THEME	TYPE OF VISIT	REFERENCE NUMBER
MR – Mauritania	Fishery products	audit	2019-6691
	Listing request (oysters)	audit	2019-6617
MY – Malaysia	Plant health – alert list	audit	2019-6738
MX – Mexico	Listing request (beef)	audit	2019-6614
NA – Namibia	Fishery products	audit	2019-6692
PY – Paraguay	Products from mammals	audit	2019-6683
	Animal health (beef exports)	audit	2019-6615
	Residues in food	audit	2019-6656
RU – Russian Federation	Fishery products	audit	2019-6693
	Residues in food	audit	2019-6657
SR – Suriname	Plant health – alert list	audit	2019-6740
TH – Thailand	Products from poultry	audit	2019-6686
	Residues in food	audit	2019-6659
TN – Tunisia	Fishery products	audit	2019-6694
TW – Taiwan	Products from mammals and poultry	audit	2019-6685
UA – Ukraine	Products from poultry	audit	2019-6687
UG – Uganda	Plant health – alert list	audit	2019-6737
US – United States	Microbiological contamination	audit	2019-6699
	Contaminants	audit	2019-6714
	Plant health – derogations (softwood)	audit	2019-6742
	Plant health – derogations (hardwood)	audit	2019-6743

In addition, six audits are planned of recognised control bodies operating in countries outside the EU in the area of organic farming.

One further audit will be performed of a country outside the EU exporting small amounts of fishery products (the country will be decided following a desk study).

Also, up to four audits are envisaged of countries outside the EU seeking country listing for commodities of food of animal origin they wish to export to the EU (depending on the readiness of the applications).

Some audits will be combined into one visit.

Annex 5. On-the-spot activities in the health protection area in 2019

COUNTRIES	THEME	TYPE OF ACTIVITY	ESTIMATED NUMBER OF ACTIVITIES
Member States	AMR - One Health	Country visits, jointly with the ECDC	Up to six (contingent upon invitation by the respective country)
Member States, EFTA countries and mutual recognition agreement partners	Medical devices (under the current Implementing Regulation and the new Regulations on medical devices and <i>in-vitro</i> diagnostic devices)	Joint assessments	Approximately 40
Countries outside the EU	Active pharmaceutical ingredients	Audits	Two

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