

DG Health and Food Safety

> Health and food audits and analysis programme 2022

Health and <u>Food Sa</u>fety

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

This document, the Health and food audits and analysis work programme 2022, presents the Directorate and its controls, priorities for controls in 2021-2025 and the detailed activities planned for 2022.

Multi-annual plan 2021-2025

The Directorate has a very broad control universe due to both an extensive body of EU legislation in the Food and Health domains, and the high number of countries involved. Therefore, the Directorate has to prioritise and plan carefully to ensure it 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. The multi-annual plan 2021-2025 results from this process. It establishes the selected priority themes and, for each of these, the objectives of controls, including the country coverage for the five-year period.

Control activities in 2022

In 2022, the Directorate plans to perform 281 controls. From those, 172 are audits and similar controls (joint assessments, joint country visits, remote assessments, Union controls and fact-finding missions and studies), and 109 are analyses (office-based controls). In addition, the Directorate will perform other controls, for which numbers cannot be estimated, as they are demand-based or depend on fulfilment of certain conditions before a control can be performed. Control activities in 2022 cover around three-quarters of the priority themes identified in the multiannual plan 2021-2025.

Controls in the Food domain

Controls in the Food domain account for the majority of controls planned in 2022. These will address a number of priority themes from the multi-annual plan and in particular:

- food and feed safety: More than half of the controls in the Food domain will cover food safety issues, targeted in the light of identified risks. Controls on feed safety will also continue;
- animal diseases and plant pests with a high impact on or representing a significant threat to the EU economy and the health of EU citizens and the environment;

- **sustainability of the agri-food chain** with the sustainable use of pesticides and animal welfare in the context of the Farm to Fork Strategy. Controls on animal welfare in livestock vessels and at control posts will start in 2022;
- third country listing and market access as well as third countries' compliance with EU requirements for the export of food, feed, animals and plants to the EU; and
- fact-finding missions to assess **laboratories and testing facilities'** adherence to the applicable standards for carrying out tests and studies submitted to the European Food Safety Authority for risk assessment of regulated products.

Controls in the Health domain

Controls in the Health domain will cover a number of areas such as medical devices (including re-assessments of notified bodies starting in 2022), clinical trials for human medicines, active pharmaceutical ingredients for human use and antimicrobial resistance. The Directorate will also continue working on a newly introduced series of desk-based reviews of Member States' "AMR One Health National Action Plans", initiated in 2021.

The annexes to this document include priorities for 2021-2025 and the detailed work programme for 2022.

Other activities planned in 2022

The Directorate will continue working on the other non-control activities. In particular on:

- the **sustainable use of pesticides**, the adoption of a legislative proposal to revise the sustainable use of pesticides directive based on the outcome of the evaluation and impact assessment carried out in 2021. Work will also continue on the European harmonised risk indicators and integrated pest management. This work will contribute to progress towards the reduction in use and risk of chemical pesticides in line with the Green Deal and objectives of the Farm to Fork Strategy;
- **networking** activities with Member States' competent authorities with respect to the **multi-annual national control plans** and the **national audit systems**;
- the **Better Training for Safer Food** (BTSF) programme, the range of training options and delivery through virtual classes will be further developed;
- the development and operation of the European Commission's rapid alert and notification system for plant pest EUROPHYT-Outbreaks and analyses of plant health surveys carried out by Member States;
- the management of the lists of **third countries' food-producing establishments** exporting or wishing to export to EU;
- the coordination of **enforcement actions** addressing the Directorate's recommendations from its audits and similar controls addressed to Member States;
- the assessment of National Strategic Plans (NSPs) for the new Common Agricultural Policy (CAP); and

• the input into the review or development of legislation in different areas or sectors (e.g. the support in the revision of the legislation on food contact materials).

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

Table of Contents

| 1. | Intro | duction | |
|------|----------|--------------------------------------------------------------------|----|
| 2. | Prese | ntation of the Directorate for Health and food audits and analysis | 5 |
| 3. | Audit | s and controls | |
| 3.1 | • | Objectives and role | 6 |
| 3.2 | 2. | Types of controls | 7 |
| | 3.2.1. | Audits and similar controls | 7 |
| | 3.2.2. | Analyses | 9 |
| 4. | Multi | -annual plan 2021-2025 | 9 |
| 5. | Cont | ol activities in 2022 | |
| 6. | Othe | r activities planned in 2022 | |
| 6.1 | • | Sustainable use of pesticides | |
| 6.2 | | EUROPHYT-Outbreaks | |
| 6.3 | . | Plant health surveys | 14 |
| 6.4 | | Member State networks | |
| 6.5 | | Better Training for Safer Food | |
| 6.6 | | Third country establishment listing | |
| 6.7 | | Enforcement | |
| 6.8 | 5. | Other activities | |
| 7. | Furth | er information | |
| Anne | x 1— I | Multi-annual plan 2021-2025 and controls planned in 2022 | |
| Hu | ıman | health protection | |
| Or | ne He | alth | |
| An | imal | health | |
| An | imal | welfare | |
| Pla | ınt he | alth | |
| Fo | od an | d food safety | |
| Fee | ed saf | ety and animal by-products | |
| Qu | ality | standards | |
| Im | port a | and export controls | |
| Th | ird co | puntries access to EU market | |
| Ac | cessio | on countries | |
| Ag | ri-foc | d chain | |
| Anne | x 2 – | Audits and similar controls in Member States planned in 2022 | |
| Anne | x 3 – | Controls in candidate countries planned in 2022 | |
| Anne | x 4 – | Controls in third countries planned in 2022 | |

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 2022.

The Commission has adopted an implementing decision¹ establishing a 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 regulation². The multi-annual plan, set out in this publication, 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 important activities such as the coordination of enforcement in relation to Directorate F audit recommendations addressed to EU Member States, development of policy

¹ OJ L 354, 26.10.2020, p. 9.

² OJ L 95, 7.4.2017, p. 1.

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. In 2022, the Directorate will also continue to work on the assessment of National Strategic Plans for the new Common Agricultural Policy (CAP).

The Directorate has a team of some 160 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 website³. The Directorate also publishes overview reports and analyses.

3.Audits and 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 (e.g. inspections). 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

³ <u>https://ec.europa.eu/food/audits-analysis/audit_reports/index.cfm</u>

entry and the risk associated with the type of animal or product. 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. 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 since autumn 2020 has performed most of these controls remotely, using the latest developments in video-conferencing. In 2022, depending on the evolution of the COVID-19 pandemic, the Directorate will use 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 will be decided in consultation with the competent authorities nearer the time of the audit or similar control.

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 the 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 marking⁴. Since 2017, the designation and re-assessment of these notified bodies involve joint assessment teams, composed of experts from the Commission and 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 antimicrobial resistance in a One Health⁵ 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 antimicrobial resistance.

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

⁴ 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.

⁵ 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>

competent authorities. These consist in analyses (see section 3.2.2) complemented by on-site controls of the facilities, when necessary.

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 or guidance to assist Member States, the preparation of subsequent audits, or into the review or development of legislation. Specifically, the Commission 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 examples 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 is reviewing 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). These sections are further broken down

into specific areas within each section (white circles), showing the cross-sector control activities (dark circles).

Therefore, 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.

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

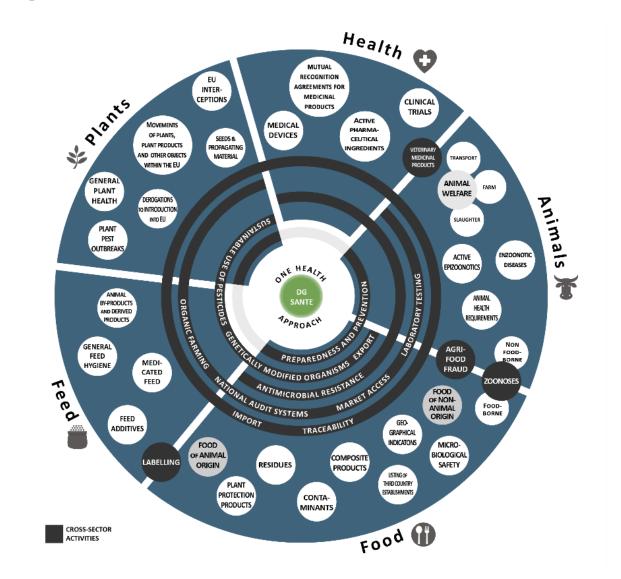
- In the Food domain, the choice of topics and countries covered by the plan takes into account legal requirements, food safety and health risks (associated with products, their origin, production or trade volumes, evidence of non-compliance, and the outcome of past audit activities) and policy considerations.
- 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. As a result of its annual revision, the following adjustments have been introduced:

- New priority theme on review of Member States' AMR One Health National Action Plans under One Health domain was added;
- New genomic techniques were included in the scope of the genetically modified organisms' policy area;
- Review of corrective and preventive (CAPA) plans, in the policy area of medical devices, has now been included in the table as a separate entry; and
- eHealth audits have been removed from the Directorate's multi-annual plan, as the lead for this work has been taken over by another Directorate within Directorate-General for Health and Food Safety.

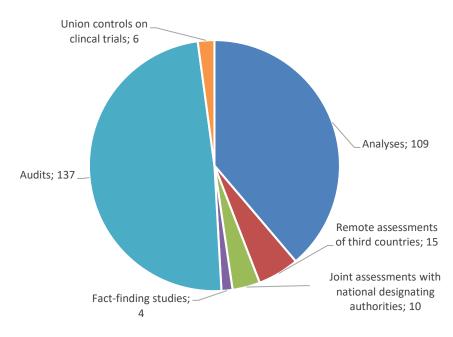
Figure 2: Control universe



5.Control activities in 2022

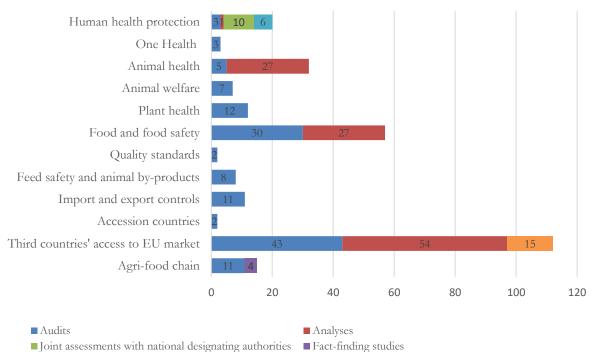
The Directorate carries out its controls in accordance with the multi-annual plan. Controls planned in 2022 amount to 281 in total, which includes 172 audits and similar controls, and at least 109 analyses (see details in figure 3). In addition to these planned controls, the Directorate will perform other controls which are **demand driven** (e.g. analyses of border control posts, joint assessments on medical devices) 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 or estimated in 2022 per type



Controls in 2022 cover all policy domains in the control universe (see figure 4), and address three quarters of the priority themes identified in the multi-annual plan 2021-2025. In the Food domain, which represents 92% of all controls and most of the audits planned, overall more than half of the controls focus on food safety (in figure 4, these are labelled "food and food safety" and they account for 80% of controls on "third countries' access to EU market").

Figure 4 Number of controls (all types) per policy domain



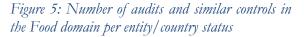
Union control on clinical trials

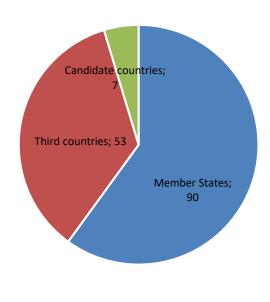
Remote assessments of third countries

In 2022, the Directorate will commence its work on several priority themes covered by the multiannual plan. These include:

- animal welfare of calves in control posts during intra-EU transport,
- animal welfare of animals in livestock vessels;
- plant passports used during movement of plants, plant products and other objects within the EU;
- re-assessments of notified bodies in the area of medical devices; and
- Union controls on clinical trials.

Of the 172 audits and similar controls planned in 2022, 150 concern the Food domain. As shown in figure 5, roughly two-thirds of these are planned in the Member States because most food consumed in the EU is also produced in the EU. Nonetheless, a significant number of audits are planned in third countries wishing to export or exporting to the EU.





The Directorate may review the controls planned in 2022 (as detailed in the Annexes to this document) 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 the absence of a timely reply to pre-audit questionnaires or security issues).

• Annex 1 provides all controls planned in 2022 along with their objectives by policy domain and area. For certain controls, and in particular analyses, countries have not been identified yet.

• Annexes 2 to 4 list the controls planned in 2022 per country. Annex 2 relates to Member States, Annex 3 relates to candidate countries and Annex 4 to third countries.

6. Other activities planned in 2022

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 Strategy⁶ 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 2022, the Directorate will notably:

- focus on the adoption by the Commission of the legislative proposal to revise the SUD based on the outcome of the evaluation and impact assessment;
- 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; and organise Better Training for Safer Food (BTSF) programmes providing training to MS experts on the implementation of the legislation;
- disseminate information on SUD via the European Commission webpage;
- proceed with the development of a Commission legislative proposal to modify one of the two harmonised risk indicators as part of the legislative proposal to revise the SUD;
- support Member States to develop agreed criteria, which could be used to verify compliance with the principles of integrated pest management at farm level.

6.2. EUROPHYT-Outbreaks

EUROPHYT-Outbreaks is the European rapid alert system for the notification by Member States of plant pest outbreaks. The Directorate develops 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 2022, the Directorate will produce a report on the system and its data.

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

⁶ <u>https://ec.europa.eu/food/farm2fork_en</u>

2022 survey analysis for a number of plant pests will be presented, including potato pests and others, which are subject to emergency legislation (e.g. *Xylella fastidiosa*, *Bursaphelenchus xylophilus* and *Anoplophora* spp.).

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 2022, the networks will monitor the annual reporting on official controls (AROC), including the development of new analytical tools for the AROC data. They will take part in the development of a new outline for the Commission's Annual Report, a new country profile web portal and a new template for the control systems description in the country profile. 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. External contractors deliver the training in the EU and in non-EU countries exporting to the EU.

Since 2021 training has been delivered in virtual classrooms. Training in 2022 will take place either in virtual classrooms or face-to-face, should the epidemiological conditions permit. Since the start of the COVID-19 pandemic, competent authorities have made great use of the existing eLearning modules. These modules will be updated and translated and further modules added to broaden the range and accessibility of training options in 2022.

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 establishments⁷. 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). Currently, this Directorate is responsible for maintaining the lists of food-producing establishments in TRACES. In 2020, the Directorate received 504 requests for additions, modifications or deletions to the list of food-producing establishments in TRACES. This resulted in 3285 amendments of establishments eligible for export to the EU. In 2021, it is estimated that the Directorate will received roughly 600 listing requests, which will result in approximately 4000 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 State⁸. 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

In 2022, the Directorate will continue to work closely with Directorate-General for Agriculture and Rural Development (DG AGRI) on the assessment of National Strategic Plans (NSPs) for the new Common Agricultural Policy (CAP)⁹ in relation to pesticides, antimicrobial resistance, animal welfare, biosecurity, sustainable diet and food waste. Member States are required to submit their proposed CAP National Strategic Plans by 1 January 2022.

The Directorate will also 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

⁷ 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>

⁸ https://ec.europa.eu/food/audits-analysis/country_profiles/index.cfm

⁹ https://ec.europa.eu/info/food-farming-fisheries/key-policies/common-agricultural-policy/new-cap-2023-27 en

their controls, into the review or development of legislation on different aspects. For instance, in 2022, the Directorate will support the revision of the legislation on food contact materials.

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 2022

Human health protection

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|-----------------|-----------------------------------------------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------|
| | 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. | 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, 3 years after the notification of designation, starting in 2022 | 10 re-assessments (initiated with an on-site assessment) |
| 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. | Number of scope extensions (initiated with an on-site assessment) depending on requests |
| | Review of corrective and preventive (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. This is the most resource consuming part of the assessment process, of which it is an integral part. In applicant notified bodies, and in notified bodies already designated as part of their re-assessment or in the context of their scope extension, based on demand. | Number of CAPA plans reviewed depending on requests. |

| Medical devices | Peer reviews | Member States | To support exchange of experience and coordination of administrative practice between the designating authorities. In all designated authorities, over a rolling three-year cycle, starting in 2023. | |
|---------------------------|----------------------------------------------------------------------------------|-----------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| an 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 |
| Pharmaceuticals 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 | 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. | - |

One Health

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|--------------------------|-------------------------------------------------|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------|
| istance | 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. |
| Antimicrobial resistance | Review of National action plans | Member States | To review Member States' AMR One Health National Action Plans. In all Member States, starting in September 2021 | Analyses (desk-based reviews) |
| Antimi | AMR monitoring (zoonotic and commensal | 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. | |
| | bacteria) | | ➢ In a sample of Member States in 2023 and 2024 | |
| 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. | 2 audits: Bulgaria and Romania |
| | | | In 4 - 8 Member States selected based on audit history and risk based criteria | |

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|---------------------------|----------------|---------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------|
| 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. | 1 audit: Poland |

| Animal health |
|---------------|
| |

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|----------------------------------|-----------------------------------------|---------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------|
| A diseases under I 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. | 2 audits: Hungary 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 highly pathogenic avian influenza and the implementation of official controls thereon. In Member States with difficulties to control the disease. | 3 audits: France, Germany and Sweden |

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|---------------------------------------------------------|-----------------------------------------------------------|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------|
| 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. | |
| Category B and C diseases under Animal Health Law | Tuberculosis, Brucellosis | 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. | |
| Pharmaceuticals for veterinary use | Control systems of veterinary medicinal products | Member States | To verify the appropriateness of the controls carried out by the competent authorities in relation to veterinary medicinal products In the Member States, starting in 2023 at the earliest. | |
| 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 2022 |
|----------------|-----------------------|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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. | Controls carried out in 2021, overview report to be published in 2022 |
| 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. | |
| Ę | 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: Ireland, Italy and Spain |
| 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. | 4 audits: Croatia, Portugal, Romania and Spain Analyses of information (authorisation of transporters and completeness of journey logs), in Member States involved in this type of trade |

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|----------------|----------------|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| Transport | 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 2022 |
|--------------------------------------------|---------------------------------------------------|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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 ▶ 6 - 8 controls per year in response to outbreaks of plant pests subject to emergency measures (<i>Xylella fastidiosa</i>, Tomato brown rugose fruit virus (ToBRFV), pinewood nematode, <i>Anoplophora</i> long-horn beetles) and other priority pests such as <i>Trioza</i>, the vector of Citrus greening disease. | 7 audits: Belgium (Tomato Brown Rugose Fruit Virus),Croatia (<i>Anoplophora</i> longhorn beetles), France (<i>Anoplophora</i> longhorn beetles, <i>Xylella fastidiosa</i>), Italy (<i>Xylella</i> <i>fastidiosa</i>), Poland (potato ring rot) and Portugal (<i>Xylella</i> <i>fastidiosa</i>) |
| 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. | |

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|----------------------------------------|----------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------|
| 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 | 5 audits: Austria, Hungary, Ireland, Netherlands and Romania |
| 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. | |

Food and food safety

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|--------------------|-------------------------------------------------------------------|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------------------------------------------------------------------------|
| nal 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) |
| Food of animal | | 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. | 7 audits: Finland, Hungary, Latvia, Lithuania, Romania, Slovenia and Spain |
| l of animal origin | 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: Belgium, Czech Republic, Finland, Greece and the Netherlands |
| | 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. | 8 audits: Austria, Croatia, Denmark, Finland, France, Latvia, Portugal and Slovakia |
| Food of | 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 | 3 audits: Italy, Spain and Sweden |

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|----------------------------------|---------------------------------------------------------------------------|----------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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. In 1 Member State per year; Member State with an EU approved (and co-financed) <i>Salmonella</i> national control programme per year. | 1 control: Germany |
| Food of non- animal origin | Chemical safety - Contaminants | Member States | To verify, based on Member States' multi-annual national control plans and reports thereon, 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. | Analyses (questionnaires) (continuation from 2021) 1 audit (country to be determined) |
| mal origin | 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. | 3 audits: Estonia, Ireland and Lithuania |
| Food of non-animal origin | 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. | 2 audits: Bulgaria and Hungary Analyses of official controls over importers of food of non-animal origin in Member States with significant volume of imports (number and countries to be determined) |

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|------------------------------|---------------------------|---------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| and non-animal gin | 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. | |
| Food of animal and origin | 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 2022 |
|----------------|------------------------------------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------|
| | 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. | 0 |
| | 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. | |

Quality standards

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|----------------|-----------------------------|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------|
| y 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. In 15 Member States selected based on audit history and risk-based criteria. | |
| Food quality | 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. ➢ In 15 Member States selected based on audit history and risk-based criteria. | 2 audits: Austria and France |

Import and export controls

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|-----------------------------------------|-----------------------------|----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------|
| 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. | analyses and (if necessary) audits on the spot is demand- |
| Animals and goods entering the Union | 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. | Ireland, Lithuania, Netherlands, Spain and |

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|-------------------------------------------------------------------|---------------------------------------------|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------|
| 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 | 4 audits: Belgium, Greece, Lithuania and Netherlands |
| Animals and goods originating in the EU | Official export controls | Member States | Commission oversight on Member States' controls on the implementation of certification requirements for exports ➤ In Member States | |

Third countries access to EU market

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|----------------------------------------|---------------------------------------------------------------------|----------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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:A number of audits and countries depending on listing requestsListed countries:8 audits on animal health to listed third countries: Argentina (poultry), Bosnia and Herzegovina (fresh meat from ungulates), Brazil (highly pathogenic influenza), Moldova (pasteurised dairy products), Peru (live bivalve molluscs), South Africa (equidae), United States (highly pathogenic influenza) and United States (live bivalve molluscs).5 remote assessments: Malaysia, Montenegro, Namibia, North Macedonia and Singapore 2 analyses (questionnaires): Georgia and Ukraine |

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|-----------------------|---------------------------------------------------------------------------|---------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | Chemical safety - Residues | Third 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) |
| Food of animal origin | | Third 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. | 6 audits: Canada, China, India, Malaysia, Montenegro and Ukraine |
| Food of a | Safety of products of mammals and birds for human consumption | Third 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, Brazil, Canada, Chile, North Macedonia, Republic of Moldova and Uruguay A number of listing and follow-up audits to be determined A number of remote assessments on egg products to be determined |

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|-----------------------|---------------------------------------------------|---------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------|
| | Safety of fishery products | Third 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: Mauritius, Mexico, Morocco, Philippines and Uganda A number of listing and follow-up audits, to be determined |
| Food of animal origin | Safety of fishery products | Third 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) |
| Food of an | Production hygiene of live bivalve molluscs | Third 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 Tunisia |
| | Official controls in establishments | Third 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. | 6 analyses (questionnaires): Cuba, French Polynesia, Grenada (fishery products) and three countries to be determined (frog legs and snails) |

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------|
| e | Chemical safety - Contaminants Third 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. | | 3 audits: Egypt, Iran and Turkey | |
| Food of non-animal origin | Microbiological safety | Third 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: India and Turkey |
| Fc | Chemical safety - Pesticides controls | Third 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, country to be determined |
| 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 up to 30 control bodies operating in third countries or third countries with an equivalency status or requesting it, depending on availability of resources. | 4 audits, countries to be determined |

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|------------------------------------------------|-----------------------------------------------------------------------|---------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Quality standards | Seeds & propagating material - recognition of equivalency | Third 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. | Demand based |
| Plants, plant products and other objects | Phytosanitary conditions for export to the EU | Third 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. | 4 audits: China (plants and plant products), Israel (Tomato brown rugose fruit virus), Kenya (false codling moth on roses) and South Africa (false codling moth in citrus) |

Accession countries

| | olicy rea | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 | |
|--------|--------------|------------------------------------|---------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------|-----|
| 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 | 2 audits: Bosnia a Herzegovina and Serbia | and |

Agri-food chain

| Policy area | Priority theme | Country status/ entity | Objectives 2021-2025 | Controls 2022 |
|-----------------|-------------------------|-----------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------|
| 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. | 1 audit on Chemical safety - Residues 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. | 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: Bulgaria, Czech Republic, Estonia, Finland, Germany, Luxembourg, Malta, Portugal, Slovenia, Spain and Sweden |
| | 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 2022 |
|-----------------|---------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| | Emerging problems and new developments | Member States | To investigate and collect information in relation to emerging 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. | 2 fact-finding studies: Bulgaria and Portugal |
| 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 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 studies (the number to be determined) |
| | 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 | 2 fact-finding missions on new genomic techniques, Germany and Netherlands |

Annex 2 – Audits and similar controls in Member States planned in 2022

| Country name | Priority theme |
|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Belgique/België (Belgium) | Safety of fishery products Official measures to control plant pest outbreaks (Tomato brown rugose fruit virus) Official plant health import controls of plants, plant products and other objects entering the EU |
| България (Bulgaria) | Microbiological safety of food of non-animal origin Sustainable use of pesticides Feed hygiene Official import controls of animals and goods entering the EU Systematic follow-up Agri-food chain - fraud |
| Česká republika (Czech Republic) | Safety of fishery products Systematic follow-up |
| Danmark (Denmark) | Safety of meat of mammals and birds and products thereof Animal by-products and derived products |
| Deutschland (Germany) Highly pathogenic avian influenza Foodborne zoonoses - Salmonella Genetically Modified Organisms – new genomic techniques Official import controls of animals and goods entering the EU Systematic follow-up | |
| Eesti (Estonia) | Chemical safety – authorisation, marketing and use of pesticides Systematic follow-up |
| Éire/Ireland | Animal welfare – transport (control posts) Chemical safety – authorisation, marketing and use of pesticides Movement of plants within the EU – plant passports Official import controls of animals and goods entering the EU |
| Ελλάδα (Greece)Safety of fishery productsΕλλάδα (Greece)Official plant health import controls of plants, plant products and other entering the EU Animal by-products and derived products | |

| Country name | Priority theme |
|--------------|---------------------------------------------------------------------------------------------------|
| | Safety of milk and products thereof |
| | Animal welfare – transport (control posts) |
| España | Chemical safety - residues in food of animal origin |
| (Spain) | Official import controls of animals and goods entering the EU |
| | Animal welfare - livestock vessels |
| | Systematic follow-up |
| | Safety of meat of mammals and birds and products thereof |
| | Highly pathogenic avian influenza |
| France | Food quality standard - geographical indications |
| | Official measures to control plant pest outbreaks (<i>Anoplophora</i> longhorn beetles) |
| | Official measures to control plant pest outbreaks (Xylella fastidiosa) |
| | Safety of meat of mammals and birds and products thereof |
| Hrvatska | Official measures to control plant pest outbreaks (<i>Anoplophora</i> longhorn beetles) |
| (Croatia) | Animal welfare - livestock vessels |
| | Animal by-products and derived products |
| | Safety of milk and products thereof |
| Italia | Animal welfare – transport (control posts) |
| (Italy) | Official measures to control plant pest outbreaks (Xylella fastidiosa) |
| | Safety of meat of mammals and birds and products thereof |
| Latvija | Feed hygiene |
| (Latvia) | Chemical safety - residues in food of animal origin |
| | Chemical safety – authorisation, marketing and use of pesticides |
| Lietuva | Official plant health import controls of plants, plant products and other objects entering the EU |
| (Lithuania) | Chemical safety - residues in food of animal origin |
| | Official import controls of animals and goods entering the EU |
| Luxembourg | Systematic follow-up |
| | Microbiological safety of food of non-animal origin |
| Magyarország | African swine fever |
| (Hungary) | Movement of plants within the EU – plant passports |
| | Chemical safety - Residues in food of animal origin |
| Malta | Systematic follow-up |

| Country name | Priority theme |
|-----------------------------------|---------------------------------------------------------------------------------------------------|
| | Safety of fishery products |
| | Genetically Modified Organisms – new genomic techniques |
| Nederland (Netherlands) | Official plant health import controls of plants, plant products and other objects entering the EU |
| | Movement of plants within the EU – plant passports |
| | Official import controls of animals and goods entering the EU |
| | Safety of meat of mammals and birds and products thereof |
| Österreich (Austria) | Movement of plants within the EU – plant passports |
| | Food quality standard - geographical indications |
| Polska | Non-food borne zoonoses - rabies |
| (Poland) | Official measures to control plant pest outbreaks (Potato ring rot) |
| | Safety of meat of mammals and birds and products thereof |
| | Official measures to control plant pest outbreaks (Xylella fastidiosa) |
| | Animal by-products and derived products |
| Portugal | Systematic follow-up |
| | Animal welfare - livestock vessels |
| | Agri-food chain - fraud |
| | African swine fever |
| | Movement of plants within the EU – plant passports |
| România | Sustainable use of pesticides |
| (Romania) | Feed hygiene |
| | Animal welfare - livestock vessels |
| | Chemical safety - residues in food of animal origin |
| Slovenija | Animal by-products and derived products |
| (Slovenia) | Chemical safety - residues in food of animal origin |
| Slovensko | Systematic follow-up |
| (Slovakia) | Safety of meat of mammals and birds and products thereof |
| | Safety of fishery products |
| Suomi | Safety of meat of mammals and birds and products thereof |
| (Finland) | Chemical safety - Residues in food of animal origin |
| | Systematic follow-up |

| Country name | Priority theme |
|--------------|---------------------------------------------------------------|
| | Safety of milk and products thereof |
| Sverige | Highly pathogenic avian influenza |
| (Sweden) | Official import controls of animals and goods entering the EU |
| | Systematic follow-up |

Annex 3 – Controls in candidate countries planned in 2022

| Country name | Priority theme | Types of control |
|----------------------------------|-----------------------------------------------------------------------------------------------|----------------------|
| Црна Гора (Montenegro) | Animal health in countries requesting to be listed/listed (poultry) | Remote assessment |
| (Montenegro) | Chemical safety - residues in food of animal origin | Audit |
| Северна Македонија | Safety of products of mammals and birds for human consumption (meat, milk and dairy products) | Audit |
| (North Macedonia) | Animal health in countries requesting to be listed listed | Remote assessment |
| Србија (Serbia) | Official animal health controls | Audit |
| Türkiye | Chemical safety - contaminants of food of non-animal origin | Audit |
| (Turkey) | Microbiological safety of food of non-animal origin | Audit |

Annex 4 – Controls in third countries planned in 2022

| Country name | Priority theme | Types of control |
|-----------------|------------------------------------------------------------------------------------------|--------------------------|
| | Safety of products of mammals and birds for human consumption (horse meat) | Audit |
| AR - Argentina | Animal health in countries requesting to be listed/listed (poultry) | Audit |
| BA - Bosnia and | Animal health in countries requesting to be listed/listed (fresh meat from ungulates) | Audit |
| Herzegovina | Official animal health controls | Audit |
| | Safety of products of mammals and birds for human consumption (poultry) | Audit |
| BR - Brazil | Animal health in countries requesting to be listed/listed (poultry) | Audit |
| CA - Canada | Safety of products of mammals and birds for human consumption (bovine and pig meat) | Audit |
| GAI-Gailada | Chemical safety - residues in food of animal origin | Audit |
| CL - Chile | Safety of products of mammals and birds for human consumption (poultry meat) | Audit |
| | Phytosanitary conditions for export to the EU (plants and plant products) | Audit |
| CN - China | Chemical safety - residues in food of animal origin | Audit |
| CU - Cuba | Official controls in fishery products establishments | Analysis |
| EG - Egypt | Chemical safety - contaminants in food of non-animal origin | Audit |
| GD - Grenada | Official controls in fishery products establishments | Analysis |
| GE - Georgia | Animal health in countries requesting to be listed/listed (dairy) | Analysis (questionnaire) |
| IL - Israel | Phytosanitary conditions for export to the EU (Tomato brown rugose fruit virus) | Audit |
| IN - India | Microbiological safety of food of non-animal origin | Audit |
| in india | Chemical safety - residues in food of animal origin | Audit |
| IR - Iran | Chemical safety - contaminants in food of non-animal origin | Audit |
| JM - Jamaica | Production hygiene of live bivalve molluscs | Audit |
| KE - Kenya | Phytosanitary conditions for export to the EU (False codling moth) | Audit |
| MA - Morocco | Safety of fishery products | Audit |
| MD - Moldova | Safety of products of mammals and birds for human consumption (listing poultry and eggs) | Audit |
| Republic of | Animal health in countries requesting to be listed/listed (dairy) | Audit |

| Country name | Priority theme | Types of control |
|----------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------|-------------------------------|
| MU - Mauritius | Safety of fishery products | Audit |
| MY – Malaysia | Animal health in countries requesting to be listed/listed (poultry) Chemical safety - residues in food of animal origin | Remote assessment Audit |
| MX - Mexico | Safety of fishery products | Audit |
| NA - Namibia | Animal health in countries requesting to be listed/listed (poultry and ungulates) | Remote assessment |
| PE - Peru | Animal health in countries requesting to be listed/listed (live bivalve molluscs) | Audit |
| PF - French Polynesia | Official controls in fishery products establishments | Analysis |
| PH - Philippines | Safety of fishery products | Audit |
| SG - Singapore | Animal health in countries requesting to be listed/listed (poultry) | Remote assessment |
| TN - Tunisia | Production hygiene of live bivalve molluscs | Audit |
| UA - Ukraine | Animal health in countries requesting to be listed/listed (heat treated pork products, hatching eggs) | Analysis (questionnaire) |
| | Chemical safety - residues in food of animal origin | Audit |
| UG - Uganda | Safety of fishery products | Audit |
| UK – United Kingdom in respect of Great Britain | To be determined | Audit |
| UK - United Kingdom in | Chemical safety - residues in food of animal origin | Analysis |
| respect of Northern Ireland | Chemical safety - residues in food of animal origin | Audit |
| US - United | Animal health in countries requesting to be listed/listed (live bivalve molluscs) | Audit |
| States | Animal health in countries requesting to be listed/listed (highly pathogenic avian influenza) | Audit |
| UY - Uruguay | Safety of products of mammals and birds for human consumption (horse meat) | Audit |
| ZA - South | Animal health in countries requesting to be listed/listed (horses) | Audit |
| Africa | Phytosanitary conditions for export to the EU (False codling moth) | Audit |

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