

DG Health and Food Safety

> Health and Food Safety

Health and food audits and analysis programme 2024

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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Executive summary

The Directorate-General for Health and Food Safety of the European Commission develops and implements the Commission's policies on food safety and public health. Its Directorate for Health and food audits and analysis ("the Directorate") dedicates most of its resources to controls. These monitor the implementation and enforcement of European Union (EU) legislation in the areas of food and feed safety, animal health, animal welfare, plant health (the agri-food chain domain) and in certain areas of human health (the health domain).

This document, the Health and food audits and analysis work programme 2024, presents the Directorate and its controls, priorities for controls in 2021-2025 and the detailed activities planned for 2024.

Multi-annual plan 2021-2025

The Directorate carries out its controls in accordance with a multi-annual plan. The multi-annual plan 2021-2025 establishes the priorities and objectives of its controls for the five-year period. It results from a comprehensive prioritisation process aiming to ensure that the Directorate fulfils its obligation to carry out Commission controls whilst covering the various policy areas in proportion to the risks posed in those areas. The prioritisation also ensures consistency with the Commission's political priorities, and in particular the Farm to Fork Strategy.¹

The multi-annual plan 2021-2025 is subject to an annual review and, where appropriate, it is amended to reflect any new control priorities identified or other adjustments needed.

Control activities in 2024

In 2024, the Directorate intends to perform 234 planned controls, of which 134 are audits, complemented by "on-demand" controls, for which numbers cannot be estimated.

In 2024, controls will continue on most of the priorities addressed in previous years and will commence on several priority themes of the multi-annual plan, namely:

- New cycle of re-assessments of designated notified bodies in the medical devices area;
- One Health Highly pathogenic avian influenza and One Health Pandemic transmission pathways;
- Animal welfare on-farm for turkeys;
- Plant health preparedness and prevention, with focus on contingency plans and survey programmes;
- Monitoring of the status of Category B and C animal health diseases in Member States.

The annexes to this document provide an overview of the multi-annual plan 2021-2025 and the detailed control activities for 2024.

¹ <u>https://ec.europa.eu/food/farm2fork_en</u>

Controls in the agri-food chain domain

In 2024, there are 214 controls planned in the agri-food chain domain, including 129 audits. These and other "on-demand" controls will address a range of priority themes identified in the multi-annual plan such as:

- food and feed safety,
- animal diseases and plant pests,
- animal welfare,
- third country listing and market access as well as third countries' compliance with EU requirements for the export of animals and goods to the EU and
- laboratories and testing facilities' adherence to the applicable standards for the risk assessment of regulated products.

Controls in the health domain

In 2024, controls in the health domain, most of which are demand-based, will continue to cover the areas of medical devices, clinical trials for human medicines, active pharmaceutical ingredients for human use, and antimicrobial resistance.

Other activities planned in 2024

The Directorate will continue working on the other non-control activities, in particular on:

- the sustainable use of pesticides, with the negotiation process on the legislative proposal for a new EU Regulation on the Sustainable Use of Plant Protection Products. This new proposal is part of a package of measures to reduce the environmental footprint of the EU's food system. This proposal aims to overhaul the existing rules on the Sustainable Use of Pesticides (Directive 2009/128/EC) once approved by Member States in the Council and the European Parliament, under the normal legislative procedure;
- networking activities with the competent authorities of Member States and Norway and Iceland with respect to the multi-annual national control plans, the national audit systems and animal welfare during transport;
- the Better Training for Safer Food (BTSF) programme, offering a range of training options to staff of competent authorities to improve the knowledge and implementation of EU rules under the remit of the Directorate-General for Health and Food Safety;
- the management of the lists of third countries' food-producing establishments eligible to export food of animal origin to the EU;
- the coordination of enforcement actions aimed at Member States to ensure that corrective action is taken in response to the Directorate's audit recommendations;
- the input into the review or development of legislation in different areas or sectors.

Further details on these activities are provided in section 6 of this document.

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1.Introduction

The Directorate-General for Health and Food Safety of the European Commission is responsible for monitoring the implementation and enforcement of European Union (EU) legislation governing food and feed safety, animal health and welfare, plant health and certain areas of human health. To this end, its Directorate for Health and food, audits and analysis carries out controls in EU Member States and in third countries exporting plants, animals and food to the EU. Every year, it publishes the details of controls planned for the following year, as part of the annual Health and food audits and analysis work programme.

This programme presents the priorities for Commission controls in 2021-2025 and the detailed activities planned for 2024.

The Commission has adopted Implementing Decision (EU) 2023/1811,² which amends Implementing Decision (EU) 2020/1550, by establishing the programme of Commission controls for 2024 in the Member States to verify the application of Union agri-food chain legislation.³ The programme established by this Decision is reflected in this document.

2.Presentation of the Directorate for Health and food audits and analysis

The Directorate-General for Health and Food Safety develops and implements the Commission's policies on food and feed safety, animal health and welfare, plant health and public health. It has a specific Directorate that dedicates most of its resources to conducting controls. The implementation and enforcement of EU legislation are essential for citizens to be confident that their interests are protected.



The Directorate for Health and food audits and analysis, Grange, County Meath, Ireland

The European Commission created the Directorate for Health and food, audits and analysis ("the Directorate"), formerly known as the Food and Veterinary Office, in 1997. This Directorate is located in Ireland.

The Directorate performs controls in the areas of food and feed safety, animal health, animal welfare, plant health (the agri-food chain domain) and in certain areas of human health protection (the health domain). It is also responsible for

² OJ L 234, 22.9.2023, p. 196.

³ OJ L 95, 7.4.2017, p. 1.

other activities such as the coordination of enforcement in relation to the Directorate's audit recommendations addressed to EU Member States, the development of policy on the sustainable use of pesticides, networking activities with Member States, the management of the Better Training for Safer Food (BTSF) programme, and the input into the review or development of legislation based on the outcome of its controls.

The Directorate has a team of some 139 staff originating from most EU Member States and with a wide range of professional experience.

The Directorate produces reports on its control activities, which are, with few exceptions, publicly available on the European Commission's website.⁴ The Directorate also publishes overview reports and analyses.

3.Controls and other related activities

3.1. Objectives and role of controls



Figure 1: Levels of controls of EU safety standards in the agri-food chain domain

In the EU, **operators** in the <u>agri-food chain</u> (such as farms, slaughterhouses, food-processing establishments and importers) have the primary responsibility for ensuring compliance with EU safety standards. In turn, **Member States**' authorities (competent authorities) are responsible for checking operators' compliance by means of official controls. Member States also have to set up a system to assure themselves that they carry out their official controls effectively and consistently. **Commission controls** verify the effectiveness of Member States' official control systems.

Imported animals and goods have to comply with EU requirements. With some exceptions, the competent authorities of **third countries exporting** goods to the EU are responsible for checking that the operators involved in the export chain comply with specific EU requirements and for certifying that exported goods meet EU requirements. For animals and animal products, before any export can take place, third countries must demonstrate their capacity to provide the above guarantees and the countries are duly listed in various Commission regulations.

Commission controls play a central role in the decision-making process **for country listing** and allowing **animals and animal products** originating in third countries to have access to the EU market. These controls also concern already listed third countries which are exporting food, feed, animals or plants to the EU. The Directorate targets countries according to risks associated

⁴ <u>https://food.ec.europa.eu/horizontal-topics/official-controls-and-enforcement/health-and-food-audits-and-analysis/work-programmes_en</u>

with their exports to the EU, such as the volume of exports, non-compliant consignments identified at EU points of entry and the risks associated with the particular type of animal or goods. Commission controls also cover countries with free trade agreements with the EU.

A negative outcome of any control in a third country performed by the Directorate may result in the imposition of trade-restrictive measures to protect the health of European citizens and animal and plant health. This also encourages the third country authorities and the implicated food business operators to take the necessary corrective measures swiftly. Examples of traderestrictive measures include increased checks at EU borders and, as a last resort, suspension of imports. The Commission reviews such measures periodically.

<u>In the health domain</u>, the Directorate's work aims at protecting citizens across the EU and addressing emerging challenges. In particular, the programme contributes to the effective implementation of the Union's regulatory framework in the areas of medical devices, active pharmaceutical ingredients and clinical trials, as well as supporting Member States in the design and implementation of their national action plans to prevent the development of antimicrobial resistance (AMR). A negative outcome of a control performed by the Commission may result, for example in the area of active pharmaceutical ingredients, in the non-listing of a third country as equivalent, or its de-listing.

3.2. Types of controls and other related activities

The Directorate carries out a range of controls amongst which roughly 60% are audits while the remainder are fact-finding studies, inspections and desk assessments. The Directorate also performs other related activities of an advisory nature targeted on Member States.

Some of these activities are performed with another competent authority or entity. For instance, the Directorate performs joint controls with the European Free Trade Association (EFTA) Surveillance Authority (ESA) on the basis of the EEA (European Economic Area) agreement and an administrative arrangement on cooperation between the Directorate-General for Health and Food Safety and ESA. This includes active participation in each other's audits, as well as joint assessment of compliance of border control posts in EFTA States before their designation by their respective competent authorities.

3.2.1. Audits

Audits are the most common form of Commission control in the agri-food chain domain (pursuant to Article 116 and 120 of the Official Control Regulation (EU) 2017/625). They are a valuable tool to verify the effectiveness of the implementation of official controls performed by competent authorities to check on how EU legislation is enforced.

Audits are also performed in the health domain, although they could be referred to in a different manner. For instance, as Union controls, in the area of clinical trials on medicinal products for human use.

The Directorate is mandated to perform audits defined as fact-finding missions in the Transparency Regulation (EU) 2019/1381), in laboratories carrying out testing in support of regulated product submissions to the European Food Safety Authority (EFSA) for risk assessment. These controls aim to verify testing facilities' adherence to any applicable standards against which studies submitted to EFSA have been performed and to bring any non-compliances identified to the attention of the appropriate regulatory authorities.

An audit typically involves a team of two auditors and occasionally (if appropriate) a national expert from a Member State. Following the development of pre-audit questionnaires and the analysis of responses received from the competent authorities of the country concerned, the audit team devotes one to two weeks to meetings with national, regional and local authorities as well as carrying out visits to relevant sites (e.g. food business operators, slaughterhouses, processing plants, testing laboratories, farms etc.) to see how competent authority controls are implemented on the spot. The Directorate issues an audit report after each audit, which may include recommendations to the competent authority to address any systemic or significant non-compliances identified.

The Directorate follows up systematically on the actions taken by Member States in addressing these recommendations. In addition, when sectoral audits identify serious non-compliances in a Member State or in a third country, the Directorate may carry out follow-up audits to verify the implementation of the agreed corrective actions.

Traditionally, the Directorate has carried out in-country audits. Since the COVID-19 pandemic, the Directorate has adapted its approach and uses a combination of remote technology (videoconferencing) and in-country visits to conduct its audits. The methodology to be used for individual controls is decided in consultation with the competent authorities on a case-by-case basis.

In some cases, the Directorate performs desk-based audits, also called remote assessments, to check that the official controls carried out by the competent authorities of listed third countries are appropriate to verify the compliance of the exported animals and goods with EU requirements and reliably certify compliance with those requirements. This is done primarily through the auditees' reply to a comprehensive specific questionnaire. Remote assessments typically include animal and/or public health requirements within their scope. The decision to perform remote assessments can be based on a number of factors such as export volumes, performance in previous Commission controls, and the degree of risk posed by the specific commodities for which the country is listed.

3.2.2. Fact-finding studies

In general, fact-finding studies are organised in anticipation of the applicability of legal requirements, or in areas where the Commission needs to complete its knowledge about the operation of legislation. The results of these studies provide input into the preparation of overview reports and/or guidance to assist Member States, the preparation of subsequent audits, or into the review or development of legislation. The approach is very similar to that

implemented for audits, including a preliminary questionnaire, meetings with competent authorities and visits to relevant sites as appropriate.

3.2.3. Inspections

These controls consist of the assessment of compliance with EU legislation of entities such as notified bodies (conformity assessment bodies for medical devices) and border control posts, based on the analysis of documents, meetings, interviews and/or visits. Inspections are either demand driven or depend on the fulfilment of certain conditions before a control can be performed.

In the area of medical devices, notified bodies are conformity assessment bodies responsible for checking that medical devices meet the relevant legal requirements, resulting in certification and CE marking.⁵ The designation and re-assessment of these notified bodies involves joint assessment teams, composed of experts from the Member States and from the Commission, together with the national designating authorities. The Directorate coordinates and participates in these joint assessment teams. Joint assessments aim to ensure that only appropriately resourced, adequately performing and reliable notified bodies are designated.

3.2.4. Desk assessments

These controls are based on the assessment of documents in order to verify compliance with EU legislation. Most of the desk assessments performed by the Directorate are specifically required by EU legislation. Examples include the assessment of the floor plans and structure of border control posts and inspection centres in the EU Member States as a prerequisite for their (re-) designation by the competent authorities. Another example is the assessment of control plans for residues of pharmacologically active substances in animals and animal products from Member States and control plans for residues of pharmacologically active substances, pesticides and contaminants in animals and animal products from third countries which are either already listed or are requesting approval for the export of animals and animal products to the EU. The Directorate has also elaborated product-specific pre-country listing questionnaires for third countries seeking market access to the EU (covering animal health and public health requirements) and it assesses the responses to determine whether the country can satisfy the EU import requirements for the commodities in question and be listed accordingly.

⁵ Manufacturers can place a CE (Conformité Européenne) **mark** on certain **medical devices** only if a notified body has issued a certificate of conformity for the concerned devices.

3.2.5. Other related activities

The Directorate may also perform other activities targeted at Member States, which are not *sensu stricto* controls, as illustrated below.

Since 2017, the Directorate has carried out, jointly with the European Centre for Disease Prevention and Control (ECDC), country visits to EU Member States on AMR in a One Health⁶ perspective. The aim of the visits is to support Member States in the preparation and implementation of their national action plans on preventing the development of AMR. Recently, these visits have been extended to the Western Balkans.

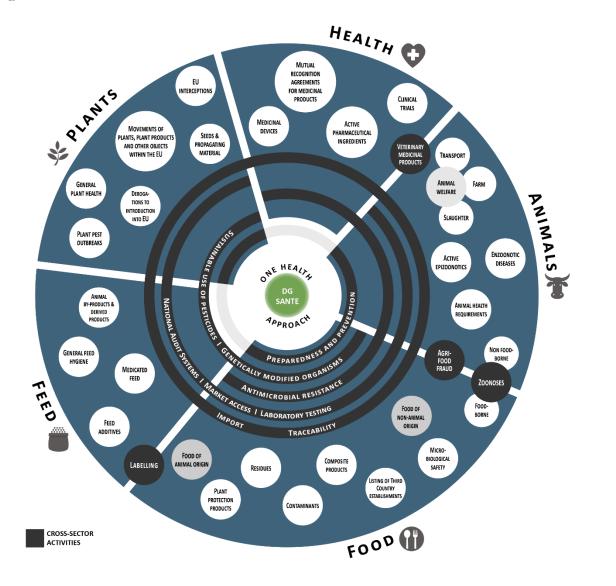
In the context of the EU One Health Action Plan against AMR, the Directorate has reviewed the national action plans prepared by Member States, as a first step in gathering a complete picture concerning the antimicrobial resistance situation and antimicrobial use across the EU.

⁶ A European One Health Action Plan against Antimicrobial Resistance (AMR) can be found on: <u>https://ec.europa.eu/health/sites/default/files/antimicrobial resistance/docs/amr 2017 action-plan.pdf</u>

4. Multi-annual plan 2021-2025

The **control universe** is an inventory of the policy areas that the Commission has the legal mandate to check. The scope and span of this control universe are very broad due to both the extensive body of EU legislation in the domains of agri-food chain and health and the high number of countries involved. Figure 2 presents the extent of the control universe, broken down into five main sections (health, animals, food, feed and plants), with specific (white circles) and cross-sector (dark circles) areas.

Figure 2 Control universe



The Directorate has to prioritise and plan carefully to ensure it fulfils its obligation to carry out its controls whilst covering the various policy areas in proportion to the risks posed in those areas. The prioritisation also ensures consistency with the European Commission's political priorities, and in particular the Farm to Fork Strategy. Food and feed safety, animal health and welfare, and plant health contribute significantly to this Strategy and the mission letter from President von der Leyen to Commissioner Kyriakides, requires that the Directorate-General for Health and Food Safety focuses on implementing and enforcing the extensive Union legislation in the areas of food safety and animal and plant health. Audits are a crucial tool for this, whether they be conducted in Member States or in third countries. Food, whether it is produced in the EU or imported, must meet the EU's safety standards.

The multi-annual plan establishes the priorities for the Directorate's controls in 2021-2025.

- In the agri-food chain domain, the choice of topics and countries covered by the plan reflects the Commission's political priority, identified in the Commissioner's mandate letter, to focus on the implementation and enforcement of the extensive legislation in the areas of food safety and animal and plant health and takes into account legal requirements, food safety and health risks (associated with products, their origin, production or trade volumes, evidence of non-compliance, and the outcome of past audit activities) and policy considerations.
- In the health domain, priority themes relate to the Commission's political priorities, identified in the Commissioner's mandate letter or in the Commission's pharmaceutical strategy, and/or explicit legal requirements for the conduct of Commission controls. Many controls in this domain are demand driven.

Annex 1 presents the multi-annual plan 2021-2025. It identifies the priority themes and objectives for controls, including the country coverage, which will be addressed at different stages during the five-year period.

The multi-annual plan 2021-2025 is a reference document for the annual selection of controls during this period, subject to annual revision. Its annual revision for 2024 onward confirmed most of the existing priorities and their objectives and identified the following new priority themes :

- One Health Highly pathogenic avian influenza to study existing collaboration mechanisms between public and animal health authorities to ensure swift alert and appropriate response, in case of spill-over;
- One Health Pandemic transmission pathways to study pandemic preparedness and control mechanisms following a One Health approach, for non-foodborne zoonotic agents presenting a significant risk to human health;
- Animal welfare of turkeys on farm, to support the development of derived EU legislation;
- Status of Category B and C animal health diseases in Member States, to monitor the application of the requirements in Council Implementing Regulation (EU) 2021/620.

As of 2024, the Directorate will no longer be involved in conducting Commission controls on organics as the responsibility for these has been transferred to the Directorate-General for Agriculture and rural development.

5.Control activities in 2024

The Directorate carries out its controls in accordance with the multi-annual plan. Controls planned for 2024 amount to 234, of which 134 are audits. In addition to these planned controls, the Directorate will perform other controls and related activities which are demand driven (e.g. the assessment of border control posts, joint assessments of notified bodies for medical devices, joint country visits) or will depend on the fulfilment of certain conditions before a control can be performed (e.g. fact-finding missions to testing facilities, controls related to third country market access applications for listing).

Controls in 2024 cover all of the policy domains (see figure 3) and a range of priority themes identified in the multi-annual plan 2021-2025. In the agri-food chain domain, the Directorate intends to perform 214 planned controls, including 129 audits. Controls planned on food safety both in Member States and third countries, account for two-thirds of the planned controls in the agri-food chain domain.

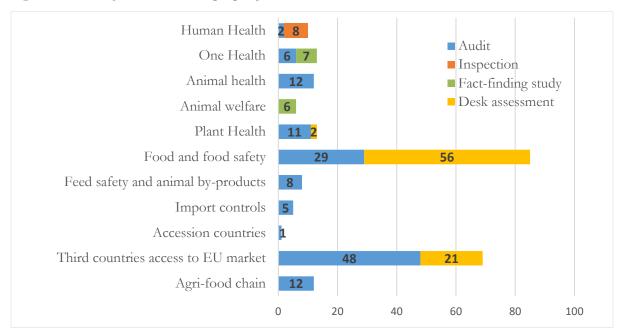


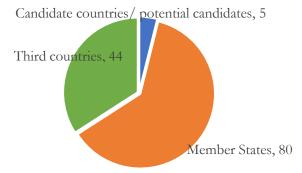
Figure 3 Number of controls in 2024 per policy domain

In 2024, the Directorate will commence its work on several priority themes covered by the multiannual plan. These include:

- New cycle of re-assessment of designated notified bodies in the medical devices area (see Annex 1 page 19)
- One Health Highly pathogenic avian influenza and One Health Pandemic transmission pathways (see Annex 1 page 22);
- Monitoring of the status of Category B and C animal health diseases in Member States (see Annex 1 page 24);

- Animal welfare on-farm for turkeys (see Annex 1 page 25);
- Plant health preparedness and prevention, with controls on contingency plans and survey programmes (see Annex 1 page 28).





Of the 129 audits planned in 2024 in the agri-food chain domain, 62% are planned in the Member States because most food consumed in the EU is also produced in the EU and 38% are planned in non-EU countries wishing to export or exporting to the EU.

Control activities in 2024 are detailed in the annexes:

- Annex 1 provides the list of controls per priority theme of the multi-annual plan. For certain controls, countries have not been identified yet.
- Annexes 2 to 4 list the controls planned in 2024 per country. Annex 2 relates to Member States, Annex 3 relates to candidate countries/potential candidate and Annex 4 to third countries.

The Directorate may review the controls planned for 2024 if the circumstances require a change of priorities (such as emerging risks or crises, new political priorities) or prevent the performance of a control (such as security issues).

6. Other activities planned in 2024

6.1. Sustainable use of pesticides

The aim of the sustainable use of pesticides directive (SUD) is to reduce the risks and impacts of pesticides use on human health and the environment. It forms part of the EU legal framework covering pesticides and their use. By promoting the use of integrated pest management and of alternative approaches and techniques, such as non-chemical alternatives to pesticides, the SUD supports the achievement of the targets set out in the Farm to Fork Strategy for reducing the risks and use of pesticides.

The Directorate is responsible for the development of the policy on the sustainable use of pesticides. This encompasses a range of activities performed in close cooperation with other Commission services and authorities in the Member States.

In June 2022, the European Commission adopted proposals for a new Regulation on the Sustainable Use of Plant Protection Products (SUR), including EU wide targets to reduce by 50% the use and risk of chemical pesticides by 2030, in line with the EU's Farm to Fork and Biodiversity strategies.

In 2024, the Directorate will notably:

- focus on supporting and facilitating the co-legislator in the negotiation process on the proposal for a new SUR;
- publish updated trends for harmonised risk indicators as well as the indicators showing progress towards the Farm to Fork pesticide targets;
- organise and chair working groups on pertinent issues with Member States' representatives, and meet with stakeholders as appropriate;
- disseminate and update information on the SUD via the European Commission webpage.

6.2. EUROPHYT-Outbreaks

EUROPHYT-Outbreaks is the European rapid alert system for the notification by Member States of plant pest outbreaks. The Directorate has developed and operates this system in close cooperation with Member States in such a way that it provides an overview of the outbreak situation in the EU and data analysis supporting Member States and Commission policy making decisions and targeting of official and Commission controls.

6.3. Plant health surveys

EU plant health legislation requires Member States to carry out annual surveys for the presence of identified priority pests, and certain other quarantine pests, presenting a significant threat to

the EU economy and the environment. Since 2021, Member States are using an IT-tool, EUROPHYT-Surveys, for reporting the results of these surveys to the Commission. The Directorate analyses and prepares presentations on survey results for the Standing Committee on Plants, Animals, Food and Feed. These reports support informed policy decision making at EU level on these plant pests. In 2024, analysis for a number of plant pests will be presented, including potato pests, longhorn beetles, pinewood nematodes and others.

6.4. Member State networks

The Directorate manages two Member State networks that aim to enhance official control systems in the Member States and EFTA countries. These concern the multi-annual national control plans (MANCP) and the national audit systems (NAS). Each network meets regularly in plenary or subgroup meetings chaired by the Directorate, with the objective to:

- exchange experiences in implementing the MANCPs and the national audit systems,
- discuss better ways to address common problem areas, and
- consolidate agreed principles and good practices into reference documents.

In 2024, the MANCP network will review and update the EU standard model for Member States annual reporting on official controls⁷. In parallel, the network will also update the Commission Notice on a guidance document that assists Member States in completing their annual report on official controls. The network will continue to assist Member States in using the electronic version of the standard model form (AROC – Annual Report on Official Controls) and will complete the update of the existing reference document on "Risk-based planning of official controls" and start the update on the "Verification of effectiveness of official controls" document.

The NAS network will complete the update of the existing network reference documents on the "Auditing effectiveness of Official Control systems" and "Independent scrutiny" documents.

With the help of the networks, the Directorate will promote better implementation of the Official Controls Regulation and will receive valuable information on the uptake of Commission Notices on guidance documents and agreed network reference documents.

The Directorate also chairs and manages the expert group of Member States' liaison bodies on animal welfare during transport. This group substitutes the former Member State network of national contact points on the same subject. The group's tasks are to facilitate cooperation and coordination between the Commission and Member States on questions relating to the implementation of Union legislation, programmes and policies in the field of the protection of animals during transport and to bring about an exchange of experience and good practice in the field of the protection of animals during transport.

⁷ Rules established by Commission Implementing Regulation (EU) 2019/723

6.5. Better Training for Safer Food

Better Training for Safer Food (BTSF) is a European Commission training initiative destined to staff of competent authorities, to improve the knowledge and implementation of EU rules covering food, feed law, animal health and welfare, plant health, and plant protection products. In 2022, it trained over 7000 staff face-to-face and 2000 through eLearning. The Directorate establishes the training programme according to the Commission's priorities and in consultation with policy units. External contractors deliver the training in the EU and in third countries exporting or interested in exporting to the EU. BTSF has a strong role in training candidate and potential candidate countries' staff to meet the technical standards required for accession to the EU.

All training courses (except eLearning) have returned to face-to-face delivery. BTSF is expanding the provision of eLearning modules (now 14) and in 2024, it will introduce 3 new hybrid contracts featuring eLearning followed by face-to-face courses. BTSF Academy⁸ provides a library of training materials, information on upcoming courses and other resources and hosts BTSF eLearning. It has more than 4,000 active users. BTSF Academy now incorporates automatic translation of all stored training materials, including eLearning, into all EU official languages which enables widespread dissemination and further use of its contents.

6.6. Third country establishment listing

Third countries are eligible to export food of animal origin to the EU only if the country is listed for export of the specific category of food of animal origin to the EU and if the products are produced in EU-approved establishments.⁹ The establishments are inspected by the competent authorities in the third country and, if found to be in compliance with EU hygiene rules, are submitted to the Commission for inclusion in the Commission's Trade Control and Expert System (TRACES) database. Publication in TRACES allows stakeholders and control authorities in the Member States to readily identify EU-approved establishments. The third country competent authorities are responsible for keeping the lists of establishments up to date and to inform the Commission of any changes (including information in case an establishment no longer fulfils the requirements).

The Directorate is responsible for maintaining the lists of food-producing establishments in TRACES. In 2023 to date, the Directorate received 807 listing requests for additions, modifications or deletions to the lists of food-producing establishments in TRACES. These resulted in 3595 amendments of establishments.

⁸ <u>https://btsfacademy.eu/training/</u>

⁹ The procedure to follow and the updated lists of EU approved establishments can be found here: <u>https://ec.europa.eu/food/safety/biological-safety/food-hygiene/non-eu-countries-authorised-establishments en</u>

6.7. Enforcement

The Directorate's recommendations from audits and similar controls addressed to EU Member States are systematically followed up to verify that corrective actions have been taken. The follow-up is achieved mainly through General Follow-up audits to Member States. The results of these audits (and other follow-up activities) are published in updated country profiles for each Member State.¹⁰ This model of systematic follow-up and dialogue with the Member States achieves the satisfactory resolution and closure of the vast majority of audit recommendations. However, in a minority of cases, enhanced follow-up and enforcement actions may prove necessary. This includes targeted follow-up or sectoral audits and high level meetings and, as a last resort, legal actions may have to be considered. The Directorate is responsible for coordination of the enforcement actions in these cases.

6.8. Other activities

The Directorate will continue to support the work of other policy Directorates within the Directorate-General for Health and Food Safety by providing input, based on the outcome of their controls, into the review or development of legislation in different areas.

7.Further information

Further information on the work of the Directorate can be found on the Commission's <u>website</u>. This includes information on:

- audit reports (of an individual audit or a similar control);
- overview reports (of a series of controls on a specific topic);
- annual reports (describing the overall outcome of the national and Commission control activities);
- EU Member States' country profiles;
- live map of audits and similar controls in a particular year; and
- informative videos on how the Directorate carries out its controls.

¹⁰ <u>https://ec.europa.eu/food/audits-analysis/country_profiles/index.cfm</u>

Annex 1- Multi-annual plan 2021-2025 and controls planned in 2024

Human health protection

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
	Designation of notified bodies	Member States	 To coordinate and participate in the joint assessment team, which evaluates, together with the designating authority, that the applicant notified body satisfies the necessary requirements to fulfil the tasks for which it has applied for designation under the applicable Regulation. ➢ In applicant notified bodies, based on demand upon receipt of a preliminary assessment report. Legal obligation 	Number of assessments for designation (initiated with an on-site assessment) depending on requests
Medical devices	Re-assessment of notified bodies	Member States	 To coordinate and participate in the joint assessment team which re-evaluates, together with the designating authority, that the notified body continues to satisfy the necessary requirements to fulfil the tasks for which it was designated under the applicable Regulation. ➢ In all notified bodies, at the frequency of re-assessment required. Legal obligation. 	8 re-assessments based on legal obligations
Medic	Scope extension of notified bodies	Member States	 To coordinate and participate in the joint assessment team which evaluates, together with the designating authority, that the notified body satisfies the necessary requirements to extend the range of devices it can certify. In designated notified bodies, based on demand upon receipt of a preliminary assessment report. Legal obligation. 	Number of scope extensions (initiated with an on-site assessment) depending on requests
	Review of corrective and preventive action (CAPA) plans	Member States	 To coordinate and participate in the joint assessment team which reviews the CAPA plan of a notified body submitted by the designating authority. ➤ In applicant notified bodies and notified bodies (scope extensions or reassessment), based on demand, upon receipt of CAPA plan. Legal obligation. 	Number of CAPA plans reviewed depending on requests

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
l use	Clinical trials in Member States	Member States	 To verify whether Member States correctly supervise compliance with Regulation (EU) No 536/2014 on clinical trials. ➢ In 4 Member States per year, starting in 2022 	Union controls consisting in a series of assessments based on questionnaires
ls for human	Clinical trials in third countries	Third countries	To verify whether the regulatory system applicable to clinical trials conducted outside the EU ensures that the relevant requirements are complied with. ➤ In 2 third countries per year, starting in 2022	
Pharmaceuticals for	Active pharmaceutical ingredients & Mutual recognition agreements		To verify whether third countries' regulatory framework applicable to active pharmaceutical ingredients exported to the EU and the respective control and enforcement activities ensure a level of protection of public health equivalent to that of the EU, and to participate in the re-assessment of mutual recognition agreements (MRAs) in this area.	2 audits, countries to be determined

One Health

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
	One-Health	Member States	To assist the competent authorities in further developing and implementing their	Number of country visits
	country visits	and Western	national strategies and policies against AMR based on a One Health perspective.	depending on invitations
		Balkans	Country visits are performed jointly with the ECDC, in Member States requesting a	received.
			visit, or in Western Balkans (following an invitation by the ECDC).	
			In a maximum of 4 countries per year	
Ice	Review of	Member States	To review Member States' AMR One Health National Action Plans.	
Antimicrobial resistance	National action plans		➤ In all Member States in 2021 and 2022	
l res	AMR	Member States	To verify Member States' compliance with the legislation governing the monitoring of	3 audits: Greece,
bia	monitoring	Member States	antimicrobial resistance in zoonotic and commensal bacteria and by this contributing	Netherlands and Poland
cro	(zoonotic and		to the full implementation of the 2017 European One Health Action Plan against	r tothornarido arid r onarid
timi	commensal		antimicrobial resistance.	
An	bacteria)		▶ In a sample of Member States in 2023 and 2024	
	Veterinary	Member States	To verify the appropriateness of the controls carried out by the competent authorities	3 audits: Greece, Italy and
	medicinal		in relation to veterinary medicinal products, targeting those aspects of the Regulation	Netherlands
	products (VMPs)		(EU) 2019/6 more closely linked to the fight against AMR, including adherence to the	
			list of antimicrobials reserved for human use.	
			➢ In the Member States, starting in 2023 at the earliest	

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
CUD	Sustainable use of pesticides	Member States	To verify the Member States' compliance with the applicable EU legislation governing the sustainable use of pesticides (SUD), and the implementation of official controls thereon. Due to the ongoing discussion on a proposal for draft Regulation on the sustainable use of pesticides, which would replace Directive 2009/128/EC of the European Parliament and of the Council, there are no controls on the sustainable use of pesticides in 2023.	
	Highly pathogenic avian influenza	Member States	 To collect and assess information on mechanisms of collaboration between public and animal health authorities to ensure rapid alert in case of spill over, with a view to inform the European Commission to public health strategies. ➤ The project will involve fact-finding studies performed in synergy with animal health audits in Member States 	4 fact-finding studies: Belgium, Italy, Poland and Portugal.
Non-foodborne zoonoses	Pandemic transmission pathways	Member States	 To collect and assess information on the level of surveillance in mink farms for zoonotic infections with zoonotic agents such as SARS-CoV2 and avian influenza, minks being sentinel animals providing early warning for pandemic preparedness, with a view to inform the European Commission to public health strategies. ➤ The project will involve fact-finding studies in Member States producing minks. 	3 fact-finding studies: Finland, Poland and Spain
Non-I Zo	Rabies	Member States and neighbouring countries	 To verify Member States' compliance with the applicable EU legislation governing the control of rabies, with a particular focus on the level of implementation and effectiveness of the EU co-financed eradication; programme, and the implementation of official controls thereon. In Member States with an EU approved (and co-financed) rabies national control programme and in 3 countries neighbouring the EU with an EU co-financed programme in place with sporadic rabies cases detected in regions adjacent to the EU border. 	

Animal health

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
diseases under Health Law	African swine fever	Member States and neighbouring countries	 To verify Member States' compliance with the applicable EU legislation governing the control of African swine fever and the implementation of official controls thereon. In Member States with difficulties to control the disease. To verify the compliance with EU legislation of the third country's legislation and the capacity of its control system to prevent the re-entry of African swine fever in the EU. In 2-3 countries neighbouring the EU where the disease is present. 	3 audits: Estonia, Greece, and Romania
Category A Animal	Highly pathogenic avian influenza	Member States	 To verify Member States' compliance with the applicable EU legislation governing the control of the disease and the implementation of official controls thereon. In Member States with difficulties to control the disease. 	4 audits: Belgium, Italy, Poland and Portugal
0	Sheep and goat pox			1 audit: Spain
Animal health requirements	Surveillance, traceability, etc.	Member States	 To verify Member States' compliance with the applicable EU legislation governing animal health and the implementation of official controls thereon. > In all Member States. 	These aspects are included in the scope of audits performed on category A, B and C diseases under animal health law

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
ry B and C diseases under Animal Health Law	Tuberculosis, brucellosis Fish diseases	Member States	 To verify Member States' compliance with the applicable EU legislation governing the control of enzootic diseases, with a particular focus on the level of implementation and effectiveness of the EU co-financed eradication programme, and the implementation of official controls thereon. ➢ In 2 - 4 Member States with an approved national control programme and difficulties to control enzootic diseases. 	1 audit: France
Category B and C Animal Hea	Status for B and C diseases		 To monitor the application of the requirements in Council Implementing Regulation 2021/620 and verify the reliability of Member States' declarations on disease freedom and on their implementation of eradication programmes. ▶ periodic questionnaires and up to 3 controls per year with a view to cover all Member States over a period of 7-10 years 	3 controls: Austria (bovine tuberculosis), Italy (brucellosis) and Spain (bovine tuberculosis)
Preparedness and prevention	Contingency plans	Member States	To verify Member States' compliance with the applicable EU legislation governing preparedness to cope with multiple outbreaks of epizootic diseases and the implementation of official controls thereon. In all Member States	

Animal welfare

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
	Laying hens	Member States	 To verify Member States' compliance with the applicable EU legislation governing the welfare of laying hens during rearing and the implementation of official controls thereon. ➢ All Member States, 8-10 Member States by means of an audit and the other Member States by means of a questionnaire. 	
On-farm	Cattle (beef production)	Member States	 To verify the effectiveness of the Member States' official controls to avoid any avoidable pain and suffering to cattle kept in farms for beef production ➤ All Member States, 4 Member States by means of an audit and the other Member States by means of a questionnaire 	
	Turkeys	Member States	. To provide an overview of the animal welfare of turkeys on farm in the EUThe project will involve bibliographic research, questionnaires, exchange of views with Member States, fact finding studies and possibly 'technical visits'.	0 ,
On-farm, slaughter and transport	Fish	Member States	 To provide an overview of the fish farming sector in the EU with special focus on animal welfare matters. The project will involve bibliographic research, questionnaires, exchange of views with Member States, fact finding studies and 'technical visits'. 	Finland, France, and Spain

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
Slaughter	Ruminants and poultry	Member States	 To verify Member States' compliance with the applicable EU legislation governing the welfare of ruminants and poultry at slaughter and the implementation of official controls thereon. ➢ In 4 - 5 Member States amongst those not controlled before 2021. 	
	Control posts	Member States	 To verify Member States' compliance with the applicable EU legislation governing the welfare of unweaned calves during transport and the implementation of official controls thereon. In 10 - 12 Member States with a view to produce an overview of intra-EU transport of calves, starting in 2022. 	
Transport	Livestock vessels	Member States	 To verify Member States' compliance with the applicable EU legislation governing the welfare of animals in livestock vessels and the implementation of official controls thereon. In all Member States with exit ports for animals (7 Member States concerned), starting in 2022. 	
	Unfit animals	Member States	 To verify Member States' compliance with the applicable EU legislation governing the welfare of unfit animals during transport and the implementation of official controls thereon In 8 Member States, where the proportion/number of unfit animals is higher than the EU average, due to the size of dairy farms and piglet producers. 	

Plant health

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
Outbreaks presenting a significant risk	Official control measures	Member States	 To verify Member States' compliance with the applicable EU legislation governing the control of EU plant pests found on the EU territory and the implementation of official controls thereon ➢ Up to 6 - 8 controls per year in response to outbreaks of plant pests subject to emergency measures (<i>Xylella fastidiosa</i>, pinewood nematode, <i>Anoplophora</i> longhorn beetles) and other quarantine pests such as <i>Diaphorina citri</i>, a vector of Citrus greening disease. 	3 audits: Greece (Spodoptera frugiperda), Italy (Aleurocanthus and Popillia), and Romania (Clavibacter sepedonicus).
General plant health	Implementation of the Plant Health controls	Member States	 To verify Member States' compliance with the applicable EU plant health legislation, and official controls thereon. > In Member States not controlled for other plant health related themes in 2021-2025. 	
Movement of plants within the Union	Plant Passports	Member States	 To verify Member States' compliance with the applicable EU plant health legislation governing the movement of plants, plant products and other objects within the EU and the implementation of official controls thereon. In 15 Member States starting in 2022, with the aim to carry out at least one plant health audit in each MS in 2021-2025. 	4 audits: France, Germany, Slovenia and Sweden

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
and prevention	Contingency Plans	Member States	 To verify Member States' compliance with the applicable EU legislation governing the drawing up and update of plant health contingency plans. Analysis of Member States' plant health contingency plans for priority pests. 	1 analysis on the outcome of the assessment of Member States contingency plans.
Preparedness a	Plant health survey programmes	Member States	 To assess the planning and implementation of survey programmes for quarantine and priority pests under plant health law. Analysis of Member States' multi-annual survey programmes. Audits in 15 Member States, starting in 2024, with the aim to carry out at least one plant health audit in each Member State in 2021-2025. 	4 audits: Bulgaria, Finland, Greece and Slovakia 1 analysis on the outcome of the assessment of Member States survey programmes.

Food and food safety

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
Food of animal origin	Chemical safety - Residues	Member States	 To verify that control plans for residues of pharmacologically active substances in animals and food of animal origin submitted by all Member States comply with the requirements laid down in the relevant EU legislation. All Member States' and Northern Ireland's control plans every year. 	27 Member States' plans plus Northern Ireland. (1 national risk-based control plan and 1 randomised surveillance plan per country) = 56 assessments.
		Member States	 To verify Member States' compliance with the applicable EU legislation governing residues of pharmacologically active substances, pesticides and contaminants in live animals and food of animal origin. ➢ In 80% of Member States risk-based selected. 	6 audits: Czechia, Denmark, Estonia, Greece, Malta and Sweden
	Safety of fishery products	Member States	 To verify Member States' compliance with the applicable EU food safety legislation governing the production and placing on the market of fishery products, and the implementation of official controls thereon. ➢ In the majority of Member States. 	5 audits: Estonia, France, Italy, Poland, and Portugal
	Safety of meat of mammals and birds and products thereof	Member States	To verify Member States' compliance with the applicable EU food safety legislation governing the production and placing on the market of meat of mammals and birds and products thereof, and the implementation of official controls thereon.	5 audits: Belgium, Bulgaria, Lithuania, Poland, and Sweden
	Safety of milk and products thereof	Member States	 To verify Member States' compliance with the applicable EU food safety legislation governing the production and placing on the market of milk and products thereof, and the implementation of official controls thereon. In the majority of Member States. 	4 audits: Hungary, Latvia, Portugal and Slovenia

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
Food of animal origin	Production hygiene of live bivalve molluscs	Member States and EFTA countries	 To verify Member States' compliance with the applicable EU safety legislation governing the production and placing on the market of live bivalve molluscs and the implementation of official controls thereon. ➢ In up to 2 Member States or EFTA country every year. 	
Foodborne zoonoses	Salmonella	Member States	 To verify Member States' compliance with the applicable EU legislation governing the control of <i>Salmonella</i>, with a particular focus on the level of implementation and effectiveness of the EU co-financed programme, and the implementation of official controls thereon. 1 Member State per year (on average); Member State with an EU approved (and co-financed) <i>Salmonella</i> national control programme per year. 	
Food of non-animal origin	Chemical safety - Contaminants	Member States	 To verify, based on Member States' multi-annual national control plans and reports thereon, and/or audits that official controls on contaminants in food of non-animal origin comply with the requirements laid down in the relevant applicable EU legislation. ➢ In all Member States starting in 2021. 	Completion of the desk study based on questionnaires already returned from Member States and data provided from EFSA.
	Chemical safety - authorisation, marketing and use of pesticides	Member States	To verify Member States' compliance with the applicable EU legislation governing the authorisation, marketing and use of plant protection products, including illegal plant protection products, and where relevant, pesticide residues, and aspects related to the sustainable use of pesticides, and the implementation of official controls thereon. In 10 - 15 Member States selected based on audit history and risk-based criteria.	4 audits: Bulgaria, Finland, Germany, Romania, and Spain
	Microbiological safety	Member States	 To verify Member States' compliance with the applicable EU food safety legislation governing the production and placing on the market of food of non-animal origin, and the implementation of official controls thereon. ➢ In the majority of Member States. 	4 audits: Cyprus, Denmark, Malta and Spain

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
Food of animal and non-animal origin	Food contact materials	Member States	 To verify Member States' compliance with the applicable EU legislation on food contact materials and the implementation of official controls thereon. ➢ In Member States. ➢ Following adoption of a revised legislation on food contact materials and other Commission initiatives. 	
	Labelling and claims	Member States	 To verify Member States' compliance with the applicable EU legislation on food information to consumers and health and nutrition claims, and the implementation of official controls thereon. In Member States. Following adoption of a revised legislation on food information to consumers and after a suitable implementation time. 	

Feed safety and animal by-products

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
	Animal by- products and derived products	Member States	To verify Member States' compliance with the applicable EU legislation governing the handling, use and/or disposal of animal by-products (ABP) and derived products (DP) generated in the EU or placed on the EU market and the implementation of official controls thereon. In all the Member States	
Feed safety	Feed hygiene	Member States	To verify Member States' compliance with the applicable EU legislation governing feed hygiene (with a particular focus on approval and registration of establishments, contaminants, traceability and labelling and the implementation of official controls thereon. In all Member States (the project started in 2020) 	5 audits: Austria, Croatia, Denmark, Estonia and Sweden
	Medicated feed	Member States	 To verify Member States' compliance with the new EU requirements governing the production of medicated feedingstuffs, applicable from January 2022 (Regulation (EU) 2019/4). ➢ In all Member States, starting in 2023. 	Addressed as part of audits on feed hygiene, starting in 2023.

Import and export controls

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
Animals and goods entering the Union	Border control posts	Member States and EFTA countries	To verify that border control posts proposed for designation by Member States comply with the minimum requirements for border control posts laid down in the applicable EU legislation (Article 64 of the OCR) before such posts are designated. To verify that border control posts re-designated in accordance with Article 61(2) of Regulation (EU) 2017/625, designated border control posts and control points other than border control posts, referred to in Article 53(1)(a) of Regulation (EU) 2017/625 comply with the applicable minimum requirements.	The number of desk-based analyses and (if necessary) audits on the spot is demand- based. Joint analysis and audit with EFTA Surveillance Authority (demand based)
	Official import controls	Member States	To verify that Member States meet their obligations with regard to conducting official controls on animals and goods entering the EU from third countries, as established in particular in Regulation (EU) 2017/625 and related delegated and implementing acts and thus verify that such animals and goods comply with the applicable EU general and specific requirements for entry into the EU. There will be a special focus on the new requirements established by Regulation (EU) 2017/625 and the related Delegated and Implementing Acts in this area.	5 audits: Austria, Denmark, Italy, Romania and Slovakia

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
Plants, plant products and other objects entering the Union		Member States	 To verify that Member States meet their obligations with regard to conducting official plant health controls on plants, plant products and other objects and thus verify that such goods comply with the applicable EU plant health requirements for entry into the EU. There will be a special focus on new requirements established by Regulation (EU) 2017/625 and Regulation 2016/2031 and related Delegated and Implementing Acts in this area, in particular Regulation 2019/2072. ➢ In 15 - 20 Member States, with the aim to carry out at least one plant health audit in each Member States in 2021-2025. 	

Third countries access to EU market

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
Live animals and food of animal origin	Animal health in countries requesting to be listed /listed	Third /candidate countries	 To verify the compliance with EU legislation of the third country's legislation and the capacity of its control system to ensure that consignments of live animals, meat and/or animal products exported to the EU comply with EU animal health requirements or with requirements recognised to be at least equivalent, where so established. In 2 - 6 third countries per year; third country requesting to be listed for the export of live animals, meat and/or animal products. In 2 - 4 third countries listed per year amongst those listed for such export to the EU, selected based on audit history and the presence of relevant diseases in the exporting country. 	 Listing requests: Audits may be performed depending on listing requests. Listed countries: 5 audits on animal health to listed third countries: Argentina (beef), Brazil (poultry), Thailand (horses), United Kingdom (poultry) and Uruguay (beef).

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
	Chemical safety - Residues	Third /candidate countries	 To verify that third countries' control plans for residues of pharmacologically active substances, pesticides and contaminants in animals and animal products, offer guarantees with an effect at least equivalent to that foreseen in the relevant EU legislation allowing for country listing in Annex -I to Regulation (EU) 2021/405. ➢ All third countries' residue control plans on a 5-year cycle. 	20 third countries to be assessed plus 1 multi-country analysis (13 third countries listed solely for honey)
Food of animal origin		Third /candidate countries	 To verify that third countries meet the requirements for their listing in Annex -I to Regulation (EU) 2021/405 in respect of the provision of guarantees with an effect equivalent to that foreseen in the EU legislation governing residues of pharmacologically active substances, pesticides and contaminants in animals and animal products. ➤ In approx. 5 - 8 third countries per year; (countries already listed, based on factors such as trade volume and previous audit history or countries seeking to be listed. 	5 audits: Brazil, Saudi Arabia, South Africa, Switzerland and Vietnam. Note that residues will also be covered in the public health audits scheduled for Peru and Paraguay.
	Safety of products of mammals and birds for human consumption	Third /candidate countries	 To verify the compliance with EU requirements of the third country's legislation and the capacity of its control system to ensure that consignments of products of mammal and bird origin for human consumption exported to the EU comply with EU food safety requirements or with requirements recognised to be at least equivalent thereto. ➤ A number of third countries per year, selected based on audit history and risk- based criteria. 	6 audits: Bosnia Herzegovina (Poultry), Great Britain (UK) (milk and dairy products), Mexico (horse meat), Montenegro (Beef, lamb and pork meat), Paraguay (beef and casings) and Serbia (milk and dairy products). A number of audits following listing requests and/or the outcome of previous audits.

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
	Safety of products of mammals and birds for human consumption	Third /candidate countries	 To verify on the basis of the country's reply to a questionnaire, that official controls on food business operators (products other than fishery products) in third countries (a) are performed and are suitable to verify those operators' compliance with the applicable EU rules and (b) in the event that non-compliances have been detected, action will be taken to bring the operators back into compliance. ➤ A number of third countries exporting small quantities of such products or commodities not subject to regular controls 	3 remote assessments on casings (countries to be determined)
Food of animal origin	Safety of fishery products	Third /candidate countries	 To verify the compliance with EU requirements of the third country's legislation and the capacity of its control system to ensure that consignments of fishery products exported to the EU comply with EU food safety requirements or with requirements recognised to be at least equivalent, where so established. A number of third countries selected each year based on audit history and risk- based criteria. 	5 audits: Canada, Colombia, India, Peru and United States A number of audits following listing requests and/or the outcome of previous audits.
		Third /candidate countries	 To verify on the basis of the country's reply to a questionnaire, that official controls on food business operators (fishery products) in third countries (a) are performed and are suitable to verify those operators' compliance with the applicable EU rules and (b) in the event that non-compliances have been detected, action will be taken to bring the operators back into compliance. ➢ Approx. 10 remote assessments per year, covering third countries exporting small quantities of fishery products. 	10 remote assessments (countries to be determined)

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
Food of animal origin	Production hygiene of live bivalve molluscs Official controls in establishment	Third /candidate countries Third /candidate countries	 To verify the compliance with the EU requirements of the third country's legislation and the capacity of its control system to ensure that consignments of live bivalve molluscs exported to the EU comply with EU food safety requirements or with requirements recognised to be at least equivalent, where so established. ➢ In 1 third country per year, amongst those listed for such export to the EU. To verify on the basis of documentary evidence that official controls on food business operators (food of animal origin) in third countries (a) are performed and suitable to verify 	2 audits: Canada and New Zealand
Food e	S		 those operators' compliance with the applicable EU rules in respect of exports to the EU and (b), in the event that non-compliances have been detected, action has been taken to bring the operators back into compliance. 6 - 7 third countries per year; third countries listed and exporting food of animal origin to the EU and cannot be visited for logistical or security reasons. 	
Food of non-animal origin	Chemical safety - Contaminants	Third /candidate countries	 To verify the compliance with EU requirements of the third country's legislation and the capacity of its control system to ensure that consignments of food of non-animal origin intended for export to the EU comply with EU requirements on contaminants or with requirements recognised to be at least equivalent thereto ➤ In 10 - 15 third countries selected based on audit history and risk-based criteria. 	2 audits: Iran and Türkiye

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
al origin	Microbiologic al safety	Third /candidate countries	To verify the compliance with EU requirements of the third country's legislation and the capacity of its control system to ensure that consignments of food of non-animal origin exported to the EU comply with the EU food safety requirements or with requirements recognised to be at least equivalent, where so established.	2 audits: Egypt and Uganda
Food of non-animal origin			In approx. 2 third countries per year, selected based on audit history and risk- based criteria including countries subject to increased level of official controls on import.	
Food of 1	Chemical safety - Pesticides controls	Third /candidate countries	To verify whether a control system is in place in the third country and its capacity to ensure that consignments of food of non-animal origin intended for export to the EU comply with EU pesticides maximum residue limits.	2 audits: China and India
			In up to 4 - 8 third countries selected based on audit history and risk-based criteria, starting in 2022.	
Feed safety	Animal by- products and derived products	Third /candidate countries	To verify the capacity of the third country control system to ensure that consignments of goods exported to the Union (animal by-products and derived products) comply with relevant requirements established in the Union ABP- legislation or with requirements recognised to be at least equivalent thereto. In third countries selected on risk-based criteria	3 audits: Brazil, China and Morocco

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
Quality standards	Seeds & propagating material - recognition of equivalency	Third /candidate countries	 To verify the equivalence with EU legislation of the country's legislation and the capacity of its control system to ensure that consignments of seeds and propagating material intended for export to the EU comply with the EU requirements or with requirements recognised to be at least equivalent thereto ➢ In up to 1 - 2 third countries per year, based on third countries' requests for recognition of equivalence. 	
Plants, plant products and other objects	Phytosanitary conditions for export to the EU	Third /candidate countries	 To verify the compliance with EU requirements of the third country's legislation and the capacity of its control system to ensure that consignments of plant, plant products and other objects exported to the EU comply with EU plant health requirements or with requirements recognised to be at least equivalent thereto. ➢ In up to 6 - 8 third countries per year, selected based on audit history and risk-based criteria including the number of interceptions of EU plant pests in consignments entering the EU. 	3 audits: Cameroon (mangoes), Egypt (potatoes) and another country to be determined.

Accession to the EU

Policy area	Priority th	ieme	Country status/ entity	Objectives 2021-2025	Controls 2024
Animal health	Official health contro		Candidate countries /potential candidates	 To verify the compliance of the official framework for animal health controls for accession into the EU In candidate countries or potential candidates 	1 audit: Kosovo

Agri-food cha	in
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Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
Agri-food chain	UK-NI	Third country	To verify that the United Kingdom in respect of Northern Ireland complies with EU requirements in the context of its obligations pursuant to the Ireland/Northern Ireland protocol to the withdrawal agreement between the UK and the EU (as amended by the Windsor Framework). This will include the assessment of the planned border control posts in UK-NI, verification of implementation of official controls on imports of animals and goods in the border control posts, and application of other EU legislation in the region.	of potential further controls including audits, to be

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
	UK-GB	Third country	 To verify that the United Kingdom in respect of Great Britain and its Crown dependencies, complies with EU requirements as regards exports of animals and goods to the EU. ➢ Audits will be carried out in the period 2021-2025, as necessary. 	2 audits on the safety of milk and dairy products for human consumption and animal health (poultry/highly pathogenic avian influenza)
Agri-food chain	Systematic follow-up	Member States	To verify that Member States take appropriate follow-up measures to remedy any specific or systematic shortcomings identified by Commission controls.	7 general follow-up audits: Austria, Cyprus, Denmark, France, Ireland, Lithuania and the Netherlands 4 targeted follow-up audits: Germany, Hungary, Portugal and Sweden
Agri	Sectoral follow- up	Member States and third countries	 To verify that Member States and third countries take appropriate follow-up measures to remedy any specific or systematic shortcomings identified by Commission controls ➢ In Member States and third country where appropriate, for example where important or recurring problems have been identified by previous controls. 	Planned controls are indicated in the relevant policy domains
	Any emergency situations, emerging problems & new developments	Member States	 To investigate and collect information in relation to any emergency situations, emerging problems or new developments in the Member States. ➤ Where necessary. 	Controls will take place in response to emerging situations

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2024
	Fraud	Member States	 To collect information on the suitability and effective implementation of national arrangements to fight fraud along the agri-food chain in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council. ➢ In a representative sample of 6 Member States. 	
Agri-food chain	Regulated product submissions - Adherence to study standards	Testing facilities in Member States and in third countries with which there is an agreement	To verify laboratories and testing facilities' adherence to any applicable standards against which studies submitted to EFSA in support of regulated product submissions have been performed and to bring any non-compliances identified to the attention of the appropriate regulatory authorities.	Fact-finding missions (number to be determined based on applications submitted to EFSA)
Agri	Genetically modified organisms (GMOs) (e.g. authorisation, marketing, traceability, labelling, new genomic techniques)	Member States	 To verify, as appropriate, Member States' compliance with the applicable EU legislation governing the authorisation/ marketing of Genetically Modified Organisms, their traceability and labelling in food and feed and the implementation of official controls thereon. To contribute to and build up expertise for the evaluation of new genomic techniques. In Member States. 	1 audit on GMOs: Belgium

Annex 2 – Controls in Member States planned in 2024

Country name	Priority theme	Control type
	One Health - Highly pathogenic avian influenza	Fact-finding study
Belgique/België	Animal Health - Avian influenza	Audit
(Belgium)	Food of Animal Origin - Slaughter of mammals and/or birds	Audit
	Genetically Modified Organisms	Audit
	Plant Health - Plant Health Survey Programmes	Audit
България	Food of Animal Origin - Slaughter of mammals and/or birds	Audit
(Bulgaria)	Food of Non-Animal Origin - Plant Protection Products - Authorisation, Marketing and Use	Audit
Česko (Czechia)	Food of animal origin - Residues of pharmacologically active substances, pesticides and contaminants	Audit
	Food of animal origin - Residues of pharmacologically active substances, pesticides and contaminants	Audit
	Food of Non-Animal Origin - Microbiological safety	Audit
Danmark (Denmark)	Feed Safety - Feed hygiene	Audit
	Entry into the Union - Animals and Goods	Audit
	General follow-up	Audit
	Animal Welfare - Animal welfare - on-farm (turkeys)	Fact-finding study
Deutschland	Plant Health - Plant Passports	Audit
(Germany)	Food of Non-Animal Origin - Plant Protection Products - Authorisation, Marketing and Use	Audit
	Targeted follow-up of audit recommendations 2024	Audit
	Animal Health - African swine fever	Audit
Eesti	Food of Animal Origin - Fishery products	Audit
(Estonia)	Food of animal origin - Residues of pharmacologically active substances, pesticides and contaminants	Audit
	Feed Safety - Feed hygiene	Audit
Éire/Ireland	Feed Safety - Hygiene, traceability and channelling of animal by-products (ABP) and derived products	Audit
	General follow-up	Audit

Country name	Priority theme	Control type
Ελλάδα	AMR monitoring in zoonotic and commensal bacteria	Audit
	AMR - Antimicrobial Veterinary Medicinal Products	Audit
	Animal Health - African swine fever	Audit
(Greece)	Plant Health - Plant pest outbreaks (Spodoptera frugiperda)	Audit
	Plant Health Survey Programmes	Audit
	Food of animal origin - Residues of pharmacologically active substances, pesticides and contaminants	Audit
	One Health - Pandemic transmission pathways	Fact-finding study
	Animal Health - Sheep and goat pox	Audit
España	Animal Health - Monitoring system for B and C diseases	Control
(Spain)	Animal welfare - Fish	Fact-finding study
	Food of Non-Animal Origin - Microbiological Safety	Audit
	Food of Non-Animal Origin - Plant Protection Products - Authorisation, Marketing and Use	Audit
	Animal Health - Aquatic animal health	Audit
	Animal Welfare - Animal welfare - Fish	Fact-finding study
France	Animal Welfare - Animal welfare - on-farm (turkeys)	Fact-finding study
Trance	Plant Health - Plant Passports	Audit
	Food of Animal Origin - Fishery products	Audit
	General follow-up	Audit
Hrvatska (Croatia)	Feed Safety - Feed hygiene	Audit
	AMR - Antimicrobial Veterinary Medicinal Products	Audit
	One Health - Highly pathogenic avian influenza	Fact-finding study
	Animal Health - Avian influenza	Audit
Italia (Italy)	Animal Health - Monitoring system for B and C diseases	Control
	Animal welfare - on-farm (turkeys)	Fact-finding study
	Plant Health - Plant pest outbreaks (<i>Aleurocanthus</i> and <i>Popillia</i>)	Audit
	Food of Animal Origin - Fishery products	Audit
	Feed Safety - Hygiene, traceability and channelling of animal by-products (ABP) and derived products	Audit
	Entry into the Union - Animals and Goods	Audit

Country name	Priority theme	Control type
Κύπϱος (Cyprus)	Food of Non-Animal Origin - Microbiological safety	Audit
	General follow-up	Audit
Latvija (Latvia)	Food of Animal Origin - Dairy	Audit
Lietuva	Food of Animal Origin - Slaughter of mammals and/or birds	Audit
(Lithuania)	General follow-up	Audit
Magyarország	Food of Animal Origin - Dairy	Audit
(Hungary)	Targeted follow-up of audit recommendations 2024	Audit
Malta	Food of animal origin - Residues of pharmacologically active substances, pesticides and contaminants	Audit
	Food of Non-Animal Origin - Microbiological safety	Audit
	AMR - Antimicrobial Veterinary Medicinal Products	Audit
Nederland (Netherlands)	AMR monitoring in zoonotic and commensal bacteria	Audit
(incinentatios)	General follow-up	Audit
	Animal Health - Monitoring system for B and C diseases	Control
Österreich	Entry into the Union - Animals and Goods	Audit
(Austria)	Feed Safety - Feed hygiene	Audit
	General follow-up	Audit
	AMR monitoring in zoonotic and commensal bacteria	Audit
	One Health - Pandemic transmission pathways	Fact-finding study
	One Health - Highly pathogenic avian influenza	Fact-finding study
Polska	Animal Health - Avian influenza	Audit
(Poland)	Food of Animal Origin - Slaughter of mammals and/or birds	Audit
	Food of Animal Origin - Fishery products	Audit
	Feed Safety - Hygiene, traceability and channelling of animal by-products (ABP) and derived products	Audit
	One Health - Highly pathogenic avian influenza	Fact-finding study
Portugal	Animal Health - Avian influenza	Audit
	Food of Animal Origin - Dairy	Audit
	Food of Animal Origin - Fishery products	Audit
	Targeted follow-up of audit recommendations 2024	Audit

Country name	Priority theme	Control type
România (Romania)	Animal health- African swine fever	Audit
	Plant Health - Plant pest outbreaks (Clavibacter sepedonicus)	Audit
	Food of Non-Animal Origin - Plant Protection Products - Authorisation, Marketing and Use	Audit
	Entry into the Union - Animals and Goods	Audi
Slovenija	Plant Health - Plant Passports	Audit
(Slovenia)	Food of Animal Origin - Dairy	Audit
Slovensko	Plant Health Survey Programmes	Audit
(Slovakia)	Entry into the Union - Animals and Goods	Audit
	One Health - Pandemic transmission pathways	Fact-finding study
Suomi/Finland (Finland)	Animal welfare - Fish	Fact-finding study
	Plant Health Survey Programmes	Audit
	Food of Non-Animal Origin - Plant Protection Products - Authorisation, Marketing and Use	Audit
Sverige (Sweden)	Plant Health - Plant Passports	Audit
	Food of Animal Origin - Slaughter of mammals and/or birds	Audit
	Food of animal origin - Residues of pharmacologically active substances, pesticides and contaminants	Audit
	Feed Safety - Feed hygiene	Audit
	Targeted follow-up of audit recommendations 2024	Audit

Annex 3 – Controls in candidate countries/ potential candidates planned in 2024

Country/entity name	Priority theme	Control type
Bosna i Hercegovina/ Босна и Херцеговина (Bosnia and Herzegovina)	Safety of meat from mammals and birds for human consumption (Poultry meat and products thereof)	Audit
Kosovo	Animal health pre-accession	Audit
Црна Гора (Montenegro)	Safety of meat from mammals and birds for human consumption (Beef, lamb and pork meat)	Audit
Србија (Serbia)	Safety of meat from mammals and birds for human consumption (milk and dairy products)	Audit
Türkiye	Food of Non-Animal Origin - Contaminants	Audit

Annex 4 - Controls in third countries planned in 2024

Country name	Priority theme	Control type
AR - Argentina	Animal Health in countries listed (beef)	Audit
	Animal health in countries listed (poultry)	Audit
BR - Brazil	Hygiene, traceability and channelling of animal by-products (ABP) and derived products	Audit
	Food of animal origin - Residues of pharmacologically active substances, pesticides and contaminants	Audit
CA - Canada	Production hygiene of live bivalve molluscs	Audit
	Food of animal origin - Safety of fishery products	Audit
CH - Switzerland	Food of animal origin - Residues of pharmacologically active substances, pesticides and contaminants	Audit
CM - Cameroon	Phytosanitary conditions for export to the EU (mangoes)	Audit
	Food of Non-Animal Origin - Pesticide Residues Control	Audit
CN - China	Hygiene, traceability and channelling of animal by-products (ABP) and derived products	Audit
CO - Colombia	Food of animal origin - Safety of fishery products	Audit
FC Found	Food of non-animal origin - Microbiological safety	Audit
EG - Egypt	Phytosanitary conditions for export to the EU (potatoes)	Audit
TNT T 1'	Food of non-animal origin - Pesticide Residues Control	Audit
IN - India	Food of animal origin - Safety of fishery products	Audit
IR - Iran	Food of non-animal origin - Contaminants	Audit
MA - Morocco	Hygiene, traceability and channelling of animal by-products (ABP) and derived products	Audit
MX - Mexico	Safety of meat from mammals and birds for human consumption (horse meat)	Audit
NZ – New Zealand	Production hygiene of live bivalve molluscs	Audit
PY - Paraguay	Safety of meat from mammals and birds for human consumption (Beef and casings)	Audit
PE - Peru	Food of animal origin - Safety of fishery products	Audit
SA – Saudi Arabia	Food of animal origin - Residues of pharmacologically active substances, pesticides and contaminants	Audit
TH - Thailand	Animal health in countries requesting to be listed/listed (horses)	Audit
UG - Uganda	Food of non-Animal origin - Microbiological safety	Audit
UK – United	Animal health in countries listed (poultry)	Audit
Kingdom in respect of Great Britain	Safety of meat from mammals and birds for human consumption (Milk and dairy products)	Audit

Country name	Priority theme	Control type
US - United States	Food of animal origin - Safety of fishery products	Audit
UY - Uruguay	Animal Health in countries listed (beef)	Audit
VN - Vietnam	Food of animal origin - Residues of pharmacologically active substances, pesticides and contaminants	Audit
ZA - South Africa	Food of animal origin - Residues of pharmacologically active substances, pesticides and contaminants	Audit

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