



# Management Plan 2024

DG Health and Food Safety (SANTE)

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## Introduction

In the current mandate the Directorate-General for Health and Food Safety (DG SANTE) has elevated the files under its responsibility to new levels and will continue to do so in the next



year. The very intense on-going work in and between the two areas of food safety and public health is an increasing embodiment of the **One Health** approach. The reorganised structure of DG SANTE will continue to create the synergies necessary to fully operationalise the One Health approach and thus optimise the DG's already considerable contribution to the Commission's political priorities.

Recent epidemics and pandemics have made it clear that human, animal, plant and environmental health cannot be dealt with separately. In line with the **One Health** approach, DG SANTE will pay close attention to the link between human, animal and plant health when implementing its core mission – namely to protect the **health of citizens, animals and plants**; to promote a **high level of food and animal feed safety**; to contribute to the Union's efforts to ensure **sustainable food systems**; and to enable the health and food sectors to achieve their **full economic potential**.

A **One Health** approach to **cross-border health threats**: One year since the Regulation on serious cross-border health threats entered into force, the European Union has made huge strides in boosting its preparedness to withstand potential pandemics or other health threats like Antimicrobial Resistance, thanks to the creation of a strong European Health Union. DG SANTE has been at the centre of efforts in this area and key actors such as the European Food Safety Authority and the European Centre for Disease Prevention and Control are brought together, for example, to foster One Health surveillance and monitoring or to issue joint risk assessments, reports and recommendations.

To pursue our contribution to the Commission's **headline ambitions**, we will continue building a strong **European Health Union**, thereby strengthening the European way of life (General Objective 2 of this plan). We will continue working with Member States to implement the **legislative health security framework** for better longer-term preparedness, and we will also work closely with the European Centre for Disease Prevention and Control and with the European Medicines Agency. We will continue to implement the **Pharmaceutical Strategy for Europe**, roll out the **comprehensive approach to mental health**, and build on the positive momentum already achieved in implementing **Europe's Beating Cancer Plan**. We will support the co-legislators to reach an inter-institutional agreement on the Commission proposal for a **European Health Data Space** and adoption of the revision of the EU legislation on the safety and quality of **substances of human origin**, while pursuing inter-institutional negotiations on the **reform of the EU's pharmaceutical legislation**.

The continued availability of safe, effective and affordable medicines for patients is a cornerstone of the European Health Union. DG SANTE is taking action to prevent or mitigate critical shortages at EU level – and, in particular, to ensure the security of supply of the most critical medicines at all times, in line with the Communication on Addressing medicine shortages <sup>(1)</sup>.

We will continue protecting people during health crises, supporting our key public health initiatives and strengthening EU health systems with the **EU4Health Programme**, supported by the European Health and Digital Executive Agency (HaDEA). We will also continue rolling out the legal framework on **medical devices** and **in vitro diagnostic medical devices**, and take any necessary measures to protect patients and mitigate the risk of shortages.

In 2024, DG SANTE will strive to contribute to inter-institutional negotiations on pending proposals linked to the ambitions of the **Farm to Fork** Strategy – a central plank of the European Green Deal (General Objective 1 of this Plan): the **sustainable use of pesticides**; the



introduction of **food waste reduction targets**; the regulation on **animal welfare during transport**; the regulation on the **welfare of dogs and cats kept for economic purposes**; the specific legislation for plants resulting from certain **new genomic techniques**; the revision of the legislation on the marketing of **plant and forest reproductive material**; and on a targeted amendment of the current **plant health law**. Together, these proposals will benefit human, animal, plant and environmental health, and thus secure a healthier future for all EU citizens. In addition, DG SANTE will actively contribute to the strategic dialogue on the future of agriculture in the EU, announced by President von der Leyen in her State of the Union address in September 2023.

At the same time, **Russia's aggression against Ukraine** and the ongoing conflict have had an inevitable impact on food sustainability initiatives and on the attitudes towards them, shifting the focus from long-term food sustainability to immediate food security and sovereignty – with a strong emphasis on greater productivity. This shift has resulted in a very **challenging environment** for some ongoing Farm to Fork flagship initiatives.

In 2023, there were major **outbreaks of animal diseases** such as African swine fever and highly pathogenic avian influenza and of **plant pests** such as *Xylella fastidiosa* and

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<sup>(1)</sup> [Communication medicines shortages EN 0.pdf \(europa.eu\)](#)

Tomato brown rugose fruit virus. In response, veterinary and phytosanitary measures will account for the largest budget share of the Food Chain strand of the Single Market Programme. They will support disease prevention, emergency measures, crisis management and permanent availability of strategic vaccines in EU-funded vaccine banks. Based on the Animal Health Law, the coordinated **surveillance of zoonotic pathogens** threatening the EU offers a concrete example of how DG SANTE operationalises the One Health approach. With the crucial support of EFSA and in coordination with ECDC, collected data is regularly reviewed and the risk of emerging and re-emerging zoonotic threats - such as highly pathogenic avian influenza, Rift Valley fever, rabies, and West Nile fever- consistently assessed from a One Health perspective.

DG SANTE devotes the same energy to **implementing and enforcing** the legislation in force as it does to delivering political priorities and managing crises. The latest figures show that, within the Commission, DG SANTE is responsible for 48.5% of all written adoption procedures, for 43,7% of implementing acts, and for over 80% of the Commission regulatory procedures subject to political scrutiny <sup>(2)</sup>. In 2024, the DG will continue to work closely with Member States to ensure all legislation under its responsibility in food safety (including authorisation and approval of substances) and animal and plant health is regularly updated, properly implemented and enforced and, where relevant, subject to sound financial management and appropriate risk assessment and risk management procedures. DG SANTE will also continue to ensure the implementation and application of the pharmaceutical legislation, including decisions related to EU-wide authorisation and monitoring of medicinal products.

In 2024, DG SANTE will continue its efforts to **reduce administrative burden** stemming from its legislation with a view to maintaining the **competitiveness** of European businesses. DG SANTE has prepared a plan to simplify and rationalise the **reporting requirements** and reduce related burden on businesses and/or national administrations, without undermining the policy objectives. The plan includes a list of concrete measures planned for 2024 and beyond to progress towards the goal of 25% reduction of such burden. These measures cover:

(1) in the area of medical devices the staggered roll-out of the IT tool EUDAMED. This would substantially simplify the mandatory registration and exchanges of information in the area of medical devices thus reducing burden in particular for the numerous SMEs active in the notification and certification process;

(2) a fully operational platform digitising exchanges between Member States, Commission and external parties (notably health technology developers) for efficient joint work on health technology assessment at EU level;

(3) improvements of its IT systems in the food chain area which will (a) simplify the recording of veterinary certificates for the movement of animal by-products; (b) eliminate the current duplicate documentation requirements for food imports; (c) automate the

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<sup>(2)</sup> Report from the Commission to the European Parliament and the Council on the working of committees in 2022, COM(2023) 664 final, 26 October 2023.

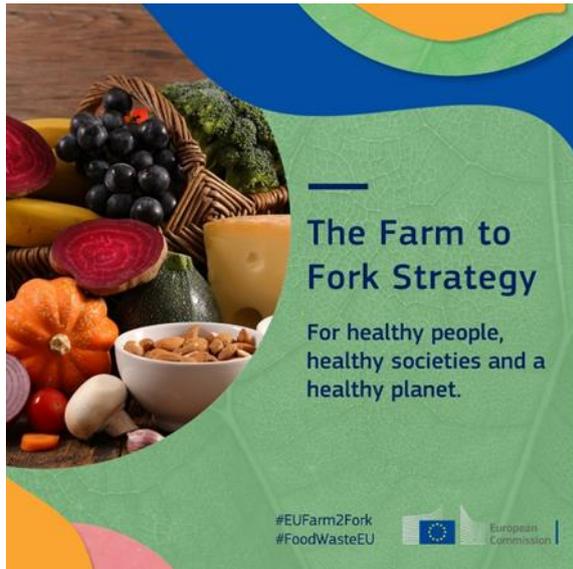
verification of Common Health Entry Documents; (d) streamline and digitalise the annual reports on post-market environmental monitoring on authorised Genetically Modified Organisms.

At **international level**, DG SANTE will strongly advocate for a One Health-based global solution for pandemic prevention, preparedness and response in the negotiations on an international agreement. In the context of global efforts to strengthen food systems' sustainability, we will pursue **"green partnerships"** with like-minded non-EU countries, sustainable food chapters or provisions in free trade agreements, and enhanced cooperation in multilateral fora.

# PART 1. Delivering on the Commission's priorities: main outputs for 2024

## General Objective 1: A EUROPEAN GREEN DEAL

In 2024, DG SANTE's work on safe and sustainable food will keep on contributing to the European Green Deal, particularly by following up to the adoption by the College of key legislative proposals under the Farm to Fork Strategy (F2F). The DG will pursue discussions with the European Parliament and the Council on the proposal on the **sustainable use of**



**pesticides**, as well as on the introduction of **food waste reduction targets**, on the regulatory framework for plants resulting from certain **new genomic techniques** and on the revision of the legislation on the marketing of **plant and forest reproductive material**, as well as a **targeted amendment of the Plant Health Law**, with a view to achieving progress towards final adoption of these legislations. The DG intends to discuss with the European Parliament and the Council the proposals for the revision of EU rules on the **protection of animals during transport** and on the **welfare of dogs and cats kept**

**for economic purposes**. In addition, DG SANTE will continue including and negotiating the new Chapter to cooperate on the Sustainability of the Food Systems in all the new trade agreements.

In 2024, the narrative and the communication actions around the Farm to Fork strategy will take into account President von der Leyen's intention to launch a strategic dialogue on the future of agriculture in the EU, as announced during the State of the Union address on 13 September 2023, as well as DG SANTE participation in such dialogue.

Alongside the delivery of the political priorities, ensuring **food and feed safety**, by complying with the applicable legal obligations remains one of DG SANTE main activities. This is reflected in the very high number of ongoing initiatives at EU and international level, many of which are politically sensitive. Although inherently difficult to anticipate, responding effectively to **foodborne crises** is also a key component of the portfolio of the DG.

DG SANTE will continue to closely monitor the flow of goods subject to sanitary and phytosanitary requirements across the **EU-Ukrainian** border to avoid any delays and ensure, in close cooperation with the Member States, appropriate alternatives to border controls. In addition, DG SANTE will contribute to the preparation and implementation of a road map on actions announced under the EU-Ukraine Association Agreement/Deep and Comprehensive Free Trade Area which can be advanced, and/or additionally developed

while safeguarding food safety in the Member States. Next to it, work on enlargement with candidate countries covering the SPS acquis will be a priority in line with the 2023 State of the Union address.

DG SANTE is also responsible for monitoring the implementation of EU sanitary and phytosanitary (SPS) legislation applicable to and in the United Kingdom in respect of Northern Ireland under the **Windsor Framework** and the implementation of the Trade and Cooperation Agreement in the SPS field through the work of the Trade Specialised Committee on SPS.

**Working in partnership with the EU's decentralised agencies.** DG SANTE's work is supported by five decentralised EU agencies: the Community Plant Variety Office (CVPO), the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), the European Centre for Disease Prevention and Control (ECDC), and the European Chemicals Agency (ECHA). Collaboration amongst agencies, and between the latter and DG SANTE, is crucial in the light of the DG's "One Health" approach and of the "one substance – one assessment" principle featured in the Chemicals Strategy for Sustainability. In relation to the latter's implementation, DG SANTE will pay particular attention to its impact on EFSA.

**EU funding in the food chain area.** Following the adoption of the 2021-2027 Multiannual Financial Framework (MFF), the food chain strand under the **Single Market Programme (SMP)** governs EU funding in the area for the 2021-2027 period. The proposed 2024 budget for the food chain strand under the SMP is EUR 234.5 million.

In 2024, DG SANTE will implement veterinary and phytosanitary emergency measures as well as actions on IT and communication. As foreseen in the delegation instrument, the European Health and Digital Executive Agency (HaDEA) will implement the remaining parts of the programme. In addition, in 2024 DG SANTE will produce a report on the conclusions of the evaluation of Regulation (EC) 652/2014 on the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material.

### **Specific Objective 1.1: Food and feed safety**

DG SANTE aims to ensure proper implementation of the extensive legislation on food and feed safety and animal and plant health, to manage it and to simplify it where possible. It systematically adopts a "One Health" approach to preparedness and prevention, integrating human, animal, plant and environmental health. The effectiveness of DG SANTE's work in these areas must be assessed against external factors such as the epidemiological evolution of animal diseases and pest outbreaks, the successful implementation and enforcement of EU measures by the Member States, and the positions and demands of other EU Institutions.

**Ensuring animal health and managing and isolating outbreaks of major animal diseases.** DG SANTE manages measures to prevent, control and eradicate animal diseases

transmissible to animals or humans. One of our most important tasks is to ensure that the EU can rapidly isolate and eradicate **outbreaks of major animal diseases**, such as African swine fever and highly pathogenic avian influenza in line with One Health principles. In 2024, DG SANTE will continue to ensure the smooth evolution and management of the **EU Animal Health Law (AHL)**, including the launch of its **evaluation**. Whilst paying specific attention to transmissible animal diseases, DG SANTE will continue to adapt EU rules to reflect the evolving disease situation and provide financial support for measures implemented in the EU and neighbouring non-EU countries. In particular, the DG will follow up on the launch, in the context of the 2022 EU4Health work programme, of financial support to Member States for setting up a One Health-based coordinated surveillance system for certain cross-border pathogens. On the basis of a preliminary risk assessment by EFSA and ECDC, already 23 Member States applied to carry out surveillance which is scheduled to start in 2024 until 2026. A harmonised data collection and risk assessment by EFSA, in coordination with ECDC, will allow DG SANTE to point out future zoonotic threats for EU.



**Preventing plant pests.** New threats due to climate change and globalisation have increased the risk of plant pest infestations. DG SANTE manages the **EU Plant Health Law (PHL)** to protect crops, fruits, vegetables, flowers, ornamentals and forests from pests and diseases.

In 2024, DG SANTE will support discussions with the co-legislators on the proposal for a **targeted revision** of the Plant Health Law, adopted in 2023 as a follow up of the two reports sent to the EP and Council in 2021, with a view to improve efficiency and reduce reporting obligations, and will prepare a series of acts under the Plant Health Law e.g. in response to high risk plant dossiers from non-EU countries, .

In addition, DG SANTE will launch an **evaluation of the legislation on Community Plant Variety Rights and the Plant Variety Office**, while ensuring the proper implementation of the current legislation.

DG SANTE works proactively to **detect early, notify, contain and eradicate pests** found in the EU. Prevention, preparedness and management of plant health outbreaks will remain a core part of our work in 2024 (e.g. of Citrus Black Spot, False Codling Moth, Xylella fastidiosa, Spodoptera frugiperda). The lists of quarantine pests, regulated non-quarantine pests, import and internal movement requirements, and of protected zones will be updated.

EU support for veterinary and phytosanitary programmes still accounts for a large proportion of spending under the food chain strand of the SMP. In 2024, the budget for implementing national veterinary programmes is set at EUR 40.7 million and for phytosanitary programmes at EUR 8 million.

**Ensuring market access to safe substances and products.** DG SANTE is responsible for implementing the **General Food Law Regulation**, ensuring a high level of protection of human health and consumers' interests, based on the risk analysis principle. Based on the advice of the EU regulatory Agencies, DG SANTE adopts **risk management measures** to regulate potentially hazardous substances present in food and feed and ensures effective and inclusive risk communication on those decisions. This is reflected in the very high number of planned initiatives, usually tertiary legislation, most of which is **politically sensitive**. Through this work strand, DG SANTE contributes to several initiatives under the European Green Deal, such as the Farm to Fork and Biodiversity Strategies, the Zero Pollution Ambition, and the Chemicals Strategy for Sustainability or Europe's Beating Cancer Plan. The work on endocrine disruptors, the cumulative effects of chemicals, and the inter-agency collaboration in the light of "one substance - one assessment" continues to be part of the DG's work for 2024.

Further to the entry into application of the **Transparency Regulation** in March 2021, in 2024 DG SANTE will monitor its implementation, as well as the progress of potentially sensitive EFSA opinions. In 2024, DG SANTE will also launch an external study to support the evaluation of EFSA's performance in accordance with Commission guidelines, to be finalised in 2026.

DG SANTE oversees the **authorisation and approval procedures for substances** used in food and feed production and processing. In 2024, DG SANTE will continue to authorise a range of substances whose safety has been positively assessed.

The DG will further work on the implementation of legislation on health and nutrition claims made on foods, and on the addition of vitamins and minerals and of certain other substances to foods, including the prohibition or restriction of substances. In this context, it will also pursue preparatory work for the adoption of the Commission Regulation setting the **maximum amounts of vitamins and minerals added to foods**, including food supplements.

On nutrition, the **work on baby food composition** related in particular to levels of sugar, fat, salt, and on **claims targeting to infant and young children** will be resumed.

In the course of 2024, DG SANTE will issue an increasing number of decisions on new approvals and renewals of previously approved active substances in **plant protection products and biocides**, as EFSA will deliver conclusions for many substances for which earlier 'stop the clock' periods to assess endocrine disrupting properties come to an end.

In 2024, DG SANTE will continue its work on **food improvement agents**, including additives, enzymes and flavourings as well as smoke flavourings. Maximum levels for

**contaminants in food and feed** are also to be set based on EFSA opinions. In 2024, it is foreseen to set or review maximum levels for several contaminants, such as nickel, inorganic arsenic, mineral oils, acrylamide or glycidyl esters. These actions will also feed into the prevention pillar of Europe's Beating Cancer Plan.

Moreover, DG SANTE will continue to adopt decisions on the authorisation of **genetically modified food and feed** applications based on EFSA opinions. In a context where biotechnology is emerging as a focus area for 2024, as demonstrated by President von der Leyen's announcement <sup>(3)</sup>, DG SANTE will start preparatory work with a view to assessing the need for future policy initiatives, e.g. in the area of genetically modified micro-organisms.

For **veterinary medicines**, in 2024, the DG will continue to prepare the tertiary legislation necessary for the full implementation of Regulation (EU) 2019/6 on **veterinary medicinal products** and Regulation (EU) 2019/4 on **medicated feed**.

DG SANTE will propose re-evaluations of authorisations, new authorisations or modifications and renewal of authorisations of **feed additives** (around 90 applications) based on the outcome of safety evaluations.

DG SANTE contributes to a high level of food safety through better **food hygiene**. In 2024, it will continue updating the relevant legal framework, taking account of new scientific evidence and technological developments. DG SANTE also contributes to the control of major **foodborne zoonosis**, such as salmonellosis and listeriosis, and coordinates the management of **cross-border food-borne incidents** as necessary.

**Performing effective, efficient and reliable controls.** Strict enforcement of the EU's rules on food safety, animal health, plant health and animal welfare is essential to ensure that our high standards are not compromised. Member States' authorities monitor and enforce these requirements by performing official control activities, as required by Regulation (EU) 2017/625, the **Official Controls Regulation (OCR)**.

In 2024, DG SANTE will further complement and update the legal framework on official controls, particularly as regards the rules on border checks on goods or the adaptation of the rules governing the Information Management System for Official Controls (IMSOC), and will continue to work on guidance for a more harmonised implementation of the legislation. The DG will also handle the SPS aspects of the "Green line Regulation" in Cyprus, with a view to ensure the trade of Halloumi across the Green Line before the end of 2024.

DG SANTE will continue to check, through **audits and other controls**, the performance of official controls in Member States and non-EU countries exporting animals and goods to the EU. Audits are explicitly mentioned in Commissioner Kyriakides' Mission Letter as a crucial tool to implement and enforce the EU's extensive legal framework on food safety.

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<sup>(3)</sup> EU Biotech and Biomanufacturing Initiative as announced in the SOTEU Letter of Intent.

The overall **work programme** for 2024 includes 230 planned controls - complemented by “on-demand” controls - in the area of food and feed safety, animal health, animal welfare, plant health and certain areas of human health protection in both EU and non-EU countries. The planned controls include 154 audits and similar controls, and 76 analyses. During 2024, DG SANTE will use a combination of **on-the-spot missions** and **remote assessment tools** to conduct the audits and similar controls. DG SANTE will continue to support the competent authorities of Member States and third countries to address identified areas of weakness by providing training and capacity building through the **Better training for safer food (BTSF)** initiative.

With a budget of EUR 21 million in 2024, the **EU Reference Laboratories (EURLs)** will contribute to the better implementation of EU legislation in the agri-food chain, support the Commission and national reference laboratories and help to provide state of the art analytical and diagnostic services to national authorities and enforcement bodies.

**Maintaining well-developed rapid alert systems.** Crisis management in the food and feed sector is supported by a number of well-established tools, notably the EU’s rapid alert systems. The project of a **second generation Alert and Cooperation Network** will be pursued in 2024 to provide better support to the alert and cooperation network in managing day-to-day incidents as well as crises.

This will be achievable thanks to the design of the RASFF-NT, the **new iRASFF** (the IT platform for the Rapid Alert system for Food and Feed) which will replace the current system, looking at synergies and better integration with the IMSOC system (including TRACES of and ADIS).



In 2024, the Animal Disease Information System (ADIS) will continue its development by facilitating data exchange with other databases, and by simplifying the notification procedure for animal diseases through a single-entry point for the legally required double notification to both the World Organisation for Animal Health and to the Commission.

### **Specific Objective 1.2: Sustainable food systems – the ‘Farm to Fork’ Strategy**

In line with the mission letter to Commissioner Kyriakides, DG SANTE leads on the Farm to Fork (F2F) Strategy for a fair, healthy and environmentally friendly food system, which lies at the heart of Europe's Green Deal.

In 2024, DG SANTE will follow negotiations between co-legislators on the **several legislative proposals** already delivered under the F2F Strategy, and will follow-up other aspects of the latter’s implementation, including by managing the **Advisory Group on the Sustainability of Food Systems**. The DG will also work on topics related to a

**framework law on sustainable food systems** in close collaboration with DG AGRI, DG ENV and DG MARE.

Moreover, together with DG JRC, ESTAT, EEA, and other relevant Commission services, DG SANTE will launch a **monitoring framework** in the form of a dashboard to be published in 2024, as well as preparatory work for a review of the F2F Strategy.



Following the entry into force in 2021 of the **Code of Conduct on Responsible Food Business and Marketing Practices**, DG SANTE will continue taking part in its governance mechanisms, together with DG GROW and ENV, in particular with a view to ensure appropriate

mapping and analysis of existing and new pledges, and to monitor reporting by the Code signatories.

In 2024, DG SANTE will pursue its contribution to the monitoring of Member States' implementation of the CAP National Strategic Plans.

**Communication actions** - including media briefings - to support ongoing legislative processes on SUR, NGTs, food waste targets, pland and forest reproductive materials, and animal welfare will be organised, to highlight the importance of these files. In 2024, the communication around the Farm to Fork Strategy will help to showcase how innovation and safety are key in achieving a sustainable food system.

**Reducing dependency on and promoting the sustainable use of pesticides.** DG SANTE works towards reducing dependency on chemical pesticides and stimulating the take-up of low-risk and non-chemical alternatives for plant health protection.

In 2024, DG SANTE will continue discussions with the European Parliament and the Council on the Commission's 2022 proposal for a **Regulation on the Sustainable Use of Plant Protection Products (SUR)**. In addition, DG SANTE will continue working to improve the existing **indicators** for measuring changes in the use and risk of chemical pesticides, as well as supporting Member States in the **implementation** of the existing legal requirements on the sustainable use of pesticides, including through BTSF trainings to exchange best practices specifically on Integrated Pest Management (IPM).

To continue facilitating the placing on the market of **alternatives to chemical pesticides**, in 2024 DG SANTE will continue to work with Member States experts to support the implementation of the new data requirements for micro-organisms. It will aim at more rapid and easier processing of dossiers, via the development of harmonised approaches for

the interpretation of the data requirements and through two studies. DG SANTE will also examine, as necessary, possible further actions to facilitate the approvals for low-risk chemical substances (such as pheromones and plant extracts) and the authorisation of products containing them, e.g. via EU guidance, or adaptation of data requirements and assessment criteria.

**Improving the efficiency and effectiveness of the pesticide legislation.** DG SANTE will continue to address the inefficiencies of the current legislation on pesticide identified in the 2020 evaluation. It will implement the actions outlined in the report to the Parliament and the Council through non-legislative and legislative action. In particular, where relevant, DG SANTE will take into account **environmental concerns of global nature** (such as the decline of pollinators or pollution by substances that are persistent, bioaccumulating and toxic) when reviewing Maximum Residue Levels and assessing requests for **import tolerances** for pesticide substances no longer approved in the EU. The DG will continue using diplomacy, trade policy and development support instruments to promote the phasing out, as far as possible, of such pesticides and support the use of alternatives globally.

**Reducing the use of antimicrobials in animals to contribute to the fight against antimicrobial resistance (AMR).** DG SANTE will capitalise on the EU **Regulations on veterinary medicinal products and medicated feed** to pursue the achievement of the F2F target of halving the overall EU sales of antimicrobials for farmed animals and aquaculture by 2030. In particular, in 2024 DG SANTE will continue to prepare and adopt the tertiary legislation necessary to enable the application of these Regulations. Particularly sensitive due to their impact on trade are two acts related to the system for imports of animals and products of animal origin into the Union intended for human consumption, which includes the listing of authorised third countries, whose adoption will require targeted communication actions. In addition, DG SANTE will pursue **AMR monitoring in food** and food-producing animals based on EFSA opinions, and will also work on the preparation of a baseline study on AMR in aquaculture animals, in line with the One Health approach followed in the Commission's actions to fight AMR (see below).

**Fostering the use of innovative and more sustainable feeds.** To reduce the environmental and climatic impact of animal production, DG SANTE strives to facilitate the placing on the market of sustainable and innovative **feed additives**. Currently there are 224 feed additives that have positive effects on sustainability, and 50 or so more are currently in the pipeline for a possible (re-)authorisation subject to favourable EFSA opinions.

**Reducing food loss and waste.** The Commission is committed to reaching the United Nations Sustainable Development Goal (SDG) Target 12.3 to halve per capita food waste at retail and consumer levels by 2030 and reduce food loss across the supply chain. Following the adoption in 2023 of the legislative proposal for setting **legally binding EU food waste reduction targets**, DG SANTE will support inter-institutional discussions with a view to progress towards adoption of the legislation. It will continue operating the **EU Platform on Food Losses and Food Waste** to drive and reinforce action at national level, and - in cooperation with ESTAT - support Member States in the implementation of

provisions on food waste measurement. Together with JRC, it will support all actors in taking action to reduce consumer food waste by creating online tools and disseminating the findings of the **European Consumer Food Waste Forum**. The EU Food Loss and Waste Prevention Hub will further facilitate exchange of knowledge and experience between actors on the ground.

Finally, cooperation with international organisations such as the Food and Agriculture Organization and the UN Environment Programme will be pursued in the context of monitoring progress towards SDG Target 12.3 and of the fifth International Day on Food Loss and Waste (29 September 2024), as well as in the context of the international 'Food is never waste' coalition launched following the United Nations Food Systems Summit.

### **Ensuring sustainable food production that improves the welfare of animals.**

Upholding animal welfare and the good treatment of animals is an integral part of sustainable food production. In 2024, DG SANTE will pursue discussions with the Council and European Parliament on the proposals of revision of EU rules on the **protection of animals during transport** and on the **welfare of dogs and cats kept for economic purposes**. In the

context of the Strategic Dialogue on the future of farming and in the context of the EU Animal welfare Platform, the DG will work on topics related to the **revision of other existing animal**

**welfare rules**, including the phasing out of cages, as set out in the 2021 Commission Communication positively responding to the ECI "End the cage age".



Furthermore, DG SANTE's management of the **EU Animal Welfare Platform** will allow to exchange on the ongoing work on the revision of the animal welfare legislation, and will also be used to exchange with stakeholders on the EU approach to animal welfare at global level, and to consult on the development of animal welfare indicators and tools for better support to animal welfare via the Common Agriculture Policy. DG SANTE will also work on enforcement of current EU rules, by initiating discussions with Member States on tertiary legislation under the Official Controls Regulation to improve the enforcement of current EU animal welfare rules.

In 2024, DG SANTE will continue to ensure the supervision of the existing three **Animal Welfare Reference Centres**, and will launch the creation of a new Centre on farmed fish.

**Fighting against food fraud.** Combating food fraud is essential to protect the safety and quality of EU food products, to protect consumers, engender their trust in the integrity of food systems and promote sustainable food systems. DG SANTE will continue in 2024 to provide Member States with intelligence on agri-food fraud matters and will launch new

coordinated actions with the EU Food Fraud Network and relevant Commission services. DG SANTE also engages with **authorities in non-EU countries** to cooperate about potentially fraudulent practices and to develop a common understanding about food fraud through training courses under the BTSF initiative.

**Empowering consumers to make sustainable and healthy food choices through the provision of food information.** DG SANTE will continue to work to improve consumer information, in particular through the consideration of the national notifications and the contacts with the national authorities and the stakeholders. In 2024, DG SANTE will work on topics related to the **revision of the Regulation on food information to consumers (FIC)**.

**Supporting innovation in the food chain, especially via the promotion of novel foods, plant reproductive materials and innovative techniques.** DG SANTE will facilitate new opportunities under Horizon Europe to deliver new knowledge and data to support the F2F Strategy, including on reduction of food loss and waste, finding alternatives to antimicrobials and synthetic chemical pesticides and improving access to healthy diets.

In the field of novel food, authorisation applications processed by DG SANTE (see Specific Objective 1.1 – Market access for safe substance) cover - among others - requests for authorisations of insects, plant-based proteins and algae-derived products as novel foods in Europe, based on EFSA's scientific advice. Requests for the authorisation of cell cultures derived food (e.g. cultured meat) are expected in 2024.

Following the adoption in 2023 of the legislative proposal on plants obtained by certain **new genomic techniques (NGT)**, DG SANTE will support discussions in the European



Parliament and the EU Council to ensure progress towards the adoption of this legislation which can support the agricultural sector in its transition to sustainability and ensure an appropriate regulatory framework for certain products of new biotechnologies.

DG SANTE will also support inter-institutional discussions on the adopted proposals for a revision of the legislation on **marketing standards for plant and forest reproductive material**, while continuing to ensure the implementation of the existing marketing Directives, as well as of the legislation on Community Plant Variety Rights (CPVR), including the work carried out by the Community Plant Variety Office (CPVO).

**Improving the regulatory framework on Food Contact Materials (FCM).** Food packaging and processing plays a key role in food systems' sustainability. Under the F2F

Strategy, and following the conclusion of the evaluation, DG SANTE will pursue preparatory work for the revision of the **Food Contact Materials framework legislation**, including conducting an impact assessment. In the run-up to the revision, the DG will pay special attention to the reduction of citizens' exposure to endocrine disruptors and other hazardous substances of high concern, striving for coherence with the ambitions of the Chemicals Strategy for Sustainability.

DG SANTE will continue implementing the new regulation on plastic recycling adopted in 2022. This includes preparing, with a view to adopt in 2024, decisions for over 220 authorisations of mechanical **PET plastic recycling processes**, as well as the establishment of the first Union list of authorised recycling processes for PET plastics to be used as FCM. This will facilitate the uptake of recycled plastics by the food packaging industry, which accounts for a major part of plastic packaging and will represent a significant contribution to the Circular Economy Action Plan.

### **Specific Objective 1.3: International promotion of EU food safety standards**

The Green Deal and the F2F Strategy call for an ambitious international agenda. DG SANTE will foster international discussions to promote food safety standards and the shift to sustainable food systems at multilateral and bilateral level. This work contributes to the achievement of specific UN Sustainable Development Goals (SDG), especially SDG 2 *Zero hunger*, SDG 3 *Good health and well-being*, and SDG 12 *Responsible consumption and production*.

The international outreach and buy-in of the Strategy represents a major challenge, as non-EU countries may not share the ambitions of the Green Deal or may have different views on how to approach those.

**Improving multilateral relations.** In 2024, DG SANTE will continue to promote and support relevant initiatives of the Food and Agriculture Organisation (FAO), the World Health Organization (WHO) and other UN agencies and will engage with them in the work on food safety and on sustainable food systems. Following the UN Food Systems Summit Stocktaking Moment in 2023, DG SANTE coordinates the Commission presence in the strategic group of National Food Systems Convenors and in the Coalitions of Action for “Healthy Diets from Sustainable Food Systems” and “Food is never waste”.

In the context of the **World Trade Organization** (WTO), DG SANTE will contribute to the work of the WTO governing bodies and seek to seize other opportunities to promote a One Health approach and the transition to sustainable food systems and the One Health approach. Building also on the implementation of the work programme laid down by the SPS Declaration adopted at the 12<sup>th</sup> and to be reported at the 13<sup>th</sup> Ministerial Conference, DG SANTE will actively participate in the 6<sup>th</sup> review of the SPS Agreement. DG SANTE will continue to promote and defend EU interests in the field of sanitary and phytosanitary measures and EU legislation on food safety, animal health and plant health. In particular, it will continue to address the criticisms of EU policies on pesticides, including neonicotinoids, on veterinary medicines in the area of AMR and on any other relevant topic. DG SANTE will

also continue its work in the context of the WTO Committee on Technical Barriers to Trade (TBT) in relevant policy areas, such as food labelling and animal welfare.

In the **World Organisation for Animal Health** (WOAH), DG SANTE defends the EU's high animal health and welfare standards and works to influence and promote international standards. In the European Commission for the Control of Foot-and-Mouth Disease (EuFMD) aiming at assisting the campaign against foot- and-mouth disease (FMD) and other similar transboundary animal diseases, DG SANTE supports actions aiming at increasing preparedness and awareness in the EU and its neighbouring countries for FMD and other key diseases.

In 2024, DG SANTE will continue to coordinate EU positions within the **Codex Alimentarius** and lead or contribute actively to Codex work in priority areas to promote food safety at international level and ensure as far as possible that EU legislation and Codex standards are aligned. Special attention is expected to be paid to innovation and to reflections on the future of Codex, including promotion of sustainability and the One Health approach.

DG SANTE will actively participate and contribute to the intersessional activities under the **Convention on Biological Diversity (CBD) and the Cartagena Protocol (CP) on Biosafety**. In 2024, the 16th Conference of the Parties to the CBD/11th Meeting of the Parties to the CP (COP 16/MOP 11) will take place. EU positions and statements will be coordinated and used for negotiations in the technical groups of the CBD and its CP, and in COP 16/MOP 11. DG SANTE will also contribute to the biosafety component in the post-2020 global biodiversity framework.

In the **International Plant Protection Convention** (IPPC), DG SANTE will continue to coordinate the EU input on global plant health strategy, including the development of international standards and guidelines for phytosanitary measures.

At European level, DG SANTE will be intensively involved in the scientific work performed by the **European and Mediterranean Plant Protection Organisation** (EPPO) in the framework of pest risk assessment and pest risk management and will continue to coordinate the EU input.

The EU is one of the world's largest exporters of seeds. International policies on seeds are important for jobs, food security, to adapt to climate change and ensure sustainable agricultural production. In 2023, DG SANTE will continue to work towards international harmonisation and governance in the area of seeds and in particular towards developing and implementing the **OECD Seed and Forest Schemes**. It will work to improve cooperation and guidance within the **International Union for the Protection of New Varieties of Plants** (UPOV) and improve access to plant genetic resources in the context of the **International Treaty on Plant Genetic Resources for Food and Agriculture** (ITPGRFA).

**Improving bilateral trade relations.** Trade is a key instrument to promote the EU Sanitary and Phytosanitary (SPS) system and the F2F Strategy. Ensuring that trading partners adopt proportionate and scientifically justified measures respecting international

principles – in reaction to occurrences of animal diseases in particular (regionalisation) – will remain a significant challenge. DG SANTE will continue to cooperate with partners in a horizontal way, through trade agreements, Partnership instruments and training programmes. In this area, ensuring smooth trade relations with the main trading partners whilst ensuring abundance by concluded agreements and preserving EU interests is an additional challenge.

DG SANTE will continue to promote the F2F Strategy internationally, seeking to build **green partnerships** with like-minded non-EU countries and include Sustainable Food Chapters or provisions in the FTAs. DG SANTE is already actively engaged in exchanges and organised dialogues with non-EU countries on this issue, with the support of the Partnership Instruments. DG SANTE will continue to organise such dialogues which are already allowing to identify precise areas of joint interest with non-EU countries.

DG SANTE will continue leading negotiations on **SPS and Sustainable Food Systems (SFS) Chapters** in the Free Trade Agreements primarily with India, but also with Thailand, Malaysia, Indonesia, the Philippines. DG SANTE also intends to negotiate in the area of food safety with Switzerland and agreements in the areas of health with Norway and Switzerland.

Moreover, the DG will continue to pursue good **bilateral SPS relations** with key commercial partners. DG SANTE will notably manage and **implement existing agreements**, such as the EU-UK Trade and Cooperation Agreement, Eastern Partnership agreements, and agreements with Canada, Singapore, Vietnam, Chile, Central America, Colombia-Ecuador-Peru, Japan and New Zealand. DG SANTE will monitor the Mutual Recognition Agreements (MRA) in place with Australia, New Zealand and Switzerland. Among countries not covered by agreements, the key priorities remain USA, China, India, Turkey, Brazil and Argentina.

As confirmed in the last SOTEU, **enlargement** and **neighbourhood policy** have gained momentum due to the Russian aggression against Ukraine. Strong focus is on Ukraine, Moldova, Western Balkans and Georgia where DG SANTE will actively support the enlargement process regarding the food safety *acquis*. At the same time, managing existing Association Agreements on SPS remains crucial.

DG SANTE will continue to support trade facilitation from and to Ukraine under the Solidarity Lanes provisions and to manage the relations with Turkey, the Eastern and Southern Partnership and the Africa Strategy on food matters.

## General Objective 2: PROMOTING OUR EUROPEAN WAY OF LIFE

**European Health Union.** In 2024, DG SANTE will oversee the further strengthening of the **European Health Union**. DG SANTE will continue working with Member States to prepare for and respond to public health emergencies and cross-border threats to health through a new legislative health security framework.



DG SANTE will also continue its work on the implementation of **Europe's Beating Cancer Plan** and the **Pharmaceutical Strategy for Europe** and will work towards reaching an inter-institutional agreement on the **European Health Data Space** and on the revised **regulation on substances of human origin**.

In 2024, DG SANTE will contribute to the **support to Ukraine** following the Russian military aggression, for instance by backing the unprecedented medical evacuation operations as well as providing mental health and psycho-social support for Ukrainians. The Health Policy Platform, as an agile mechanism for stakeholder involvement and consultation, will contribute to helping Ukrainian refugees.

Following the adoption of the new comprehensive approach to **mental health** in June 2023 and the high-level event, on 10 October 2023, to mark World Mental Health Day, DG SANTE will support Member States in implementing flagship actions, in addition to collaborating with WHO and OECD. With the support of the Public Health Expert Group, the initiative **"Healthier together – EU Non-Communicable Diseases"** will continue to support Member States in addressing major causes of mortality and morbidity, such as cardiovascular diseases, diabetes, chronic respiratory diseases, mental health, and neurological disorders, as well as health determinants (such as tobacco, alcohol, nutrition, and physical activity). It supports the Member States in achieving the UN Sustainable Development Goals, namely the objective of reducing the burden of non-communicable diseases. The evaluation study on the EU Childhood Obesity Action Plan (2014 – 2020) will inform possible further action in this area.

**EU funding for health.** In 2024, DG SANTE in liaison with the European Health and Digital Executive Agency (HaDEA), will monitor the implementation of the previous EU4Health annual work programmes and prepare, with the EU4Health Steering Group and consulting stakeholders, the work programme for 2025.

DG SANTE will also work with other DGs, services and institutions to deliver synergies across relevant EU funding programmes and instruments and carry out the interim evaluation of the EU4Health Programme. DG SANTE will also continue its work on the association, as appropriate, of non-EU countries to the Programme and its role as co-chair of the health Cluster under Horizon Europe.

**International cooperation.** In line with the **Global Health Strategy** <sup>(4)</sup>, DG SANTE will continue to reinforce EU's role in various multilateral fora, in particular the WHO, G7, G20 and the UN. In this context, DG SANTE will actively promote the One Health approach, particularly on pandemic prevention, preparedness, and response, improving the global health security architecture, and contributing to the fight against antimicrobial resistance. The negotiations of the pandemic agreement and the revision of the International Health Regulations will be central. DG SANTE will also further strengthen its cooperation with the WHO European Region. DG SANTE will provide leadership at the 10<sup>th</sup> Conference of the Parties to the WHO Framework Convention on Tobacco Control, which will take place in February 2024 in Panama.

In **bilateral cooperation**, DG SANTE will actively support the enlargement process regarding the EU health *acquis communautaire* with Ukraine, Moldova, Western Balkans, and Georgia. A special role will be given to the **relations with Ukraine** with the required support for its health sector, assistance to refugees and coordination of activities with the Member States. Key partners on health matters include Canada, the US, India, South Korea, China, Japan, South Africa and the African Union.

**Specific Objective 2.1: Diminishing the impact of cancer in Europe - Europe's Beating Cancer Plan.** In line with the Mission Letter to Commissioner Kyriakides, DG SANTE leads the implementation of **Europe's Beating Cancer Plan**. DG SANTE is co-leading the Horizon Europe Cancer Mission with DG RTD, to ensure synergies with the Cancer Plan. After its adoption, the **prevention package** will be discussed in the Council. It comprises: a **proposal for a Council Recommendation on vaccine-preventable cancers** caused by the Hepatitis B virus and human papillomavirus (HPV) and a **proposal for a revised Council Recommendation on smoke-free environments**.

DG SANTE will prepare a proposal for a **Commission recommendation on reducing the health risks associated with using sunbeds** <sup>(5)</sup> and facilitate the development of a **code of conduct on fairness in accessing financial services for cancer survivors** ("right to be forgotten"), together with DG FISMA.

It will support the implementation in the Member States of the **Council Recommendation on cancer screening** <sup>(6)</sup> and prepare for the establishment of an EU network of Comprehensive Cancer Infrastructures and Centres by the end of 2025. This includes mapping and support to reinforcing national capacities, and the establishment of new networks of expertise focusing on more common cancers and cancer conditions.



<sup>(4)</sup> [https://health.ec.europa.eu/system/files/2022-12/international\\_ghs-report-2022\\_en.pdf](https://health.ec.europa.eu/system/files/2022-12/international_ghs-report-2022_en.pdf).

<sup>(5)</sup> The term "sunbed" refers to all types of artificial tanning devices that emit UV radiation, which are used for cosmetic purposes.

A high-level cancer event will be organised in January 2024 to showcase the progress made within the Cancer Plan and the successful EU funded projects that are contributing to implementation. A conference on the EU code of conduct on access to financial services for cancer survivors will be co-organised with DG FISMA in March. The successful campaign on cancer screening will continue in 2024, targeting adults aged 40-60 from disadvantaged backgrounds, in several additional target countries.

The Commission will continue with the development of a **Cancer Inequality Registry** to help identify trends, disparities and inequalities between Member States and regions. DG SANTE will continue the evidence gathering for health warnings on alcoholic beverage products.

The work will continue on **EU-US cooperation** in view of establishing a structured transatlantic dialogue on both cancer policies and research collaborations, with focus on lung and children/young adult cancer.

**Tobacco control.** DG SANTE has long engaged in efforts in the EU and globally to reduce tobacco consumption. In 2024, DG SANTE will finalise the evaluation of the **tobacco control legislation** and will launch complementary studies targeted at closing evidence gaps. DG SANTE will continue to work on the implementation of the tobacco products directive. It will contribute to supervising the expansion of the EU system of tobacco product traceability to other tobacco products than cigarettes and roll-your-own tobacco products.

## **Specific Objective 2.2: Patients' access to safe, innovative and affordable medicines and medical devices**

**Pharmaceutical Strategy for Europe** <sup>(7)</sup> aims to ensure Europe's supply of safe and affordable medicines for citizens and to reinforce the EU's global position as an innovator and world leader, as defined in the President's mission letter to Commissioner Kyriakides.



In 2024, inter-institutional negotiations will take place on the **reform of the pharmaceutical legal framework** <sup>(8)</sup>, including medicines for children and rare diseases. The process will be supported by communication actions on traditional and social media. Starting in 2024, the DG will perform

preparatory work concerning new “regulatory concepts”, such as “unmet medical need” and “regulatory sandboxes” through pilots or working groups.

<sup>(7)</sup> [Commission Communication on a Pharmaceutical Strategy for Europe COM\(2020\) 761 final.](#)

<sup>(8)</sup> [Reform of the EU pharmaceutical legislation - European Commission \(europa.eu\)](#)

Further key actions in 2024 by DG SANTE linked to the pillars of the Pharmaceutical Strategy include:

- Adoption of a delegated act to revise the **Variation Regulation** to simplify and increase efficiency in the lifecycle management of medicines;
- Availability/shortages: follow-up actions to the Communication on shortages of medicines <sup>(9)</sup> and to the Staff Working Document on security of supply, and support to and cooperation with the European Medicines Agency (EMA) in the management of shortages. DG SANTE will implement several actions put forward in the Communication on medicines shortages in order to address shortages of medicines and enhance their security of supply in the EU. Among others, DG SANTE will develop with EMA the “Voluntary Solidarity Mechanism for medicines” to support Member States experiencing critical shortages and supervise and follow the development of a Union list of critical medicines, building on work with the EMA and the Member States.
- Affordability: develop the agenda with the *Group of national competent authorities on pricing and reimbursement and public healthcare payers* (NCAPR) through mutual learning and best practice identification on pricing mechanisms, procurement, willingness to pay, real world evidence, access monitoring and data sharing. In particular, as announced in the Communication on shortages, voluntary collaboration will be further facilitated on the interaction between national pricing, reimbursement and procurement policies and security of supply. Through continued work with experts and national authorities, DG SANTE/the Commission will issue EU guidance on procurement to support Member States and procurers in their procurement practices that can make a direct contribution to security of supply and availability of medicines. DG SANTE will analyse the results of the study commissioned with the purpose to analyse the functioning of Council Directive 89/105/EEC (better known as the “Transparency Directive”) and discuss these as appropriate with the relevant national authorities. In the longer run, evaluation of the existing Directive gives the opportunity to look at an important tool for cooperation on pricing and reimbursement.
- Quality: DG SANTE will monitor and update, if needed, the Good Manufacturing and Distribution Practices, inspection programmes and progress on the strategic framework on the pharmaceuticals in the environment.

**Implementation and application of the pharmaceutical legislation.** DG SANTE oversees the authorisation of human medicinal products by the Commission under the centralised procedure, based on a positive scientific assessment performed by the European Medicines Agency. In 2024, the DG will continue to authorise new medicinal products and modifications of already authorised products within the legal deadlines, including some COVID-19 related procedures. <sup>(10)</sup> DG SANTE will also provide legal and regulatory support as regards treatments and vaccines and close collaboration with EMA

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<sup>(9)</sup> [Communication medicines shortages EN 0.pdf \(europa.eu\)](#)

<sup>(10)</sup> As regards medicinal products for human use, it is estimated that, in 2024, DG SANTE will handle approximately: 92 new authorisations, 15 referral procedures, 84 renewals of marketing authorisations, 30 line-extensions of marketing authorisations, 96 pharmacovigilance procedures and 9000 variations to the terms of the marketing authorisations. Estimates based on European Medicines Agency [Final programming document 2023-2025 \(europa.eu\)](#)

will continue. It will continue to work on Advanced Therapy Medicinal Products and will conduct a study on innovation through the hospital exemptions.

DG SANTE will continue to monitor the implementation of the **Clinical trials regulation** and it will monitor compliance with the rules on the **falsification of medicines**.

The new legislative proposal on the **organisation of the fees to be paid to EMA** will be implemented in 2024.

**International cooperation in pharmaceuticals.** DG SANTE, in close collaboration with EMA, will continue its bilateral relations with key strategic partners and exercise leadership in key international cooperation fora that promote harmonisation of technical requirements and high-level standards for quality, safety and efficacy of pharmaceuticals. DG SANTE will also foster regulatory convergence and facilitate information-sharing through multilateral cooperation<sup>(11)</sup>. It will continue its efforts, in close collaboration with EMA and the EU national competent authorities, to get the EU regulatory system on pharmaceuticals recognised as a 'single entity' and, as such, eligible for designation as a WHO Listed Authority. DG SANTE will monitor the implementation of the mutual recognition agreement with the US and will monitor the implementation of EU pharmaceutical legislation applicable to and in the United Kingdom in respect of Northern Ireland under the Windsor Framework<sup>12</sup> and manage the post-Brexit situation in Malta, Cyprus and Ireland.

**Health Technology Assessment (HTA).** In 2024, six implementing acts and additional guidance documents will be adopted, as stipulated in the HTA Regulation, in preparation for the date of application in January 2025. The EC secretariat will continue to support the **HTA Coordination group and its four sub-groups** and further develop the dedicated IT platform for the joint work. The newly created **HTA Stakeholder Network** will be integrated in the IT platform. Four regional HTA information and awareness raising events in Member States will take place in collaboration with the Heads of HTA agencies group.

**Medical Devices and In Vitro Diagnostic Medical Devices.** DG SANTE will continue to implement the legal framework on medical devices and in vitro diagnostic medical devices. Following the adopted extension of the medical device regulation transition timelines (under certain conditions) **and the one planned for the in vitro medical devices regulation**, DG SANTE will continue developing practical guidance for the transitional provisions and targeted activities to avoid shortages of devices in particular for small patients' populations. In parallel, DG SANTE will start evaluative work, launching a reflection on structural elements, to assess whether additional actions are needed, in particular to support SMEs and innovation. Together with the EMA, DG SANTE will continue to manage

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<sup>(11)</sup> This is done through the Commission's membership in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), the International Coalition of Medicines Regulatory Authorities (ICMRA) and the International Pharmaceutical Regulators Programme (IPRP). The Commission is participating as an observer in the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

<sup>(12)</sup> Joint Declaration No 1/2023 of the Union and the United Kingdom in the Joint Committee established by the Agreement on the withdrawal of the United Kingdom of Great Britain and Northern Ireland from the European Union and the European Atomic Energy Community of 24 March 2023 (OJ L 102, 17.4.2023, p. 87

the work of the Expert Panels on medical devices. DG SANTE will further implement the medical devices legislation by continuing the development of the database **EUDAMED** as well as by adopting or amending tertiary legislation acts. DG SANTE will continue to chair and manage the **Medical Device Coordination Group** and its sub-groups to ensure coherent implementation and to facilitate coordination and exchanges according to the MDR and IVDR, including in vigilance and market surveillance. It will continue to engage in **international discussions** regarding medical devices.

### **Specific Objective 2.3: Effective response coordination of serious cross-border health threats**

DG SANTE will continue to be at the core of the coordination of EU's work regarding prevention, preparedness, and response to cross-border health threats, such as outbreaks with epidemic potential. A "One Health" approach will be further pursued to ensure sound and integrated actions addressing AMR and zoonotic diseases. Closer collaboration with and between the relevant EU agencies like EFSA and ECDC will be fostered. DG SANTE will increase efforts to address climate-induced health threats posing risks for emerging infectious diseases.

As negotiator for issues falling under EU competence, the Commission will continue to be fully engaged in the negotiations to draft a **new international agreement on pandemic prevention, preparedness, and response**, as well as in the negotiations to **amend the International Health Regulations (2005)**. DG SANTE leads the Commission's work in both negotiation processes, expected to be concluded by the 77th World Health Assembly in May 2024. In doing so, DG SANTE closely coordinates with relevant Commission services and EU Member States, while working with WHO Member States and involving relevant stakeholders, to ensure a successful outcome of the negotiations and deliver significant improvements in pandemic prevention, preparedness, and response, in the interest and benefit of all.

**Preparedness and Response.** DG SANTE will further implement the **Regulation on serious cross-border threats to health** <sup>(13)</sup>, which will reinforce the framework for EU prevention, preparedness, and response. This includes coordination with Member States via the Health Security Committee and its working groups, the development of a Union preparedness plan, implementation of a reporting framework for Member States, and development of its assessment, strengthening surveillance, setting-up a new risk assessment framework, and improving the early warning and response system. The Regulation will be evaluated before the end of the year while its implementation will require the adoption of several implementing and delegated acts. DG SANTE will work closely with **European Centre for Disease Prevention and Control** (ECDC) and the **EMA** and with the **Health Emergency Response Authority (HERA)** for the medical countermeasures, to ensure complementarity of the work on all these actors.

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<sup>(13)</sup> <https://eur-lex.europa.eu/eli/reg/2022/2371>

**Vaccination.** In 2023, DG SANTE will continue to build upon the successful EU Strategy for COVID-19 vaccines <sup>(14)</sup>. DG SANTE will continue to support regulatory actions, policy-related activities and access to COVID-19 vaccines, and support Member States. External communication activities will focus on raising awareness of the benefits of lifelong vaccination, with a specific focus on vaccine preventable cancers. This will be closely coordinated with ECDC, EMA and national authorities. Member States efforts on vaccination and on HIV/AIDS, tuberculosis and hepatitis policies will continue to be supported via exchange of best practices and knowledge. Close links will be sought with the WHO/Europe and Commission actions linked to addressing misinformation.

**Antimicrobial Resistance (AMR).** DG SANTE will coordinate the implementation of the Council Recommendation adopted in 2023 to reach concrete outcomes in reducing the spread of AMR. Particularly important will be the cooperation with EU Agencies, stakeholders, and Member States through the AMR One Health Network. DG SANTE will continue to contribute to the fight against AMR at international level, during the High-Level meeting at the 2024 United Nations General Assembly, as well as in the context of the Pandemic Agreement negotiations and in the Quadripartite Stakeholder Platform.

An EU-wide communications campaign aimed at young people will raise awareness of the need for prudent use of antimicrobials, as well as the EU's actions to promote a One Health approach in combatting AMR, focusing on countries which show the lowest levels of knowledge of the correct use of antimicrobials.

#### **Specific Objective 2.4: More effective, accessible, and resilient health systems**

In line with the priorities set out in the mission letter of Commissioner Kyriakides, DG SANTE will continue to support Member States in improving the effectiveness, accessibility, and resilience of their health systems in 2024. This work supports the Member States in achieving the UN Sustainable Development Goal 3 (Ensure healthy lives and promote well-being for all at all ages), as well as improving health systems' resilience.



**Digital health.** In 2024, DG SANTE will work towards reaching an inter-institutional agreement on the proposal for a regulation on the **European Health Data Space**. In parallel, preparatory actions for the implementation of the EHDS will be conducted via projects under the EU4Health programme and other funding instruments.

Communication and awareness raising activities including promotional videos, specialised events and workshops will be launched to support the last phase of the inter-institutional process. On primary use of

health data, DG SANTE will continue to support and coordinate the actions of the Member

<sup>(14)</sup> [Communication from the Commission to the European Parliament, the European Council, the Council and The European Investment Bank: EU Strategy for COVID-19 vaccines, COM/2020/245 final.](#)

States in the **eHealth Network** in deploying **MyHealth@EU** digital infrastructure for cross-border exchanges of **electronic Patient Summaries** and **ePrescriptions** and their further expansion. On secondary use of data, DG SANTE will continue the work on a framework for a governance for access to data, interoperability and data quality, as well as the technical infrastructure **HealthData@EU** through a **pilot project**. Two Joint Actions on primary and secondary use of health data will be launched. Direct grants to Member States from the EU4Health programme will also support the cross-border digital infrastructures.

In line with the Global Health Strategy, DG SANTE is strengthening its commitment towards the international dimension of digital health ensuring cooperation with WHO and exchanging information with OECD as well as with relevant third countries (e.g. the US). After the expiry of the EU Digital Covid Certificate (EU DCC) Regulation, an administrative arrangement was established with WHO to contribute to the setting up and development of the WHO Global Digital Health Certification Network, a system for issuing and verifying health documents based on the EU DCC system, which will continue in 2024 and beyond.

**Health systems.** DG SANTE will continue to generate country-specific and cross-country knowledge on health systems, through the start of the 5<sup>th</sup> cycle of the **State of the Health in EU** project with OECD and the Observatory on Health Systems and Policies and continuing to produce the reputable Health at a Glance in the EU and Country Health Profiles publications. The implementation of a portfolio of projects under EU4Health addressing health workforce challenges and access to healthcare will continue.

In 2024, DG SANTE will continue to act as secretariat for the **Expert Group on Health Systems Performance Assessment**, which has a broadened mandate to focus on a more strategic approach to transforming health systems. This Expert Group is expected to publish a report on identifying low value healthcare and start work on a new workplan including topics on mental health, health workforce, greening health systems, health inequalities and governance.

DG SANTE will contribute to the **European Semester process**, which is integrated with the Recovery and Resilience Facility, by providing detailed country-specific analyses and Annexes to the Semester country reports on health and health systems and contribute to assessing health milestones and targets as part of the monitoring of the **Recovery and Resilience plans**.

To support improvement of diagnosis and care and the cross-border support for patients with rare diseases, **European Reference Networks** are further developed, and their functioning enhanced, following up to the results of the evaluation which was finalised at the end of 2023 and the provision of funding for the next four years (2024-2027) as EUR 77 million of grants. A Joint Action, starting in 2024, aims at integrating them in the national health systems, with a view to establishing a more self-sustainable operation.

DG SANTE will work with the Expert Group on Public Health and its subgroups (cancer, non-communicable diseases, mental health, and vaccination) to scale-up of best practices on health promotion and disease prevention. The **Scientific Committees** will provide targeted

scientific advice for policy making in the areas of consumer safety and health and environment. DG SANTE will also continue to support the European Monitoring Centre for Drugs and Drug Addiction.

**Substances of human origin.** DG SANTE will support the finalisation and adoption of the **new EU legislation on the safety and quality of substances of human origin** <sup>(15)</sup> and then ensure its implementation and prepare for the next steps on the entry into application of the new framework.

**Patients' rights to cross-border healthcare.** EU citizens have the right to access healthcare in any EU country and to be reimbursed for care abroad. DG SANTE will continue to undertake compliance checks and bilateral structural dialogues with the Member States regarding the provisions of **Directive 2011/24/EU on Cross-border Healthcare**. A series of workshops with policy makers, citizens, healthcare providers, insurers, will be organised at national level and in border regions to raise awareness about patients' rights in cross-border healthcare, as a follow-up action after the 2022 evaluation of the directive.

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<sup>(15)</sup> COM/2022/338.

## **PART 2. Modernising the administration: main outputs for 2024**

The internal control framework <sup>(16)</sup> supports sound management and decision-making. It notably ensures that risks to the achievement of objectives are taken into account and reduced to acceptable levels through cost-effective controls.

DG SANTE has established an internal control system tailored to its particular characteristics and circumstances. The effective functioning of the service's internal control system will be assessed on an ongoing basis throughout the year and will be subject to a specific annual assessment covering all internal control principles.

### **A. Human resource management**

2024 will be an 'election' year. DG SANTE will finalise the last initiatives under this Commission and concentrate on preparing for the next period of 5 years. From an organisational and HR perspective DG SANTE will focus on activities preparing DG SANTE for the next Commission. This covers in particular the areas of digital and organisational transformation, data and digital for policy and fostering staff's understanding of how DG SANTE works and collaborates across teams. It includes creating better understanding of how to work more efficiently in a hybrid working environment, improve 'data' literacy and improve the integration of newcomers.

DG SANTE will continue its efforts to implement its successful policy for recruiting on pre-management positions to ensure sufficient instream of talent at desk officer and junior management positions to maintain its very good gender balance records. As a result DG SANTE reached equal gender balance at Head of Unit and Deputy Head of Unit level. Moreover, in accordance with the Commission Decision on new 2023/2024 objectives for first female appointments at middle management level, DG SANTE will carry out in 2024 at least two first female HoU recruitments.

To further boost staff engagement DG SANTE will also continue to focus on stimulating collaboration and communication through clear communication channels from top to bottom and vice versa, promoting staff involvement and the provision of valuable feedback. The regular morning coffee sessions with the Director General, the SANTE management seminars and dedicated thematical sessions plus the many knowledge hour discussions covering a wide range of topics will keep the finger on the pulse of DG SANTE's activities. They will help to stimulate the exchange of ideas and their uptake by the policy domains and ensure integration in the daily working processes of the DG.

Finally, we will invest in promoting the 'Be Well at Work' action plan in DG SANTE. Our purpose is to promote a culture of caring about mental well-being amongst managers,

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<sup>(16)</sup> [Communication C\(2017\)2373 - Revision of the Internal Control Framework](#).

including the respect of the dignity of the individual in an ever more demanding and stressful environment.

## **B. Sound financial management**

DG SANTE uses the organisational structure and the internal control systems suited to achieving its policy and internal control objectives in accordance with the internal control principles set by the Commission <sup>(17)</sup>. DG SANTE has established an internal control strategy including all control and anti-fraud measures for all types of expenditure directly managed by the DG in the health and food safety policy areas. The control measures encompass risk assessment and risk management integrated into the planning process, and control activities including ex-ante and ex-post verifications, the aim being to ensure that resources are managed in accordance with the principles of sound financial management.

The internal control strategy, in its latest version of December 2017, is an evolving document and will be aligned to the new corporate guidelines on the establishment of a control strategy for financial operations. It will also reflect the organisational and procedural changes that have been implemented in 2021 and 2022 further to the decisions taken in the context of the Multi-annual Financial Framework 2021 to 2027 and given DG SANTE's new organisational structure as of 1 October 2022. Of particular importance continues to be the supervision of budget implementation tasks transferred to the Health and Digital Executive Agency (HaDEA), and the co-operation with the Health Emergency Preparedness and Response Authority (HERA) based on the established Memoranda of Understanding in 2022. DG SANTE will strive to have cost-effective controls in place which give the necessary guarantees concerning the legality and regularity of the underlying transactions.

On a regular basis, management is informed about budget implementation and control results to monitor budget execution indicators, including payment delays and error rates. In addition, DG SANTE receives feedback from audits of the Commission's Internal Audit Service and the European Court of Auditors and compiles, implements and monitors the corresponding action plans. In its internal control system, DG SANTE embedded continuous monitoring measures to ensure that its management and internal control framework is effective.

Annual management assessments of the effectiveness of key internal control systems are carried out to ascertain whether the components of internal control are present and functioning and whether deficiencies are remedied in a timely manner. In 2024, DG SANTE will continue to follow the methodology proposed in the "implementation guide of the internal control framework of the Commission".

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<sup>(17)</sup> Commission Communication (2017) 2373 on the revision of the Internal Control Framework.

## C. Fraud risk management

Fraud risks are addressed by specific controls designed and implemented to mitigate the risks. To this end, DG SANTE has developed and implemented its own anti-fraud strategy and action plan since 2013 (latest update of November 2021), on the basis of a specific fraud risk assessment and a methodology provided by OLAF. The controls to prevent and detect fraud are basically the same as those intended to ensure the legality and regularity of the transactions. An assessment of the risks of fraud is included in the annual risk management exercise.

In 2024, DG SANTE will continue to organise awareness raising activities on anti-fraud matters, strengthen the cooperation with OLAF and EPPO, and strive to ensure a high implementation rate of measures foreseen in DG SANTE's anti-fraud action plan for 2024. At the same time, DG SANTE aims to contribute to the implementation of the revised Commission Anti-Fraud Strategy's Action plan <sup>(18)</sup> where applicable.

Of particular importance is the re-launch of DG SANTE's inter-agencies' task force and the close co-operation on anti-fraud matters with the EU decentralised agencies. In 2023, DG SANTE will continue to support the decentralised agencies and the Health and Digital Executive Agency (HaDEA) in updating their anti-fraud strategies and action plans. All the above-mentioned measures contribute to the objectives of the Commission Anti-Fraud Strategy (2019 CAFS) and are linked directly to 12 actions of the 2019 CAFS action plan.

Most of the actions are already well embedded in existing procedures. The internal control officers monitor the implementation of DG SANTE's anti-fraud action plan and report the results to DG SANTE management twice a year, i.e. in February and September.

## D. Digital transformation and information management

DG SANTE started the digital transformation three years ago with an IT modernisation and rationalisation study to review our portfolio and propose solutions and approach for modernisation. We have now a complete high-level cartography of our business and we are doing the detailed cartography of our technical solutions. DG SANTE implements its digital transformation across the axes defined by the corporate bodies and new digital strategy, pursuing a practical stepwise approach with the aim to streamline and modernise the portfolio of solutions in business terms by simplifying processes and digital implementation, technical terms and by moving to the cloud and more connected systems. We will continue to adjust the approach to delivering and procuring IT solutions and services to be more reactive, agile and business oriented, and in line with the corporate 'dual-pillar' approach.

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<sup>(18)</sup> [Communication from the Commission 'Commission Anti-Fraud Strategy Action plan - revision 2023 COM\(2023\) 405 of 11 July 2023](#) – 'the Communication on the 2023 revision' – and the accompanying document, [SWD\(2023\) 245](#) – 'the revised Action Plan

Details of the digital transformation and information management in DG SANTE are defined in DG SANTE's Digital and Data Master Plan (DDMP) for 2024. It is an important instrument to oversee the annual digital and data investments in DG SANTE, including an alignment with the Commission's new digital strategy and corporate governance on IT and Data. The Master Plan also addresses all aspects of IT security, cybersecurity, IT security risk management and IT security compliance management and provides annual objectives, and capability improvements. DG SANTE management will adopt the 2024 DDMP by December 2023 and in 2024 will receive reports on its implementation on a regular basis.

## Digital transformation

DG SANTE actions on the new Commission Digital Strategy objectives are as follows:

- Objective 1. Foster a digital culture

The IT Unit in SANTE sets out actions to drive transformation from the business side, deliver a modern landscape integrating data and digital aspects, as well as innovative technologies including AI and Data Analytics, and pursuing reuse of data and common solutions across the DG and Agencies. The key outcomes expected in 2024 are to operationalise AI@SANTE, use the HPAC (Health Policy Agencies Collaboration) data lake as the key repository of data, the platform for data analytics, maintain being vigilant in Cyber Security, deploy more applications in the SANTE cloud, and provide a practical solution for GDPR compliance for all systems.

All these actions are part of the efforts to **improve the digital culture for DG SANTE as a whole** and provide services in SANTE with digital tools and skills fit for the new working practices and environment. This includes the rollout of **modern teleconference rooms and equipment** across all sites, the **use of AI, data analytics and intelligence and automation of tasks** to increase the efficiency of the processes, the optimisation of the **use of M365**, dedicated **training and coaching** for all staff and **improved digital workflows**. Providing these technologies to staff, in combination with practical knowledge hours, trainings and coaching will improve their **digital skills** and will also increase their appetite for more facilitation of agility and productivity in their work through digitalisation and digital solutions. To this end the newly launched **efficiencies in SANTE group** will also become a means to request and put in place for more digital skills and culture towards better delivery of outputs for the DG and SANTE policy overall.

- Objective 2. Enable digital-ready EU policymaking

As regards **digital support for policy**, an important effort will be the development of flagship systems for "health", including (1) the **new CPMS 2.0**, the platform for sharing information on rare diseases; (2) a common infrastructure for the European Health Data Space **HealthData@EU**; (3) extensions for **MyHealth@EU** to support the citizen with cross-border healthcare; and (4) the **new Health Technology**

**Assessment** and (5) **Substance Of Human Origin-X** platforms. DG SANTE will complete the development of medical devices database **EUDAMED MDR**, using a Minimum Viable Product approach and proceed to the readiness audit during 2024. On the “food sustainable” side, we will analyse and design the new **IRASFF** (Rapid Alert system for Food and Feed) to replace the current system, looking at synergies with SG and better integration with the IMSOC (Integrated Management System for Official Controls) ecosystem.

With respect to the **IT Unit’s involvement in the policy cycle, DG SANTE management considers the IT Unit as a partner to achieve the strategic objectives**: (1) the Director General organises quarterly “extended” SANTE Management Boards inviting all senior and middle managers to discuss policy priorities and the related flagships; (2) SANTE’s annual Work Programmes consider the Data and Digital aspects for policy making. Thus, the digital and data aspects are already at the core of DG SANTE’s activities and will remain so in 2024. DG SANTE uses the Data and Digital Steering committee (DDSC) to steer digital ready policy making in the domains of health and food sustainability, by looking first at the existing digital solutions and then by pursuing further possibilities for digitalisation across DG SANTE and Member States by further enhancing the scope and quality of cross-border exchanges and Member States data collection and monitoring.

- Objective 3. Empower business-driven digital transformation

With limited resources, DG SANTE must review the existing business processes for **rationalisation, performance improvement** or opportunities for **efficiency gains**. Our approach to re-design and optimise business processes, verify and test in practice, and then proceed with Digitalisation the Automation bringing the efficiency to a higher level. In cases of complex problems with no practical solution DG SANTE may use, where promising, different AI technologies and pipelines. Bearing in mind that AI investment costs are usually high, we pursue synergies with other DGs, take into account the cost/benefit and use the **innovation lab** approach to test small before proceeding to large scale applications.

- Objective 4. Ensure a seamless digital environment

DG SANTE applies and will continue to use the Dual Pillar approach with a proper analysis in all digital investments, will continue to pursue the reuse of solutions, as for example reuse CASE@EC from DG COMP (integrated with HAN) for the SANTE IMSA solution. We will continue to follow the **cloud-first approach**, having all new solutions in the cloud (HealthData@EU, SOHO-X, CPMS2.0) or using the established SANTE cloud (with the approval of the Cloud Council) for the transfer of solutions to the cloud. Combining the cloud and datalake services, DG SANTE arrive to the **integrated data ecosystem** allowing the interoperability and integration of systems and data. The SANTE digital landscape can only be as good if the processes to build and operate it are stable and is continuously checked for cybersecurity. To these ends DG SANTE will introduce new delivery models following the DevSecOps paradigm for

all transition to the cloud and will integrate more **security by design** and recurring **security and accessibility checks** pursuing the best value and results for end users around EU or DG SANTE.

- Objective 5. Green, secure and resilient infrastructure

DG SANTE will continue to follow the corporate provisions and guidelines, benefiting from all evolution of the offering from the central services that are better positioned for defining and providing secure and resilient infrastructures, fit for purpose devices accommodated by high level corporate cybersecurity arrangements. On the cloud domains, DG SANTE is already using the corporate **cloud brokerage services** putting in place all **Cloud Centre of Excellence** recommendations in the SANTE cloud, ensuring the highest level of compliance and security available at our organisation for our new systems and digital transformation.

DG SANTE makes extensive use of the new sets of collaborative tools made available under the corporate roll-out of Microsoft Teams and its associated toolset. For the next period DG SANTE intends to take advantage of the new set of 'low code' tools such as 'Microsoft Power BI' and "Microsoft Power APPS" which will help empower staff to discover their own insights from data.

To ensure a modern user experience where accessibility is an inherent element of each solutions design, DG SANTE will also identify a number of information systems that require updates and will align the user interface with the latest version of the eUI <sup>(19)</sup> corporate building block to ensure longevity of the solution and reduce the related supporting maintenance costs.

Most DG SANTE IT systems are mandated by legislation and have high performance and availability requirements. Cybersecurity is a crucial concern for DG SANTE, who will continue to use ITSRM for security assessment and consequent plans for all systems with enforcing audits and improving the resilience of our digital solutions to mitigate against cyberattacks. This approach is applied for all systems being developed internally or outsourced and hosted in the DIGIT Datacenter or in the Cloud in alignment with Cybersecurity recommendations of the Security Directorate.

## Information and IT security rules

In the scope available for DG SANTE, we have been steadily progressing towards those objectives as communicated by the Semestrial IT Security Report and the IT Security Risk Report and we are well positioned to meet the corporate objectives. In pursuing those objectives, DG SANTE makes extensive use of a number of DIGIT services through the Unified Memorandum of Understanding such as the c-LISO service, IT Security Plans (ITSP) or the GRC coaching service for our compliance efforts.

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<sup>(19)</sup> User Interface.

DG SANTE will continue to enhance its IT security posture by doing periodic application security testing (AST), reviewing code security for major releases and reacting promptly on security announcements of critical vulnerabilities. Through a newly established quality process for all new developments and deployments, we will be monitoring and increasing the security and resilience of our applications continuously.

On the cybersecurity awareness front, DG SANTE will continue to offer specific training session for the different SANTE officials including HoUs, Senior Management and System Owners but also external people working on the digital technologies in SANTE. We will maintain active participation in cybersecurity awareness activities such as Secure Code Warrior tournament and we will encourage actively colleagues to join our Cyber-Ambassadors team.

## Data, information and knowledge management

DG SANTE's policies and legislation increasingly include a "digital" aspect and/or a need for data gathering and data processing tools. These are aligned with the dual-pillar corporate objective of modernising our use of digital technologies and management of data assets. DG SANTE implements this approach and monitors the developments through the SANTE Data and Digital Steering Committee (DDSC), and with the actions of the SANTE data strategy.

In alignment with the Commission's data platform DG SANTE has put in place the necessary technical elements in the form of the SANTE data lake and related services and we will use it to maintain all SANTE data, provide access and publication of these data (through the Open Data Portal where applicable). During 2024 DG SANTE intends to complete the cataloguing of all data assets including reference data and automate all processes for data dissemination and ingestion and provide the capabilities for data analytics for these sets through standard tools.

The DDSC is acting as a central governance structure to steer and monitor decisions on data and digital related investments that support DG SANTE's policy objectives whilst looking forward to meeting future needs of the DG. It also aims to raise data literacy and data management capabilities for DG SANTE staff. In 2024, the SANTE data strategy will concentrate on a few priority actions. DG SANTE will continue its efforts in identifying potential for streamlining and simplification of its data governance by mapping its processes for identifying data needs and selecting relevant tools & technologies for addressing those needs. DG SANTE will offer awareness raising activities on data governance, availability and use and advertising corporate training paths. To display to its staff the kind of data at its disposal, and to simplify its use, DG SANTE will provide a single point of access to available and relevant data sources, both internal and external. As follow-up to the mapping exercise, DG SANTE will focus on establishing its in-house data expertise, aiming – first in certain areas – to accommodate the needs of policy units for securing and analysing data.

DG SANTE will develop further its data analysis capacity to support policy development with a special focus on medical products and will explore Artificial Intelligence for information gathering and sharing in support of briefings, analysis of consultations and similar summarising tasks.

## Data protection

In 2024, DG SANTE will continue to focus on maintaining full compliance with data protection rules and constant implementation of therein-embodied principles. In particular, it will ensure that all actions, digital solutions and systems, including legislative proposals, which might lead to potential processing of personal data, respect the data protection principles, including data protection by design and by default. The necessary awareness will be achieved by a variety of trainings, ranging from general to dedicated ones, developed for particular categories of DG SANTE staff with particular attention to online trainings. In addition, DG SANTE will further focus on implementation of corporate initiatives relating to protection of personal data.

## E. Sound environmental management

To fulfil the Commission's commitment to become carbon neutral by 2030, its greenhouse gas emissions will have to be reduced by at least 60% compared to 2005. This requires a significant reduction in the environmental impact of missions, meetings and conferences. DG SANTE will contribute to this ambitious objective<sup>4</sup>. Accordingly, within its administrative budget of year 2024, DG SANTE will apply, on top of a standard reduction of 15% as compared to the 2023 voted budget, an additional 600.000 EUR reduction of the expenditure for meetings and committees, while not reducing the missions' budget. To meet this target, the DG will have to reduce the number of in-person meetings and organise and offer more hybrid and remote meetings.

DG SANTE has four buildings in three different Member States, Belgium, Luxembourg and Ireland. SANTE's two buildings in Brussels and the building in Luxembourg fall under the responsibility of OIB and OIL respectively. DG SANTE's building and site in Grange, Ireland, where DG SANTE itself manages the day-to-day running of the site, are fully integrated into EMAS (Commission's Eco-Management and Audit scheme).

DG SANTE and its staff in all three sites are committed to participating in the sound environmental management of the Commission's building and to reducing our negative impact on the environment.

DG SANTE obtained the EMAS registration for the Grange site in 2015 and since then has retained it every year. In 2024, DG SANTE aims to maintain the EMAS registration for the site. This will involve efforts throughout the year to monitor and improve its environmental performance. Grange site will therefore play its role in ensuring that the Commission targets set for 2024 will be achieved, with reduced consumption of both utilities and resources, and reduced emissions and waste. As in the previous year, the performance in

that regard will be influenced by behavioural factors and the relative balance between telework and on-site presence allowed by the flexible working policy of the Commission.

In 2024, the management of the environmental performance of the site in Grange will continue to focus on efficiencies and the reduction of environmental impacts associated with the functioning of the site. To this end, one section of the main office building will continue to be shut down to reduce energy use. In addition, efforts will be made to maintain the already good performance of the current waste management regime for non-hazardous waste. At the end of first quarter 2024, a new facilities management contract will commence in Grange. This contract will place additional obligations on the contractor regarding environmental aspects of the site management and is expected to yield additional environmental benefits.

Green public procurement will continue to be a cornerstone of the DG's procurement activities.

## **F. Initiatives to improve economy and efficiency of financial and non-financial activities**

### **Preparation for the use of the new corporate accounting tool SUMMA**

The Commission prepares for the use of a new corporate financial tool, SUMMA, that will replace ABAC. In view of this launch, DG SANTE has focussed its attention on analysing and preparing the budget structure to be put in place, so that the SUMMA tool will answer DG SANTE's needs in terms of management, operational and financial objectives. The new SUMMA tool will need to combine robust security settings with the necessary flexibility in the budget implementation and will need to contain sufficient operational information to allow for clear, correct and reliable reporting. In 2024, DG SANTE will spend considerable time in preparatory work, training and testing to ensure a smooth migration to SUMMA by 1 January 2025. Once operational, SUMMA will modernise, harmonise and standardise EU financial business processes offering a significant increase in efficiency, flexibility and speed.

### **Cataloguing data in SANTE**

As of 2023, the Data and Digital Master Plan (DDMP) provides a common vehicle for DG SANTE to address Data and Digital needs in an integrated way and with a closer collaboration of the relevant SANTE teams. In the course of this period, work has focused on technologies and capabilities for data cataloguing as input for policy and decision making and use of Artificial Intelligence as a tool to process large amounts of data and draw useful conclusions for policy officers.

On the domain of data cataloguing, DG SANTE has launched two different activities:

(i) automatic cataloguing of data already available in the current SANTE IT systems and solutions; once fully in place, it will empower users to identify data and create their own simple reports as well as publish data automatically using data pipelines to the EU open

data portal; (ii) identification and sharing of information amongst DG SANTE and its Agencies (HPAC members). Following the positive results from the pilot on pesticides data sharing with EFSA, DG SANTE intends to proceed using this pilot as the blueprint for sharing other information on health and food sustainability with the different Agencies during 2024.

# ANNEX: Performance tables - main outputs for 2024

## Part 1 - Delivering on the Commission's priorities

<b>General objective :</b> A European Green Deal		
<b>Specific Objective:</b> Ensuring food and feed safety		
<i>Related to spending programme(s):</i>		<i>Single Market Programme</i>
<b>Main outputs in 2024:</b>		
<b>Initiatives linked to regulatory simplification and burden reduction</b>		
<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EU) 2016/2031 of the European Parliament and of the Council as regards multiannual survey programmes, notifications concerning the presence of regulated non-quarantine pests, temporary derogations from import prohibitions and special import requirements and establishment of procedures for granting them, temporary import requirements for high risk plants, plant products and other objects, the establishment of procedures for the listing of high risk plants, the content of phytosanitary certificates, the use of plant passports and as regards certain reporting requirements for demarcated areas and surveys of pest (Plant Health Law) COM (2023) 661 2023/0378/COD	Support to co-legislators	In the course of 2024
<b>Evaluations and fitness checks</b>		
<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Evaluation of Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights	Finalisation of supporting study	Q4 2024
Evaluation of Regulation (EU) 2016/429 on transmissible animal diseases ("Animal Health Law")	Launch tender for supporting study	Q4 2024

External communication actions		
Output	Indicator	Target
<p><b>Press and Media</b></p> <p>Communicate on actions being taken by the EU especially during times of outbreaks</p> <p><b>Social Media</b></p> <p>Sustained tweets throughout the year on the various aspects of Food and feed safety</p> <p><b>Website</b></p> <p>Update of related webpages</p>	<p>Awareness: media items in national print media covering the EU's actions if/when outbreaks are reported</p> <p>Increase engagement on X/Twitter</p> <p>Reach: increase in the number of visits to the SANTE food and feed related webpages</p>	<p>Media coverage by at least 10 EU countries</p> <p>Average a minimum of 90 engagements per own tweet with #EUFoodSafety (all engagements) on X/Twitter.</p> <p>5% increase (Baseline 2023 – 8,763,391 entries / 20,306,687 page views *)</p> <p><i>*Projection. During 2023, DG COMM changed the domain names of a number of our websites. This may influence the accuracy of the 2023 analytics.</i></p>
Other important outputs		
Output	Indicator	Target
<b>Animal health and animal diseases</b>		
Amendments to Implementing Regulation (EU) 2021/620 on animal health statuses in the EU	Adoption	In course of 2024, as necessary, according to the epidemiological situation
Amendments to Implementing Regulation (EU) 2021/404 on the list of third countries	Adoption	In course of 2024
Amendments to Implementing Regulations (EU) 2020/2235, 2020/2236 and 2021/403 on animal health and official certificates	Adoption	In course of 2024
Commission emergency decisions on handling evolving epidemiological situations	Adoption of emergency decisions as necessary, according to the epidemiological situation	In course of 2024
Commission Regulation amending Commission Regulation (EU) No. 2011/142 on animal by-products	Adoption	Q4 2024
Amendment to Delegated Regulation (EU) 2020/687 on disease control measures	Adoption	Q2 2024

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
<b><i>Plant health and diseases</i></b>		
Regulations on high-risk plants dossiers	Adoption	The no. of adopted regulations depends on the number of requests and of EFSA opinions
Commission Regulations on new or updated measures for quarantine pests known to occur in or approaching the EU territory	Adoption	Ongoing activity for 16 pests
Commission Decisions on emergency measures against some specific pests	Adoption according to (new) outbreak situations	In course of 2024
Commission Decisions with specific import requirements for trade lines where there are too many import interceptions	Adoption according to import interception notifications from Member States	In course of 2024
Commission Regulations with derogations from standard requirements under specific conditions	Adoption according to requests from third countries	In course of 2024
<b><i>Market access for safe substances and products</i></b>		
Regulatory measures on contaminants in feed and food following EFSA opinions	Adoption	In course of 2024
Authorisations of health and nutrition claims, generic descriptors.	Adoption	In course of 2024
Authorisations of health claims made on foods and referring to children's development	Adoption	In course of 2024
Commission delegated Regulation laying down specific compositional and information requirements for baby foods and processed cereal-based foods	Preparatory work	In course of 2024
Commission Regulations prohibiting, restricting or banning the use of substances other than vitamins and minerals in food (Article 8 procedure)	Adoption	In course of 2024
Authorisations of vitamins and mineral substances that can be added to foods and/or to food supplements or foods for specific groups	Adoption	In course of 2024
Commission Regulation setting minimum and maximum amounts of vitamins and minerals in foods and food supplements	Preparatory work	In the course of 2024
Authorisation of novel foods under the Regulation on Novel Foods	Adoption	Up to 25 in course of 2024
Authorisation of traditional foods from third countries under the Regulation on Novel Foods	Adoption	3 in course of 2024

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Decisions on data protection under the Regulation on Novel Foods	Adoption	Ongoing regular activity in 2024, when requested as part of the authorisation process
Authorisations for new substances and new uses of already authorised substances used as food additives or food flavourings	Adoption	Ongoing regular activity in 2024; adoption of approx. 10 acts amending the uses and use levels for food additives and flavourings.
Follow-up of the EFSA opinions related to the renewal of the authorisation for eight smoke flavourings	Adoption of decisions	Q1 2024
Authorisations for new substances and new uses of already authorised substances used in food contact materials, or adaptation of existing authorisations in line with new scientific evidence	Adoption	Ongoing regular activity in 2024, authorisation of approximately five new substances
Ban of the intentional use of Bisphenol A in Food Contact Materials	Adoption	Q2 2024
Authorisations of GMO for food / feed	Adoption	Ongoing regular activity in 2024
Implementing Regulations approving/not approving or renewing/not renewing approvals of active substances for plant protection products	Adoption	Ongoing regular activity in 2024
Regulation amending Annex II to Regulation (EC) No 1107/2009 to align the approval criteria for active substances related to endocrine disruption and PBT properties with the amended CLP Regulation	Adoption	Q4 2024
Regulations establishing maximum residue levels (MRL) for pesticides	Adoption	Ongoing regular activity in 2024
Cumulative risk assessment method for pesticides residues	Development	Ongoing activity in 2024
Implementing Regulations approving/not approving or renewing/non-renewing the approval of biocidal active substances	Adoption	Ongoing regular activity in 2024
Implementing Regulations granting or amending Union authorisation of biocidal products	Adoption	Ongoing regular activity in 2024
Re-evaluations of authorisations, new authorisations, denial of authorisation, modifications of authorisations and renewal of authorisations of feed additives	Adoption	Ongoing regular activity in 2024
Authorisations of veterinary medicinal products	Adoption	Ongoing regular activity in 2024

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Setting of MRLs for substances used in veterinary medicinal products	Adoption	Ongoing regular activity in 2024
Implementing Regulation on a list of abbreviations and pictograms to be used on the labelling of veterinary medicinal products	Adoption	Q1 2024
Implementing Regulation on uniform rules on the size of small immediate packaging units for veterinary medicinal products	Adoption	Q1 2024
Implementing Regulation on a list of essential substances for equine species	Adoption	Q4 2024
Implementing Regulation on a list of substances which may be used in food-producing aquatic species	Preparatory work	In the course of 2024
Implementing Regulation on uniform rules on good manufacturing practice for veterinary medicinal products and active substances	Adoption	Q4 2024
Implementing Regulations on amendments of the list of variations not requiring assessment	Adoption	In the course of 2024
Guidance to applicants on Veterinary Medicinal Products	Adoption	Q1 2024
Commission rules on safe imports, trade and related aspects	Adoption	In course of 2024
Delegated and implementing Regulations reviewing food hygiene rules and controls of biological hazards, including in relation to transmissible spongiform encephalopathies (TSEs) and possible authorisation of decontamination of products of animal origin.	Adoption	In course of 2024
Implementing Regulation strengthening microbiological criterion for <i>Listeria monocytogenes</i> in ready-to-eat food.	Adoption	In course of 2024
Cross-contamination limits for antimicrobials in non-target feed	Adoption	In course of 2024
<b><i>Control systems, including audits, and rapid alert systems</i></b>		
Implementing acts on commodities to be checked at border control posts	Adoption	In course of 2024
Implementing acts reviewing import control measures for food and feed of non-animal origin	Adoption	In course of 2024
Implementing Regulation reviewing IMSOC rules notably as regards RASFF	Adoption	In course of 2024

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
European Reference Laboratories	Number of laboratories funded	51
European Reference Centres	Number of centres funded	5
Audits in the area of food safety, animal health, animal welfare and plant health	Approx. 138 audits and similar controls completed	In the course of 2024
Organisation of regular meetings of networks of Member State officials responsible for the multi-annual national control plans and national audits to facilitate exchanges of experiences and the preparation of guidance to enhance official control systems	Number of meetings held	2 plenary meetings 4 subgroup meetings
Organisation of meetings with Member State experts on the sustainable use of pesticides to discuss common problems and exchange best practices identified	Number of meetings held	1-2 meetings of the working group on the Sustainable Use Directive
Assessment of planned facilities of Border Control Posts (BCPs)	Assessments carried out	Approx. 75 per year, based on the figures from 2023 (82 until 9/10/2023). This is a demand-based activity.
Evaluation of Member States' and non-EU countries' control plan for residues in animals and animal products (food of animal origin)	Number of evaluation carried out	27 Member States plans, plus UK (Northern Ireland) (national risk-based control plans and randomised surveillance plans for residues of pharmacologically active substances); 20% of non-EU country control plans for residues of pharmacologically active substances, pesticides and contaminants.
Management of lists of approved non-EU country establishments for the production of food of animal origin	Number of requests managed	Based on 2023 data to date, ca 2000 listing requests for additions, modifications and deletions affecting around 3700 establishments in TRACES-NT
Operation and further development of the notification system EUROPHYT for plant health interceptions, outbreaks and reporting on plant pests	Publication on Europhyt monthly and annual statistics and reports	In course of 2024
Plant health surveys	Member States' survey results for harmful organisms presented to Standing Committee on PAFF	In course of 2024
<i>Computerised systems + IT (e.g. TRACES, ADIS, EUROPHYT)</i>		
TRACES	No of active end-users	200.000
ADIS	No of active end-users	514
iRASFF	No of active user accounts	9566
AROC (Annual Reporting on Official Controls)	No of active end-users	195

**General objective 1 : A European Green Deal**

**Specific Objective: Ensuring sustainable food systems – the ‘Farm to Fork’ Strategy**

*Related to spending programme(s): Single Market Programme*

**Main outputs in 2024:**

**New policy initiatives**

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Regulation on the Sustainable Use of Plant Protection Products, repealing the Sustainable Use Directive for pesticides COM(2022)305 final 2022/0196 (COD)	Support to co-legislators	In the course of 2024
Proposal for a Directive of the European Parliament and of the Council amending Directive 2008/98/EC on waste (food waste reduction targets) COM(2023) 420 final 2023/0234 (COD)	Support to co-legislators	In the course of 2024
Proposal for a Regulation of the European Parliament and of the Council on plants obtained by certain new genomic techniques and their food and feed, and amending Regulation (EU) 2017/625 COM(2023) 411 final 2023/0226 (COD)	Support to co-legislators	In the course of 2024
Proposal of revision of Regulation (EC) No 1/2005 on the protection of animals during transport COM(2023) 770 final 2023/0448(COD)	Support to co-legislators	In the course of 2024
Proposal for a Regulation of the European Parliament and of the Council on the welfare of dogs and cats and their traceability COM(2023) 769 final 2023/0447(COD)	Support to co-legislators	In the course of 2024
Proposal for a legislative framework for a Union sustainable food system	Work on the impact assessment and the legislative proposal	In the course of 2024
Proposal for a revision of the Regulation on food information to consumers	Preparatory work	In the course of 2024

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Proposal for a Regulation on the protection of animals at the time of killing, repealing Council Regulation (EC) No 1099/2009	Work on the impact assessment and the legislative proposal	In the course of 2024
Proposal for a Regulation by the Council and the European Parliament on the welfare of animals kept for economic purposes, repealing Council Directive 98/58/EC, Council Directive 1999/74/EC, Council Directive 2007/43/EC, Council Directive 2008/119/EC, and Council Directive 2008/120/EC ('Animal Welfare Law')	Preparatory work	In the course of 2024
Proposal for a Regulation by the Council and the European Parliament on animal welfare labelling for food	Preparatory work	In the course of 2024
<b>Initiatives linked to regulatory simplification and burden reduction</b>		
<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Proposal for a Regulation on the production and marketing of plant reproductive material in the Union, amending Regulations (EU) 2016/2031, 2017/625 and 2018/848 of the European Parliament and of the Council, and repealing Council Directives 66/401/EEC, 66/402/EEC, 68/193/EEC, 2002/53/EC, 2002/54/EC, 2002/55/EC, 2002/56/EC, 2002/57/EC, 2008/72/EC and 2008/90/EC COM(2023) 414 final 2023/0227(COD)	Support to co-legislators	In the course of 2024
Proposal for a Regulation on the production and marketing of forest reproductive material, amending Regulations (EU) 2016/2031 and 2017/625 of the European Parliament and of the Council and repealing Council Directive 1999/105/EC (Regulation on forest reproductive material) COM/2023/415 final 2023/0228(COD)	Support to co-legislators	In the course of 2024
Proposal for a revision of the food contact materials Regulation, including ceramic and vitreous food contact materials	Work on the impact assessment	In the course of 2024
<b>Evaluations and fitness checks</b>		
<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Review of the Farm to Fork Strategy	Launch preparatory work	Q3/Q4 2024

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Evaluation of EFSA's performance	Launch of the external study	Q1 2024
<b>External communication actions</b>		
<b>Output</b>	<b>Indicator</b>	<b>Target</b>
<b>Press and Media</b> Communicate on the various proposals	Awareness : media items in national print media coverage of EU's actions when proposals adopted	Media coverage by at least 20 EU countries
<b>Conferences</b> Participation in the Paris and Berlin Agriculture fairs, together with DG AGRI	Reach: number of contacts made (visitors to the Commission stand	Average daily figures* Paris: 4165 visitors per day Berlin: 5000 visitors per day *years when events did not take place due to the pandemic have not been taken into account in the calculations; note for the latest, post-pandemic editions: COVID measures meant restrictions on the overall number of people
<b>Social Media</b> Sustained tweets throughout the year on the various aspects of Farm to Fork and its implementation. The hashtag #EUFarm2Fork monitored continuously. Contract for Audiovisual material for maximum of four videos and supporting social media material	Increase engagement on X/Twitter	Average a minimum of 90 engagements per own tweet with #EUFarm2Fork (all engagements) on X/Twitter.  Average a minimum of 100K views per video,
<b>Website</b> Update of the Farm to Fork webpage to include any ongoing consultations and the implementation progress	Increase in the number of visits	2.5 % increase (2023 baseline: 137,772 entries / 235,615 page views *) <i>*Projection. During 2023, DG COMM changed the domain names of a number of our websites. This may influence the accuracy of the 2023 analytics.</i>
Communication campaign to raise awareness of AMR among young people 12-16	Percentage of target audience who have seen, used, or engaged with campaign content in MS where Commission has conducted paid media activities	60% of target audience in Romania, Cyprus, Hungary, Spain, Greece, & Bulgaria
<b>Other important outputs</b>		
<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Farm to Fork Strategy monitoring framework	Launch, including one meeting held with stakeholders and MS to present the proposed dashboard indicators	Q1 2024
EU Code of Conduct for responsible food business and marketing practices	Annual mapping study of given commitments	Q4 2024

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Advisory group on the sustainability of food systems	Meetings held	Two meetings, respectively by Q2 and Q4 2024
<b><i>Plant Protection Products and sustainable use thereof</i></b>		
Literature review on the occurrence and population levels in soil of micro-organism species used in plant protection – to facilitate dossier compilation for applications	Publication of report	Q4 2024
Review of biology and ecology of micro-organism species used in plant protection – to facilitate dossier compilation for applications	Interim report (finalisation in 2025)	Q3 2024
<b><i>Reduction in the use of antimicrobials in animals to contribute to fight AMR</i></b>		
Implementing Regulation on a List of antimicrobials forbidden for cascade use in animals, or authorised for cascade use subject to certain conditions	Adoption	Q2 2024
Delegation Regulation on Oral administration of veterinary medicines - Rules on appropriate measures to ensure effective and safe use of veterinary medicinal	Adoption	Q1 2024
Implementing Regulation on a List of Third countries authorised to export to the Union as regards prohibition of certain antimicrobial medicinal products	Adoption	Q2 2024
Implementing Regulation amending model certificates for certain animals and products derived therefrom	Publication	Q1 2024
<b><i>Sustainable feeds</i></b>		
Authorisations of feed additives contributing to more sustainable feed	Authorisations in response to the 65 requests received in 2023	In the course of 2024
<b><i>Food loss and waste</i></b>		
Operational support services for the EU Platform on Food Losses and Food Waste	Operation of digital platform and user activity	Ongoing regular activity in 2024
Meetings of the EU Platform on Food Losses and Food Waste	2 meetings held	Q2 and Q4 2024
Meetings of the sub-groups of the EU Platform on Food Losses and Food Waste	10 meetings held	In course of 2024
European Consumer Food Waste Forum: dissemination of results	Online tools and public event	Q2 2024

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Study supporting implementation of use of surplus food (assessment of barriers to food donation and use of avoided food waste to produce feed)	Publication	Q4 2024
<b>Animal Welfare</b>		
EU Reference Centre for the welfare of aquatic animals	Launch of the Centre's activities	Q2 2024
Study on animal welfare indicators	Launch study	Q3 2024
Tertiary legislation under the OCR to improve enforcement of current EU AW rules	Discussions in the OCR expert group	Q4 2024
Study on digitalisation in the animal welfare area	Launch study	Q3 2024
Preparatory action on "Developing a system for the automated measuring of tail length and tail lesions of pigs at the slaughter line"	Prototype of automated system	Q4 2024
Preparatory action on non-aversive stunning methods for pigs	Implementation report	Q4 2024
<b>Food Contact Materials</b>		
Authorisation of recycling processes for plastics used in food contact materials	Adoption	Around 220 processes to be authorised in the course of 2024

**General objective :** A European Green Deal

**Specific Objective:** Increased EU influence in international fora

Related to spending programme(s): Single Market Programme

**Main outputs in 2024:**

**External communication actions**

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
<b>Website</b> Update of webpages related to the international work of DG SANTE  (see also indicator under objective 1.2: Participation with a stand in international events on Farm to Fork)	Number of visits to the related webpages (International Affairs web section)	2.5% increase (Baseline 2023: 32,353 entries / 65,523 page views )* <i>*Projection. During 2023, DG COMM changed the domain names of a number of our websites. This may influence the accuracy of the 2023 analytics.</i>

**Other important outputs**

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
<b>Multilateral SPS relations</b>		

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Common positions coordinated with EU Member States to promote the alignment of existing and planned EU legislation and initiatives with Codex standards	Delivered	In course of 2024
Coordinated EU position for the WOAHA aquatic and terrestrial Code and Manual	Delivered	In course of 2024
Coordinated EU Statements for the World Organisation for Animal Health (WOAH) General Assembly	Delivered	In course of 2024
Coordinated EU positions for the European and Mediterranean Plant Protection Organization (EPPO)	Delivered	In course of 2024
Coordinated EU positions for the International Plant Protection Convention (IPPC)	Delivered	In course of 2024
Coordinated EU positions for the International Union for the Protection of New Varieties of Plants (UPOV)	Delivered	In course of 2024
Coordinated EU positions in the resolutions of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)	Delivered	In course of 2024
Input to the coordination for the Commission on Genetic Resources for Food and Agriculture	Delivered	In course of 2024
Coordinated EU positions in OECD Seed and OECD Forest schemes	Delivered	In course of 2024
Coordinated EU positions in the World Trade Organisation SPS	Delivered	In course of 2024
Coordinated EU statements and position, as well as negotiations, for the Conference of the Parties of the Cartagena Protocol on Biosafety and coordinated EU position regarding synthetic biology and gene drives for the Conference of the Parties of the Convention on Biological Diversity	Delivered	In course of 2024
<b><i>Bilateral SPS relations</i></b>		
Bilateral trade negotiations (SPS Chapter)	Negotiate comprehensive SPS Chapter that includes all the necessary tools to ensure safe and secure trade and facilitate the access of EU products to non-EU markets.	Balanced SPS Chapter within the ongoing Free Trade Agreement agreements

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Negotiate with non-EU countries harmonised export conditions that ensure the cohesion of the EU as regards exports (EU single entity) by ensuring that the same conditions are applied to all the EU territory having the same sanitary or phytosanitary level	Negotiate harmonised export certificates for EU products	In course of 2024
Coordinate EU position in negotiations of Agreements with non-EU countries	Delivered	In course of 2024
Coordinate EU position on the management of the SPS Committees of the Agreements in force	Delivered	In course of 2024
Meetings of the EU-US Animal Health Technical Working Group and Plant Health Technical Working Group: Facilitate trade and better cooperation on animal, plant health and food safety issues with the US	1 AHTWG and 2 PHTWG meetings held	In course of 2024
Meeting of the EU-US Food Safety Working Group	Yearly meeting	In course of 2024
Meetings of the EU-JP Animal Health Technical Working Group	Yearly meeting	In course of 2024
Meetings of the EU-Japan mutual recognition project on animal health regionalisation. Facilitate trade and better cooperation on regionalisation approach with Japan	Monthly meetings.	In course of 2024
Meetings under the EU-China Memorandum of Understanding Animal Health (regionalisation project) and food safety issues. Facilitate trade and better cooperation on regionalisation approach with China	Quarterly meetings.	In course of 2024
Meeting of the EU-Central America Subcommittee on SPS matters	Yearly meeting	In course of 2024
Meeting of the EU-Andean countries (Colombia-Ecuador and Peru) Subcommittee on SPS matters	Yearly meeting	In course of 2024
Biotechnology dialogues with US, Canada and Argentina	Bi-yearly (US, CAN) and yearly (ARG) meetings	In course of 2024

## General objective 2 : Promoting our European way of life

### Specific Objective: *Diminishing the impact of cancer in Europe*

Related to spending programme(s): *EU4Health and others*

#### Main outputs in 2024:

##### New policy initiatives

Output	Indicator	Target
Commission proposal for Commission Recommendation on sunbeds	Adoption	Q1 2024
Commission proposal for a Council Recommendation on vaccine-preventable cancers	Adoption	Q1 2024
Commission proposal for the revised Council Recommendation on smoke-free environments	Adoption	Q1 2024

##### Evaluations and fitness checks

Output	Indicator	Target
Evaluation of the Tobacco Products Directive and the Tobacco Advertising Directive	Finalisation of the SWD	Q4 2024

##### Enforcement actions

Output	Indicator	Target
Compliance checks finalised for 25 Member States (tobacco)	Completion	Q4 2024

##### External communication actions

Output	Indicator	Target
<b>Press and media</b> Communicate on actions being taken throughout the year	Awareness: items in national print media covering the EU's actions	Media coverage by at least 20 EU MS
<b>Event:</b> World Cancer Day event in January 2024	Number of participants	300
<b>Social media</b> Continuous communication throughout the year, with specific focus on proposals linked to the prevention package, World Cancer Day event and the European Week Against Cancer	Increase engagement on X/Twitter	Average a minimum of 90 engagements per tweet with #EUCancerPlan (all engagements)
<b>Communication campaign:</b> campaign to raise awareness of the need for and benefits of cancer screening	Reach: numbers 60% target potential target audience (contacts) in proposed focus countries and/or regions  Awareness:	10 million  + 5% increase in awareness compared to baseline survey

Output	Indicator	Target
<b>Website</b> Update of related webpages	Increase in the number of visits to the Cancer related pages	2.5% increase (Baseline 2023 – 45,200 entries / 74,963 page views *Projection. During 2023, DG COMM changed the domain names of a number of our websites. This may influence the accuracy of the 2023 analytics.
<b>Other important outputs</b>		
Output	Indicator	Target
Implementation of Europe's Beating Cancer Plan	Ongoing implementation	Throughout the year
Study on mapping and evaluating the implementation of Europe's Beating Cancer Plan	Finalisation	Q2 2024
Study on job retention and return to work	Finalisation	Q2 2024
European Cancer Inequalities Registry overarching report on <i>"Beating Cancer Inequalities in the EU: Special Focus on Cancer Prevention and Early Detection"</i>	Publication	Q1 2024
Evaluation study on the EU Childhood Obesity Action Plan (2014 – 2020)	Finalisation	Q4 2024

## General objective 2 Promoting our European way of life

**Specific Objective: Patients' access to safe, innovative and affordable medicines and medical devices**

*Related to spending programme(s): EU4Health and others*

### Main outputs in 2024:

#### Initiatives linked to regulatory simplification and burden reduction

Output	Indicator	Target
Review of Regulation 1234/2008 (variation of medicinal products)	Adoption	Q2 2024

#### Evaluations and fitness checks

Output	Indicator	Target
Targeted evaluation of Regulations (EU) 2017/745 and (EU) 2017/746 (medical devices and in-vitro diagnostic devices)	Launch	2024

External communication actions		
Output	Indicator	Target
<b>Press and media</b> Communicate on actions being taken throughout the year	Awareness: items in national print media coverage of EU's actions	Media coverage by at least 20 EU MS
<b>Social media</b> Continuous communication of actions throughout the year	Engagement: Number of engagements per post	Average a minimum of 60 engagements per tweet from SANTE accounts with #EUGlobalHealthStrategy, #AMR, #OneHealth or similar related (all engagements)
<b>Website</b> Update of related webpages	Increase in the number of visitors to the Pharma Strategy pages and the medical devices website.	2.5% increase (Baseline 2023 – 98,992 entries / 181,732 page views) * *Projection. During 2023, DG COMM changed the domain names of a number of our websites. This may influence the accuracy of the 2023 analytics.
Four information events on the implementation of the Health Technology Assessment Regulation	Percentage of participants satisfied with the overall content of the events.	70%
Other important outputs		
Output	Indicator	Target
Implementation of the Pharmaceutical Strategy	Ongoing implementation	Throughout the year
Negotiation with the Parliament and Council of the proposal on the pharmaceutical reform	Support to co-legislators	Throughout the year
Negotiation with the Parliament and Council of the proposal on Substances of human origin	Support to co-legislators	In the course of 2024
Report on falsified medicines	Publication	Q1 2024
Report ex Article 54(4) of Medical Devices Regulation (EU) 2017/745: clinical evaluation consultation procedure and expert panels	Endorsement	Q4 2023
Implementing acts on harmonised standards for Medical Devices Regulation (EU) 2017/745 and In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746	Adoption	Q4 2024
Re-assessment of notified bodies (Medical Device Regulation and In Vitro Diagnostic Medical Device Regulation)	Launch (on-site) within 4 months of the re-assessment becoming due (5 years after notification)	85%
Joint assessments of conformity assessment bodies (Medical Device Regulation and In Vitro Diagnostic Medical Device Regulation)	Launch of the assessment (on-site) within 3 months following receipt of the preliminary assessment report	85%

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Study on Regulatory Governance and Innovation in the field of Medical Devices	Finalisation	Q4 2024
Commission Implementing Regulation amending Commission Implementing Regulation (EU) 2022/1107 as regards common specifications for certain class D in vitro diagnostic medical devices.	Adoption	Q4 2024
Six implementing acts to be adopted in 2024 under the Health Technology Assessment (HTA) Regulation	Adoption	Q4 2024
Guidance documents for the implementation of the HTA Regulation	Adoption	Throughout the year
Meetings of the Member State Coordination Group on Health Technology Assessment	At least four meetings	Throughout the year
Meetings of the four subgroups of the Member State Coordination Group on Health Technology Assessment	At least four meetings for each subgroup	Throughout the year
Consultations and meetings with the Health Technology Assessment Stakeholder Network	At least two meetings and additional workshops as needed	Throughout the year

## **General objective 2: Promoting our European way of life**

**Specific Objective: Effective response coordination of serious cross-border health threats**

*Related to spending programme(s): EU4Health and others*

### **Main outputs in 2024:**

#### **Evaluations and fitness checks**

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Evaluation of Regulation (EU) 2022/2371	Finalisation of Staff Working Document Report to the EP and the Council	Q4 2024
Study assessing the functioning of the Joint Procurement Agreement for medical countermeasures	Publication	Q2 2024
Evaluation of Regulation 851/2004 establishing a European center for disease prevention and control (ECDC)	Launch	Q2 2024

<b>External communication actions</b>		
<b>Output</b>	<b>Indicator</b>	<b>Target</b>
<b>Press and media</b> Communicate on actions being taken throughout the year	Awareness: items in national print media coverage of EU's actions	Media coverage in at least 20 EU MS
<b>Social media</b>	Increase engagement on X/Twitter	Average a minimum of 60 engagements per own tweet with #EUHealthSecurity or similar keywords
<b>Communication campaign:</b> Raising awareness of the benefits of vaccination	Gross reach: number of contacts made during the campaign	10 million contacts
<b>Website</b> Update of related webpages.	Increase in the number of visitors to the Cross-border Healthcare web section.	5% increase (Baseline 2023 - 15525 entries / 29493 page views * *Projection. During 2023, DG COMM changed the domain names of a number of our websites. This may influence the accuracy of the 2023 analytics.
<b>Other important outputs</b>		
<b>Output</b>	<b>Indicator</b>	<b>Target</b>
<b>Implementing/delegated acts to implement the Regulation on cross-border health threats</b>		
Article 13 Implementing act -list notifiable diseases at EU level & correspondent case definitions	Publication	Q1 2024
Article 13 implementing act-diseases surveillance network	Publication	Q4 2024
Under ECDC's new mandate: adopt an implementing act on the European Health Task Force	Publication	Q4 2024
Article 8 Delegated act – process, standards, and criteria for the assessment of countries' preparedness	Publication	Q1 2024
Article 14 – Platform for surveillance	Publication	Q4 2024
Article 18 - Early warning and response system	Publication	Q4 2024
Article 21 – Implementing act - information exchange, consultation and coordination within the Health Security Committee	Publication	Q4 2024
Article 28 - Protection of personal data concerning the EWRS selective messaging functionality	Publication	Q4 2024
<b>International relations</b>		
Coordinate EU position in the negotiation of a new Pandemic instrument and IHR review	Delivery ongoing	Q2 2024

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
In line with the Global Health Strategy, coordinate and strengthen EU position in multilateral fora (G7, G20, WHO, UN, OECD)	Delivery	Throughout the year
Article 30 - framework for enhanced cooperation with the WHO	Framework developed and agreed with WHO/EURO	Framework signed in Q2/2024
<b>Bilateral relations</b>		
Alignment with enlargement candidate countries	Negotiate health chapter with candidate countries	Throughout the year
Proximity with Neighbourhood countries; cooperation with other third countries and micro states (in line with obligations under cooperation agreements)	Number of meetings and positions delivered	Throughout the year
Special relations with third countries	High level Dialogue with Canada, EU-US Health Task Force	1 or 2 meetings per year
Negotiation of data sharing agreements with candidate countries to enable their access to the EWRS	Signature of agreements	Q4 2024
Joint Procurement Agreement for medical countermeasures	Signature by the Republic of Moldova and other EU Candidate Countries (as requested)	Q4 2024

## **General objective 2: Promoting our European way of life**

### **Specific Objective: More effective, accessible and resilient health systems**

*Related to spending programme(s): EU4Health and others*

### **Main outputs in 2024:**

#### **Evaluations and fitness checks**

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Interim evaluation of the EU4Health Programme (Report on the interim evaluation to co-legislators, related SWD and external supporting study).	Finalisation	Q4 2024

#### **External communication actions**

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
<b>Social media</b>	Increase engagement on X/Twitter	Average a minimum of 75 engagements per own tweet with #EU4Health or #HealthUnion

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
<b>Website</b> Update of related webpages	Increase in the number of visits to the eHealth and European Health Data Space (EHDS) webpages	2.5% increase. Baseline 2023 – 153,259 entries / 259,197 page views)* *Projection. During 2023, DG COMM changed the domain names of a number of our websites. This may influence the accuracy of the 2023 analytics.
<b>Other important outputs</b>		
<b>Output</b>	<b>Indicator</b>	<b>Target</b>
Negotiations with the Parliament and Council of the proposal on the European Health Data Space	Support to co-legislators	In the course of 2024
Follow-up evaluation cross-border healthcare directive - Organisation of workshops at local level to raise awareness on patients' right about cross border healthcare	Number of workshops organised, countries involved, participants	At least 8 workshops in border regions, participation of policy makers, national focal points, health providers and insurers, citizens
Reports and workshops by Health Systems Performance Assessment expert group	Reports published and workshop held	Q2-Q3 2024
Conference health workforce (summary of results of the cluster of 5 projects under the Third Health Programme with forward -looking reflection)	Conference organised	Q1 2024
Training for health workers with the focus on digital skills (EU4Health training initiative)	At least 20.000 health workers trained	2024-2025
5 <sup>th</sup> State of Health cycle: "Health at a Glance: Europe 2024"	Publication	Q4 2024

## Part 2 – Modernising the administration

### A. Human resource management

**Objective:** DG SANTE employs a competent and engaged workforce and contributes to gender equality at all levels of management to effectively deliver on the Commission’s priorities and core business.

#### Main outputs in 2024:

Output	Indicator	Target
Recruitment of new female middle managers	Number of first appointments of female managers validated	2 appointments validated by end 2024
Staff consultation, collaboration and engagement events to improve efficiency in DG SANTE (follow up to DG SANTE management seminar of 10/2023)	+/- 5 events organised	By 31/12/2024
Training and awareness actions to assist managers in better understanding and promoting 'Be Well at Work'	DG SANTE 'Well being and worklife balance' and 'Inclusion and fairness' index as communicated by DG HR staff survey	Overall index above Commission average
Learning how to respect and dignity of the individual in an ever more demanding and stressful working environment	One general awareness rising seminar for managers. 2 workshops on specific action managers can take to implement on the work floor	End of 2024

### B. Sound financial management

**Objective:** The authorising officer by delegation has reasonable assurance that resources have been used in accordance with the principles of sound financial management and that cost-effective controls are in place which give the necessary guarantees concerning the legality and regularity of underlying transactions.

#### Main outputs in 2024:

Output	Indicator	Target
Effective controls: Legal and regular transactions	Risk at payment	Remains < 2 % of relevant expenditure
	Estimated risk at closure	Remains < 2 % of relevant expenditure
Effective controls: Safeguarded assets ( <i>stock of vaccines/antigens for animal diseases</i> )	Compliance with regulatory provisions and accounting closure instructions after audit/review corrections	Remains 100% compliant
Efficient controls	Budget execution and  Timely payments	Remains >95% of payment appropriations and  Remains >95% of amount of payments paid on time
Economy of controls	Overall estimated cost of controls	Remains <2% of funds managed

Output	Indicator	Target
Update of DG SANTE's internal control strategy	Validation by the DG of the control strategy	30/09/2024

## C. Fraud risk management

**Objective:** The risk of fraud is minimised through the application of effective anti-fraud measures and the implementation of the Commission Anti-Fraud Strategy (CAFS) <sup>(20)</sup> aimed at the prevention, detection and correction <sup>(21)</sup> of fraud.

### Main outputs in 2024:

Output	Indicator	Target
Training and awareness raising in DG SANTE and through promoting ethics training	Annual implementation rate of awareness activities	>90%
Actions linked to handling "conflict of interest" in agencies, scientific committees and expert groups	Annual meeting of the SANTE inter-agencies task force on independence	1 meeting per year (possibly in September 2024, with all-agencies for which SANTE is partner)
Participation in the network "Fraud Prevention and Detection" (FPD) chaired by OLAF and dissemination of the relevant information stemming from these networks	Participation in the FPDnet meetings and feed-back given to the financial cell.	At least 4 FPDnet meetings per year and sub-group meetings
Implementation of the anti-fraud strategy as planned for 2024	% implementation of actions planned for 2024 as per the anti-fraud strategy	At least 90%

## D. Digital transformation and information management

**Objective:** SANTE is using innovative, trusted digital solutions for better policy-shaping, information management and administrative processes to forge a truly digitally transformed, user-focused and data-driven Commission

### Main outputs in 2024:

Output	Indicator	Target
Increase in awareness of staff on data protection compliance (22)	Percentage of staff attending awareness raising activities	100% newcomers; 20% all staff

<sup>(20)</sup> [Communication from the Commission 'Commission Anti-Fraud Strategy Action plan - revision 2023 COM\(2023\) 405 of 11 July 2023](#) –'the Communication on the 2023 revision' – and the accompanying document, [SWD\(2023\) 245](#) – 'the revised Action Plan'.

<sup>(21)</sup> Correction of fraud is an umbrella term, which notably refers to the recovery of amounts unduly spent and to administrative sanctions.

<sup>(22)</sup> Follow-up indicator from SANTE's multi-annual strategic plan 2020-2024.

<b>Output</b>	<b>Indicator</b>	<b>Target</b>
<p><b>Digital Culture</b></p> <p>Identify outputs related to digital skills training needs required for the digitalisation of the department, promote and monitor staff's digital skills.</p> <p>Promote outputs related to the use of online collaborative tools, incentivise and empower staff.</p> <p>Keep outputs related to track of and increase cybersecurity awareness training for all staff.</p>	% of statutory staff following at least one training on IT or digital skills or collaboration technologies (SANTE)	50%
	Average participation rate of cyber awareness training (SANTE)	50%
<p><b>Digital-Ready EU policymaking</b></p> <p>Ensure outputs related to digital consideration that are taken into account in <i>the early stages of the design of policy initiatives</i>.</p>	<i>% of statutory personnel that has followed the digital-ready policymaking course on EU Academy/EU Learn</i>	20%
<p><b>Business-driven Digital Transformation</b></p> <p>Establish outputs related to a common approach to document, automate (where possible) and rethink business processes using digital tools.</p> <p>Ensure outputs related to the sharing and publishing of and the reusability of the data assets of the department.</p>	% of datasets originating from relevant SANTE solutions published on EU open data portal	30
	% of datasets originating from SANTE solutions accessible from the corporate data catalogue	100%
<p><b>Seamless Digital Environment</b></p> <p>Ensure outputs related to the Information Systems that are streamlined, fit for purpose and running on supported technologies.</p> <p>Promote outputs related to a cloud first approach with Information Systems owned by the department.</p>	Ratio of fully supported IT systems hosted in the corporate data centre	70%
	Number of systems upgraded to Weblogic 14 in preparation for moving to the Cloud	7
	% of IT systems utilising cloud infrastructure services compared to the total number of IT systems (SANTE)	20%
	Number of AI technical capabilities implemented across systems (SANTE)	3
<p><b>Green, Resilient and Secure Digital Infrastructure</b></p> <p>Ensure outputs related to the continuous improvement of the department's performance as captured in the risk maturity quadrant (RMQ). All SANTE solutions have a recent security plan (not older than 2 years) and are attested in the GRC corporate governance, risk, compliance platform</p>	Evolution of the RMQ risk and maturity indicators (per department).	Remain above EC average score.
	% of completion of SANTE solutions having a recent security plan (not older than 2 years) and being attested in the GRC platform	100%

Output	Indicator	Target
List of key actions on information management and data protection	% of SANTE IT solutions audited for data protection	75%
	% of new IT systems with completed data protection questionnaires to ensure systems implement data protection by design and by default	100%
Preparation, adoption and implementation of a “Digital transformation” action plan.	% of completion	100% Preparation and adoption
ERN-CPMS	% of completion of system and availability in the form of open-source libraries for reuse	40%
TRACES	#certificates managed by the system (restricted to finalized certificates in the domains CHED, COI, EU Intra / Export / Import)	3.5 million following introduction of new certificates types in the system

## E. Sound environmental management

**Objective:** DG SANTE takes account of its environmental impact in their actions and actively promotes measures to reduce the related day-to-day impact of the administration and its work, with the support their respective EMAS Correspondents/EMAS Site Coordinators.

### Main outputs in 2024:

#### I. More efficient use of resources (energy, water, paper)

Output	Indicator	Target
Actions to reduce energy use including in the framework of EMAS corporate campaigns and/or in collaboration with OIB/OIL 7 where appropriate.	Number of actions	2 actions
	% of SANTE sites informed/participated	75%
Participation in the seasonal energy saving action, by closing down DG’s buildings.	% of SANTE’s buildings shut down in winter	75% of SANTE’s buildings participated
	% of SANTE’s buildings shut down in summer	75% of SANTE’s buildings participated
	Permanent closure of one section of GRAN building	Implemented
Actions to reduce use of resources other than energy (water, paper etc.) including in the framework of EMAS corporate campaigns and/or in collaboration with OIB/OIL where appropriate.	Number of actions to reduce use of resources other than energy	1 action
	% of SANTE sites informed/participated	100%

Output	Indicator	Target
<b>II. Reducing CO<sub>2</sub>, equivalent CO<sub>2</sub> and other atmospheric emissions</b>		
Output	Indicator	Target
Communication and awareness raising on Velo Mai	% of SANTE sites informed/participated	100%
Gradual increased use (and number of) VC 9 meeting rooms for meetings with stakeholders (avoiding business trips) in the DG, in collaboration with DG SCIC, OIB and OIL.	% of use of VC meeting rooms (number of VC meeting rooms has substantially increased since Covid pandemic. With the progressive return to work greater use of these facilities will be possible)	Increase in comparison to baseline 2019.
Review of DG's business travel trends /patterns (based on corporate EC-staff's professional trips (missions) 10) with a view to , optimise and gradually reduce CO2 emissions (e.g. by optimising the number of participants in the same mission, promoting more sustainable travelling options, promoting videoconferencing/ virtual events as an alternative).	Number of mission days per person compared to 2019	Net decrease in days
	CO2 (t) emissions from DG's missions (% means of transportation used)	Reduce DG's CO2 emissions from missions 11 (%)
<b>III. Reducing and management of waste</b>		
Output	Indicator	Target
Actions to reduce waste and improve waste sorting, incl. in the framework of EMAS corporate campaigns	Number of actions	1
	% of SANTE sites informed/ participate	75%
	% of non-hazardous waste recycling at Grange site	Min. 90%
<b>IV. Promoting green public procurement (GPP)</b>		
Output	Indicator	Target
Application of GPP criteria in contracts	% of contracts incorporating green criteria, as a share of relevant contracts  (relevant contracts are of min. €140,000 value and involve CPV codes which can facilitate GPP)	100% (2 out of 2 contracts)
<b>V. Corporate management of environmental performance</b>		
Output	Indicator	Target
Continuous improvement of environmental performance of the Commission site in Grange	Retention of EMAS registration	Achieved