DG Health and
Food Safety

Health and food audits
and analysis programme
2023

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, EU quality standards (the Food domain) and in certain areas of human health (the Health domain).

This document, the Health and food audits and analysis work programme 2023, presents the Directorate and its controls, priorities for controls in 2021-2025 and the detailed activities planned for 2023.

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 for carrying out Commission controls whilst ensuring that it covers 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, an amendment. In this context, four new control priorities have been identified for the period 2023-2025: animal welfare of fish, animal welfare of cattle kept for the production of beef, animal by-products and derived products intended for export to the EU and plant health survey programmes. Other adjustments are detailed in section 4 of the document.

Control activities in 2023

In 2023, the Directorate intends to perform 288 planned controls complemented by "on-demand" controls, for which numbers cannot be estimated. From those 288, 165 are audits and similar controls (e.g. joint assessments, joint country visits, remote assessments, and fact-finding studies), and 123 are analyses (office-based controls).

In 2023, controls will continue on most priorities addressed in previous years and will commence on several priority themes of the multi-annual plan:
- Antimicrobial resistance (AMR), on two additional priorities: i) AMR monitoring in zoonotic and commensal bacteria and ii) veterinary medicinal products, with an emphasis on the fight against AMR;

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

- Animal welfare, with the welfare of fish and the welfare of cattle kept for the production of beef;
- Feed safety, with medicated feed being addressed as part of the scope of audits on feed hygiene and animal by-products and derived products will be covered in third countries.

The annexes to this document provide an overview of the multi-annual plan 2021-2025 and detail of control activities for 2023.

Controls in the Food domain

In 2023, planned controls in the Food domain account for 273 controls, including 150 audits and similar controls. These and other "on-demand" controls will address some 43 priority themes from 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 risk assessment of regulated products.

Controls in the Health domain

In 2023, 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 AMR. Controls on AMR will step up, covering 4 priority themes as of 2023.

Other activities planned in 2023

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 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 and the national audit systems, to enhance official control systems in the Member States and European Free Trade Association (EFTA) countries;
- the Better Training for Safer Food (BTSF) programme, the range of training options and delivery through BTSF ACADEMY will be further developed;
- the management of the lists of third countries' food-producing establishments exporting or wishing to export to the EU;
- the coordination of enforcement actions addressing the Directorate's recommendations from its audits addressed to Member States;
- 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.

Table of Contents

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 safety and certain areas of human health. To this end, it 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 in the following year, as part of the annual Health and food audits and analysis work programme.

This programme presents the priorities for controls in 2021-2025 and the detailed activities planned for 2023.

The Commission has adopted Implementing Decision (EU) 2022/1947[2], which amends Implementing Decision (EU) 2020/1550, updating the multi-annual programme of Commission controls for the period 2021-2025 to be carried out in EU Member States on areas falling within the scope of the Official Control Regulation[3] and by a establishing programme of controls for 2023. The Decision incorporates this programme.

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 safety and public health. It has a specific Directorate that dedicates most of its resources to 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, EU quality standards (the Food domain) and in certain areas of human health protection (the Health domain). It is also responsible for other activities such as the coordination of enforcement in relation to

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[2] OJ L 268, 14.10.2022, p. 31.

[3] OJ L 95, 7.4.2017, p. 1.

Directorate F audit recommendations addressed to EU Member States, 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 on different aspects, based on the outcome of its controls.

The Directorate has a team of some 145 staff originating from most EU Member States and with a wide range of professional experience.

The Directorate produces reports of 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. Audits and other controls

3.1. Objectives and role

Figure 1: Levels of controls of EU safety standards in the Food domain

In the EU, **operators** in the agri-food chain (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 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 third countries exporting food, feed, animals or plants to the EU. The Directorate targets countries according to risks associated with their exports to the EU, such as the volume of exports, non-compliant consignments identified at EU points of

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

entry and the risk associated with the particular type of animal or good. 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 trade restrictive measures include increased checks at EU borders and, as a last resort, suspension of imports. The Commission reviews those measures periodically.

In the **Health domain,** 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 regulatory framework in 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 in the area 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 on a third country as equivalent, or its de-listing.

3.2. Types of controls

The Directorate carries out a range of control activities. Audits and similar controls represent roughly two-thirds of the control activities while the remaining third concerns analyses.

3.2.1. Audits and similar controls

Traditionally, the Directorate carries out audits and similar controls, travelling to the targeted countries. Due to the COVID-19 restrictions, the Directorate adapted its approach and from autumn 2020 performed most of these controls remotely, using the latest developments in video-conferencing. Since then, the Directorate uses a combination of on-the-spot and remote (e.g. video-conference) assessment tools to conduct its audits and similar controls. The methodology to be used for individual controls is decided in consultation with the competent authorities on a case by case basis.

3.2.1.1. Audits

Audits are the most common form of control, in particular in the Food domain. 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. An audit typically involves a team of two auditors and occasionally (if appropriate) a national expert from a Member State. Following the development of audit questionnaires and the analysis of responses received from the competent authorities of the concerned country, 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 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.

3.2.1.2. Joint assessments

Notified bodies in the area of medical devices 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 involve 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.

3.2.1.3. Union controls

In the area of clinical trials on medicinal products for human use, Union controls aim to verify that Member States correctly supervise compliance with the Clinical Trials Regulation. In respect of trials conducted outside the EU, these controls aim to verify that the governing regulatory systems ensure that the applicable requirements are complied with.

3.2.1.4. Joint country visits

Since 2017, the Directorate carries out, jointly with the European Centre for Disease Prevention and Control (ECDC), country visits to EU Member States on AMR in a One Health[6] 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.

3.2.1.5. Joint controls with the European Free Trade Association Surveillance Authority

In 2019, the Directorate-General for Health and Food Safety and the European Free Trade Association (EFTA) Surveillance Authority (ESA) signed an administrative arrangement on cooperation between the two services, which includes active participation in each other's audits. On this basis, the Directorate also carries out joint controls with ESA for the assessment of compliance of border control posts in EFTA States before their designation by their respective competent authorities. These consist in analyses (see section 3.2.2) complemented by on-site controls of the facilities, when necessary.

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[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.

[6] A European One Health Action Plan against Antimicrobial Resistance (AMR) can be found on: https://ec.europa.eu/health/sites/default/files/antimicrobial_resistance/docs/amr_2017_action-plan.pdf

3.2.1.6. Fact-finding studies and missions

In general, fact-finding studies and missions 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 controls 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. Specifically, the Directorate is mandated to perform fact-finding missions in laboratories carrying out testing in support of regulated product submissions to the European Food Safety Authority for risk assessment.

3.2.1.7. Remote assessments

Remote assessments check the official controls carried out by third countries listed to export certain animal-based commodities into the EU market. They typically include animal and/or public health within their scope. The decision to perform remote assessments instead of audits can be based on a number of indicators such as export volumes, performance in previous controls carried out by Commission experts, and the degree of risk posed by the specific commodities for which they are listed to export into the EU market.

3.2.2. Analyses

Analyses are controls based on assessment of documents in order to verify compliance with EU legislation. Most of the analyses performed by the Directorate are specifically required by EU legislation. Examples include the assessment of the floor plans and structure of border control posts in the EU Member States as a prerequisite for their (re-)designation by the competent authorities. Another example is the assessment of residues monitoring plans from Member States and from third countries already listed or requesting approval for the export of animals and animal products to the EU. In the context of the EU One Health Action Plan against antimicrobial resistance, 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. The Directorate has also elaborated product-specific pre-country listing questionnaires for third countries seeking market access to the EU and it assesses the responses to determine whether the country can satisfy the EU import requirements for the commodities in question.

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 an extensive body of EU legislation in the domains of Food 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 for carrying out its controls whilst ensuring that it covers 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 legislation in the areas of food safety and animal and plant health. Audits are a crucial tool for this, notably to ensure that food imported to the EU meets our safety standards.

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

- In the Food domain, the choice of topics and countries covered by the plan reflects Commission 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 Commission political priorities, identified in the Commissioner's mandate letter or in the pharmaceutical strategy, and/or explicit legal requirements for 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 2023 onward confirmed most of the existing priorities and their objectives, identified some new priority themes and a few adjustments necessary as detailed below.

➢ Four new priority themes were added concerning
- Animal welfare of fish, to support the development of EU legislation;
- Animal welfare of cattle kept on farm for beef production, to support the development of specific welfare requirements;
- Animal by-products and derived products in third countries to verify that third countries exporting to the EU meet their certification requirements;
- Plant health survey programmes, to assess the implementation in Member States of legal requirements applying since the end of 2019.

➢ On medical devices, the re-assessments of notified bodies have been postponed until 2024 due to the expected change of the frequency of the re-assessments to a five-year cycle. In addition, peer reviews of designating authorities have been removed from the Directorate's multi-annual plan, as it is unlikely that the Commission will be involved in this activity.

➢ Export controls have been removed from the multi-annual plan. Indeed, recognising the roles and responsibilities of food business operators and Member State competent authorities in this regard, Commission controls on this aspect are no longer considered a priority.

➢ Finally, responsibility for controls on organics will be transferred progressively to Directorate-General for Agriculture and rural development (DG AGRI). As a result, DG SANTE will phase out its involvement entirely on organics and on geographical indications by the end of 2023.

5. Control activities in 2023

The Directorate carries out its controls in accordance with the multi-annual plan. Controls planned in 2023 amount to 288, including 165 audits and similar controls, and 123 analyses (see details in figure 3). In addition to these planned controls, the Directorate will perform other controls which are demand driven (e.g. analyses of border control posts, joint assessments on

medical devices, joint country visits) or depend on fulfilment of certain conditions before a control can be performed (e.g. fact-finding missions to testing facilities, controls on third country listing for export to the EU).

Figure 3 Number of controls planned in 2023 per type
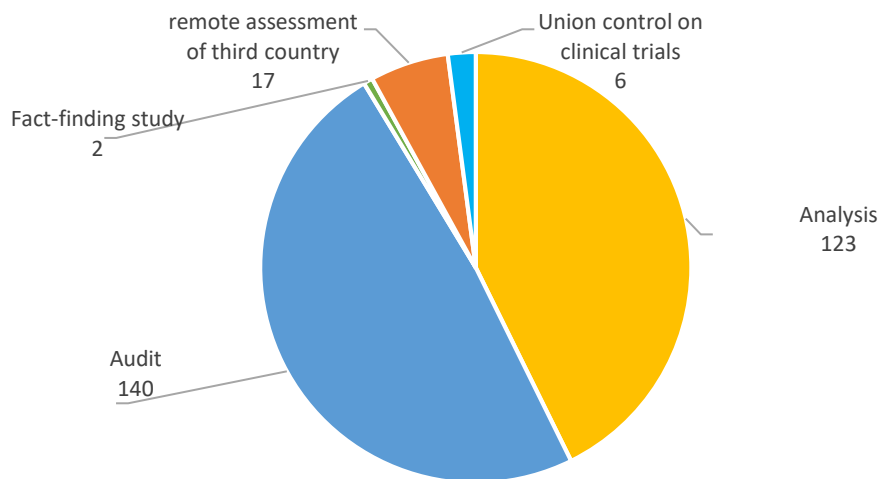
Controls in 2023 cover all policy domains (see figure 4), and address 52 priority themes identified in the multi-annual plan 2021-2025. In the Food domain, the Directorate intends to perform 272 planned controls, including 150 audits and similar controls. These and other "on-demand" controls will address some 43 priority themes. Controls planned on food safety both in Member States and third countries, account for more than half of the planned controls in the Food domain.

Figure 4 Number of controls (all types) in 2023 per policy domain
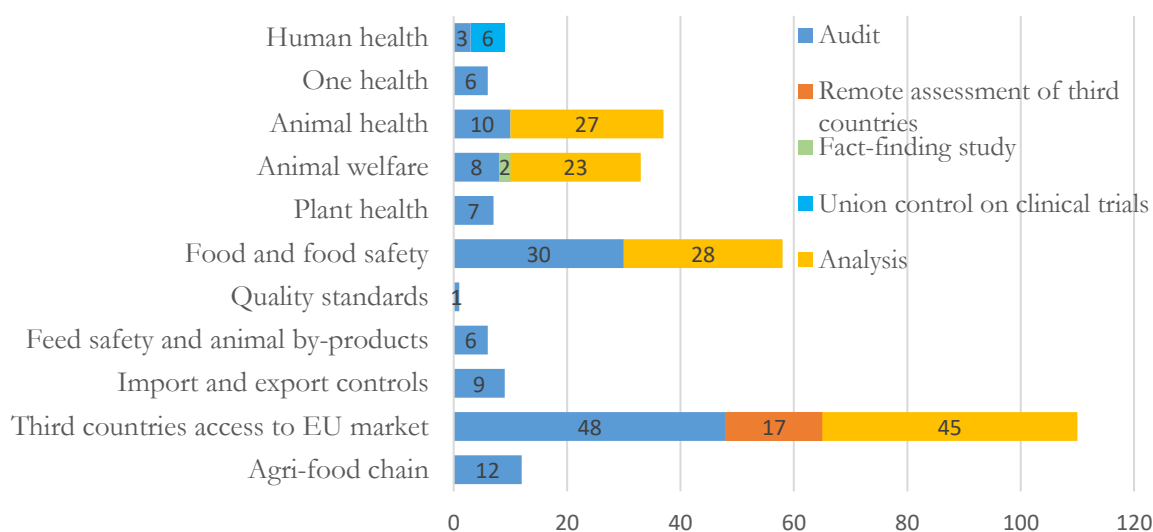
In 2023, the Directorate will commence its work on several priority themes covered by the multi-annual plan. These include:

- On **AMR**, with two additional priorities: i) **AMR monitoring in zoonotic and commensal bacteria** and ii) **veterinary medicinal products**, with an emphasis on the fight against AMR;

- On **animal welfare**, with the **welfare of fish** and the **welfare of cattle** kept for the production of beef;

- **On feed safety, medicated feed** will be addressed as part of the scope of audits on feed hygiene and **animal by-products and derived products will be covered in third countries**.
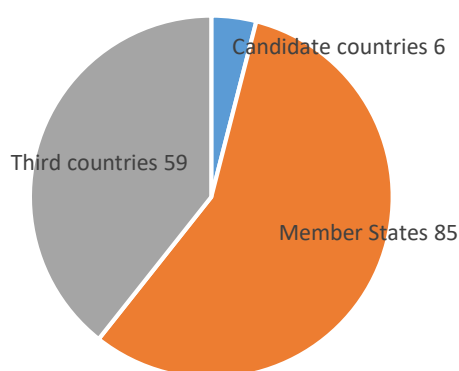
Figure 5: Number of audits and similar controls in the Food domain per country status

Candidate countries 6
Third countries 59
Member States 85

Of the 150 audits and similar controls planned in 2023 in the Food domain, 57% of these are planned in the Member States because most food consumed in the EU is also produced in the EU (see figure 5) and 43% are planned in third countries wishing to export or exporting to the EU.

Control activities in 2023 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 2023 per country. Annex 2 relates to Member States, Annex 3 relates to candidate countries and Annex 4 to third countries.

The Directorate may review the controls planned in 2023 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 2023

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 has 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 2023, the Directorate will notably:

- focus on supporting and facilitating the co-legislator in their 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, meetings with stakeholders as appropriate; and organise Better Training for Safer Food (BTSF) programmes providing training to MS and non-EU competent authority staff s on the implementation of Union legislation;
- disseminate and update information on 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. In 2023, the Directorate will produce a report with an overview and analysis of the data provided.

6.3. Plant health surveys

EU plant health legislation requires Member States to carry out annual surveys for the presence of certain plant pests presenting a significant threat to the EU economy and the environment, and to send the results of these surveys to the Commission. The Directorate collects, analyses and prepares presentations on these 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. Since 2021, Member States started sending reports through a new IT-tool, EUROPHYT-Surveys. The data synopsis and analysis under the new tool is being developed. In 2023 survey analysis for a number of plant pests will be presented, including potato pests and others, which are subject to emergency legislation.

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. Each network regularly meets 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 2023, the networks will continue to monitor the annual reporting on official controls (AROC) raise awareness to the (new) Country Profile Web Portal. They will update the existing reference documents, on "Risk-based planning of official controls", "Verification of effectiveness of official controls", "Risk-based planning for audits of official control systems", "Auditing effectiveness of Official Control systems" and "Independent scrutiny".

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.

6.5. Better Training for Safer Food

Better Training for Safer Food (BTSF) is a European Commission training initiative to improve the knowledge and implementation of EU rules covering food, feed law, animal health and welfare, plant health, and plant protection products. 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 non-EU countries exporting or interested in exporting to the EU.

Since 2021 training has been delivered online, in virtual classrooms and face-to-face, and in 2023 all of them will continue. Since the start of the COVID-19 pandemic, competent authorities have made great use of the existing eLearning modules. These modules are in the process of being

updated and will incorporate automatic translation to all EU official languages. The improved training platform BTSF Academy[7] provides a library of training materials, information on upcoming courses and other resources.

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[8]. 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 is no longer fulfilling the requirements).

The Directorate is responsible for maintaining the lists of food-producing establishments in TRACES. In 2022, the Directorate received 1221 listing requests for additions, modifications or deletions to the lists of food-producing establishments in TRACES. These resulted in 6411 amendments of establishments.

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 are 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[9]. 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.

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[7] https://btsfacademy.eu/training/

[8] The procedure to follow and the updated lists of EU approved establishments can be found here: https://ec.europa.eu/food/safety/biological-safety/food-hygiene/non-eu-countries-authorised-establishments_en

[9] https://ec.europa.eu/food/audits-analysis/country_profiles/index.cfm

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 on different aspects.

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.

Annex 1– Multi-annual plan 2021-2025 and controls planned in 2023

Human health protection				

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
Medical devices	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
	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.	Re-assessments due to resume in 2024, in line with the expected change of frequency to a five-year cycle
	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 re-assessment), 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 2023
Pharmaceuticals for human 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	4 Union controls, countries to be determined
	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	2 Union controls, countries to be determined
	Active pharmaceutical ingredients & Mutual recognition agreements	Third countries	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. ➢ In up to 3 third countries per year	3 audits, countries to be determined

One Health

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
Antimicrobial resistance	One-Health country visits	Member States	To assist Member States in further developing and implementing their national strategies and policies against antimicrobial resistance based on a One Health perspective. Country visits are performed jointly with the ECDC, in Member States requesting a visit. ➢ In a maximum of 4 Member States requesting a visit per year	Number of country visits depending on requests.
	Review of National action plans	Member States	To review Member States' AMR One Health National Action Plans. ➢ In all Member States in 2021 and 2022	Completed
	AMR monitoring (zoonotic and commensal bacteria)	Member States	To verify Member States' compliance with the legislation governing the monitoring of antimicrobial resistance in zoonotic and commensal bacteria and by this contributing to the full implementation of the 2017 European One Health Action Plan against antimicrobial resistance. ➢ In a sample of Member States in 2023 and 2024	4 audits: Croatia, Ireland, Malta and Portugal
	Veterinary medicinal products	Member States	To verify the appropriateness of the controls carried out by the competent authorities in relation to veterinary medicinal products, targeting those aspects of the Regulation (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	2 audits: Denmark and Poland

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
SUD	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.	
Non-foodborne zoonoses	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.	Completed

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Animal health

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Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
Category A diseases under Animal 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.	5 audits: Italy, Germany, Lithuania, Romania and Slovakia
	Highly pathogenic avian influenza	Member States	To verify Member States' compliance with the applicable EU legislation governing the control of highly pathogenic avian influenza and the implementation of official controls thereon. ➢ In Member States with difficulties to control the disease.	3 audits: Hungary, Netherlands and 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
Category 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.	2 audits: Denmark and Germany

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
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	27 analyses of specific procedures in Member States' contingency plans

Animal welfare

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
On-farm	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.	Completed
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	4 audits: Belgium, France, Ireland and Germany 23 questionnaires
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 research, questionnaires, exchange of views with Member States, fact finding studies and 'technical visits'.	2 fact-finding studies: Denmark and Germany

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
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.	
Transport and Slaughter	Sectoral 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. ➢ In Member States where appropriate, for example where important or recurring problems have been identified by previous controls.	1 audit: Greece
Transport	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.	3 audits: France, Netherlands and Poland
	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.	Completed

Plant health

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
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 (*Xylella fastidiosa*, Tomato brown rugose fruit virus (ToBRFV), pinewood nematode, *Anoplophora* long-horn beetles) and other priority pests such as *Trioza*, the vector of Citrus greening disease.	3 audits: Germany (longhorn beetles), Poland (potato quarantine pests) and another Member State (to be determined)
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; starting at the latest in 2024.	
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: Austria, Czech Republic, Denmark, and Greece

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
Preparedness 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. ➢ In 15 Member States starting at the latest in 2024, with the aim to carry out at least one plant health audit in each Member State in 2021-2025.	
	Plant health survey programmes	Member States	To assess the planning and implementation of survey programmes for quarantine and priority pests under plant health law ➢ In 15 Member States starting at the latest in 2024, with the aim to carry out at least one plant health audit in each Member State in 2021-2025. ➢ To be carried out together with audits on plant health contingency plans (see above).	

Food and food safety

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
Food of animal origin	Chemical safety - Residues	Member States	To verify that residues monitoring plans submitted by all Member States comply with the requirements laid down in the relevant EU legislation. ➤ All Member States' and Northern Ireland's monitoring plans every year.	28 analyses (assessments of residue monitoring plans)
		Member States	To verify Member States' compliance with the applicable EU legislation governing residues of veterinary medicinal products, pesticides and contaminants in live animals and food of animal origin. ➤ In 80% of Member States risk-based selected.	5 audits: Belgium, Croatia, Greece, Poland 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: Ireland, Latvia, Lithuania, Spain and Sweden
	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. ➤ In the majority of Member States.	5 audits: Bulgaria, Estonia, Hungary, Luxembourg, and Romania
	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: Austria, Germany, Greece and Slovakia

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
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.	2 audits: Bulgaria and Romania
Foodborne zoonoses	*Salmonella*	Member States	To verify Member States' compliance with the applicable EU legislation governing the control of *Salmonella*, 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) *Salmonella* 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.	1 audit: Netherlands
	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, 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: Czech Republic, France, Ireland and Italy
	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: Germany, Greece, Portugal and Slovakia

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
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 2023
Feed safety	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	3 audits: Austria, Estonia and Lithuania
	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)	3 audits: Czech Republic, Malta and Slovakia
	Medicated feed	Member States	To verify Member States' compliance with the new EU requirements governing the production of medicated feeding stuffs, 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.

			Quality standards		
Policy area	**Priority theme**	**Country status/ entity**	**Objectives 2021-2025**		**Controls 2023**
Food quality standard	Organic	Member States	To verify the Member States' compliance with the applicable EU legislation governing the production and labelling of organic produce, and the implementation of official controls thereon. ➢ From 2023, DG AGRI will take over the responsibility for Commission Controls in Member States.		
	Geographical Indications	Member States	To verify the Member States' compliance with the applicable EU legislation governing the production and labelling of geographical indications, and the implementation of official controls thereon. ➢ DG SANTE will phase out its involvement entirely on geographical indications by the end of 2023.		1 audit: Czech Republic

Import and export controls				

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
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. ➢ In all border control posts before designation (demand based).	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. ➢ All Member States on a 4-year control cycle.	7 audits: Croatia, Estonia, Lithuania, Slovenia, Sweden, Portugal and Romania

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
Plants, plant products and other objects entering the Union	Official plant health import controls	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.	2 audits: Italy and Spain

Third countries access to EU market

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
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.	<u>**Listing requests:**</u> 1 audit: Korea (fresh poultry meat). Other audits depending on listing requests. <u>**Listed countries:**</u> 5 audits on animal health to listed third countries: Brazil (highly pathogenic influenza), Botswana (foot and mouth disease), Canada (highly pathogenic influenza), Japan (highly pathogenic influenza, classical swine fever) and United States (highly pathogenic influenza). 4 remote assessments: Colombia, Israel, Türkiye and United Arab Emirates

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
Food of animal origin	Chemical safety - Residues	Third /candidate countries	To verify that third countries' residue monitoring plans covering residues of veterinary medicinal products, pesticides and contaminants in animals and food of animal origin, offer guarantees with an effect at least equivalent to that foreseen in the relevant EU legislation allowing for country listing in Decision 2011/163/EU. ➢ All third countries' residue monitoring plans on a 5-year cycle.	45 analyses (assessment of residue monitoring plans)
		Third /candidate countries	To verify that third countries meet the requirements for their listing in Decision 2011/163/EU in respect of the provision of guarantees with an effect equivalent to that foreseen in the EU legislation governing residues of veterinary medicinal products, pesticides and contaminants in live animals and food of animal origin. ➢ 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.	7 audits: Albania, Chile, China, Colombia, Great Britain, North Macedonia and Serbia
	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.	7 audits: Argentina (poultry meat and game), Bosnia Herzegovina (milk and dairy products), Japan (beef and porcine meat), Chile (beef, ovine and porcine meat), Mexico (beef), Türkiye (milk and dairy products) and Brazil (poultry). 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 2023
Food of animal origin	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 egg products: Albania, Mexico and North Macedonia
	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: Bangladesh, Canada, Greenland, Thailand and Vietnam 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 2023
Food of animal origin	Production hygiene of live bivalve molluscs	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.	2 audits: Jamaica and South Africa (listing request)
	Official controls in establishments	Third /candidate countries	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 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.	Completed
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.	4 audits: Georgia, India, Iran and Türkiye

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
Food of non-animal origin	Microbiological 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. ➢ 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.	2 audits: Brazil and Morocco
	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 ➢ In up to 4 - 8 third countries selected based on audit history and risk-based criteria, starting in 2022.	1 audit: China
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: Argentina, India and Thailand
Quality standards	Organic farming	Third countries/ control bodies in third countries	To verify that the control system in place for certifying export of organic products to the EU ensures that the products comply with EU requirements or with requirements recognised to be at least equivalent thereto. ➢ In control bodies operating in third countries or third countries with an equivalency status or requesting it, depending on availability of resources. In 2023, the audits will be carried out jointly between DG SANTE and DG AGRI. From 2024 onwards, they will be performed by DG AGRI.	6 audits, countries to be determined

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
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.	5 audits: Argentina (Citrus), Brazil (Citrus), China (Plants and plant products), Israel (Plants and plant products) and Ivory Coast (Mango)

Accession countries

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
Animal health	Official animal health controls	Candidate country	To verify the compliance of the official framework for animal health controls for accession into the EU ➢ In candidate countries	

Agri-food chain				
Policy area	**Priority theme**	**Country status/ entity**	**Objectives 2021-2025**	**Controls 2023**
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. 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. ➢ Audits will be carried out in the period 2021-2025, as necessary.	Number, objective and scope of potential further controls including audits, to be determined
	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.	1 audit on Chemical safety - Residues Number, objective and scope of controls including audits, to be determined
	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.	11 audits: Belgium, Bulgaria, Croatia, Greece, Hungary, Italy, Latvia, Luxembourg, Poland, Romania and Slovakia
	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

Policy area	Priority theme	Country status/ entity	Objectives 2021-2025	Controls 2023
Agri-food chain	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
	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.	Completed
	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)
	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: Portugal

Annex 2 – Audits and similar controls in Member States planned in 2023

Country name	Priority theme	Control type
Belgique/België (Belgium)	Animal welfare - on-farm - cattle for beef production	Audit
	Residues in live animals and food of animal origin	Audit
	General follow-up	Audit
България (Bulgaria)	Safety of meat of mammals and birds and products thereof	Audit
	Production hygiene of live bivalve molluscs	Audit
	General follow-up	Audit
Česká republika (Czech Republic)	Movement of plants within the Union - plant passports	Audit
	Authorisation, marketing and use of plant protection products and pesticides residues	Audit
	Geographical indications (wine)	Audit
	Feed hygiene	Audit
Danmark (Denmark)	AMR - Veterinary Medicinal Products	Audit
	Aquatic animal health	Audit
	Animal welfare - on-farm, slaughter and transport - fish	Fact-finding study
	Movement of plants within the Union - plant passports	Audit
Deutschland (Germany)	African swine fever	Audit
	Aquatic animal health	Audit
	Animal welfare – on-farm - cattle for beef production	Audit
	Animal welfare - on-farm, slaughter and transport - fish	Fact-finding study
	Plant pest outbreak – official control measures (Long-horn beetles)	Audit
	Safety of milk and dairy products	Audit
	Microbiological safety of food of non-animal origin	Audit
Eesti (Estonia)	Safety of meat of mammals and birds and products thereof	Audit
	Animal by-products and derived products	Audit
	Official import controls of animals and goods entering the EU	Audit
Éire/Ireland	AMR monitoring (zoonotic and commensal bacteria)	Audit
	Animal welfare - on-farm - cattle for beef production	Audit
	Safety of fish products	Audit
	Authorisation, marketing and use of plant protection products and pesticides residues	Audit

Country name	Priority theme	Control type
Ελλάδα (Greece)	Animal welfare – transport and slaughter	Remote assessment
	Movement of plants within the Union - plant passports	Audit
	Residues in live animals and food of animal origin	Audit
	Safety of milk and dairy products	Audit
	Microbiological safety of food of non-animal origin	Audit
	General Follow-up	Audit
España (Spain)	Highly pathogenic avian influenza	Audit
	Safety of fishery products	Audit
	Official plant health import controls	Audit
France	Animal welfare - on-farm - cattle for beef production	Audit
	Animal welfare – transport (control posts)	Audit
	Authorisation, marketing and use of plant protection products and pesticides residues	Audit
Hrvatska (Croatia)	AMR monitoring (zoonotic and commensal bacteria)	Audit
	Residues in live animals and food of animal origin	Audit
	Official import controls of animals and goods entering the EU	Audit
	General follow-up	Audit
Italia (Italy)	African swine fever	Audit
	Authorisation, marketing and use of plant protection products and pesticides residues	Audit
	Official plant health import controls	Audit
	General follow-up	Audit
Latvija (Latvia)	Safety of fishery products	Audit
	General follow-up	Audit
Lietuva (Lithuania)	African swine fever	Audit
	Safety of fishery products	Audit
	Animal by-products and derived products	Audit
	Official import controls of animals and goods entering the EU	Audit

Country name	Priority theme	Control type
Luxembourg	Safety of meat of mammals and birds and products thereof	Audit
	General follow-up	Audit
Magyarország (Hungary)	Highly pathogenic avian influenza	Audit
	Safety of meat of mammals and birds and products thereof	Audit
	General follow-up	Audit
Malta	AMR monitoring (zoonotic and commensal bacteria)	Audit
	Feed hygiene	Audit
Nederland (Netherlands)	Highly pathogenic avian influenza	Audit
	Animal welfare – transport (control posts)	Audit
	Contaminants in food of non-animal origin	Audit
Österreich (Austria)	Movement of plants within the Union - plant passports	Audit
	Safety of milk and dairy products	Audit
	Animal by-products and derived products	Audit
Polska (Poland)	AMR - Veterinary Medicinal Products	Audit
	Animal welfare – transport (control posts)	Audit
	Plant pest outbreak – official control measures (Potato quarantine pests)	Audit
	Residues in live animals and food of animal origin	Audit
	General follow-up	Audit
Portugal	AMR monitoring (zoonotic and commensal bacteria)	Audit
	Microbiological safety of food of non-animal origin	Audit
	Official import controls of animals and goods entering the EU	Audit
	Genetically modified organisms - authorisation, marketing, traceability and marketing	Audit
România (Romania)	African swine fever	Audit
	Safety of meat of mammals and birds and products thereof	Audit
	Production hygiene of live bivalve molluscs	Audit
	Official import controls of animals and goods entering the EU	Audit
	General follow-up	Audit
Slovenija (Slovenia)	Official import controls of animals and goods entering the EU	Audit

Country name	Priority theme	Control type
Slovensko (Slovakia)	African swine fever	Audit
	Safety of milk and dairy products	Audit
	Microbiological safety of food of non-animal origin	Audit
	Feed hygiene	Audit
	General follow-up	Audit
Sverige (Sweden)	Residues in live animals and food of animal origin	Audit
	Safety of fishery products	Audit
	Official import controls of animals and goods entering the EU	Audit

Annex 3 – Controls in candidate countries planned in 2023

Country name	Priority theme	Control type
Shqipëria (Albania)	Residues in live animals and food of animal origin	Audit
Северна Македонија (North Macedonia)	Residues in live animals and food of animal origin	Audit
Србија (Serbia)	Residues in live animals and food of animal origin	Audit
Türkiye	Animal health in countries requesting to be listed/listed	Remote assessment
	Safety of milk and dairy products	Audit
	Contaminants in food of non-animal origin	Audit

Annex 4 – Controls in third countries planned in 2023

Country name	Priority theme	Control type
AR - Argentina	Safety of products of mammals and birds for human consumption (Poultry meat and game)	Audit
	Animal by-products and derived products	Audit
	Phytosanitary conditions for export to the EU (Citrus)	Audit
BD - Bangladesh	Safety of fishery products	Audit
BA - Bosnia and Herzegovina	Safety of milk and dairy products	Audit
Botswana	Animal health in countries requesting to be listed/listed (Beef)	Audit
BR - Brazil	Animal health in countries requesting to be listed/listed (poultry)	Audit
	Microbiological safety of food of non-animal origin	Audit
	Phytosanitary conditions for export to the EU (Citrus)	Audit
CA - Canada	Animal health in countries requesting to be listed/listed (poultry meat, eggs and products thereof)	Audit
	Safety of fishery products	Audit
CL - Chile	Residues in live animals and food of animal origin	Audit
	Safety of products of mammals and birds for human consumption (Beef, ovine and porcine meat)	Audit
CN - China	Residues in live animals and food of animal origin	Audit
	Phytosanitary conditions for export to the EU (Plant and plant products)	Audit
	Pesticides residues in food of non-animal origin	Audit
CO - Colombia	Animal health in countries requesting to be listed/listed (dairy)	Remote assessment
	Residues in live animals and food of animal origin	Audit
GE - Georgia	Contaminants in food of non-animal origin	Audit
GL - Greenland	Safety of fishery products	Audit
IL - Israel	Animal health in countries requesting to be listed/listed (dairy)	Remote assessment
	Phytosanitary conditions for export to the EU (plants and plant products)	Audit
IN - India	Contaminants in food of non-animal origin	Audit
	Animal by-products and derived products	Audit
IR - Iran	Contaminants in food of non-animal origin	Audit
CI - Ivory Coast	Phytosanitary conditions for export to the EU (mango)	Audit

Country name	Priority theme	Control type
JM - Jamaica	Production hygiene of live bivalve molluscs	Audit
JP - Japan	Animal health in countries requesting to be listed/listed (highly pathogenic influenza, classical swine fever)	Audit
	Safety of products of mammals and birds for human consumption (Beef and porcine meat)	Audit
KR - Korea	Animal health in countries requesting to be listed/listed (Poultry meat)	Audit
MA - Morocco	Microbiological safety of food of non-animal origin	Audit
MX - Mexico	Safety of products of mammals and birds for human consumption (Beef)	Audit
TH - Thailand	Safety of fishery products	Audit
	Animal by-products and derived products	Audit
UA – United Arab Emirates	Animal health in countries requesting to be listed/listed (Dairy)	Remote assessment
UK – United Kingdom in respect of Great Britain	Residues in live animals and food of animal origin	Audit
US - United States	Animal health in countries requesting to be listed/listed (poultry meat, eggs and products thereof)	Audit
VN - Vietnam	Safety of fishery products	Audit
ZA - South Africa	Animal health in countries requesting to be listed/listed (live bivalve molluscs)	Audit

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