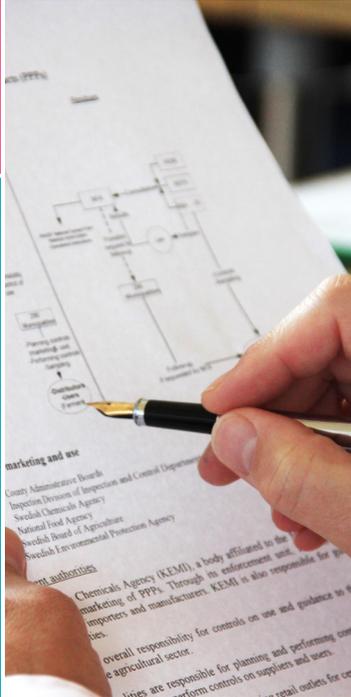




European
Commission



DG Health and
Food Safety

Health and Food Audits and Analysis Programme 2020

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 control activities to verify that EU legislation on food and feed safety, animal health, animal welfare, plant health and some areas of human health is properly implemented and enforced. The results of these activities support the development of evidence-based policies and contribute to the Commission's priorities for jobs, growth, investment and competitiveness in two of the EU's most important economic sectors – health and food.

DG Health and Food Safety establishes a multi-annual audit and analysis programme in line with key Commission strategic priorities. The 2020 audit and analysis programme will aim at ensuring effective implementation and enforcement of EU legislation on food and feed safety, animal health, animal welfare, plant health and some areas of human health with a particular focus on:

- better preparedness, prevention and response to human, animal and plant health threats;
- ensuring a safe and sustainable food and feed production systems;
- ensuring effective implementation of EU food legislation;
- effective, efficient and reliable controls in the areas of food and feed safety, food quality, animal health, animal welfare and plant health;

- contributing to human health protection by ensuring patients' access to safe medical devices and medicines.

Chapter 3 presents an overview of the projects and activities DG Health and Food Safety plans to perform in 2020, with a summary of their objectives, methodology and outputs. As shown in Annex 1, some of these projects already started in 2019, others will be carried forward into 2021 or 2022. While some work is desk-based (for example, the assessment of countries' residue monitoring plans or the development and operation of Europhyt¹), the majority of projects involve audits, fact-finding missions or other on-site visits to Member States, candidate and third countries.

In the areas of food and feed safety, food quality, animal health and welfare and plant health, DG Health and Food Safety plans 167 audits and other on-sites visits in Member States, candidate and third countries (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, together with designating authorities in Member States, up to 30 joint assessments of the performance and designation of notified bodies in the medical devices sector. It will also perform up to 33 on-site control activities on antimicrobial resistance, clinical trials, active pharmaceutical ingredients and eHealth (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 2020 audit and analysis work programme also contains a summary of the audits performed in 2018 (chapter 4).

The programme can be found on the Commission's website: http://ec.europa.eu/food/audits_analysis/audit_programmes_en



Introduction and priorities for Audit and Analysis for 2020 – 2022

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 in the areas of food and feed safety, food quality, animal health, animal welfare, plant health and some areas of human health. This is achieved by carrying out audits and other control activities in Member States and third countries exporting to the EU (including those involved in a free trade agreement with the EU) as well as, policy development tasks and networking activities with Member States. The results of these activities support the development of evidence-based policies and contribute to the Commission's priorities for jobs, growth, investment and competitiveness in two of the EU's most important economic sectors – health and food.

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 aim of the audit and analysis strategy for the 2020 to 2022 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:

- **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 2020.

In both the **animal** and **plant health** areas, the globalisation of animal and plant trade has substantially increased the risk of introduction of pests in the EU. Recent outbreaks of African swine fever, highly pathogenic avian influenza in the area of animal health, and *Xylella fastidiosa* and the Pine Wood Nematode in the plant health area, manifest the important risks confronting the EU. If not quickly detected and effectively treated or controlled, such infestations or diseases can expand uncontrollably and have devastating effects for the agricultural economy, public budgets and the environment. Crisis preparedness and response capability are therefore equally important in both areas.

- **Ensuring a 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.

Good treatment of animals is an integral part of 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 2020 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.

- **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 third countries exporting animals, plants and food products to the EU. In 2020, control activities in the agri-food sector will have a particular focus on the implementation of new EU requirements notably those of the new Official Control Regulation (EU) 2017/625.

The increased country knowledge built through these activities is presented in “country profiles” of 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 effective, efficient and reliable controls in the areas of food and feed safety, food quality, animal health, animal welfare and plant health**

A number of projects in the 2020 programme 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 third countries 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.

- **Protecting human health by contributing to patients’ access to safe medical devices and medicines**

DG Health and Food Safety carries out control and support activities in the area of medical devices and active pharmaceutical ingredients for human use with a view to improve and protect human health and to ensure that all medical and medicinal products in the EU are safe. Assessment activities will also carry on in order to make the most of the potential of e-health. Finally, in 2020, 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.



3.

Audit and Analysis Work Programme 2020

DG Health and Food Safety's audit and analysis programme for 2020 comprises 46 projects and up to 230 audits and other on-the-spot visits in the EU Member States and third countries.

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.

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 46 projects on audit and analysis that DG Health and Food Safety plans to carry out in 2020, by area and by sector.

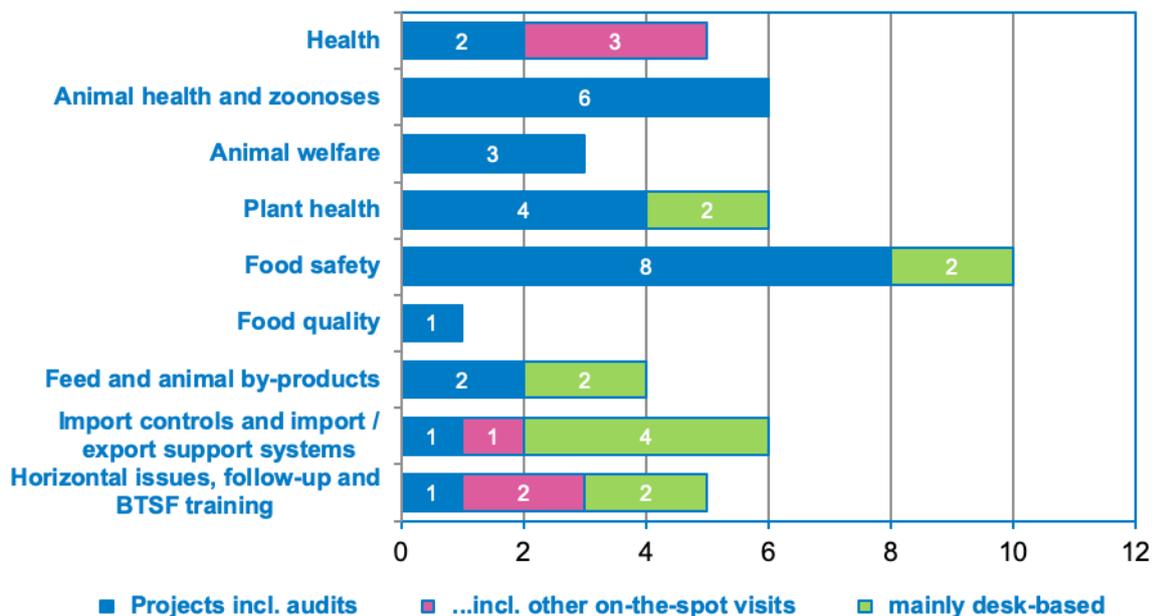
As shown in Chart 1, the majority of projects, 22%, will be in the area of food safety. 13% of projects each will take place on animal and plant health and import controls and 6.5% on animal welfare. 8.5% of projects deal with feed safety and one project is planned on food quality. Finally, 11% of projects cover the area of human health protection and horizontal issues including 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). 61% of all projects include audit series, and 13% other on-the-spot visits. 26% 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. A few of the projects had their on-the-spot visits carried out in the previous year(s) and the results of the series will

be summarised in 2020 in an overview report. 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 2020, by main area



As shown in Chart 2, 59% of all projects are in Member States (or deal with Member States). 15% of projects deal with third countries while 26% deal with both Member States and third countries.

Chart 2: Breakdown of projects in 2020 by region

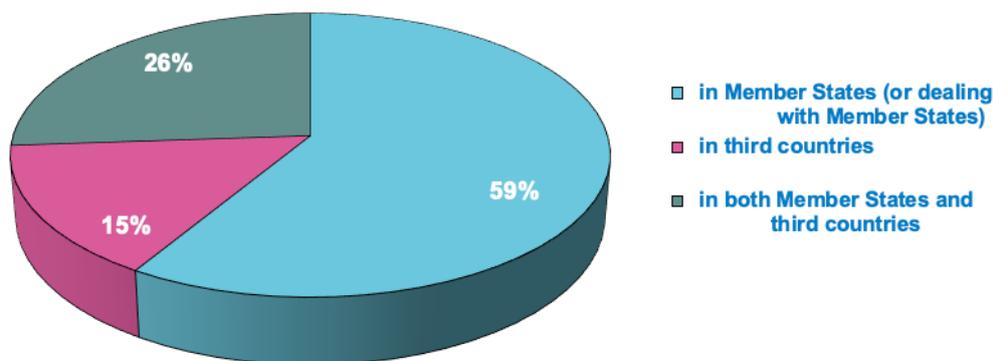
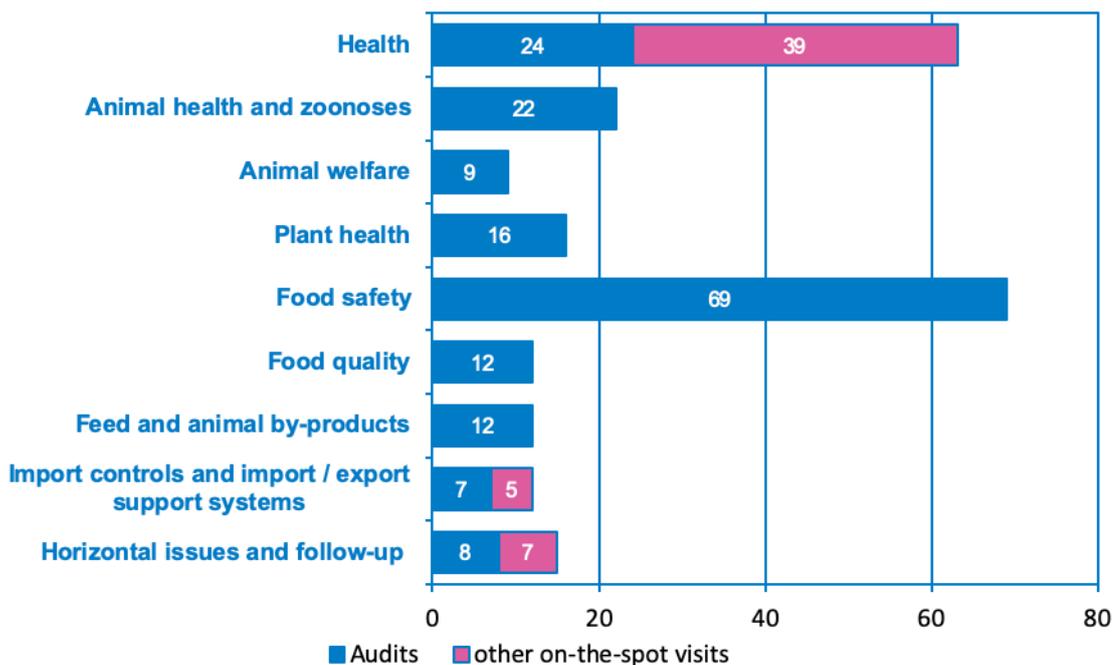


Chart 3 shows the number of audits (78% of all visits) and other on-the-spot visits (22% of visits) by main area. 30% of audits deal with food safety while 27% of visits are planned in the area of health protection. 13% of audits focus on animal health and welfare, and 7% on plant

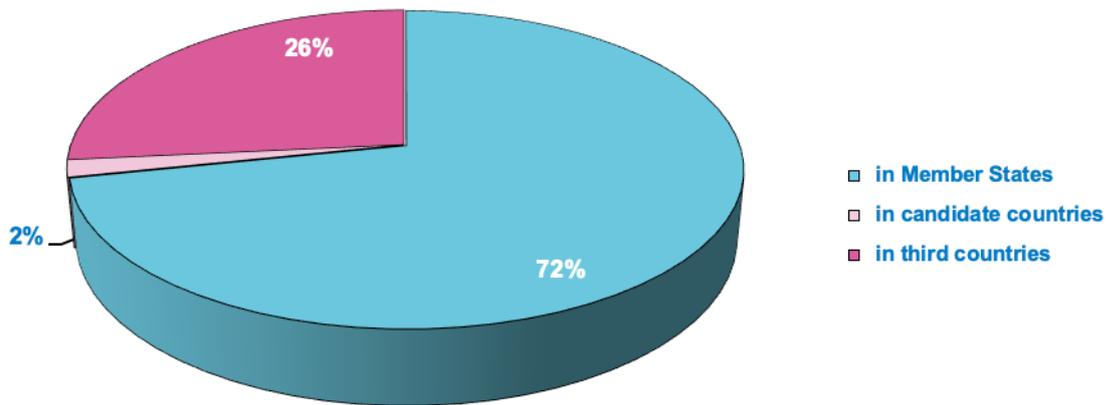
health. 6.5% of the on-the-spot work will be carried out on general follow-up and other horizontal issues. Finally, 5% of audits and other on-the-spot visits each will be carried out in the areas of food quality, feed safety and import controls.

Chart 3: Number of audits and other on-the-spot visits in 2020, by main area



Of the 230 audits and other on-the-spot visits, up to 165 are planned in Member States, 4 in candidate countries and up to 61 in third countries (see also chart 4).

Chart 4: Breakdown of audits and other on-the-spot visits in 2020 by region



The following subchapters provide summaries of each project planned for 2020.

[Annex 1](#) shows an overview of all projects.

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



The Commission contributes to the effective implementation of the new regulatory framework on medical devices to protect patients and ensure it addresses

new and emerging challenges. In particular, the Commission coordinates the joint assessments of notified bodies. Joint assessments are one of the elements of increased scrutiny laid down in the new regulatory framework ensuring that only appropriately resourced, well-performing and reliable notified bodies are designated in the medical devices field.

The Commission contributes to guarantee that imported active substances (active pharmaceutical ingredients – APIs) used for manufacturing human medicines in the EU are produced in line with good manufacturing practices, therefore strengthening the oversight over the supply chain

of pharmaceuticals. To that end, the Commission carries out audits and fact-finding missions to third countries exporting APIs to the EU.

The Commission contributes to make the most of the potential of eHealth. In particular, the Commission audits national eHealth contact points prior to their joining the eHealth network for exchanging e-prescriptions and e-patient summaries.

Antimicrobial resistance (AMR) – the ability of microorganisms to resist antimicrobial treatments, especially antibiotics – has a direct impact on human and animal health. In June 2017, the Commission adopted the EU One Health Action Plan against AMR, with the overarching goal of preserving 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.

AMR – One Health country visits

Objective	To support Member States in the design and implementation of their national One Health Control Programmes 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. That means recognising the role played by and interactions between human, veterinary and environmental factors.</p> <p>These visits have been carried out since 2017 and are organised following an invitation by the Member State concerned.</p>
Outputs 2020	Up to four country visits, together with the European Centre for Disease Prevention and Control.

Clinical trials for human medicinal products

Objective	To verify whether Member States correctly supervise compliance with Regulation (EU) No 536/2014 on clinical trials, and that these trials are organised following equivalent principles if they are conducted in third countries.
Project summary	This project is organised in preparation for the EU controls in this area, which will be organised once the Regulation (EU) No 536/2014 becomes applicable.
Outputs 2020	Two fact finding missions to Member States and one to third countries.

Joint assessments of notified bodies for medical devices and in vitro diagnostic devices

Objective	To ensure that only appropriately resourced, adequately performing and reliable notified bodies are designated in the field of medical devices.
Project summary	<p>Notified bodies are conformity assessment bodies responsible for assessing that medical devices meet the relevant legal requirements, resulting in the certification and CE marking of such devices. The field is very wide, with tens of thousands of devices ranging from plasters to pacemakers. The Directorate has been participating in the joint assessment of notified bodies since 2013.</p> <p>Under Regulation (EU) 2017/745 on medical devices and Regulation 2017/746 on in vitro diagnostic medical devices, the Commission coordinates the joint assessment teams carrying out, together with the national designating authorities, the assessment of notified bodies. Such an assessment is required prior to the designation of these notified bodies, which allows them to certify devices.</p>
Outputs 2020	It is estimated that approximately 25-30 joint assessments under Regulations (EU) 2017/745 and 2017/746 will be performed in 2020.

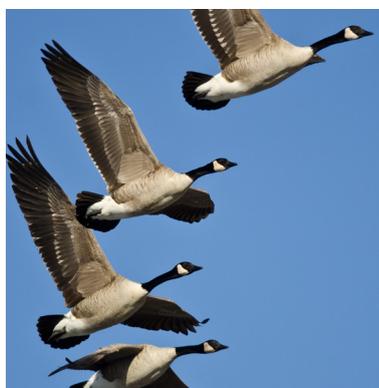
eHealth

Objective	To assess compliance of the National Contact Points for eHealth (NCPeHs) with the applicable requirements and to conclude on potential risks to the confidentiality, integrity and availability of health data.
Project summary	<p>Once a NCPeH considers itself ready to join the network for the exchange of e-prescriptions or e-patient summaries, it submits a request for an audit with the corresponding supporting information. Having assessed this information as satisfactory, an audit is carried out. The audit, and its potential follow-up activities, will form the basis for a draft recommendation on the NCPeH concerned joining the network, which would have to be adopted by the Member States.</p>
Outputs 2020	Up to 22 audits in Member States, based on demand, are anticipated.

Human medicinal products – active pharmaceutical ingredients

<p>Objective</p>	<p>To contribute to the health protection of EU citizens in relation to active pharmaceutical ingredients (APIs) imported from third countries for the manufacturing of human medicines in the EU. To promote progress in meeting the applicable standards in non-listed third countries which are major exporters of APIs to the EU.</p>
<p>Project summary</p>	<p>The Commission assesses applications for listing received from third countries 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 regularly those third countries already listed as equivalent. The assessments include desk evaluations and/or on-site visits.</p>
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • Contribution to the evaluation of new applications. • Two audits to third countries. • Up to two fact-finding missions to third countries which are major exporters of APIs to the EU.

3.3. Animal health and zoonoses



The projects in the area of animal health aim to increase preparedness for major animal diseases and to improve the management and control of their outbreaks. There are

Zoonoses are diseases or infections that are naturally transmissible from vertebrate animals to people. Two projects are ongoing in 2020 to support the continued eradication of rabies in wildlife and the elimination of salmonella from poultry populations.

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

two projects for the main diseases present in the EU - African swine fever and avian influenza- and a third for assessing animal disease management.

Animal disease management

Objective	To assess the overall management of animal diseases in certain Member States (including surveillance, diagnostics, reporting and notification).
Project summary	Some Member States have significant delays in notifying animal diseases. This project, through audits, allows the Commission to assess the capacity of Member States to detect animal diseases at an early stage and to communicate them promptly. These two factors are important as they have direct implications for effective eradication and management of diseases in these Member States.
Outputs 2020	Audits to Austria, France, Ireland, Italy, Sweden and Romania

African swine fever

Objective	To improve an early detection, rapid response and effectiveness of control measures in Member States affected by African swine fever.
Project summary	The project aims to improve the capacity of the Member States and neighbouring countries to prepare, promptly detect, contain and control the African swine fever.
Outputs 2020	Audits to Member States: Belgium, Estonia, Latvia, Romania and Audit to one neighbouring country: Republic of Moldova

Avian influenza

<p>Objective</p>	<p>To 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.</p>
<p>Project summary</p>	<p>The project entails a further audit 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.</p>
<p>Outputs 2020</p>	<p>Audit to Spain</p>

Animal health – third countries

<p>Objective</p>	<ul style="list-style-type: none"> • To evaluate requests by third countries for approval of exports of live animals or food of animal origin to the EU. • To review animal health controls by third countries already exporting to the EU.
<p>Project summary</p>	<p>Third countries wishing to export live animals, germinal products or a category of food of animal origin must be on 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>
<p>Outputs 2020</p>	<p><u>Listing requests:</u></p> <ul style="list-style-type: none"> • Audit to Belarus (dairy) <p><u>Reviews:</u></p> <ul style="list-style-type: none"> • Audits to Brazil (beef, poultry meat + hatching eggs and day old poultry), China (live bivalve molluscs), Morocco (live bivalve molluscs), Thailand (poultry meat), United States (live poultry (day old chicks and hatching eggs) + eggs), and United Arab Emirates (equine semen collection centres + export of live horses)

Salmonella Control Programmes

Objective	<ul style="list-style-type: none"> To further reduce the number of foodborne outbreaks in the EU by improving the effectiveness of control programmes in live poultry. To obtain information, on-the-spot, to support a well-informed evaluation of Member States' co-financing requests
Project summary	<p>Eggs remain the main cause of human salmonellosis. In the EU, over 91,000 salmonellosis cases are reported each year. The European Food Safety Authority estimated that the overall economic burden of human salmonellosis could be as high as €3 billion a year. The Commission audits the correct implementation of <i>Salmonella</i> control programmes for poultry populations in Member States.</p>
Outputs 2020	<p>Audit to Estonia</p>

Rabies eradication in the EU

Objective	<p>To 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.</p>
Project summary	<p>The project verifies the effectiveness of the rabies eradication programmes co-financed by the European Commission. It is important to keep the disease outside the EU. Following audits to EU Member States in 2017-2019 an audit to one EU neighbouring country will be carried out in 2020.</p>
Outputs 2020	<p>Audit to Serbia</p>

3.4. Animal welfare



The audit and analysis programme on animal welfare supports DG Health and Food Safety's animal welfare policy. There is one project related to better implementation

of existing legislation, focussing on animal welfare at slaughter. The other project is looking for indicators which could be used either to better target official controls or to indicate the real state of welfare in a production sector.

DG Health and Food Safety also host the network of national contact points for animal welfare during transport.

Long-distance transports to third countries

<p>Objective</p>	<p>To reduce animal suffering during long distance transport to third countries with focus on main exit points for sea transport.</p>
<p>Project summary</p>	<p>The project focusses on improving the performance of official controls at departure points, improving communication within and between Member States' authorities and improving co-operation and communication with third country authorities as well achieving better risk-based official checks on live animals for export.</p> <p>Three audits on sea transport and seven on road transport have been already carried out and two overview reports are in preparation.</p>
<p>Outputs 2020</p>	<p>Audit to France</p>

Animal welfare at slaughter

Objective	To assess the protection of animals at the time of slaughter (Regulation (EC) No. 1099/2009) and follow up the corrective actions to non-compliances from previous audits.
Project summary	There are EU rules to ensure than animals are spared any avoidable suffering at the time of slaughter and it is important to ensure their correct implementation and enforcement across the Union in order to avoid distortion of the internal market and to harmonise protection of the animals.
Outputs 2020	Audits to Belgium, France, Italy and Spain

Quality controls and indicators for animal welfare

Objective	<ul style="list-style-type: none"> • To improve MS reporting on controls of production sites on which animals are kept for farming purposes. • To determine whether <ul style="list-style-type: none"> • Member States have a strategic approach to enforcement of EU requirements for animal welfare on-farm, • controls are carried out following “quality management” principles and • animal welfare indicators are used to measure the extent, severity 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 concerned on policy and use of indicators, the Commission will continue with audits in 2020. In addition, it will consider organising a meeting with the groups concerned and with Member States’ authorities to agree a methodology for reporting on-farm inspections.</p>
Outputs 2020	<ul style="list-style-type: none"> • Audits to Czech Republic, Ireland, Lithuania and Portugal • One stakeholders meeting • Report on the above meeting to be presented at the Standing Committee for Plants, 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.

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 third country trading partners.

The projects presented below include audits in Member States (in particular rapid responses to outbreaks and import controls) and in targeted third countries exporting to the EU (to follow up on non-compliant imports to the EU). Projects also include desk based activities related to Member States' plant health surveys and reports, in particular the further development of EUROPHYT-Outbreaks, the rapid alert system for outbreaks of harmful organisms.

The main aim of the audit and analysis activities in the plant health area is to prevent the introduction into and

Plant pest outbreaks

<p>Objective</p>	<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>
<p>Project summary</p>	<p>The EU legislation for plant health will change significantly in December 2019. It will place greater emphasis on contingency planning, surveillance and prompt eradication of outbreaks; in particular of EU priority pests whose economic, environmental and social impact on EU territory is the most severe.</p> <p>In 2020, the project will mainly focus on outbreaks of priority pests and those pests for which emergency measures have been adopted. The Commission will perform audits to evaluate the appropriateness and compliance of control measures implemented, which will follow-up existing outbreaks and respond to new or recent ones. The number and scope of such audits will be reviewed regularly in light of developments and changes in pest status.</p> <p>Audit results will be presented at the Standing Committee on Plants, Animals, Food and Feed and will be used for review and enforcement, as appropriate, of EU legislation, including emergency measures.</p>
<p>Outputs 2020</p>	<p>Up to 6 audits in 2020 related to:</p> <ul style="list-style-type: none"> • <i>Xylella fastidiosa</i> in Spain and Portugal • Longhorn beetles notably <i>Anoplophora chinensis</i> and <i>A. glabripennis</i> in Germany and Italy • <i>Popillia japonica</i> (Japanese beetle) in Italy • <i>Trioza erytreae</i> (vector of the citrus greening bacterium) in Portugal • One to be determined in the light of developments during the year <p>Presentation of audit results at the Standing Committee on Plants, Animals, Food and Feed.</p>

Plant health import controls

Objective	<p>To assess the capacity and performance of Member States plant health import controls on plants, plant products and other objects, in order to contribute to minimising risks of introduction of harmful organisms into the EU whilst maintaining a dynamic trade environment.</p>
Project summary	<p>The EU legislation on plant health import controls changes significantly as of 14 December 2019. Member States are expected to implement the new requirements swiftly and effectively.</p> <p>This project will start in the second semester 2020 with one joint audit covering the new import requirements for animal and plant health and food, which will be followed by audits in a number of Member States from 2020 onwards, depending on the outcome of the joint audit. The audits will evaluate compliance with EU requirements and the effectiveness of Member States' import controls for plant health, including scientific imports and reduced frequency of checks.</p>
Outputs 2020	<p>One joint audit in Poland and one plant health audit in the Netherlands</p>

Seeds and propagating material

Objective	<p>To contribute to ensuring that only healthy seeds and propagating material of the required quality are marketed in the EU.</p>
Project summary	<p>The project involves activities related to both Member States and third countries intending to export to the EU.</p> <ul style="list-style-type: none"> • Seeds produced in third countries and intended for export to the EU must offer the same guarantee of quality as EU seeds. Desk evaluations and audits are carried out based on requests by third countries to obtain seed equivalence. • Similar provisions are in place concerning the import and marketing of certain fruit plants, including grape-vine. • The EU legislation provides for official controls during production and marketing of propagating material and fruit plants. This new part of the project will start with an exploratory visit. Based on its results further fact-finding missions or audits will be organised.
Outputs 2020	<p>One audit to Republic of Moldova (import of grape-vine)</p>

Plant health surveys

Objective	To analyse and report on the results of the harmful organism surveys that Member States carry out under emergency Decisions and control Directives (currently 12 organisms).
Project summary	The Commission analyses the results of the annual surveys concerning 12 harmful organisms, carried out by Member States in their territories and provides reports on these results 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.
Outputs 2020	Presentations to the Standing Committee on Plants, Animals, Food and Feed.

EUROPHYT-Outbreaks

Objective	To operate and develop a rapid alert system for the reporting of outbreaks of organisms harmful to plants in order to contribute to the successful handling of new risks and to the management of crises.
Project summary	<p>The EU legislation requires that the European Commission establishes a network for the notification of the presence of harmful organisms in the EU territory.</p> <p>EUROPHYT-Outbreaks, the notification and rapid alert system for plant pest outbreaks, has been developed in close cooperation with Member States. Since 2017, Member States have used this system to report plant pest presence to the Commission, other Member States and the European Plant Protection Organisation.</p> <p>In 2020, the Commission will continue to develop the system with a view to expand mapping inputs and outputs, increase the business intelligence capacity and improve further the user friendliness of existing features. It will also continue to provide assistance to EUROPHYT-Outbreaks users through the Helpdesk. The Commission will organise a Working Group meeting with core Member State users. The Commission will also produce an annual report on the presence of harmful organisms notified in EUROPHYT-Outbreaks.</p>
Outputs 2020	<p>Development of EUROPHYT-Outbreaks input and output features;</p> <ul style="list-style-type: none"> • Organisation of a Working Group meeting with EUROPHYT-Outbreaks core users • Monthly outbreak reports produced for the Standing Committee on Plants, Animals, Food and Feed. Annual report published on the Plants, Animals, Food and Feed. Annual report published on the website and in print.

Plant health audits in third countries

Objective	To contribute to ensuring that plants and plant products originating in third countries and intended for export to the EU are compliant with EU requirements and free from regulated harmful organisms.
Project summary	The project consists of audits that aim to cover the most important plant health issues in third countries, chosen based on the risk from their imports to the EU. Audits cover selected countries that appear on the published third country trade alert list with most EUROPHYT notifications and the certification programmes for export of wood. In addition, one audit is planned in relation to wood packaging material.
Outputs 2020	7 audits in 2020: <ul style="list-style-type: none">• Alert list countries: Argentina (citrus black spot), Brazil (citrus black spot), India, Thailand and Morocco;• Export certification of wood: United States;• Wood packaging material: Belarus; The Commission will present the results of the project to the Member States.

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.

Most of the projects and 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. Although certain projects, like tuna imports, ready-to-eat food or food improvement agents package will conclude in 2019, the outcomes and follow-up work in those areas will, as appropriate, be incorporated in other ongoing projects or those starting in 2020.

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

Food of animal origin – controls in Member States

<p>Objective</p>	<p>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.</p>
<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 TRACES² inform this process.</p> <p>A special focus in 2020 will be on official controls over dairy cull cows, including traceability and eligibility of animals for slaughter. Audits will also cover animal welfare aspects. The fishery products audits will include a verification of Member States' implementation of the action plans following the last audits related to official controls, in particular over primary production, and will also include commodities as fish oil and smoked salmon. Contaminants (heavy metals) will be covered, as well.</p>
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • <u>Bovine traceability and slaughter</u>: Czech Republic, France, Malta, Netherlands, Slovakia, Slovenia, Spain • <u>Products from mammals (follow-up)</u>: Poland • <u>Dairy</u>: Romania • <u>Fishery products</u>: Austria, Cyprus, Germany, Malta, Slovenia • <u>Ready-to-eat products (meat)</u>: Italy • <u>Ready-to-eat products (fish)</u>: Estonia Poland • <u>Live bivalve molluscs</u>: Croatia

2. 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.

Food of animal origin – controls in third countries

<p>Objective</p>	<p>To verify the compliance or equivalence of legislation and of the control systems of third countries with EU food law.</p>
<p>Project summary</p>	<p>Trade partners from outside the EU are selected for audits 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). Audits will also be planned to third countries 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. In addition, follow-up audits on foot of significant non-conformities identified in previous audits might take place.</p>
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • <u>Live bivalve molluscs</u>: China and Morocco • <u>Products from mammals</u>: Argentina, Botswana, Namibia and United States • <u>Dairy</u>: Canada, Switzerland and Ukraine • <u>Products from poultry</u>: Chile and Thailand • <u>Fishery products</u>: Guatemala, Indonesia, Mexico, Nicaragua, Panama and United States • <u>Follow-up audits</u>: the countries selected and the timing of the audits will be decided according to the suitability and implementation timeline of the action plan presented by the competent authority in response to the relevant recommendations following previous audits. • <u>Export approvals</u>, based on requests and satisfactory replies received: approximately four audits

Microbiological risks in food of non-animal origin

<p>Objective</p>	<p>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 ready-to-eat produce. Follow-up to Listeria outbreaks in this sector when relevant.</p>
<p>Project summary</p>	<p>This project is ongoing. Food of non-animal origin has proven an important source of foodborne outbreaks with corn and 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 third countries.</p> <p>In the EU, countries are selected based on recent outbreaks and audit history.</p>
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • Audits to third countries: China and India • Audits to Member States: Belgium, Estonia, Italy and Latvia

Small exporters of fishery products

Objective	To evaluate the effectiveness of the measures implemented by the competent authorities of third country trading partners exporting small amounts of fishery products to the EU.
Project summary	This multi-annual project involves a desk-based assessment of written assurances provided by third countries exporting small volumes (less than 10,000 tons) of fishery products. Pre-audit questionnaires are sent to the competent authorities in selected third 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 2020	Audits to Ukraine and one further third country to be determined based on the results of the desk analysis.

Food information to consumers and nutrition and health claims

Objective	To evaluate the performance of Member States official control systems on food information to consumers and nutrition and health claims made on foods at producers, importers and all points of entry in the market (retail).
Project summary	<p>This project focuses on issues which could generate an immediate risk to the consumer (e.g. the number of products recalled from the market internally due to false allergen labelling is increasing). The project will assess how Member States are implementing the relevant national and EU legislation (Regulation (EU) No 1169/2011 and Regulation (EC) No 1924/2006) and identify weaknesses as well as good practices.</p> <p>Audits have been carried out to Member States in 2017-2018.</p> <p>A follow-up questionnaire will be developed and provided to the Member States and the responses will be analysed. Future Commission activities in this area will be decided based on the outcome of this analysis.</p>
Outputs 2020	Overview report.

Controls of contaminants in food

<p>Objective</p>	<p>To assist the enhancement of controls on contaminants in food by competent authorities and industry and to provide input into the establishment of new legal limits and import conditions.</p>
<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 be found both in products from the EU or imported from third countries. 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 third countries.
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • Audits to Egypt, India, Islamic Republic of Iran and Turkey; • Contaminants (heavy metals) will be covered in the audit series on fishery products in Member States (Austria, Cyprus, Germany, Malta and Slovenia) and third countries (Guatemala, Indonesia, Mexico, Nicaragua, Panama and United States).

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>
<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 third 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/EU and the commodities for which they seek listing. 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 verifies whether the listed third countries have provided their annual residue monitoring plans for all the commodities for which they are listed, and also whether any third country wishes to be listed for any new commodity, for which a residue monitoring plan is required to be submitted and assessed. Third countries' residue monitoring plans are selected on a risk basis for detailed assessment starting with those for which new commodities have been requested and where previous residues audits have resulted in recommendations for improvement being made. 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 third countries in a 5-year cycle. • it reviews and contributes to the EFTA Surveillance Authority's (ESA) evaluations of the residue monitoring plans submitted by Norway and Iceland under the terms of the administrative arrangement made between ESA and DG Health and Food Safety.
<p>Outputs 2020</p>	<p>Assessment of approximately 70 plans per year :</p> <ul style="list-style-type: none"> • Assessment of all Member States' residue monitoring plans; • Assessment of a risk-based selection of third country residue monitoring plans which results in (continuation of) listing or de-listing of these third countries in the Annex to Decision 2011/163/EU for the respective commodities.

Residue audits

<p>Objective</p>	<p>To contribute to the improvement of pesticide controls in Member States and third countries exporting produce to the EU by identifying root causes for weaknesses in the control systems for marketing and use of pesticides, as well as pesticide residues in foodstuffs of plant origin.</p>
<p>Project summary</p>	<p>Residue audits in Member States in 2020 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) 2017/625.</p> <p>The programme of residue audits in third countries 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 commodity listing in Decision 2011/163/EU.</p>
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • Seven audits in Member States: Bulgaria, Estonia, Germany, Hungary, Luxembourg, the Netherlands and Slovakia; • Six audits in third countries: Bosnia and Herzegovina, Botswana, India, Namibia, Turkey and Uruguay (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 control posts.

Pesticide controls

<p>Objective</p>	<p>To contribute to the improvement of pesticide controls in Member States and third countries exporting produce to the EU by identifying root causes for weaknesses in the control systems for marketing and use of pesticides, as well as pesticide residues in foodstuffs of plant origin.</p>
<p>Project summary</p>	<ul style="list-style-type: none"> • In Member States, the project will consist of audits covering the marketing of plant protection products, aspects related to the sustainable use of pesticides Directive and pesticide residue controls. In 2020, the scope of these audits will include the authorisation of low-risk plant protection products and the biocontrol of pests/diseases. • In third countries, the audits will cover the controls of marketing and use of pesticides (including some aspects of the sustainable use of pesticides Directive, such as training and certification, and integrated pest management), as well as pesticide residue controls.
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • Two audits to Member States: Malta and the Netherlands; • Three audits to third countries: China, Israel and Uganda.

Sustainable Use of Pesticides Directive (SUD)

Objective	<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>
Project summary	<p>The Sustainable Use of pesticide Directive lays down a common legal framework for achieving a sustainable use of pesticides, taking account of precautionary and preventive approaches. Its legislative provisions were required to be brought into force by Member States by 26 November 2011, and implement relevant measures by 26 November 2016 at the latest.</p> <p>In 2020, the Commission will continue auditing Member States in order to evaluate the implementation of measures to achieve the sustainable use of pesticides.</p> <p>The Commission will also commence the evaluation of the Sustainable Use of pesticide Directive. The purpose of the evaluation is to assess the usefulness of this Directive as a policy tool, of its objectives and actions, and the results it has produced.</p>
Outputs 2020	<ul style="list-style-type: none">• Two audits to Italy and Luxembourg;• Evaluation of the Sustainable Use of pesticide Directive.

3.7. Food quality



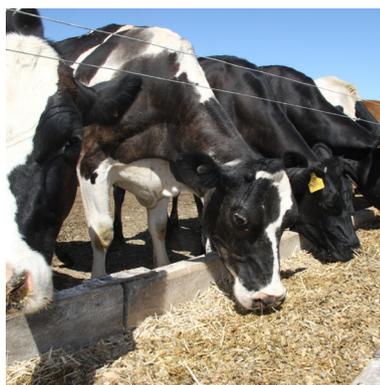
The markets for organic production and geographical indications in the EU are growing

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 specialties 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 third countries are verified through audits. In third countries, 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 2020⁵	<ul style="list-style-type: none">• 6 audits of Control Bodies operating in third countries;• 3 audits on geographical indications and guaranteed traditional specialties: Hungary, Italy and Latvia;• 3 audits on organic production: Estonia, Luxembourg and Spain.

3.8. Feed safety, animal by-products and TSEs⁴



The Commission will continue its control activities in the area of feed safety. In 2020, the Commission will issue overview reports on the results of two series of audits

conducted in 2018 and 2019 on feed additives and critical ingredients, and the traceability and trade of processed animal proteins. It will also initiate two new projects, one on general feed hygiene and one on hygiene, traceability and channelling of animal by-products (ABPs) and derived products.

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 nutrition.
<p>Project summary</p>	<p>Following a preparatory phase and ten audits in 2018 and 2019, the results will be summarised in an overview report and discussed with Member States.</p> <p>A particular emphasis of the project is 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 has been looked at, where possible, in audits carried out in 2019.</p>
<p>Outputs 2020</p>	<p>Overview report on the results of a series of ten audits performed in 2018 and 2019.</p>

4. *Transmissible Spongiform Encephalopathies*

General feed hygiene

Objective	To verify that official controls on the feed sector take place in compliance with feed legislation
Project summary	<p>The last series of audits on the feed sector with a broad scope were carried out in 2012-2014. Two recent audit series with a more limited scope (feed additives, their ingredients and traceability and processed animal proteins) have highlighted some significant and systemic weaknesses in Member States' controls justifying a deeper and broader look at the sector.</p> <p>This series of audits will include feed hygiene, approval and registration of feed establishments, HACCP, traceability, sourcing of feed materials, controls on feed imports (especially of feed additives) and feed labelling. Aspects related to feed additives from third countries, traceability and certain GM aspects will also be covered.</p> <p>Six audits in Member States will be carried out in each of 2020, 2021 and 2022.</p>
Outputs 2020	Audits in Cyprus, Finland, Italy, Luxembourg, the Netherlands and Slovenia.

Traceability and trade of processed animal proteins

Objective	To evaluate the implementation of hygiene, traceability and trade requirements for processed animal proteins (PAP).
Project summary	<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 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 and three audits in 2019, the results will be summarised in an overview report and discussed with Member States.</p>
Outputs 2020	Overview report 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.

Hygiene, traceability and channelling of animal by-products (ABPs) and derived products

<p>Objective</p>	<p>To assess if official controls are suitable to detect and prevent inappropriate handling, use and/or disposal of ABP and derived products placed on the EU market.</p>
<p>Project summary</p>	<p>The project concerns ABP of mammalian origin arising at critical points of the ABP chain. The project focuses on establishments from the meat sector dealing with ruminants and pigs and ABP processing plants, where the risk of cross-contamination or misuse of ABP derived from different species and risk of fraudulent practices is the highest.</p> <p>Six audits in Member States will be carried out in 2020</p>
<p>Outputs 2020</p>	<p>Audits in Denmark, Finland, Hungary, Malta, Slovakia and Sweden.</p>

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 exporting third countries are effective. In turn, the Commission's 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.

Technical evaluations of new border control posts (BCPs) or modified facilities in existing BCPs complement this work.

Trade-related support activities

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

It also facilitates and processes requests from third 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 third countries (for example, on request of individual Member States to support them when they are subject to audits by a third country).

Import controls on animals and goods

<p>Objective</p>	<p>To evaluate how Member States implement official controls on imports of animals and goods.</p>
<p>Project summary</p>	<p>The project will cover the effective implementation of controls on imports of animals and goods, important for the protection of the single market and the prevention of introduction of unsafe animals (diseases), food and feed into the EU as well as prevention of illegal trade.</p> <p>The project will also cover official controls on travellers' luggage in points of entry.</p> <p>An overview report will be issued on the results of a series of fourteen audits carried out in 2018 and 2019.</p> <p>In 2020, audits will look at Member States' implementation of the new rules introduced by the official control Regulation (EU) 2017/625 and will, for the most part, be carried out in the second semester given that those rules will apply only from 14 December 2019. During these audits, attention will also be paid to the BCP facilities and equipment and their compliance with applicable legislation.</p>
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • Seven audits: Bulgaria, Czech Republic, France, Latvia, Luxembourg, Malta and Poland; • Overview report on audit series performed in 2018 and 2019.

Compliance of Border Control Posts (BCPs) facilities

<p>Objective</p>	<p>To ensure that new and modified BCPs are constructed in compliance with legislative requirements and are suitable for the performance of official controls on imports of animals and goods.</p>
<p>Project summary</p>	<p>Regulation (EU) 2017/625 places the responsibility for designation of BCPs on the Member States. Under the OCR there is no longer an obligation for the Commission services to approve BCPs, but such facilities may be subject to Commission controls on the spot. The Commission still has to verify the information provided and this is taken into account when deciding if on the spot verification is required.</p>
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • Between 10 and 20 assessments of files including amendments to existing BCPs; • Between 2 and 5 visits of facilities, based on information provided.

Remote BCPs

<p>Objective</p>	<p>To verify the extent and appropriateness of competent authorities' official controls carried out in remote BCPs (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 BCP facilities should also comply with EU legislative requirements, enabling official controls to be carried out effectively.</p>
<p>Project summary</p>	<p>A desk analysis has been conducted to identify remote BCPs in three Member States (France, Spain and Portugal) and a strategy to assess their performance will be elaborated. A questionnaire on their performance was elaborated and sent to the Member States in question in April 2019.</p> <p>Responses will be analysed and desk-based follow-up activity will be pursued in the event that the analysis of the response to the questionnaire indicates that the posts are not performing as they should.</p>
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • Assessment reports on the evaluation of the remote BCPs; • A note to the file will be produced and a presentation to the working group on import controls.

Listing of third country food-producing establishments

<p>Objective</p>	<p>To ensure the accuracy and validity of all third country requests for amendment to establishment lists and update of TRACES within the deadlines laid down in EU legislation.</p>
<p>Project summary</p>	<p>The management of lists of approved establishments in third 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.</p>
<p>Outputs 2020</p>	<p>Up-to-date lists of approved third country establishments for existing commodities and new lists for previously non-harmonised commodities.</p>

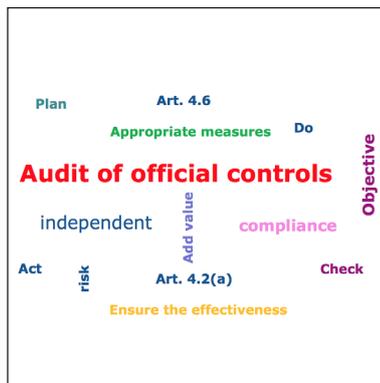
Review of rarely visited third country establishments

<p>Objective</p>	<p>To gather information on the compliance history of approved non-EU establishments producing food of animal origin in those third countries where security or other considerations prevent periodic audits being conducted by DG Health and Food Safety.</p>
<p>Project summary</p>	<p>There are third 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 EU-listed establishments to verify their compliance with EU hygiene rules.</p>
<p>Outputs 2020</p>	<p>Questionnaires to a minimum of six third 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.</p>

Market access

<p>Objective</p>	<ul style="list-style-type: none"> • To assist Member States in their efforts to secure market access for food and feed in non-countries (e.g. assisting Member States on request during controls carried out by third countries). • To facilitate and process requests from third countries seeking market access to the EU for exports of food and animals.
<p>Project summary</p>	<ul style="list-style-type: none"> • Member States' access to third 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 third countries considering import of food or animals from the EU; • At the request of the Member State concerned, accompanying third country auditors during their inspection/audit of the Member State in question. • Third countries' access to the EU <ul style="list-style-type: none"> • Elaboration, revision and management of Commission questionnaires on animal health and veterinary public health, issued to third countries seeking approval to export the animals or commodities in question to the EU; • management of third country responses to Commission questionnaires.
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • Member States' access to third 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 Member States concerned, accompany third country audit teams during their audits of those Member States. • Third countries' access to the EU market for animals and food of animal origin <ul style="list-style-type: none"> • Drawing up and sending product-specific questionnaires to third 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 third countries (subject to a confirmatory audit if necessary) and thus their eligibility to export food of animal origin to the EU.

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



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

The Commission continues to engage with Member States in network meetings and in training activities under the Better Training for Safer Food (BTSF) initiative.

In 2020, new horizontal control activities will be initiated in accordance with the new official control regulation (Regulation (EU) 2017/625). These concern a project on Commission controls on EU Reference Laboratories (EURLs) and EU Reference Centres (EURCs) as well as a project related to the identification of fraudulent practices in the agri-food sector.

of previous audits is systematically followed up and to encourage Member States' commitment to continuous improvement. The "country profiles"⁵ of each Member State provide the Commission's assessment of the actions taken by the Member States in response to its audits.

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, in particular by ensuring that DG SANTE audit recommendations to Member States are followed-up systematically and transparently; and • To provide up-to-date information to stakeholders and the Commission on the state of progress with the implementation of actions to address audit recommendations and 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 Member States in addressing recommendations of specific audits, primarily through general follow-up audits over a 3-4 year cycle.</p> <p>Good country-specific knowledge is important to inform policy-making. 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 recommendations⁶.</p> <p>In order to have more up-to-date information publically available, the approach to country profiles will be reviewed, including exploring potential synergies between the Organisation of Official Controls part of the Country Profile and Multi-Annual National Control Plan (see also outputs of MANCP networks).</p>
<p>Outputs 2020</p>	<p>Eight general follow-up audits: Belgium, Croatia, Denmark, Greece, Hungary, Lithuania, Poland and Romania.</p>

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

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

Commission controls on EU Reference Laboratories (EURLs) and Reference Centres (EURCs)

<p>Objective</p>	<p>To ensure proper oversight over the functioning of the EURLs and EURCs</p>
<p>Project summary</p>	<p>EURLs and EURCs provide important support for the proper implementation of EU legislation concerning the entire food chain. There are at present 14 EURLs for animal health, 25 for food and feed, 5 for plant health, 1 consortium (3 institutes) for animal welfare reference centres and 1 institute for a zootechnics (bovine breeding) reference centre. A second EURC for animal welfare for poultry, lagomorphs and fur animals will start operating on 01 Jan 2020 (a consortium of 4 institutes).</p> <p>Regulation (EU) 2017/625 introduced a requirement in Article 99(3) for EURLs and EURCs to be subject to Commission controls.</p> <p>Commission controls will initially be conducted over a two to three year period in order to verify:</p> <ul style="list-style-type: none"> • (a) the EURLs fulfilment of the designation criteria (see Article 93 of Regulation (EU) 2017/625) (Art. 95(3) and 97(3) for EURCs); • (b) these facilities' performance of the tasks described in Art. 94 (for EURLs) and Art. 96 and 98 (for EURCs). <p>Commission controls will comprise those already carried out on the annual work programme of the EURLs and EURCs and the prioritisation of facilities which will be subject to an on-site visit will be based on the outcome of the existing Commission control activities and other pertinent information.</p>
<p>Outputs 2020</p>	<p>Up to 5 on-site visits of facilities each year, contingent upon the outcome of desk-based assessments carried out by the Commission services responsible for assessing the annual work programmes of the facilities.</p>

Assessment of effectiveness of Member States official controls to identify fraudulent and deceptive practices

<p>Objective</p>	<p>To verify the implementation of and assess the effectiveness of the arrangements put in place by Member States in relation to controls and other official activities which are aimed at identifying and following-up fraudulent or deceptive practices.</p>
<p>Project summary</p>	<p>Regulation (EU) 2017/625 contains new provisions in relation to fraudulent or deceptive practices, which were not part of Regulation (EC) No 882/2004. The provisions are applicable as of 14 December 2019.</p> <p>The project aims to evaluate arrangements put in place by Member States in order to implement the relevant provisions, in particular regarding planning and performance of risk-based controls (Article 9(2)).</p> <p>The project has four phases: <u>Phase 1</u>: A desk study will collect basic information on the organisation of the relevant control arrangements from all Member States. <u>Phase 2</u>: Based on the results of the desk study and two pilot fact-finding missions, the audit methodology will be developed. <u>Phase 3</u>: Audits will be carried out in around eight Member States. <u>Phase 4</u>: The results of the project will be communicated to stakeholders.</p>
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • Desk study report • Two pilot fact-finding missions to Member States

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, in order 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 2019, the MANCP network finalised 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 led to the publication of Commission Implementing Regulation (EU) 2019/723 on 13/05/2019.</p> <p>In addition, this network will develop two Commission notices on guidance documents (a) on how to fill the standard model forms for annual reports and (b) on how to assist Member States in preparing the single integrated MANCP. These Commission notices will replace Commission Decisions 2008/654/EC and 2007/363/EC respectively.</p> <p>The NAS network developed a Commission Notice on a guidance document on the conduct of audits under Article 6 of Regulation (EU) 2017/625 during 2019, along with guidance on audit reporting. This forthcoming Commission notice will replace Commission Decision 2006/677/EC.</p>
<p>Outputs 2020</p>	<p><u>MANCP network</u></p> <ul style="list-style-type: none"> • Three plenary meetings are planned with the main focus on: <ul style="list-style-type: none"> • finalising the Commission Notices on guidance documents (Q1 2020): • on how to fill the standard model forms for annual reports; • to assist Member States in preparing the single integrated MANCP. • assisting Member States throughout 2020 in using the electronic version of the standard model form (preparation for submission of first annual report by 31 August 2021); • exploring potential synergies between the Organisation of Official Controls part of the Country Profile and MANCPs; and • updating the existing reference documents. <ul style="list-style-type: none"> • Two subgroup meetings are planned to undertake a review of specific reference documents. • The documents are shared by the Commission with the Network members via CIRCABC dedicated interest groups. <p><u>NAS network</u></p> <ul style="list-style-type: none"> • Two plenary meetings are planned with the main focus on: <ul style="list-style-type: none"> • finalising the Commission notice on a guidance document on conduct of audits under Article 6 of Regulation (EU) 2017/625 (Q1 2020); and • updating the existing reference documents, prioritising the document "Auditing Effectiveness of Official Controls". • Two subgroup meetings are planned in order to assist with the review of specific reference documents. <p>The documents are shared by the Commission with the Network members via CIRCABC⁷ dedicated interest groups.</p>

7. 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.

Contribution to the Better Training for Safer Food (BTSF) Programme

<p>Objective</p>	<p>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.</p>
<p>Project summary</p>	<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>
<p>Outputs 2020</p>	<ul style="list-style-type: none"> • Proposals for 2020/2021 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.



4.

Report on the Audit Programme 2018⁸

In 2018, the Commission carried out 178 audits and other on-the-spot visits in the areas of food safety and quality, animal health and welfare, and plant health. In addition, it performed 42 audits and other on-the-spot visits in the human health protection area.

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



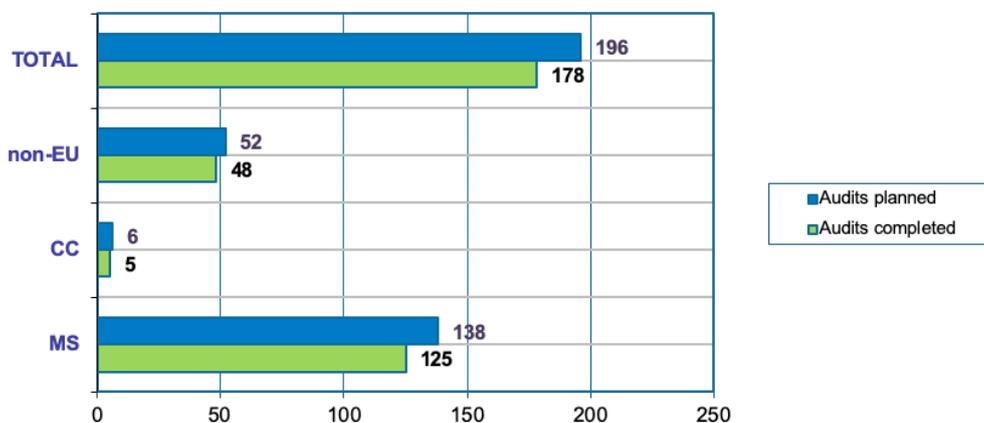
In 2018, the Commission carried out 178 audits and other on-the-spot visits in the areas of food safety and quality, animal health and welfare

and plant health, compared to 199 audits and fact-finding missions in 2017.

125 of these visits took place in Member States and 53 in candidate and third countries.

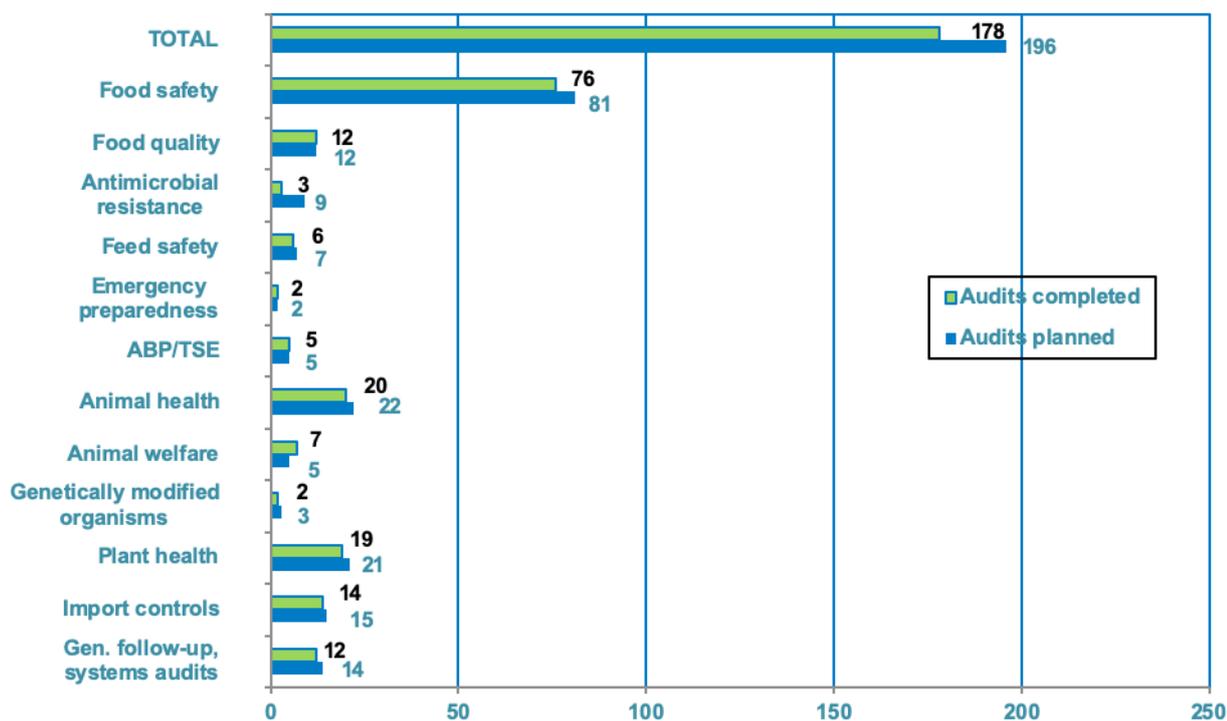
Chart 5 compares the number of planned and completed audits and missions by region.

Chart 5: Number of planned and completed audits in 2018 by region



8. 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 and other on-the-spot visit activities.

Chart 6: Number of planned and completed audits in 2018 by main area



The breakdown by area of activity (chart 6) shows that 88 (50%) audits were performed in the fields of food safety and quality. Three audits and missions (1.7%) dealt with antimicrobial resistance, while six audits (3.4%) dealt with feed safety and 27 (15%) with animal health and welfare. There were two (1%) audits each on genetically modified organisms and a cross-sectoral project on emergency preparedness for natural disasters. Five (2.8%) audits were carried out in the area of animal by-products and 19 (10.6%) in the area of plant health. Further 14 (7.8%) audits were carried out in the area of import controls. Finally, 12 audits (6.7%) were general follow-up or systems audits.

Out of the 178 completed on-the-spot visits, 150 were audits, 19 fact-finding missions, which aimed at gathering information about the operation of legislation on the ground and provided input into the review or development of legislation.

Amongst those were fact-finding missions on

- the prudent use of antimicrobials in animals;
- African swine fever ;

- biocides;
- emergency preparedness;
- food waste;
- import controls (food and live animals);
- live bivalve molluscs; and
- the sustainable use of pesticides.

The 2018 work programme included as well six General follow-up audits, two task force visits on animal welfare – reducing the systematic tail-docking of piglets, and one audit organised by EFTA surveillance Authority accompanied by the European Commission auditor.

The following two charts provide overviews on sectors and commodities covered by the on-the-spot visits in 2018 in Member States (chart 7) and candidate and third countries (chart 8).

Chart 7: On-the-spot visits in Member States in 2018 by sector

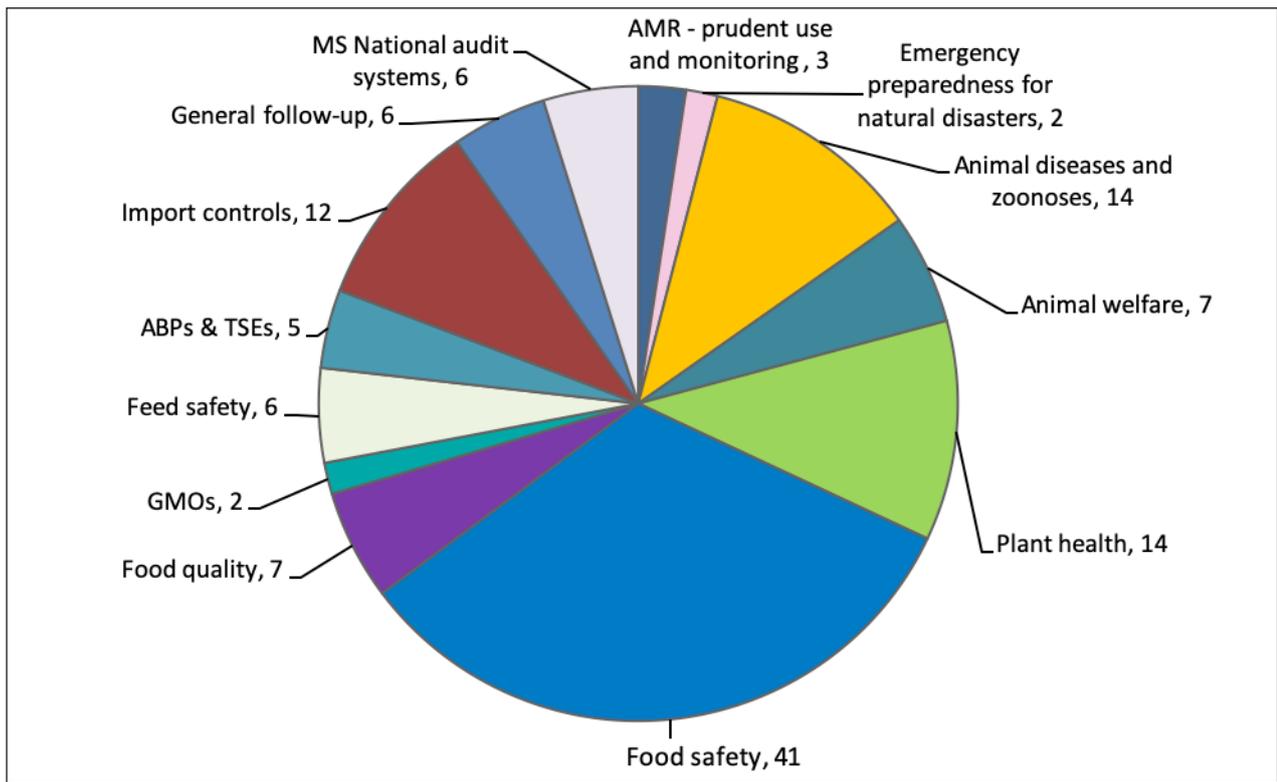
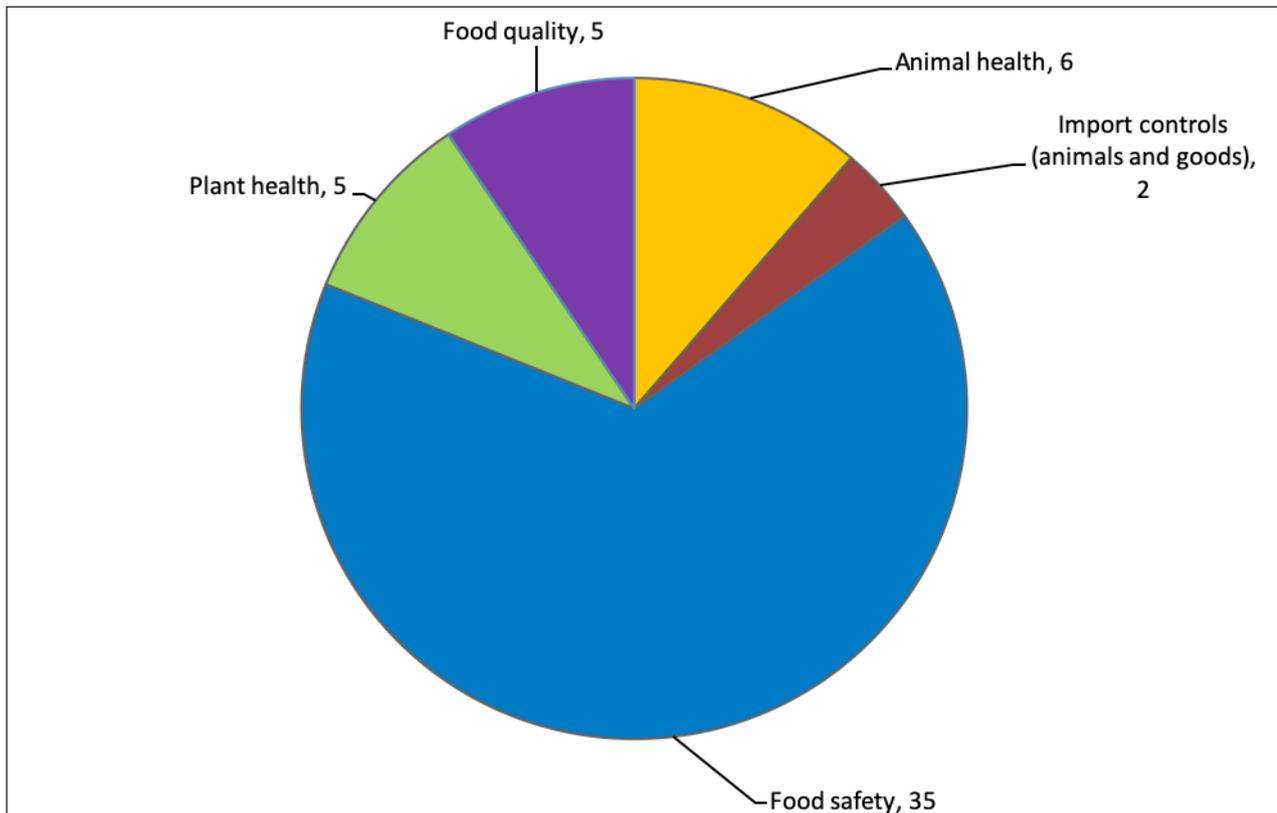


Chart 8: Audits in candidate and third countries in 2018 by sector



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

• Auditor days on the ground and participation of national experts

Commission auditors, together with national experts of the Member States, spent 4051 auditor days on the ground (excluding travel time) in 2018. These figures do not include the preparation of audits, reporting and follow-up work. 86 national experts participated in 90 audits and missions.

• Indicator achievement and programme changes

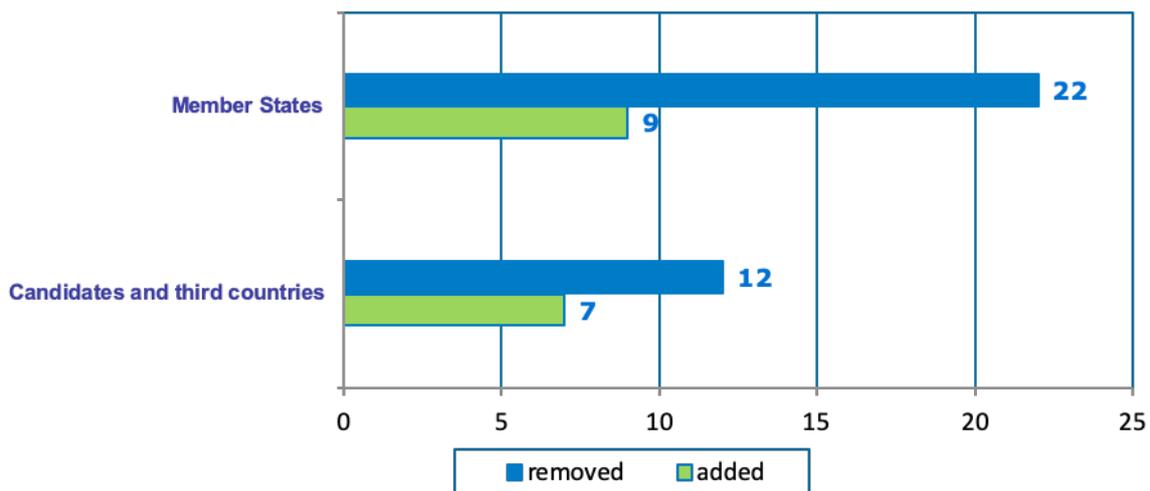
In 2018, the indicator target of performing 80% of all programmed audits and fact-finding missions was achieved (83%). The total number of audits and fact-

finding missions completed (including audits added during the year) compared to the number of programmed audits was 91%, exceeding the target of 90% for this indicator measuring use of audit capacity.

34 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 on-the-spot visits had to be replaced as new priorities emerged during the year. This resulted in total in 16 on-the-spot visits being added in 2018 (compare chart 9).

Chart 9: Overview on programme changes in 2018



• Overview reports

In 2018, the Commission published five overview reports on its audit and non-audit activities in the areas of food safety and quality, animal health and welfare, and plant health:

- Welfare of commercially farmed rabbits in the EU
- Antimicrobial Resistance - Prudent use of antimicrobials in animals

- Third countries' National Policies and Measures on Antimicrobial Resistance
- Veterinary Preparedness for Natural Disasters
- Animal Health Controls for Bivalve Mollusc Aquaculture

4.2. Activities in the health protection area



In 2018, the Commission carried out 42 audits and other on-the-spot visits in the health protection area. These included 27 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 two “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 and two audits in the area of active pharmaceutical ingredients.

68 national experts participated in these activities.

4.3. Reports publication

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 2020-2022		Projects in both Member States and third countries	
		Projects in Member States	
		Projects in third countries	
The aim of the audit and analysis strategy for the period 2020 to 2022 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	2019	2020	2021
Human health protection		Antimicrobial resistance (AMR) - One-Health country visits (jointly with the European Centre of Disease Prevention and Control (page 12)	AMR monitoring in zoonotic and commensal bacteria
			Clinical trials for human medicinal products (page 12)
		Medical devices - joint assessments of notified bodies (page 13)	
		eHealth (page 13)	
Animal health		Human medicinal products - active pharmaceutical ingredients (page 14)	
		Animal disease management (page 15)	Veterinary medicines
		Animal health - African swine fever (page 15)	
		Animal health - Avian influenza (page 16)	
Zoonoses		Animal health - third countries (review of animal health controls/requests for approval of exports) (page 16)	
		Salmonella control programmes (page 17)	
		Rabies eradication in the EU (page 17)	

AREA	2019	2020	2021	2022
Animal welfare (AW aspects also covered in audits on food of animal origin)	Animal welfare during long-distance transports to third countries (page 18)	Animal welfare at slaughter (page 19)	Animal welfare - long distance transports to third countries	
		Animal welfare at slaughter (page 19)		
	Quality controls and indicators for animal welfare (page 19)			
		Plant pest outbreaks (page 20)		
Plant health	Plant health import controls	Plant health import controls (including scientific imports and reduced frequencies) (page 21)		
	Seeds and propagating material	Seeds and propagating material (page 21)		
		Plant health surveys (page 22)		
			Plant passports	
				Plant health contingency planning
	Europhyt-Interceptions			
		Europhyt-Outbreaks (page 22)		
		Plant health audits in third countries (page 23)		
		Food of animal origin - controls in Member States (page 24)		
		Food of animal origin - controls in third countries (page 25)		
Food safety		Microbiological risks in food of non-animal origin (page 25)		
	Tuna imports from third countries			
		Small exporters of fishery products (page 26)		

AREA	2019	2020	2021	2022
Food safety	Ready-to-eat food	Food information to consumers and nutrition and health claims (page 26)		
	Food improvement agents package			
		Controls of contaminants in food (page 27)		
		Assessments of residue monitoring plans (page 28)		
		Residue audits (page 29)		
	Pesticide residues	Pesticide controls (page 29)		
		Sustainable use of pesticides Directive (page 30)		
		Organic production and geographical indications (page 31)		
		Feed additives and critical ingredients (page 32)		
			General Feed Hygiene (page 33)	
Food quality		Traceability and trade of processed animal proteins (page 33)		
		Hygiene, traceability and channelling of animal by-products and derived products (page 34)		
	Use of insects as feed			
	Feed ban/BSE			
Feed safety/ABP/TSEs				

AREA	2019	2020	2021	2022
Import controls	Import controls - animals, food and feed		Import controls on animals and goods (page 35)	
	Compliance of border inspection posts facilities		Compliance of Border Control Posts facilities (page 35)	
	Checks on animal transporters at the EU borders			
	Remote border inspection/control posts (page 36)			
Horizontal issues, follow-up & BTSF training		Listing of third country food-producing establishments (page 36)		
		Review of official controls on food-producing establishments in rarely visited third countries (page 37)		
		Market access (page 37)		
		General follow-up audits and administrative updates of country profiles for Member States (page 38)		
			Fact-finding missions in testing facilities in the context of the Transparency Regulation and amended General Food Law.	
			Commission controls on EU Reference Laboratories (EURLs) and Reference Centres (page 39)	
			Assessment of effectiveness of Member States official controls to identify fraudulent and deceptive practices (page 40)	
			Multi-Annual National Control Plan and National audit systems Networks (page 41)	
			Contribution to the Better Training for Safer Food (BTSF) Programme (page 42)	

Annexes 2 - 4 list audits, fact-finding missions and other on-the-spot visits planned in Member States, candidate countries and third countries 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 human health protection.

Annex 2: Audits in Member States in 2020, by country in alphabetical order⁹

MEMBER STATE	THEME	TYPE OF VISIT	REFERENCE NUMBER
Belgique/België (Belgium)	General follow-up	<i>follow-up</i>	2020-6907
	Microbiological contamination - Primary production	<i>audit</i>	2020-6921
	Animal welfare - slaughter	<i>audit</i>	2020-6953
	African swine fever	<i>audit</i>	2020-6966
България (Bulgaria)	Residues in food	<i>audit</i>	2020-6986
	Import controls on animals and goods	<i>audit</i>	2020-6999
Česká republika (Czech Republic)	Bovine traceability and slaughter	<i>audit</i>	2020-6925
	Animal welfare reporting	<i>audit</i>	2020-6960
	Import controls on animals and goods	<i>audit</i>	2020-7000
Danmark (Denmark)	General follow-up	<i>follow-up</i>	2020-6908
	Hygiene, traceability and channelling of animal by-products (ABP) and derived products	<i>audit</i>	2020-7005
Deutschland (Germany)	Fishery products	<i>audit</i>	2020-6917
	Residues in food	<i>audit</i>	2020-6988
	Plant pest outbreaks (<i>Anoplophora glabripennis</i> , <i>Anoplophora chinensis</i>)	<i>audit</i>	2020-7067
Eesti (Estonia)	Ready-to-eat food - fishery products	<i>audit</i>	2020-6916
	Microbiological contamination - Primary production	<i>audit</i>	2020-6922
	African swine fever	<i>audit</i>	2020-6968
	<i>Salmonella</i> control programmes - poultry	<i>audit</i>	2020-6972
	Residues in food	<i>audit</i>	2020-6987
	Organic farming*	<i>audit</i>	2020-7043
Éire/Ireland	Animal welfare reporting	<i>audit</i>	2020-6961
	Animal disease management	<i>audit</i>	2020-7073
Ελλάδα (Greece)	General Follow-Up	<i>follow-up</i>	2020-6902
España (Spain)	Bovine traceability and slaughter	<i>audit</i>	2020-6931
	Avian influenza	<i>audit</i>	2020-6943
	Animal welfare - slaughter	<i>audit</i>	2020-6954
	Organic farming*	<i>audit</i>	2020-7042
	Plant pest outbreaks (<i>Xylella fastidiosa</i>)	<i>audit</i>	2020-7066
France	Bovine traceability and slaughter	<i>audit</i>	2020-6926
	Animal disease management	<i>audit</i>	2020-6946
	Animal welfare - slaughter	<i>audit</i>	2020-6955
	Animal welfare - transport	<i>audit</i>	2020-6965
	Import controls on animals and goods	<i>audit</i>	2020-7025

⁹. 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 (31 January 2020).

MEMBER STATE	THEME	TYPE OF VISIT	REFERENCE NUMBER
Hrvatska (Croatia)	General follow-up Bivalve molluscs	<i>follow-up</i> <i>audit</i>	2020-6909 2020-6973
Italia (Italy)	Microbiological contamination - Primary production	<i>audit</i>	2020-6923
	Ready-to-eat food - meat	<i>audit</i>	2020-6932
	Animal disease management	<i>audit</i>	2020-6948
	Animal welfare - slaughter	<i>audit</i>	2020-6956
	General feed hygiene	<i>audit</i>	2020-7015
	Sustainable use of pesticides	<i>audit</i>	2020-7028
	Geographical indications (PDO, PGI, TSG)* Plant pest outbreaks (<i>Anoplophora glabripennis</i> , <i>Anoplophora chinensis</i> , <i>Popillia japonica</i>)	<i>audit</i>	2020-7047 2020-7069
Κύπρος/Kıbrıs (Cyprus)	Fishery products	<i>audit</i>	2020-6915
	General feed hygiene	<i>audit</i>	2020-7011
Latvija (Latvia)	Microbiological contamination - Primary production	<i>audit</i>	2020-6924
	African swine fever	<i>audit</i>	2020-6969
	Import controls on animals and goods	<i>audit</i>	2020-7001
	Geographical indications (PDO, PGI, TSG)*	<i>audit</i>	2020-7046
Lietuva (Lithuania)	General follow-up	<i>follow-up</i>	2020-6905
	Animal welfare reporting	<i>audit</i>	2020-6962
Luxembourg	Residues in food	<i>audit</i>	2020-6990
	Import controls on animals and goods	<i>audit</i>	2020-7002
	General feed hygiene	<i>audit</i>	2020-7013
	Sustainable use of pesticides	<i>audit</i>	2020-7029
	Organic farming*	<i>audit</i>	2020-7044
Magyarország (Hungary)	General follow-up	<i>follow-up</i>	2020-6910
	Residues in food	<i>audit</i>	2020-6989
	Hygiene, traceability and channelling of animal by-products (ABP) and derived products	<i>audit</i>	2020-7007
	Geographical indications (PDO, PGI, TSG)*	<i>audit</i>	2020-7045
Malta	Fishery products	<i>audit</i>	2020-6918
	Bovine traceability and slaughter	<i>audit</i>	2020-6927
	Import controls on animals and goods	<i>audit</i>	2020-7003
	Hygiene, traceability and channelling of animal by-products (ABP) and derived products	<i>audit</i>	2020-7008
	Pesticides	<i>audit</i>	2020-7030
Nederland (Netherlands)	Bovine traceability and slaughter	<i>audit</i>	2020-6928
	Residues in food	<i>audit</i>	2020-6991
	General feed hygiene	<i>audit</i>	2020-7014
	Pesticides	<i>audit</i>	2020-7031
	Plant health - Import controls	<i>audit</i>	2020-7072
Österreich (Austria)	Fishery products	<i>audit</i>	2020-6914
	Animal disease management	<i>audit</i>	2020-6945

MEMBER STATE	THEME	TYPE OF VISIT	REFERENCE NUMBER
Polska (Poland)	General follow-up	<i>follow-up</i>	2020-6906
	Ready-to-eat food - fishery products	<i>audit</i>	2020-6919
	Products from mammals (follow-up)	<i>audit</i>	2020-6933
	Import controls on animals and goods	<i>audit</i>	2020-7004
	Plant health - Import controls	<i>audit</i>	2020-7071
Portugal	Animal welfare reporting	<i>audit</i>	2020-6964
	Plant pest outbreaks (<i>Xylella fastidiosa</i>)	<i>audit</i>	2020-7065
	Plant pest outbreaks (<i>Trioza erytreae</i>)	<i>audit</i>	2020-7068
România (Romania)	General follow-up	<i>follow-up</i>	2020-6904
	Dairy	<i>audit</i>	2020-6934
	Animal disease management	<i>audit</i>	2020-6951
	African swine fever	<i>audit</i>	2020-6971
Slovenija (Slovenia)	Fishery products	<i>audit</i>	2020-6920
	Bovine traceability and slaughter	<i>audit</i>	2020-6930
	General feed hygiene	<i>audit</i>	2020-7016
Slovensko (Slovakia)	Bovine traceability and slaughter	<i>audit</i>	2020-6929
	Residues in food	<i>audit</i>	2020-6992
	Hygiene, traceability and channelling of animal by-products (ABP) and derived products	<i>audit</i>	2020-7009
Suomi (Finland)	Hygiene, traceability and channelling of animal by-products (ABP) and derived products	<i>audit</i>	2020-7006
	General feed hygiene	<i>audit</i>	2020-7012
Sverige (Sweden)	Animal disease management	<i>audit</i>	2020-6949
	Hygiene, traceability and channelling of animal by-products (ABP) and derived products	<i>audit</i>	2020-7010

*Provisional planning

In addition, one further audit is planned on plant pest outbreaks (Member State to be confirmed), up to five visits of Border Control Points and two pilot fact-finding missions.

Some audits will be combined into one visit.

Annex 3: Audits in candidate countries in 2020, by country in alphabetical order

CANDIDATE COUNTRY	THEME	TYPE OF VISIT	REFERENCE NUMBER
Србија (Serbia)	Rabies	<i>audit</i>	2020-6976
	Animal health preparedness in the context of pre-accession	<i>audit</i>	2020-7076
Türkiye (Turkey)	Residues in food	<i>audit</i>	2020-6997
	Contaminants	<i>audit</i>	2020-7049

Annex 4: Audits in third countries in 2020¹⁰, 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 third country audits can only be programmed provisionally.

THIRD COUNTRY	THEME	TYPE OF VISIT	REFERENCE NUMBER
AE – United Arab Emirates	Animal health (<i>Equidae exports</i>)	<i>audit</i>	2020-6978
AR - Argentina	Products from mammals	<i>audit</i>	2020-6935
	Plant health – citrus	<i>audit</i>	2020-7059
BA – Bosnia and Herzegovina	Residues in food	<i>audit</i>	2020-6993
BR - Brazil	Animal health (foot-and-mouth disease)	<i>audit</i>	2020-6977
	Animal health (poultry exports)	<i>audit</i>	2020-6981
	Plant health - Citrus	<i>audit</i>	2020-7062
BW - Botswana	Products from mammals	<i>audit</i>	2020-6936
	Residues in food	<i>audit</i>	2020-6994
BY – Belarus	Listing request (dairy)	<i>audit</i>	2020-6982
	Plant health - Alert list	<i>audit</i>	2020-7060
CA - Canada	Dairy	<i>audit</i>	2020-6937
CH - Switzerland	Dairy	<i>audit</i>	2020-6940
CL - Chile	Products from poultry	<i>audit</i>	2020-6938
CN - China	Microbiological contamination	<i>audit</i>	2020-6944
	Bivalve molluscs	<i>audit</i>	2020-6975
	Pesticides	<i>audit</i>	2020-7032
EG - Egypt	Contaminants	<i>audit</i>	2020-7051
GT - Guatemala	Fishery products	<i>audit</i>	2020-6950
ID - Indonesia	Fishery products	<i>audit</i>	2020-6952
IL - Israel	Pesticides	<i>audit</i>	2020-7033
IN - India	Microbiological contamination	<i>audit</i>	2020-6947
	Residues in food	<i>audit</i>	2020-6995
	Contaminants	<i>audit</i>	2020-7048
	Plant health - Alert list	<i>audit</i>	2020-7061
IR - Iran, Islamic Republic of	Contaminants	<i>audit</i>	2020-7050
MA - Morocco	Bivalve molluscs	<i>audit</i>	2020-6974
	Plant health - Alert list	<i>audit</i>	2020-7057

^{10.} including EFTA countries

THIRD COUNTRY	THEME	TYPE OF VISIT	REFERENCE NUMBER
MD - Moldova, Republic of	African swine fever	<i>audit</i>	2020-6970
	Vitis derogation	<i>audit</i>	2020-7064
MX - Mexico	Fishery products	<i>audit</i>	2020-6957
NA - Namibia	Products from mammals	<i>audit</i>	2020-6939
	Residues in food	<i>audit</i>	2020-6996
NI - Nicaragua	Fishery products	<i>audit</i>	2020-6958
PA - Panama	Fishery products	<i>audit</i>	2020-6959
TH - Thailand	Animal health (poultry exports)	<i>audit</i>	2020-6980
	Products from poultry	<i>audit</i>	2020-7053
	Plant health - Alert list	<i>audit</i>	2020-7058
UA - Ukraine	Dairy	<i>audit</i>	2020-6941
	Small exporter of fishery products	<i>audit</i>	2020-6967
UG - Uganda	Pesticides	<i>audit</i>	2020-7034
US - United States	Products from mammals	<i>audit</i>	2020-6942
	Fishery products	<i>audit</i>	2020-6963
	Animal health (poultry exports)	<i>audit</i>	2020-6979
	Plant health - Derogations	<i>audit</i>	2020-7063
UY - Uruguay	Residues in food	<i>audit</i>	2020-6998

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

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

Also, up to four audits are envisaged of third countries 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 2020

COUNTRIES	THEME	TYPE OF ACTIVITY	ESTIMATED NUMBER OF ACTIVITIES
Member States	AMR - One Health	Country visits, jointly with the ECDC	Germany, Hungary and up to two other countries (tbc.)
Member States, EFTA countries and mutual recognition agreement partners	Medical devices	Joint assessments	25-30
Third countries	Active pharmaceutical ingredients	Audits and fact-finding missions	Up to 4
Member States and third countries	Clinical trials for human medicinal products	Fact-finding missions	Two Member States and one non-EU country (tbc.)
Member States	eHealth	Audits	Up to 22

Medical devices joint assessments and eHealth audits are demand-based. Therefore, it cannot be excluded that the figures vary.

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