



Management Plan 2023

DG Health and Food Safety (SANTE)

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Introduction

2023 will be again a year of delivery for the Directorate-General for Health and Food Safety (DG SANTE) in which we will continue to support the sustainable **recovery** of the Union, and to contribute on all fronts to the response to COVID-19 pandemic and other health threats and to EU-led support to Ukraine. At the same time we will focus on the achievement of this Commission's political priorities.

DG SANTE will capitalise on its recent reorganisation in line with the **“One Health”** approach to ensure full consistency between human, animal and plant health when implementing our core mission to protect the **health of citizens, animals and plants**, promote a **high level of food and animal feed safety**, contribute to the Union's efforts to ensure **sustainable food systems** and enable the health and food sectors to achieve their **full economic potential**.




To pursue our contribution to the Commission's **headline ambitions**, we will continue building a strong **European Health Union**, strengthening the “European way of life” (General Objective 2 of this plan). We will continue working with Member States to prepare for and deal with public health crises, through the implementation of a **new legislative health security framework** for better longer-term preparedness.

We will deliver important flagship initiatives under the **Pharmaceutical Strategy for Europe**, such as the proposed revisions of the **general pharmaceutical legal framework** and legislation on **medicines for children and rare diseases**. Implementation of **Europe's Beating Cancer Plan** will advance at full speed and include a prevention package with proposals for a **Council recommendation on vaccine-preventable cancers**  ⁽¹⁾ and a **revised Council Recommendation on smoke-free environments** . We will work towards reaching inter-institutional agreements on the





⁽¹⁾ Initiatives that are part of the Commission Work Programme 2023 are marked with the icon



European Health Data Space and other Commission proposals in the public health area adopted in 2022, i.e. the **revision of the EU legislation on the safety and quality of substances of human origin**, and the **revision of organisation of the fees to be paid to the European Medicines Agency**. As President von der Leyen announced in her 2022 State of the Union address, DG SANTE will also contribute to the development of a comprehensive approach to **mental health** .

DG SANTE, supported by the new European Health and Digital Executive Agency (HaDEA), will monitor implementation of the **EU4Health Programme**, our main financial means of protecting people during health crises, supporting our key public health initiatives and strengthening EU's health systems. DG SANTE will also continue rolling out the new legal framework on **medical devices** and **in vitro diagnostic medical devices** effectively and adopt any necessary measures to protect patients and mitigate the risk of shortages of critical devices.

As a clear illustration of the 'One Health' approach, DG SANTE will continue supporting Member States to address the challenge of **antimicrobial resistance** (AMR), including through a proposal for a Council Recommendation in order to further reduce the spread of AMR.

Led by DG SANTE, the **Farm to Fork** Strategy – a central plank of the European Green Deal (General Objective 1 of this Plan) – will bear more fruits in 2023, with the delivery of several legislative proposals: a horizontal legislative **framework for sustainable food systems** , the introduction of **food waste reduction targets** , specific legislation for plants resulting from certain **new genomic techniques** , and the revisions of the legislation on the marketing of **plant reproductive material** and of the legislation on **animal welfare** . The initiatives on food waste reduction targets, on new genomic techniques and on animal welfare were mentioned by President von der Leyen in her Letter of Intent for 2023 as a contribution to the Conference on the Future of Europe follow-up. In addition, the DG will pursue discussions with the European Parliament and the Council on the proposal on the **sustainable use of pesticides**, with a view to progress towards the final adoption of the Regulation.

Russia's aggression against Ukraine and the ongoing conflict are having an inevitable impact on food sustainability initiatives and on the narrative revolving around them, shifting the focus from long-term food sustainability to immediate food security and sovereignty - with a strong emphasis on the greater productivity, and resulting in a very **challenging environment** for some ongoing Farm to Fork flagship initiatives.

However, there can be no food security without food sustainability. Whilst DG SANTE initiatives on food waste and on new genomic techniques can mitigate some of these concerns, our primary objective remains to usher in a **long-term transformation** of the EU food system that can contribute to facing global challenges linked to climate change and resource depletion, and ultimately deliver on the European Green Deal commitments.

In light of the major **outbreaks of animal diseases** such as African swine fever and highly pathogenic avian influenza and of **plant pests** such as *Xylella fastidiosa* and

Tomato brown rugose fruit virus in 2022, veterinary and phytosanitary measures will account for the largest share of the EU's budget for the Food Chain strand of the Single Market Programme, supporting disease prevention, emergency measures, crisis management and permanent availability of strategic vaccines in EU-funded vaccine banks.

DG SANTE 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.

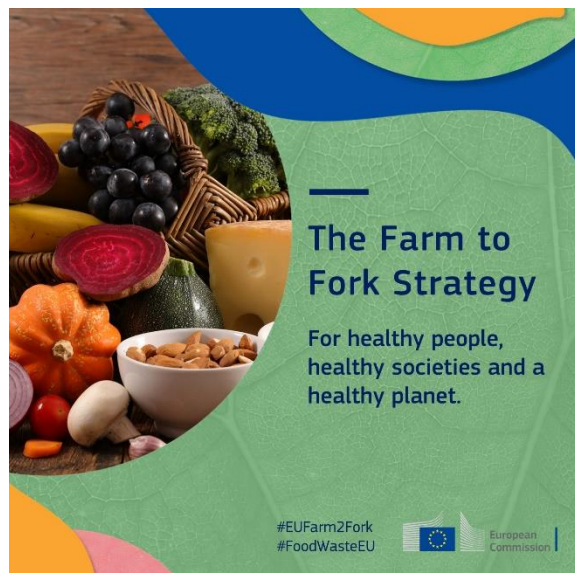
At **international level**, DG SANTE will promote global health cooperation, in line with the recently adopted Global Health Strategy, actively contribute to the discussions on improving the global health security architecture, better implementation of the International Health Regulations, the establishment of a new international agreement on pandemic prevention (covering also AMR), improving preparedness and response and strengthening the role of the World Health Organisation (WHO). We will advocate the "One Health" approach and lead global efforts to strengthen health and food systems' sustainability with best practice examples, pursuing **"green partnerships"** with like-minded non-EU countries and Sustainable Food Chapters or provisions in the Free Trade Agreements, as well as enhanced cooperation in the context of multilateral fora.

DG SANTE has become a frontline DG, attracting strong interest from media, citizens, other institutions and stakeholders. In 2023 DG SANTE **communication** activities will showcase the impact of SANTE policies and start preparing the legacy that the current Commission will leave in our policy areas.

In short, this management plan outlines DG SANTE's political priorities and planned initiatives for 2023. It follows the priorities outlined in DG SANTE's strategic plan for the 2020-2024 cycle, developed on the basis of President von der Leyen's Political Guidelines and six headline ambitions, and her mission letter to Commissioner Kyriakides. Finally, this management plan builds on the work done so far by DG SANTE - and on lessons learned - in the context of the fight against the COVID-19 pandemic.

PART 1. Delivering on the Commission's priorities: main outputs for 2023

General Objective 1: A EUROPEAN GREEN DEAL



In 2023, DG SANTE's work on safe and sustainable food will keep on contributing to the European Green Deal, particularly by delivering key legislative proposals under the Farm to Fork Strategy (F2F), most notably the **framework for sustainable food systems**, as well as the introduction of **food waste targets**, specific legislation for plants resulting from certain **new genomic techniques** and the revisions of the legislation on the marketing of **plant reproductive material** and of the legislation on **animal welfare**. The DG will pursue discussions with the European Parliament and

the Council on the proposal on the **sustainable use of pesticides**, with a view to progress towards final adoption of the Regulation.

In 2023, the narrative and the **communication** actions around the Farm to Fork strategy will be adapted to take into consideration the new geopolitical situation and more specifically the food security aspects. The opportunity of a communication campaign will need to be decided accordingly.

Alongside the delivery of the political priorities, ensuring **food and feed safety**, by complying with the applicable legal obligations remains DG SANTE main activity. This is reflected in the very high number of planned initiatives at EU and international level, many of which are politically sensitive. Inherently difficult to anticipate, ensuring the response 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 for the 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.

DG SANTE strives to ensure **safety and sustainability** amidst increasing stakeholders' interest on a growing number of aspects of its food and feed portfolio. Such attention has been heightened by the geopolitical events of 2022 and by the impact of the Russian

aggression against Ukraine on the agri-food markets. Against this backdrop, DG SANTE pays particular attention to **transparent communication** and **inclusive policy-making**.

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 featuring in the Chemicals Strategy for Sustainability.

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 2023 budget for the food chain strand under the SMP is EUR 231.3 million.

In 2023, DG SANTE will implement the veterinary and phytosanitary emergency measures as well as actions on IT and communication, and any politically sensitive actions. 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 2023 DG SANTE will produce a report on the conclusions of the evaluation of Regulation (EC) 2014/652 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 in food and feed safety and animal and plant health, to manage it and to simplify it where possible. It takes a "One Health" approach to preparedness and prevention, integrating human, animal, plant and environmental health. The effectiveness of DG SANTE work on food and feed safety 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 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, and requirements for the movement of animals and animal products within and into the EU. One of our most important tasks is ensuring the EU can rapidly isolate and eradicate **outbreaks of major animal diseases**, such as African swine fever and highly pathogenic avian influenza. In 2023, DG SANTE will continue to ensure the smooth evolution and management of the **EU Animal Health Law (AHL)**, and to adapt the EU rules to reflect the evolving disease situation and provide financial support for measures implemented in EU and neighbouring non-EU countries.

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, including movements of plants and plant products within the EU, and imports of plants and plant products that might host dangerous pests.

In 2023, DG SANTE will prepare a series of acts under the Plant Health Law e.g. in response to High Risk Plant dossiers from non-EU countries, following a risk assessments by EFSA. Detailed and up to date measures will be put in place for the quarantine pests which are known to be present in the Union. Moreover, based on the reports to the EP and Council on the enforcement and effectiveness of plant health measures relating to imports into the EU as well as experience gained from the extension of the plant passport system to all movements of plants for planting within the EU, DG SANTE will look into targeted amendments to the Plant Health Regulation to clarify and improve the legal framework.

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 2023 (e.g. of Citrus Black Spot, False Codling Moth, *Xylella fastidiosa*). 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 accounts for the largest proportion of spending under the food chain strand of the SMP. In 2023, the adopted work programme foresaw budget for implementing national veterinary programmes at EUR 107 million and for phytosanitary programmes at EUR 20 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 an effective and inclusive risk communication on those decisions. 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 the Europe's Beating Cancer Plan. The work on endocrine disruptors, 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 2023.

Further to the entry into application of the **Transparency Regulation** in March 2021, fact-finding missions will check the reliability of laboratories and testing facilities' claims of adherence to standards for studies submitted to EFSA for risk assessment.

DG SANTE oversees the **authorisation and approval procedures for substances** used in food and feed production and processing. In 2023, DG SANTE will continue to authorise a range of substances whose safety has been positively assessed.

DG SANTE - Authorisation and approval of substances	
Topic	Number of planned decisions
Uses and use levels of food additives and flavourings	ca 10
Novel foods	ca 20
Traditional foods	ca 3
Substances used in plastic food contact materials	ca 5
Plant Protection Products	
New active substances	11
Renewals	17
Basic substances	10
Maximum residues levels (MRLs) for pesticides	
Specific crop-commodity combinations	50
Full or a targeted reviews	for ca 25 active substances
MRLs lowering	for ca 35 substances
Biocides	
Approval of active substances	23
Renewals	5
Authorisations for biocidal products	30

The DG will further work on the implementation of Regulation (EC) 1925/2006 on the addition of **vitamins and minerals** and of certain other substances to foods, including on the prohibition or restriction of substances. In this context, it will also pursue preparatory

work for the revision of the Commission Regulation setting the maximum amounts of vitamins and minerals added to foods, including food supplements.

New approvals and renewals of previously approved active substances (including low-risk active substance) in **plant protection products and biocides** will be proposed on the basis of the outcome of safety evaluations conducted by Member States and EFSA or ECHA, respectively. In the course of 2023, DG SANTE will, in particular, have to prepare a Commission decision on whether the approval of **glyphosate** can be renewed. This will be controversial and specific attention will be paid to the communication around it.

DG SANTE also manages the establishment of statutory limits to the presence of certain substances. Maximum residues levels (MRLs) for pesticides will be set to guarantee that food placed on the internal market is safe. MRLs are also a requirement for food imported from non-EU countries so to maintain the same level of safety for food of plant origin, whether it is imported or produced within the EU.

Maximum levels for **contaminants in food and feed** are also to be set based on EFSA opinions. In 2023, it is foreseen to set or review maximum levels for several contaminants, such as nickel, inorganic arsenic, acrylamide or glycidyl esters. These actions will also feed into the prevention pillar of the 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.

For **veterinary medicines**, in 2023, DG SANTE will handle around 10 new authorisations, up to five referral procedures, around 30 renewals of marketing authorisations/variation procedures for unlimited validity and about five procedures for setting MRLs for veterinary medicines.

DG SANTE will propose re-evaluations of authorisations, new authorisations or modifications and renewal of authorisations of **feed additives** (around 100 applications) based on the outcome of safety evaluations and will continue to prepare the tertiary legislation necessary to the full implementation of Regulation (EU) 2019/6 on **Veterinary Medicinal Products** and Regulation (EU) 2019/4 on **Medicated Feed**.

DG SANTE contributes to a high level of food safety through better **food hygiene** and control of major foodborne zoonosis, including in relation to transmissible spongiform encephalopathies (TSEs), such as bovine spongiform encephalopathy (BSE), scrapie and chronic wasting disease. In 2023, it will continue adapting the relevant legal frameworks, taking account of technological developments and of new international standard for BSE to be adopted by the World Organisation for Animal Health in 2023. Finally, DG SANTE 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 the **Official Control Regulation (OCR)**.

In 2023, 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, 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

DG SANTE will continue to verify, through **audits and other Commission controls**, the performance of official controls in Member States and non-EU countries exporting to the EU to ensure that the EU's high food safety standards are complied with. 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.

The **audit programme** for 2023 includes 287 controls in the area of food and feed safety, animal health, animal welfare, plant health, EU quality standards and certain areas of human health protection in both EU and non-EU countries. This includes 164 audits and similar controls, and 123 analyses. During 2023, 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 2023, the **EU Reference Laboratories (EURLs)** will contribute to better implementation of EU legislation in the agri-food and support the Commission and national reference laboratories, helping to provide state of the art analytical and diagnostic services to national authorities and enforcement bodies.

DG SANTE - Rapid alert systems	
Rapid Alert System for Food and Feed (RASFF) notifications	20.000
Requests for assistance and cooperation between Member States concerning non-compliances	2.000
of which, fraud-suspicion related	300
TRACES documents	2 millions
Animal Disease Information System (ADIS) disease alert notifications	20.000

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. In 2023, the DG will launch the renewal of its collaborative IT platform “iRASFF” to support the Alert and Cooperation Network, a network established integrating the Rapid Alert System for Food and Feed and the Administrative Assistance and Cooperation Network,

including the Food Fraud Network. Moreover, the Alert and Cooperation Network will be implemented in policy areas in which it was previously not yet active such as plant health

As a consequence of the COVID pandemic, the use of electronic certification in TRACES will be expanded. For this to work with non-EU countries, the cooperation of other Commission services is crucial.

In 2023, the Animal Disease Information System (ADIS) will continue its development phase 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 WOA 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.

Following the publication of the F2F Communication in May 2020, in 2023 DG SANTE will put forward one of the main initiatives under this Specific Objective in the form of the proposal for a **new legislative framework for a Union sustainable food system**. Led by DG SANTE in association with DG AGRI, ENV and MARE, this flagship action will translate the concepts, objectives and parameters of food systems’ sustainability in a framework legislation. In this context, responding to the high expectations for a systemic change of food systems and ensuring that the vision of the F2F is accomplished whilst at the same time addressing the concern of relevant stakeholders, especially in the agricultural sector, will represent an important challenge for DG SANTE.

Moreover, together with DG JRC, AGRI, ENV, MARE, ESTAT, EEA, and other relevant Commission services, DG SANTE will launch a **monitoring framework** in the form of a dashboard to be published as main deliverable of the Farm to Fork Strategy review in 2023.

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.



In 2023, DG SANTE will pursue its contribution to the monitoring of Member States' implementation of the CAP National Strategic Plans.

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 2023, DG SANTE will pursue discussion with the European Parliament and the Council on the Commission 2022 proposal for a **Regulation on the Sustainable Use of Pesticides (SUR)** to reduce the risks and impacts of pesticide use on human health and the environment, and to improve the availability of sound data and statistics on the use of pesticides in the EU for evidence-based policymaking.

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 2023 DG SANTE will work with Member States and EFSA to implement the new data requirements for micro-organisms in plant protection products to realise the potential of

faster and easier submission and processing of dossiers via studies and guidance documents, as well as training and capacity building for Member States – among others via BTSF training and awarding of grants under the Single Market Programme. Moreover, DG SANTE intends to examine possible actions to facilitate the approvals for low-risk chemical active 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. Furthermore, a Regulation on procedures and criteria for identifying

unacceptable co-formulants in plant protection products is expected to be adopted early 2023 and a work programme for the assessment of safeners and synergists will be prepared and submitted for discussion and possible opinion of the Member States at the end of 2023.

Improving the efficiency and effectiveness of the pesticide legislation. DG SANTE will continue to address the inefficiencies of the pesticide legislation identified in the recent REFIT evaluation. It will implement the actions outlined in the report to the Parliament and the Council through non-legislative and legislative action.

In particular, 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 MRLs and assessing requests for **import tolerances** for pesticide substances no longer approved in the EU and, using diplomacy, trade policy and development support instruments, 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 AMR. DG SANTE will capitalise on the EU **Regulations on veterinary medicinal products and medicated feed** to continue actions to achieve the F2F target of reducing by 50% the overall EU sales of antimicrobials for farmed animals and aquaculture by 2030. In particular, in 2023 DG SANTE will continue to prepare and adopt the tertiary legislation necessary to enable the application of these Regulations some of which will represent a challenge, such as the adoption of a list of antimicrobials that shall not be used outside the terms of the marketing authorisation or shall only be used under certain conditions, oral administration of veterinary medicinal products and those with an international dimension (e.g. implementation of Article 118 of the veterinary medicinal products Regulation).

Fostering the use of innovative and more sustainable feeds. To reduce the environmental and climate impact of animal production, DG SANTE strives to facilitate the placing on the market of sustainable and innovative **feed additives**. Currently there are 223 feed additives that have positive effects on sustainability, and more may be authorised subject to favourable EFSA opinions. In 2023, the DG will deliver the evaluation of the existing legislation on feed additives.

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. In order to step up action to minimise food waste, the DG will finalise a proposal for setting **legally binding EU food waste reduction targets** in the context of the planned revision of the Waste Framework Directive. Food waste reduction strategies will continue to be a part of the response to the challenges to food security in the context of the impact of the Russian aggression war against Ukraine on the agri-food market.

The **EU Platform on Food Losses and Food Waste** will help drive and reinforce action at national level. The EU Food Loss and Waste Prevention Hub will further facilitate exchange of knowledge and experience between actors on the ground. As regards **external communication**, while food waste reduction is an objective that garners general support, particularly in the context of current discussions on food security, the upcoming proposal will require careful consideration of the different affected target audiences.

In addition, DG SANTE will support Member States in the implementation of the EU provisions on food waste measurement in cooperation with ESTAT, and will oversee the delivery of a “best practice” compendium in consumer food waste prevention by the **European Consumer Food Waste Forum**. DG SANTE is also managing work carried out by JRC to strengthen and improve the **food waste prevention evaluation framework** developed in 2019. Following data collection on food waste prevention initiatives carried out in 2022, actions that deliver the best results will be promoted in a public event to mark the International Day of Awareness of Food Loss and Waste on 29 September 2023.

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 fourth International Day on Food Loss and Waste (29 September 2023) as well as the international ‘Food is never waste’ coalition launched following the United Nations Food Systems Summit.

Ensuring a sustainable food production that improves the welfare of animals.

Good treatment of animals, besides being a moral imperative, is an integral part of sustainable food production. In 2023, DG SANTE will finalise a package of four legislative proposals for the **revision of the EU animal welfare legislation**, covering animal



welfare during transport, at the time of killing, animal welfare labelling and animal welfare at farm/establishment level, including the phasing out of cages, as announced in the Communication responding to the European Citizens’ Initiative “End the Cage Age”, as well as the welfare of cats and dogs kept for economic purposes.

DG SANTE’s management of the **EU Animal Welfare Platform** links directly to the preparation of the abovementioned proposal, in particular as regard the work of the Platform subgroups on pigs, poultry, calves and dairy cows, transport, welfare at the time of killing and animal welfare labelling, that will provide input for the revision of the animal welfare legislation. Furthermore, DG SANTE will complete the ongoing series of animal welfare **audits** in Member States to ensure the welfare of calves transported on long distances. It will also start two new audit series on the welfare of fish and of cattle for beef production.

In 2023, DG SANTE will continue to ensure the supervision of the existing three **Animal Welfare Reference Centres**, as well as the creation of a new Centre on farmed fish, and will manage several animal welfare pilot projects, namely on alternative methods for the stunning of pigs, on measurement of tail baiting at slaughterhouse level, on dairy cows, and on poultry.

Fighting against food fraud. Combating food fraud is essential to protect the safety and quality of EU food products, to protect consumers and their trust and ensure sustainable food systems. DG SANTE will continue in 2023 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 potential fraudulent practices and to develop a common understanding about food fraud through trainings under the BTSF initiative.

Finally, DG SANTE will discuss the need for additional measures based on the results of the fact-finding studies carried out in 2021 and 2022. An overview report summarising the main findings of such fact-finding studies will be published in 2023.

Empowering consumers to make sustainable and healthy food choices through the provision of food information. DG SANTE will work to improve consumer information, notably by looking at ways to address demands for more visible and complete information, especially on the health benefits and sustainability of food products. In 2023, 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 food, 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, find alternatives to antimicrobials and synthetic chemical pesticides and improve 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-based products (e.g. cultured meat) are expected in 2023.



To support the agricultural sector in the transition to sustainability and ensure an appropriate regulatory framework for certain products of new biotechnologies, DG SANTE will finalise the preparation of a legislative proposal on plants obtained by certain **new genomic techniques (NGT)**. DG SANTE will also finalise the proposal for a revision of the legislation on **marketing standards for plant reproductive material**. The sensitivity of the NGTs proposal but also its expected contribution to sustainability and food security aspects will require clear and transparent communication.

Meanwhile, DG SANTE will also ensure proper and timely implementation of the existing plant reproductive material marketing Directives, including equivalence requests by non-EU countries, Common Catalogue updates for new improved varieties of agricultural and vegetables crops, as well as of the legislation on Community Plant Variety Rights (CPVR), including the work carried out by the Community Plant Variety Office (CPVO).

Finally, DG SANTE will present the study on **Invertebrate Biological Control Agents**, thereby delivering on the Council's requests under Article 241 TFEU.

Improving the regulatory framework on Food Contact Materials (FCM). Food packaging 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 implement the new regulation on plastic recycling adopted in 2022. This includes preparing, with a view to adopt in 2023, decisions for over 230 authorisations of mechanical **PET plastic recycling processes**. 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 whose outcome ultimately depends on external factors as non-EU countries may not share the ambitions of the Green Deal or may have different views on how to approach this challenge.

Improving multilateral relations. In 2023, DG SANTE will promote and support relevant initiatives of the Food and Agriculture Organisation (FAO), the World Health Organisation (WHO) and other UN agencies - e.g. the development and implementation of their respective food safety strategies - and will engage with them in the work on sustainable food systems. Following the 2021 UN Food Systems Summit, DG SANTE will coordinate 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 of the work of the WTO governing bodies and seek to seize other opportunities to promote the EU regulatory system and the transition to sustainable food systems in relation with international trade. DG SANTE will actively participate in the implementation of the work programme laid down by the SPS Declaration adopted at the 12th Ministerial Conference, with particular focus on sustainable food systems. At meetings of the WTO SPS Committee, DG SANTE will promote and defend EU interests in the field of sanitary and phytosanitary measures and defend EU legislation on food safety, animal health and plant health. In particular, it will continue to address the criticisms on EU policy 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 certain policy areas, such as food labelling, halal meat 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 2023, 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 will be paid to priority or sensitive dossiers such as promoting sustainability and increasing considerations of a One Health approach in the context of the to the 60th anniversary of Codex, antimicrobial resistance, alcohol labelling, nutrient profiles tackling food fraud, and the recognition of equivalence of national food control systems.

DG SANTE will actively participate and contribute to the intersessional activities under the **Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety**. EU positions and statements will be coordinated and used for negotiations in the technical groups of the Convention on Biological Diversity and its Cartagena Protocol. 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 **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 – e.g. 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 UK whilst ensuring abidance 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 third 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 third countries.

DG SANTE will continue leading negotiations on **SPS and Sustainable Food Systems (SFS) Chapters** in the Free Trade Agreement. Until now, a SFS Chapter has been successfully agreed with Chile and New Zealand, while work is in progress with Australia, Indonesia and Thailand. DG SANTE has reached out to a large number of national

authorities of third countries to collaborate in the area of sustainability, through specifically dedicated meetings on F2F, agricultural dialogues, joint committee meetings in the context of bilateral trade agreements and high level meetings. Moreover, DG SANTE will continue to promote EU standards and facilitate market access for third countries via BTSF training for non-EU countries.

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, Mexico, Singapore, Vietnam, Japan, and Central American and Andean countries (Colombia, Ecuador and Peru). DG SANTE will also implement actions included in the different Commission Communications (Western Balkans, Eastern and Southern Partnership, Africa and Indo-Pacific region); pursue the resolution of long-standing issues of SPS market access; conduct activities on **equivalence determination and related activities** (Japan, USA); conduct activities on recognition of the principle of regionalisation and related activities by negotiating harmonised import health certificates; implement the Memorandum of Understanding agreed with the Chinese General Administration of Customs and updating the agreements with the Chinese Ministry of Agriculture and Rural Affairs and the State Administration for Market Regulation; and ensure the respect of the EU internal market rules by **negotiating harmonised export conditions** for all the EU members.

DG SANTE will also aim for successful negotiations of **enlargement related dossiers**, which got a new impetus in 2022 when Ukraine and Moldova acquired the EU Candidate Membership status as well. DG SANTE will contribute to the implementation of the Green Agenda for Western Balkans (in particular, actions aiming to establish sustainable food systems in the region); contribute to the preparedness of potential candidates (Bosnia and Herzegovina and Kosovo); screen for candidate countries and set benchmarks (North Macedonia, Albania); assess the fulfilment of benchmarks (Montenegro, Serbia and Turkey) and coordinate the Commission position on these negotiations. Jointly with DG NEAR, DG SANTE launched a new project supporting Western Balkan Countries in capacity building of veterinary and plant health services in the that region.

On the **neighbourhood policy**, the DG will continue implementing the Association Agreements and Deep and Comprehensive free trade areas (FTAs) with Ukraine, Georgia, and Moldova, which include supporting and monitoring the legislation approximation process. Additional emphasis will be given to Ukraine and Moldova, given that these countries are preparing for EU Membership.

DG SANTE will also contribute to the **EU-Africa Strategy** including possible specific agreements as part of F2F.

General Objective 2: PROMOTING OUR EUROPEAN WAY OF LIFE



European Health Union. In 2023, DG SANTE will oversee the further strengthening of the **European Health Union**. DG SANTE will continue working with Member States on all fronts to prepare for and respond to public health emergencies and cross-border threats to health. This includes response to outbreaks 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**.

In 2023, DG SANTE will contribute to the **support to Ukraine** following the Russian military aggression, for instance by backing the unprecedented medical evacuation operation. The Health Policy Platform, as a particularly agile mechanism for stakeholder involvement and consultation, will contribute to helping Ukrainian refugees.

DG SANTE will contribute to the new and comprehensive approach to **mental health**, which follows up on the proposals made during the Conference on the Future of Europe. The initiative **"Healthier together – EU Non-Communicable Diseases"** will help Member States and stakeholders address major causes of mortality and morbidity, such as cardiovascular diseases, diabetes, chronic respiratory diseases and neurological disorders, as well as health determinants (such as tobacco, alcohol, nutrition and physical activity). This initiative offers structured support to the action on mental health and complements Europe's Beating Cancer Plan. DG SANTE will strengthen its approach to supporting the Member States in achieving the UN Sustainable Development Goals, namely the objective of reducing the burden of non-communicable diseases.

EU funding for health. In 2023, DG SANTE in liaison with the European Health and Digital Executive Agency (HaDEA), will monitor the implementation of the EU4Health annual work programmes for 2021, 2022 and 2023 and prepare with the EU4Health Steering Group and stakeholders the work programme for 2024.


In the Health Funding inter-service group, DG SANTE will work with other DGs, services and institutions to deliver synergies across relevant EU funding programmes and instruments, such as the Health Cluster of the Horizon Europe research programme, including its Cancer Mission; the Cohesion Policy Funds (European Social Fund Plus (ESF+); the European Regional Development Fund (ERDF); REACT-EU; InvestEU; rescEU; the Recovery and Resilience Facility; the Technical Support Instrument, the Digital Europe Programme, and the Connecting Europe Facility 2. Complimentary funding with the European Investment Bank in implementing the Europe's Beating Cancer Plan are also being explored.

International cooperation. DG SANTE will reinforce EU's role in various **multilateral fora**, such as the WHO, OECD, G7 and G20 and the UN, in line with the new **Global Health Strategy ⁽²⁾** adopted in November 2022. DG SANTE will actively promote and communicate on priority topics in **multilateral cooperation** spanning from the COVID-19 pandemic to future preparedness and response, improving the global health security architecture and promoting the fight against antimicrobial resistance. Strengthening the role of the WHO, better implementation of the International Health Regulations, as well as contributing to establish a new international agreement on pandemic preparedness and response will be central in the work with the WHO and the UN. In line with our "health in all policies approach", we will also focus on supporting countries to achieve health-related Sustainable Development Goals (SDG), in particular SDG3 on healthy lives and well-being, and will contribute to the EU's Voluntary Review which will be submitted to the UN High Level Political Forum. DG SANTE will also further strengthen its cooperation with the WHO European Region in areas such as health security, antimicrobial resistance, cancer, mental health, sustainable food systems, health systems, one health and support related to non-EU neighbouring countries.

DG SANTE will provide leadership at the 10th Conference of the Parties to the WHO Framework Convention on Tobacco Control, promote our pharmaceutical regulatory standards and cooperate with the OECD.

In **bilateral cooperation**, DG SANTE will actively support the enlargement process regarding the EU health *acquis communautaire* with Ukraine, Moldova, with Georgia having prospects of EU Membership. It will continue its work with the six Western Balkan Eastern Partnership countries, while managing existing association or partnership agreements. 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. DG SANTE will increase cooperation on health matters of mutual interest with Canada, the US, India, South Korea, China, Japan and Latin American countries. DG SANTE will work towards the association of non-EU countries to the EU4Health programme.

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**. In 2023, the Plan's implementation will be in full swing. DG SANTE is co-leading the Horizon Europe Cancer Mission with DG RTD, to ensure synergies with the Cancer Plan. In 2023, DG SANTE will put forward a **prevention package**, comprising:

- a **Commission proposal for a Council Recommendation on vaccine-preventable cancers**  caused by the Hepatitis B virus and human papillomavirus (HPV) and

⁽²⁾ https://health.ec.europa.eu/system/files/2022-12/international_ghs-report-2022_en.pdf.

- a **Commission proposal for a revised Council Recommendation on smoke-free environments** 🏢

DG SANTE will support the implementation in the Member States of the **Council Recommendation on cancer screening** ⁽³⁾ and prepare for the establishment of an EU network of Comprehensive Cancer Infrastructures and Centres by the end of 2025 and for the setting up new networks of expertise. The communication campaign on the cancer screening will continue in 2023, targeting adults aged 40-60 from disadvantaged backgrounds, in a wide range of target countries. National data on cancer will enable local and tailored communication, in close partnership with the Commission Representations to the EU Member States, and communication actions will accompany the prevention package, underlining that 40% of cancers are preventable.

The Commission will continue with the development of a Cancer Inequality Registry to help identify trends, disparities and inequalities between Member States and regions. In this context, the first edition of cancer country profiles will be issued. DG SANTE will continue the evidence gathering for health warnings on alcoholic beverage products.

Tobacco control. DG SANTE has long engaged in efforts in the EU and globally to reduce tobacco consumption. In 2023, DG SANTE will finalise the evaluation of the **tobacco control legislation**, in line with the Cancer Plan ambition of creating a ‘Tobacco-Free Generation’, where less than 5% of the population uses tobacco by 2040. DG SANTE will continue to work on the implementation of the Tobacco Products Directive, which will involve compliance checks and bilateral structural dialogues with the Member States. It will secure the continuity of the EU system of tobacco product traceability with an award of the second concession for the system’s central elements and preparation for expanding the system 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. The strategy ⁽⁴⁾ 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. It creates synergies with the European Green Deal (hence contributing to General Objective 1 of this Plan), and our

⁽³⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022H1213%2801%29>.


⁽⁴⁾ [Commission Communication on a Pharmaceutical Strategy for Europe COM\(2020\) 761 final](#).

actions under the EU Strategic approach⁽⁵⁾ to pharmaceuticals in the environment to reduce their environmental risk, address pollution from pharmaceutical residues and promote greener manufacturing, use and disposal.

In 2023, a major action of the Strategy will be the proposal for the **revision of the general pharmaceutical legal framework**, which will be presented as a package with the revision of the legislation on medicines for children and rare diseases. It aims to improve access to high quality, safe, efficacious and affordable medicines in the EU. It aims to foster innovation including in areas of unmet medical need (including antimicrobials) and to enhance security of supply while adapting to new scientific and technological developments and to reduce regulatory burden. Drawing lessons from the COVID-19 pandemic, the proposed revision will support a future-proof and crisis-resistant pharmaceuticals system. Its focus on innovation and access to medicines work in coherence with the proposal for a European Health Data Space⁽⁶⁾ and the planned revision of the supplementary protection certificate for medicinal products⁽⁷⁾ in creating a competitive environment for innovation and investment in the EU.

The revision of the EU legislation on **medicines for children and rare diseases** will support the development of products in areas of high unmet needs for patients and ensure their timely access and affordability. It will ensure that the legislation is fit to keep the pace with technological and scientific development and will simplify existing procedures.

External communication will play a key role in explaining the proposal to revise the pharmaceutical legislation. From the adoption of the package, and until the end of the year, a series of programmes on Euronews will seek to make viewers aware of the main objectives of the proposals and their impact on European citizens.

DG SANTE will also prepare a delegated act to revise the **Variation Regulation**  to increase the simplicity and efficiency in the lifecycle management of medicines. Adoption of tertiary legislation will support the implementation of the Pharmaceutical Strategy.

Further key actions in 2023 by DG SANTE under the Pharmaceutical Strategy include:

- Availability: follow-up to the security of supply Staff Working Document. DG SANTE will continue to closely follow the ongoing issue of availability of medicines, supporting the collaborative work of EMA and the Executive Steering Group on Shortages and Safety of Medicinal Products.
- Affordability: work in the group of Competent Authorities on Pricing and Reimbursement and public healthcare payers, together with the Council presidencies;
- 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.

⁽⁵⁾ <https://ec.europa.eu/environment/water/water-dangersub/pharmaceuticals.htm>.

⁽⁶⁾ https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en.

⁽⁷⁾ SWD(2020) 292 final.

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 2023, the DG will continue to authorise new medicinal products and modifications of already authorised products within the legal deadlines (on average, there are more than 1 200 implementing decisions per year), including COVID-19 related procedures generally processed under accelerated timelines.

DG SANTE will also provide legal and regulatory support as regards treatments and vaccines (regulatory flexibility, a fast and robust authorisation process, effective post-authorisation monitoring, modifications of marketing authorisations, adaptation to new variants and related communication). Close collaboration will continue with EMA's emergency task force and committees on other COVID-19 activities (e.g. Vaccines Steering Group, procurement of therapeutics, vaccination uptake, EU Digital COVID Certificate).

DG SANTE will continue to monitor the implementation of the **Clinical Trials Regulation**, paying special attention to the developments linked to the Clinical Trial Information System (CTIS), and of other key initiatives of the pharmaceutical framework, such as the **Falsified Medicines Directive**.

In 2023, the Commission will work towards reaching an inter-institutional agreement on the legislative proposal on the **organisation of the fees to be paid to the European Medicines Agency (EMA)** ⁽⁸⁾. The proposal aims to revise the current system of fees which finances, among other sources of revenue, the functioning of EMA and the network of national agencies involved in the authorisation of medicines in the EU.

International cooperation in the area of 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 ⁽⁹⁾. DG SANTE will continue to monitor the **implementation of the mutual recognition agreement with the US** and will work towards the extension of the scope of the agreement to include veterinary medicines, vaccines and blood-based medicines.

Health Technology Assessment (HTA). In 2023, the focus will be the preparation for the implementation of the HTA Regulation, focusing on establishing the governance structures

⁽⁸⁾ <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52022PC0721>.

⁽⁹⁾ 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). Furthermore, the Commission will participate as an observer in the Pharmaceutical Inspection Co-operation Scheme (PIC/S).

for the joint work in line with the HTA Regulation (Coordination Group and its subgroups) and setting up the HTA stakeholder network. In parallel, DG SANTE will be working on the development of a dedicated IT platform as well as on the drafting of the necessary implementing legislation. General awareness raising activities on the HTA Regulation are also planned via info days in Member States and training programmes.

Medical Devices and In Vitro Diagnostic Medical Devices. DG SANTE will continue to implement the new legal framework on **Medical Devices** and **In Vitro Diagnostic Medical Devices**, in line with the Commissioner's mission letter. DG SANTE adopts any necessary measures to protect patients and mitigate the risk of shortages of critical devices and ensure continued monitoring of the market, through surveys to notified bodies and manufacturers. In this respect, on 6 January 2023, the Commission adopted a proposal ⁽¹⁰⁾ to give more time to certify medical devices to mitigate the risk of shortages. This will help address the significant challenges remaining in ensuring sufficient capacity of notified bodies and readiness of manufacturers in order to allow medical devices and in vitro diagnostic medical devices to be certified under the new Regulations and avoid shortages. DG SANTE will ensure the evaluation and designation of the **EU Reference Laboratories** under the in vitro diagnostic medical device Regulation and – together with the European Medicines Agency - continue to manage the work of the Expert Panels on medical devices. A number of actions including targeted activities supported by the EU4Health programme, closer cooperation with the Joint Research Centre and EMA support the implementation of the Medical Devices Regulations.

DG SANTE will continue the development of the highly complex database **EUDAMED**, for which the finalisation is foreseen by end 2023, as a prerequisite for the successful implementation of the medical device legislation. A number of tertiary legislation acts are planned for adoption in 2023, in order to ensure effective implementation of the MDR and IVDR, notably on harmonised standards, common specification for IVDs and rules for unique device identifiers.

DG SANTE will continue to chair and manage the **Medical Device Coordination Group** and its Working Groups to ensure coherent implementation and to facilitate coordination and exchanges according to the MDR and IVDR, including in the area of vigilance and market surveillance.

DG SANTE will continue to engage in **international discussions** regarding medical devices. In 2023 DG SANTE will lead the organisation of the EU Chairmanship of the **IMDRF** (International Medical Device Regulators Forum). DG SANTE will also continue to cooperate with WHO and regulators from other jurisdictions.

⁽¹⁰⁾ COM(2023) 10

External communication will focus in particular on issues related to capacity and preparedness in implementing effectively the new regulatory framework, mainly targeting journalists and stakeholders.

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

DG SANTE will continue to be at the core of the Commission's coordination of the EU response to the COVID-19 pandemic, and resilience to and preparedness for future serious threats in the field of human, animal and plant health and food safety, following a "One Health" approach. As mentioned above, DG SANTE, along with other Commission DGs, is fully involved in the **multilateral response to the COVID-19 crisis** and continues to stand alongside the United Nations, the World Health Organization, G7 and G20 to step up a forceful and coordinated global response to the pandemic. DG SANTE will continue to lead the Commission's work on the development of an **international agreement on pandemic prevention, preparedness and response**.

Continuing to follow a **Health in all policies** approach, DG SANTE will ensure that health implications are systematically addressed in European policies and will seek to create synergies with related policy fields, such as agriculture, environment and climate.

Preparedness and Response. 2023 will see the further strengthening of the European Health Union and the EU's resilience to cross-border threats. DG SANTE will implement the new **Regulation on serious cross-border threats to health** ⁽¹¹⁾, which will reinforce the framework for EU preparedness, surveillance, risk assessment, early warning and response, and enhance the EU's capacities to act in the face of health crises. This includes the development of a Union preparedness plan and a reporting and assessment framework for Member States. DG SANTE will continue organising the work of the EU Health Security Committee in the context of the new Regulation. This will be accompanied by targeted communication.

DG SANTE will work as well on the policy development around the Joint Procurement Agreement. Furthermore ⁽¹²⁾, DG SANTE will ensure the follow-up of the **strengthened mandates of the European Centre for Disease Prevention and Control** (ECDC) and the **European Medicines Agency** (EMA). DG SANTE will work closely with these agencies and with the **EU Health Emergency Response Authority (HERA)** for the medical countermeasures, to ensure complementarity of the work on all these actors.

⁽¹¹⁾ <https://eur-lex.europa.eu/eli/reg/2022/2371>

⁽¹²⁾ Since October 2021, joint procurement procedures under the Joint Procurement Agreement (JPA) for medical countermeasures are managed by HERA. DG SANTE is in charge of the JPA assessment and the management of framework contracts launched beforehand.

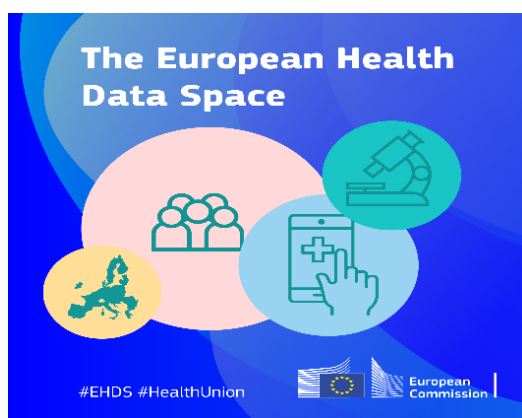
Vaccination. In 2023, DG SANTE will continue to build upon the great success of the EU Strategy for COVID-19 vaccines ⁽¹³⁾. DG SANTE will continue its work to support regulatory actions, policy-related activities and access to COVID-19 vaccines, and support Member States in ensuring successful deployment and sufficient uptake of such vaccines. External communication activities will focus increasingly on the benefits of lifelong vaccination. In line with the Mission Letter of Commissioner Kyriakides, DG SANTE will continue stepping-up its communication efforts to explain the safety and benefits of vaccines and combat the myths, misconceptions and scepticism and build **confidence in the safety and effectiveness of vaccines**.

Antimicrobial Resistance (AMR). In line with the Mission Letter of Commissioner Kyriakides, DG SANTE will continue supporting Member States to address the challenge of AMR, in line with the **“One Health”** approach, and will take forward work with our international partners for instance by advocating for the inclusion of AMR provisions in the Pandemic Agreement. DG SANTE will prepare in 2023 a **proposal for a Council Recommendation**, which will enhance actions on AMR in order to reach concrete outcomes in reducing the spread of AMR. It will be based inter alia on the review by DG SANTE of Member States’ AMR national Action Plans. Supporting the objectives of the AMR policy from the human medicines perspective is a flagship under the Pharmaceutical Strategy for Europe and is considered in the review of the pharmaceutical legislation. The proposal will be accompanied by an extensive press package and a media campaign in all EU languages.

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 2023. 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 2023, DG SANTE will work towards reaching an inter-institutional agreement on the legislative proposal on the **European Health Data Space**. The proposal will support among others access, sharing and use of health data for healthcare delivery purposes (primary use of health data) and re-use of health data for research, innovation, policy-making and regulatory purposes or development of Artificial Intelligence solutions (secondary use of health data), while preserving trust and security.



⁽¹³⁾ [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.](#)

Preparatory work will start on the governance and common requirements on interoperability and data quality.

On primary use of data, DG SANTE will continue to support and coordinate the actions of the Member States in the eHealth Network in deploying MyHealth@EU 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, including through a **pilot project for infrastructure for the secondary use of health data**.

DG SANTE will support the functioning of the **eHealth Network** and initiatives related to COVID-19 preparedness and crisis management, in particular the **EU Digital Covid-19 Certificate** and contact tracing applications, in close collaboration with DG JUST, DG CNECT and ECDC.

Health systems. DG SANTE will continue to generate country-specific and cross-country knowledge on health systems, in particular through the completion of the 4th 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. Projects on health workforce will continue.

In 2023, DG SANTE will support the activities of the **Expert Group on Health Systems Performance Assessment**, in line with its broadened mandate to focus on a more strategic approach to transforming health systems.

DG SANTE will contribute to the revamped **European Semester process** by providing detailed country-specific analyses on health systems and will continue supporting SG RECOVER/ECFIN in assessing the implementation of health systems reforms linked to investments included in the **Recovery and Resilience plans** as well as possible proposed amendments by Member States' of their plans..

The next phase of the development of the **European Reference Networks** –which are clearly delivering for patients with rare and complex diseases – will be launched in 2023. It will cover both direct support linked to ambitious targets and collaborative work with Member States in view of their integration in national health systems.

In 2023, DG SANTE will work with a newly established Expert Group on Public Health on the identification and scaling-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.

Substances of human origin. DG SANTE will work towards reaching an inter-institutional agreement on the **proposal to revise the EU legislation on the safety and quality of**

substances of human origin ⁽¹⁴⁾. The revision will reinforce the safety of the patients treated with blood, tissues and cells therapies and for the donors. It will strengthen the quality of the substances used and the oversight by national public authorities, support innovation and facilitate the development of new therapies.

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 in regard to the provisions of **Directive 2011/24/EU on Cross-border Healthcare**.

PART 2. Modernising the administration: main outputs for 2023

The internal control framework ⁽¹⁵⁾ 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.

- **Human resource management**

After several years of intense crisis management, in 2023 DG SANTE will consolidate the many initiatives launched from the lessons learned. The revision of the DG's organisational structure implemented in autumn 2022 will be complemented by action directed at rebalancing the workload between Units, Directorates and geographical sites and by the recruitment of several new managers, amongst which five Directors and a DDG. DG SANTE's continuous efforts in ensuring sufficient in-stream of female talent at desk officer and junior management positions are expected to bear fruit and will allow reaching and exceeding the Commission targets for first female management appointments.

DG SANTE will continue to ensure that staff engagement levels remain at the same high level as indicated in the December 2021 staff survey results (+6% compared to 2018 survey and +4% compared to Commission average). Special focus will be given on building capacity amongst management to better identify learning and development opportunities for staff. DG SANTE will also continue to focus on stimulating collaboration and communication by means of operating clear communication channels from top to bottom and promoting staff involvement and the provision of valuable feedback. The regular morning coffee sessions with the Director General, the SANTE management sessions and the many knowledge hour discussions covering a diverse range of topics keep the finger on

⁽¹⁴⁾ COM/2022/338.

⁽¹⁵⁾ [Communication C\(2017\)2373 - Revision of the Internal Control Framework](#).

the pulse of DG SANTE activities and stimulate the exchange of ideas and their uptake by the policy domains and ensure integration in the daily working processes of the DG.

Moreover, in the context of consolidating DG SANTE's new organisational structure we will relaunch by the end of the year a 360° feedback exercise for middle managers with the aim of further closing the gap between self-image and perception of others and improving mutual understanding of managerial abilities and impact, serving as the basis for further development actions.

As regards specific action contributing to implementing the Commission's diversity and inclusion in the workplace action plan 2023 – 2024, DG SANTE will more prominently include diversity and inclusion principles in the management charter and support managers in their efforts to implement diversity and inclusion actions in their teams.

Finally, we will consider action directed at encouraging and facilitating mobility, which is identified by staff as a major shortcoming in the Commission. Solidly based on the results of a prior fact-finding exercise and in line with the overarching life-long learning challenge, we will start creating the building blocks of a DG SANTE mobility strategy.

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 2023:

Output	Indicator	Target
Recruitment of new female middle managers	Number of first appointments of female managers validated	2 appointments validated by end 2023
Staff consultation, collaboration and involvement events	+/- 10 actions implemented	31/12/2023
Training actions to assist managers in finding ways to help staff identify learning and development opportunities	DG SANTE staff engagement index as communicated by DG HR and in particular the question on learning and development	Overall index above Commission average (>72%) Positive assessment of the specific learning and development question > 50%
360° evaluation exercise for Middle Managers	Participation rate of +70%	Launched by end 2023
Management awareness rising events on the topic of diversity and inclusion in the workplace	One general awareness rising seminar for managers. 2 workshops on specific action managers can take to implement diversity and inclusion actions in their teams	End of 2023

- **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 ⁽¹⁶⁾. 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 updated in 2023 to reflect the organisational and procedural changes that have been implemented in 2020 and 2021 further to the decisions taken in the context of the Multi-annual Financial Framework 2021 to 2027, the COVID-19 pandemic

⁽¹⁶⁾ Commission Communication (2017) 2373 on the revision of the Internal Control Framework.

and the revised organisational structure as of 1 October 2022. Of particular importance will 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 2023, DG SANTE will continue to follow the methodology proposed in the “implementation guide of the internal control framework of the Commission”.

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 2023:

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 (stock of vaccines/antigens for animal diseases)	Compliance with regulatory provisions and accounting closure instructions after audit/review corrections	Remains 100% compliant
Efficient controls	Budget execution and	Remains >95% of payment appropriations and
	Timely payments	Remains >95% of amount of payments made on time
Economical controls	Overall estimated cost of controls	Remains <2% of funds managed
Update of DG SANTE’s internal control strategy	Validation by the DG of the control strategy	30/09/2023

- **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 2023, DG SANTE will continue to organise awareness raising activities on anti-fraud matters, broaden fraud detection capabilities in budget implementation, strengthen the cooperation with OLAF and EPPO, and strive to ensure a high implementation rate of measures foreseen in the anti-fraud action plan for 2023. At the same time, DG SANTE aims to revise the standing operating procedures for the handling of allegations of fraud, other irregularities and OLAF cases.

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 CAFS action plan.

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

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) ⁽¹⁷⁾ aimed at the prevention, detection and correction ⁽¹⁸⁾ of fraud.

Main outputs in 2023:

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"	Annual meeting of the SANTE	1 meeting per year. At the

⁽¹⁷⁾ Communication from the Commission 'Commission Anti-Fraud Strategy: enhanced action to protect the EU budget', COM(2019) 196 of 29 April 2019 – 'the CAFS Communication' – and the accompanying action plan, SWD(2019) 170 – 'the CAFS Action Plan'.

⁽¹⁸⁾ Correction of fraud is an umbrella term, which notably refers to the recovery of amounts unduly spent and to administrative sanctions.

Output	Indicator	Target
of interest" in agencies, scientific committees and expert groups	inter-agencies task force on independence	moment, the meeting is foreseen to take place in September 2023, with all-agencies for which SANTE is partner
Updating fraud indicators and "red flags" for procurement and grants	Updated lists communicated to relevant staff	By the end of 2023
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
Arrangement of an appropriate level of cooperation with OLAF	Meeting OLAF-SANTE at Director level	At least 1 meeting per year
Implementation of the anti-fraud strategy as planned for 2023	% implementation of actions planned for 2023 as per the anti-fraud strategy	At least 90%
Revision the standing operating procedures (SOPs) for the handling of allegations of fraud, other irregularities and OLAF cases	SOPs endorsed by the Management Board	November 2023

- **Digital transformation and information management**

Based on the outcome of an IT modernisation and rationalisation study, DG SANTE will pursue further analysis aimed at grouping business and technical solutions in order to streamline and modernise our portfolio of IT solutions. At the same time, the DG will adjust the approach to delivering and procuring IT solutions and services to be more reactive, agile and business oriented, and in line with the new corporate 'dual-pillar' approach.

Details of the digital transformation and information management in DG SANTE are defined in DG SANTE's Digital and Data Master Plan (DDMP) for 2023. It is an important instrument to oversee the annual digital and data investments in DG SANTE, including an alignment with the Commission's 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 2023 DDMP by December 2022 and in 2023 will receive reports on its implementation on a regular basis.

DG SANTE has defined actions on most Commission Digital Strategy objectives as follows:

- Objective 1 DIGITAL CULTURE - digital talent and empowerment, we plan, in collaboration with central services to provide knowledge hours and info sessions on cybersecurity awareness, use of Artificial Intelligence for evidence that can be used in policy making (domains of Substances of Human Origins and Food Fraud);

- Objective 2 DIGITAL-READY POLICY MAKING – DG SANTE will use its Data and Digital Steering committee (DDSC) to steer digital ready policy making ⁽¹⁹⁾, in the domains of eHealth Data Spaces 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 DIGITAL TRANSFORMATION – DG SANTE has launched a strategy for digital modernisation investments, onboarding Artificial Intelligence solutions for policy making (Substances of Human Origin) and monitoring (Food Fraud) and will seek opportunities to roll out similar solutions in other policy domains. During 2023, DG SANTE will also use solutions on data lakes and data spaces to facilitate collection, dissemination and analysis of large data sets and provide for added value solutions on these data such as Artificial Intelligence assisted analysis and different data visualisation tools;
- Objective 4 SEAMLESS DIGITAL LANDSCAPE: 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 and will have phased out all but one legacy solutions based in the old ColdFusion technology, replacing it by existing solutions before the end of 2023.

Furthermore, DG SANTE will continue to extend the data it shares publicly, making available new datasets via the EU Open Data Portal as well as other exploitable tools that can be used by researchers and data scientists to help find insights from data.

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 ⁽²⁰⁾ 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.

⁽¹⁹⁾ Taking into consideration #Tool 28 of the Better Regulation Toolbox and the Commission proposal for an Interoperable Europe Act.

⁽²⁰⁾ User Interface.

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.

Data, information and knowledge management

SANTEs Data and Digital Steering Committee, created in 2022, 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 2023, the SANTE data strategy will concentrate on a few priority actions. DG SANTE will identify 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. Information sessions are planned to raise staff awareness and adherence to corporate data governance requirements. DG SANTE will run a pilot on cataloguing data collected in impact assessments and studies, develop an indicator framework for the farm to fork strategy and revise its EU Core Health Indicators data tool.

Data protection

In 2023, 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, 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

Objective: DG 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 2023:

Output	Indicator	Target
Implementation of the corporate principles for data governance for DG SANTE key data assets	Percentage of implementation of the corporate principles for data governance for DG SANTE’s key data assets ⁽²¹⁾	60%

⁽²¹⁾ Follow-up indicator from SANTE’s multi-annual startegic plan 2020-2024.

Output	Indicator	Target
Information systems and processes are at the highest level of maturity (transformed government) operating as e-services for the digital single market.	Percentage of information systems and processes at the highest level of maturity (transformed government) operating as e-services for the digital single market.	75%
Increase staff awareness in cyber-security threats	Percentage of staff completing DG SANTE's cyber-aware security education training programme on top of the DIGIT programme	- 100% newcomers; - 20% of all staff
More accessible IT solutions	Number of solutions migrated to e-UI and accessibility tests	- 7
Increase in awareness of staff on data protection compliance ⁽²²⁾	Percentage of staff attending awareness raising activities	- 100% newcomers; - 20% of all staff
Increase in awareness of staff on effective use of data, information and knowledge	Percentage staff attending awareness raising activity	- 100% middle management - 20% all staff
Information Systems security	Review of IT Security Plans older than 2 years	- 100%
Information Systems security	Implementation of EU-login for SANTE Information Systems	- 100% of SANTE Information Systems
Information Systems security	Implementation of Multi-Factor Authentication (MFA) for systems managing Sensitive Non Classified (SNC) information.	- 100% of SANTE SNC Information Systems (implemented or attested as exempt).

• Sound environmental management

In order 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 of the environmental impact of missions, meetings and conferences. DG SANTE will contribute to this ambitious objective ⁽²³⁾. Accordingly, within the administrative budget of the DG, a reduction of 20% as compared to the 2022 voted budget will be applied to expenditure for missions, meetings and conferences. In order 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 buildings in three different Member States, Belgium, Luxembourg and Ireland. SANTE's buildings in Brussels and Luxembourg fall under the responsibility of OIB and OIL respectively. DG SANTE's building and site in Grange, Ireland, where DG SANTE

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

⁽²³⁾ DG SANTE's actions are in line with the principles stated in the "Guidance note on business travel and external experts' travel in the framework of greening the Commission".

itself manages the day-to-day running of the facilities, 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 buildings and to reducing our negative impact on the environment.

In 2023, DG SANTE aims to maintain the EMAS registration for Grange and continuously improve the environmental performance of the site. DG SANTE will take measures to achieve the Commission targets set for 2023, with reduced consumption of both utilities and resources, and reduced emissions and waste. However, the performance in that regard will be dependent on behavioural factors and the relative balance between telework and on-site presence allowed by the flexible working policy of the Commission.

As in the previous years, the management of the environmental performance of the site in Grange will spearhead efficiency action and efforts to reduce environmental impacts of the administration. Notable measures planned for 2023 include: the seasonal shutdown of a section of the office building to reduce energy use in wintertime (main output I); plantation of 1 hectare of woodland to improve biodiversity and expand the carbon sink of the site (main outputs II and V); as well as installation of EV charging points to incentivise staff to use less polluting vehicles for commuting (main output II). In addition, efforts will be made to further reduce waste generation and maintain the good performance of the current waste management regime for non-hazardous waste yielding recycling rate of 94% for 2022 (main output III).

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

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 2023:

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

Output	Indicator	Target (2019 as baseline)
Staff awareness actions to reduce energy use in the framework of EMAS corporate campaigns and/or awareness actions about DG’s total energy consumption in collaboration with OIB/OIL ⁽²⁴⁾ where appropriate.	Number of staff awareness actions	2 actions
	% of staff informed/participated	85%

⁽²⁴⁾ See OIB – Environmental Building Performances for Brussels and OIL- Environmental Building Profiles for Luxembourg.

Output	Indicator	Target (2019 as baseline)
Participation in the end of the year energy saving action, by closing down DG's buildings during the Christmas and New Year's holiday period.	B232, F101. GRAN will operate at the minimum level	66% of DG buildings participating
Staff awareness actions to reduce water use (for example ensuring that staff use the technical services hotline ⁽²⁵⁾ to report leaks) in the framework of EMAS corporate campaigns and/or awareness raising actions about DG's water consumption in collaboration with OIB/OIL where appropriate.	Number of staff awareness actions to reduce water use	1 action
	% of staff informed/participated	85%
Paperless working methods at DG level (such as paperless working: e-signatories, financial circuits, collaborative working tools) and staff awareness actions to reduce office paper use in the framework of EMAS corporate campaigns and/or raise awareness about DG's office paper use in collaboration with OIB/OIL and DIGIT where appropriate.	Number of staff awareness actions to reduce office paper use	1 action
	% of staff informed/participated	85%
	Paper consumption	Reduce (in line with Commission target for 2023)

⁽²⁵⁾ For example, for Brussels: Email: OIB-55555@ec.europa.eu and Tel: 55555 and for Luxembourg: Email: OIL-DISPATCHING-CENTRAL@ec.europa.eu and Tel: 32220.

II. Reducing CO₂, equivalent CO₂ and other atmospheric emissions

Output	Indicator	Target (2019 as baseline)
Staff awareness actions on reducing GHG emissions (such as actions on sustainable commuting during EU Mobility week and VeloWalk corporate events) and/or raise staff awareness on sustainable commuting in collaboration with OIB or OIL (e.g. availability of bike parking facilities, lockers and showers, promote the reduction of parking spaces' use amongst staff).	% of staff informed/participated	85%
Gradual increased use (and number of) VC ⁽²⁶⁾ 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 (depending on the return to the office)
Analysis of DG's missions trends /patterns (based on corporate EC-staff's professional trips (missions)), optimise and gradually reduce CO ₂ 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
	CO ₂ (t) emissions from DG's missions <i>(% means of transportation used)</i>	Reduce DG's CO ₂ emissions from missions ⁽²⁷⁾ (%)
	Number of actions to promote more sustainable travelling options and use of videoconferencing / virtual events as an alternative to missions	1 action

III. Reducing and management of waste

Output	Indicator	Target (2019 as baseline)
Staff awareness actions about waste reduction and sorting in the framework of EMAS corporate campaigns and/or staff awareness actions about DG's waste generation in collaboration with OIB/OIL where appropriate (for example, promote and label the waste sorting schemes in place).	% of staff informed/participated	85 %
	% of waste generation	Reduce
	% of waste sorting	Increase

⁽²⁶⁾ VC (Videoconferencing) room.

⁽²⁷⁾ Based on data provided by the Commission's carbon footprint analysis (by HR.D.02), including business travel.

IV. Promoting green public procurement (GPP)		
Output	Indicator	Target (2019 as baseline)
Gradual introduction of GPP criteria in contracts and starting to monitor the process	Number of contracts relevant for GPP criteria	2 new contracts in 2023
	Number of GPP-relevant contracts with green criteria	2 new contracts (<i>relevant value in EUR 900,000</i>)
V. Supporting biodiversity		
Output	Indicator	Target (2019 as baseline)
Staff awareness actions on supporting biodiversity (for example for urban sites, sponsor the creation and maintenance of urban gardens, insect hotels and green roofs within EC-premises with the support of volunteers)	Number of staff awareness actions on supporting biodiversity	1 action
	% of staff involved:	100% staff informed; 10% hand-on

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

1. **Revision of the use of unit costs and lump sums in the Single Market Programme**

In view of the Single Market Programme Food chain strand, a revision of the financing system for EU support to Member States in the framework of veterinary and phytosanitary programmes and emergency measures was launched in 2020 with the Joint Research Centre. Until 2022, the revision focused on the veterinary measures and was developed based on the methodology developed by the JRC and in close co-operation with European Health and Digital Executive Agency, which implements the animal disease eradication programmes. The study should continue in 2023 whereby the JRC would review the possibilities for simplification and the possible use of unit-costs and lump-sums for the phytosanitary programmes and emergency measures. Such revision aims at reducing administrative burden and speeding up the payment process, allowing financial support to Member States against results rather than on the basis of eligibility; maintaining a sound and coherent technical reporting on the activities carried out; and last but not least reducing the error rate.

2. **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 as from 1 January 2024. In view of this launch, DG SANTE will focus 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. DG SANTE will also look into the features of the

tool, in order to reflect on the effective and efficient future organisation of its budget and finance management and adapt where necessary. Moreover, 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.

3. Cataloguing data in SANTE from Impact Assessments and studies

The Digital and Data Master Plan (DDMP) 2023 is expected to address both DIGITAL and DATA needs. It will present a roadmap listing actions that will explore bridging the divide between these two interlinked topics which are currently managed by two separate teams (Unit R4 for digital and Unit R1 for data). The pilot project on cataloguing data from impact assessments and studies is illustrating this collaboration and potential efficiency gains. The pilot will with the help of an automated tool try to categorise and catalogue data available in reports and as raw data collected in the context of impact assessments and studies. This project is expected to reduce the administrative burden to locate and identify relevant data and make them available for re-use. It will help identify relevant data more quickly, join data together and make simple reports that can support our work.

Annex: Performance tables for Part 1

General objective 1: A European Green Deal		
Specific objective 1.1: Ensuring food and feed safety		
Related to spending programme: Single Market Programme		
Main outputs in 2023:		
External communication actions		
Output	Indicator	Target
<p>Press and Media</p> <p>Communicate on actions being taken by the EU especially during times of outbreaks</p>	National print media coverage of EU's actions if/when outbreaks are reported	Media coverage by at least 10 EU countries
<p>Social Media</p> <p>Sustained tweets throughout the year on the various aspects of Food and feed safety</p>	Increase engagement on twitter	Average a minimum of 120 engagements per own tweet with #EUFoodSafety (all engagements)
<p>Website</p> <p>Update of related webpages</p>	Increase in the number of visitors to the SANTE food and feed related webpages	<p>5% increase (Baseline 2022 – 5.218.534 entries / 14.618.818 page views *)</p> <p><i>*Projection. During 2022, DIGIT changed its analytics to a new platform and, concurrently, DG SANTE migrated to the cloud and all URLs changed. These events may influence the accuracy of the 2022 analytics.</i></p>
Other important outputs		
Output	Indicator	Target
Animal health and animal diseases		
Implementing Regulation (EU) on contingency plans and simulation exercises	Adoption	Q2 2023
Amendments to Implementing Regulation (EU) 2021/620 on animal health statuses in the EU	Adoption	In course of 2023, as necessary, according to the epidemiological situation

Output	Indicator	Target
Amendments to Implementing Regulation (EU) 2021/404 on the list of third countries	Adoption	In course of 2023
Amendments to Implementing Regulations (EU) 2020/2235, 2020/2236 and 2021/403 on animal health and official certificates	Adoption	In course of 2023
Amendment to Implementing Regulation (EU) 2020/2002 on the notification and reporting of animal diseases	Adoption	Q2 2023
Commission emergency decisions on handling evolving epidemiological situations	Adoption of emergency decisions as necessary, according to the epidemiological situation	In course of 2023
<i>Plant health and diseases</i>		
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 the Union	Adoption	Ongoing activity for 20 pests
Commission Decisions on emergency measures against some specific pests	Adoption according to (new) outbreak situations	In course of 2023
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 2023
Commission Regulations with derogations from standard requirements under specific conditions	Adoption according to requests from third countries	In course of 2023
Evaluation of co-financing requests of Member States eradication measures (first year of outbreak)	No. of co-financing requests for plant health programmes that received co-financing	1 dossier for 2022 measures (until 21 October- submission possible 2 months after the outbreak notification) 4 dossiers for 2021 measures
<i>Market access for safe substances and products</i>		
Regulatory measures on contaminants in feed and food following EFSA opinions	Adoption	In course of 2023
Authorisations of health and nutrition claims, generic descriptors.	Adoption	In course of 2023

Output	Indicator	Target
Authorisations of health claims made on foods and referring to children's development	Adoption	In course of 2023
Commission Regulations prohibiting, restricting or banning the use of substances other than vitamins and minerals in food (Article 8 procedure)	Adoption	In course of 2023
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 2023
Commission Regulation setting minimum and maximum amounts of vitamins and minerals in foods and food supplements (PLAN/2020/8927)	Preparatory work	In the course of 2023
Commission Regulation on the use of Alpha Lipoic Acid under the Fortification Regulation [Decide reference not yet available]	Adoption	Q4 2023
Authorisation of novel foods under the Regulation on Novel Foods	Adoption	Up to 20 in course of 2023
Authorisation of traditional foods from third countries under the Regulation on Novel Foods	Adoption	3 in course of 2023
Decisions on data protection under the Regulation on Novel Foods	Adoption	Ongoing regular activity in 2023, 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 2022; adoption of approx. 10 acts amending the uses and use levels for food additives and flavourings.
Implementing act as regards scientific data for the evaluation of the combination effects of chemicals for food additives [Decide reference not yet available]	Adoption	Q4 2023
Authorisations for new substances and new uses of already authorised substances used in food contact materials	Adoption	Ongoing regular activity in 2023, authorisation of approximately five new substances
Authorisations of GMO for food / feed	Adoption	Ongoing regular activity in 2023

Output	Indicator	Target
Implementing Regulations approving/not approving or renewing/not renewing approvals of active substances for plant protection products	Adoption	Ongoing regular activity in 2023
Regulations establishing maximum residues levels (MRL) for pesticides	Adoption	Ongoing regular activity in 2023
Cumulative risk assessment method for pesticides residues	Development	Ongoing activity in 2023
Implementing Regulations approving/not approving or renewing/non-renewing the approval of biocidal active substances	Adoption	Ongoing regular activity in 2023
Implementing Regulations granting or amending Union authorisation of biocidal products	Adoption	Ongoing regular activity in 2023
Re-evaluations of authorisations, new authorisations, denial of authorisation, modifications of authorisations and renewal of authorisations of feed additives	Adoption	Ongoing regular activity in 2023
Authorisations of veterinary medicinal products	Adoption	Ongoing regular activity in 2023
Setting of MRLs for substances used in veterinary medicinal products	Adoption	Ongoing regular activity in 2023
Commission rules on safe imports, trade and related aspects	Adoption of Commission implementing rules	In course of 2023
Delegated and implementing Regulations reviewing food hygiene rules and controls of biological hazards, including in relation to transmissible spongiform encephalopathies (TSEs)	Adoption	In course of 2023
Control systems, including audits, and rapid alert systems		
Delegated acts on exemptions of certain goods from checks at border control posts	Adoption	In course of 2023
Implementing acts on commodities to be checked at border control posts	Adoption	In course of 2023
Implementing acts reviewing import control measures for food and feed of non-animal origin	Adoption	In course of 2023

Output	Indicator	Target
Implementing Regulation reviewing IMSOC rules notably as regards RASFF	Adoption	In course of 2023
European Reference Laboratories	Number of laboratories funded	45
European Reference Centres	Number of centres funded	5
Audits in the area of food safety and quality, animal health, animal welfare and plant health	Approx. 164 audits and similar controls completed	In the course of 2023
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	2 meetings of the working group on the Sustainable Use Directive
Assessment of planned facilities of Border Control Posts (BCPs)	Assessments carried out	Approx. 50 per year, based on the figures from 2022. This is a demand-based activity.
Evaluation of Member States' and non-EU countries' residue monitoring plans (food of animal origin)	Number of evaluation carried out	27 Member States plans, plus UK (Northern Ireland); up to 50% of non-EU country plans
Management of lists of approved non-EU country establishments for the production of food of animal origin	Number of request managed	Based on 2022 data, ca 3,300 listing requests for additions, modifications and deletions of establishments, resulting in around 6,000 changes to the list 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 2023
Plant health surveys	Member States' survey results for harmful organisms presented to Standing Committee on PAFF	In course of 2023
<i>Computerised systems + IT (e.g. TRACES, ADIS, EUROPHYT)</i>		
TRACES	No of active end-users	87000
ADIS	No of active end-users	697
iRASFF	No of active user accounts	7211

Output	Indicator	Target
EUROPHYT (Interceptions and Outbreaks)	No of active end-users	1100
AROC (Annual Reporting on Official Controls)	No of active end-users	163




General objective 1: A European Green Deal





Specific objective 1.2: Ensuring sustainable food systems – the ‘Farm to Fork’ Strategy

Related to spending programme(s): Single Market Programme

Main outputs in 2023:

New policy initiatives

Output	Indicator	Target
Regulation on the Sustainable Use of Plant Protection Products, revising the Sustainable Use Directive for pesticides COM(2022)305 final 2022/0196 (COD)	Adoption by co-legislators	Q4 2023
 Proposal for a legislative framework for a Union sustainable food system (PLAN/2021/11463)	Adoption	Q3 2023
 Proposal for a Regulation by the Council and the European Parliament on the protection of animals at the time of killing, repealing Council Regulation (EC) No 1099/2009 (PLAN/2022/1449)	Adoption	Q3 2023
 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') (PLAN/2022/1488)	Adoption	Q3 2023

Output	Indicator	Target
 Proposal for a Regulation by the Council and the European Parliament on the protection of animals during transport, repealing Council Regulation (EC) No 1/2005 (PLAN/2022/1491)	Adoption	Q3 2023
 Proposal for a Regulation by the Council and the European Parliament on animal welfare labelling for food (PLAN/2022/1489)	Adoption	Q3 2023
 Proposal for setting EU-level targets for food waste reduction (PLAN/2021/11886)	Adoption	Q2 2023
 Proposal on plant obtained by new genomic techniques (PLAN/2021/11456)	Adoption	Q2 2023
Initiatives linked to regulatory simplification and burden reduction		
Output	Indicator	Target
Proposal for a revision of the plant reproductive material legislation (PLAN/2020/7576)	Adoption	Q2 2023
Proposal for a revision of the food contact materials Regulation, including measure on ceramic and vitreous food contact materials (PLAN/2020/7637; PLAN/2018/4857)	Preparatory work	In the course of 2023
Evaluations and fitness checks		
Output	Indicator	Target
Evaluation of 2014 – 2020 food chain spending programme (PLAN/2021/10672)	Finalisation of SWD	Q3 2023
Evaluation of Regulation (EC) No 1831/2003 on additives for use in animal nutrition (PLAN/2020/8500)	Finalisation of SWD	Q1 2023
Public consultations		
Output	Indicator	Target
Public consultation on a revision of the food contact materials Regulation (PLAN/2020/7637)	Finalisation	Q1 2023

External communication actions		
Output	Indicator	Target
<p>Press and Media</p> <p>Communicate on the various proposals</p>	National print media coverage of EU's actions when proposals adopted	Media coverage by at least 20 EU countries
<p>Conferences</p> <p>Participation in the Paris and Berlin Agriculture fairs, together with DG AGRI</p>	Visitors to the Commission stand	<p>Average daily figures*</p> <p>Paris: 4165 visitors per day</p> <p>Berlin: 5000 visitors per day</p> <p>*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</p>
<p>Social Media</p> <p>Sustained tweets throughout the year on the various aspects of Farm to Fork and its implementation. The hashtag #EUFarm2Fork monitored continuously. Paid promotion of tweets</p> <p>Contract for Audiovisual material for maximum of four video and supporting social media material</p>	Increase engagement on Twitter	<p>Average a minimum of 160 engagements per own tweet with #EUFarm2Fork (all engagements)</p> <p>Average a minimum of 100K views per video, including paid-promotion</p>
<p>Website</p> <p>Update of the Farm to Fork webpage to include any ongoing consultations and the implementation progress</p>	Increase in the number of visitors	<p>Resulting in increase in web traffic on the Farm to Fork pages by 10% (when compared to 2022 baseline: 176.139 entries / 286.810 page views *)</p> <p><i>*Projection. Please take note that during 2022 DIGIT changed its analytics to a new platform and, concurrently, DG SANTE migrated to the cloud and all URLs changed. These 2 events may influence the accuracy of the 2022 analytics</i></p>
Other important outputs		
Output	Indicator	Target
Farm to Fork Strategy monitoring framework	Launch, including one meeting held with stakeholders and MS to present the proposed dashboard indicators	<p>Q4 2023</p> <p>Q2 2023</p>

Output	Indicator	Target
EU Code of Conduct for responsible food business and marketing practices	Results of the second mapping study on commitments; Meeting of the collaborative platform	Q4 2023 One meeting in Q4 2023
Advisory group on the sustainability of food systems	Meetings held	Two meetings, respectively by Q2 and Q4 2023
<i>Plant Protection Products and sustainable use thereof</i>		
Update of Communications accompanying the data requirements for active substances and plant protection products (including in relation to EDs) (PLAN/2017/921; PLAN/2017/920)	Adoption	Q1 2023
Communications accompanying the new data requirements for micro-organisms (PLAN/2021/10493)	Adoption	Q1 2023
Work programme for safeners and synergists	Preparatory work	In the course of 2023
Implementing Regulations on procedures and criteria for identifying unacceptable co-formulants (PLAN/2022/680)	Adoption	Q1 2023
<i>Reduction in the use of antimicrobials in animals to contribute to fight AMR</i>		
Ban on the use of certain antimicrobials in animals and products of animal origin imported to the Union (PLAN/2018/4503)	Adoption	Q1 2023
List of antimicrobials forbidden for cascade use in animals, or authorised for cascade use subject to certain conditions (PLAN/2020/9134)	Adoption	Q4 2023
Rules on appropriate measures to ensure effective and safe use of veterinary medicinal products for oral administration [Decide reference not yet available]	Adoption	Q4 2023
<i>Sustainable feeds</i>		
Authorisations of feed additives contributing to more sustainable feed	Authorisations in response to the 13 requests received in 2022	In the course of 2023

Output	Indicator	Target
Food loss and waste		
Operational support services for the EU Platform on Food Losses and Food Waste	Operation of digital platform and user activity	Ongoing regular activity in 2023
Meetings of the EU Platform on Food Losses and Food Waste	2 meetings held	Q2 and Q4 2023
Meetings of the sub-groups of the EU Platform on Food Losses and Food Waste	10 meetings held	In course of 2023
European Consumer Food Waste Forum compendium of best practices to prevent consumer food waste	Publication	Q2 2023
Animal Welfare		
Implementing Regulation on records of official controls performed on livestock vessels, contingency plans, approval of livestock vessels and exit points (PLAN/2020/9237)	Adoption	Q1 2023
Delegated Regulation on official controls for the transport of animals by livestock vessels (PLAN/2020/9249)	Adoption	Q1 2023
Pilot project on best practices for the welfare of dairy cows	Validated best practice guidelines	Q4 2023
Pilot project on Best Practices for Alternative Egg Production Systems	Final dissemination and communication event	Q3 2023
EU Reference Centre for the welfare of aquatic animals	Designation of the Centre	Q4 2023
Preparatory action on non-aversive stunning methods for pigs	Launch of the preparatory action	Q2 2023
Preparatory action on “Developing a system for the automated measuring of tail length and tail lesions of pigs at the slaughter line”	Signature of grant	Q2 2023
Eurobarometer on animal welfare	Final report	Q2 2023

Output	Indicator	Target
Support to innovation (including novel food, plant reproductive material and innovative techniques)		
Follow up to the study on the Union's situation regarding placing on the market and use of invertebrate biological control agents (IBCA)	Presentation to the EU Council	Q1 2023
<i>Implementation of the plant reproductive material marketing Directives</i>		
Fruit equivalence harmonisation	Adoption	Q4 2023
Amendment of EU equivalence Council Decision 2003/17/EC	Follow-up on requests	In course of 2023
Amendment of the CPVR Fees Regulation	Adoption	Q2 2023
Food Contact Materials		
Authorisation of recycling processes for plastics used in food contact materials	Adoption	Around 230 processes to be authorised in the course of 2023

General objective 1: A European Green Deal

Specific objective 1.3: Increased EU influence in international fora
Related to spending programme(s): Single Market Programme

Main outputs in 2023:

External communication actions

Output	Indicator	Target
<p>Website</p> <p>Update of webpages related to the international work of DG SANTE</p> <p>(see also indicator under objective 1.2: Participation with a stand in international events on Farm to Fork)</p>	Number of visitors to the related webpages (International Affairs web section)	<p>5% increase in the number of visitors to the related websections (Baseline 2022: 46.959 entries / 91.817 page views)*</p> <p><i>*Projection. Please take note that during 2022 DIGIT changed its analytics to a new platform and, concurrently, DG SANTE migrated to the cloud and all URLs changed. These 2 events may influence the accuracy of the 2022 analytics</i></p>

Other important outputs

Output	Indicator	Target
Multilateral SPS relations		
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 2023

Output	Indicator	Target
Coordinated EU position for the WOAH aquatic and terrestrial Code and Manual	Delivered	In course of 2023
Coordinated EU Statements for the World Organisation for Animal Health (WOAH) General Assembly	Delivered	In course of 2023
Coordinated EU positions for the European and Mediterranean Plant Protection Organization (EPPO)	Delivered	In course of 2023
Coordinated EU positions for the International Plant Protection Convention (IPPC)	Delivered	In course of 2023
Coordinated EU positions for the International Union for the Protection of New Varieties of Plants (UPOV)	Delivered	In course of 2023
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 2023
Input to the coordination for the Commission on Genetic Resources for Food and Agriculture	Delivered	In course of 2023
Coordinated EU positions in OECD Seed and OECD Forest schemes	Delivered	In course of 2023
Coordinated EU positions in the World Trade Organisation SPS	Delivered	In course of 2023
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 2023
<i>Sanitary and Phytosanitary (SPS) Bilateral relations</i>		
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

Output	Indicator	Target
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 2023
Coordinate EU position in negotiations of Agreements with non-EU countries	Delivered	In course of 2023
Coordinate EU position on the management of the SPS Committees of the Agreements in force	Delivered	In course of 2023
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 2023
Meeting of the EU-US Food Safety Working Group	Yearly meeting	In the course of 2023
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 the course of 2023
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 2023
Meeting of the EU-Central America Subcommittee on SPS matters	Yearly meeting	In course of 2023
Meeting of the EU-Andean countries (Colombia-Ecuador and Peru) Subcommittee on SPS matters	Yearly meeting	In course of 2023
Biotechnology dialogues with US, Canada and Argentina	Bi-yearly (US, CAN) and yearly (ARG) meetings	In course of 2023

General objective 2: Promoting our European way of life

Specific objective 2.1: Diminishing the impact of cancer in Europe

Related to spending programme(s): EU4Health and others

Main outputs in 2023:

New policy initiatives

Output	Indicator	Target
Commission proposal for a Council Recommendation on vaccine-preventable cancers  PLAN/2022/1346	Adopted	Q3 2023
Commission proposal for the revised Council Recommendation on smoke-free environments  PLAN/2021/12482	Adopted	Q3 2023

Evaluations and fitness checks

Output	Indicator	Target
Evaluation of the Tobacco Products Directive and the Tobacco Advertising Directive (PLAN/2021/12253)	Finalisation of the Staff Working Document (SWD)	Q3 2023

Public consultations

Output	Indicator	Target
Public consultation on the evaluation of the Tobacco Products Directive and the Tobacco Advertising Directive (PLAN/2021/12253)	Finalised	Q1 2023

Enforcement actions		
Output	Indicator	Target
Compliance checks finalised for 25 Member States (tobacco)	Completed	Q4 2023
Structured bilateral meetings with Member States in the context of compliance assessment (tobacco)	Ongoing	Q4 2023
External communication actions		
Output	Indicator	Target
Press and media Communicate on actions being taken throughout the year	National print media coverage of EU's actions	Media coverage by at least 20 EU MS
Social media 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 Twitter	Average a minimum of 140 engagements per tweet with #EUCancerPlan (all engagements)
Website Update of related webpages	Increase in the number of visitors to the Cancer related pages	5% increase (Baseline 2022 – 79.675 entries / 110.828 page views *) <i>*Projection. Please take note that during 2022 DIGIT changed its analytics to a new platform and, concurrently, DG SANTE migrated to the cloud and all URLs changed. These 2 events may influence the accuracy of the 2022 analytics</i>
Cancer plan; awareness raising multimedia campaign (cancer prevention and screening)	Reach Awareness	At least 60% of total potential target audience A positive change between the baseline and final survey (measured with statistical significance) of at least 5 percentage points
Other important outputs		
Output	Indicator	Target
Implementation of Europe's Beating Cancer Plan PLAN/2020/6485	Ongoing implementation	In course of 2023

Study on mapping and evaluating the implementation of Europe's Beating Cancer Plan	Launched	Q1 2023
Study on the EU Childhood Obesity Action Plan (2014 – 2020)	Launched	Q1 2023
Country reports on Cancer Inequalities in all EU MS (as part of the Cancer Inequalities Register)	Reports published	Q1 2023

General objective 2: Promoting our European way of life

Specific objective 2.2: Patients' access to safe, innovative and affordable medicines and medical devices


Related to spending programme(s): EU4Health and others

Main outputs in 2023:

New policy initiatives

Output	Indicator	Target
Proposal for the revision of the general pharmaceutical legislation (Directive 2001/83/EC and Regulation (EU) No 726/2004) (PLAN/2021/10601) and Commission Communication	Adoption	Q1 2023
Proposal for the revision of the - regulations on medicines for rare diseases ('orphan' medicines) Regulation (EC) No 141/2000 and on medicines for children Regulation (EC) No 1901/2006 (PLAN/2020/6688)	Adoption	Q1 2023

Initiatives linked to regulatory simplification and burden reduction

Output	Indicator	Target
Variation Regulation  PLAN/2022/1421	Adoption	Q4 2023

Evaluations and fitness checks

Output	Indicator	Target
Evaluation of the general pharmaceutical legislation	Completed	Q1 2023

Enforcement actions

Output	Indicator	Target
Joint assessments of conformity assessment bodies (Medical Device Regulation and <i>In Vitro</i> Diagnostic Medical Device Regulation)	90% of on-site assessments organised within 3 months following the corresponding request	In the course of 2023
Re-assessment of notified bodies (Medical Device Regulation and <i>In Vitro</i> Diagnostic Medical Device Regulation)	12 bodies which were notified in 2020	In the course of 2023

External communication actions		
Output	Indicator	Target
Press and media Communicate on actions being taken throughout the year	National print media coverage of EU's actions	Media coverage of at least 20 EU MS
Website Update of related webpages	Increase in the number of visitors to the Pharma Strategy pages and the Medical Devices web section	5% increase (Baseline 2022 – 944.074 entries / 2.035.363 page views) * <i>*Projection. Please take note that during 2022 DIGIT changed its analytics to a new platform and, concurrently, DG SANTE migrated to the cloud and all URLs changed. These 2 events may influence the accuracy of the 2022 analytics</i>
Multimedia campaign	Number of people reached (awareness)	5 million reach
Press and media: communicate on the Commission's activities in the Medical Devices sector	Number of subscribers/recipients; open rate, click rate	Q4 2023 Increase in Newsletter impact by 10% (when compared to 2022 baseline average data) to reach over 27,500 subscribers by end of 2023
Other important outputs		
Output	Indicator	Target
Implementation of the Pharmaceutical Strategy PLAN/2020/6954	Ongoing implementation	In course of 2023
Launch of the next phase of development of the European Reference Networks	Launch of the call for support of European Reference Networks with innovative targeted support to higher level objectives	Q4 2023
Implementing acts on harmonised standards for Medical Devices Regulation (EU) 2017/745 (PLAN/2022/139) and <i>In Vitro</i> Diagnostic Medical Devices Regulation (EU) 2017/746 (PLAN/2022/140)	Adoption	Q2 2023, Q4 2023
Implementing acts on designation of EU Reference Laboratories for <i>In Vitro</i> Diagnostic Medical Devices Regulation (EU) 2017/746 (PLAN/2019/5894, PLAN/2019/5895, PLAN/2019/5896)	Adoption	Q4 2023

Delegated act on Unique Device Identifier (UDI) for Medical Devices Regulation (EU) 2017/745 and <i>In Vitro</i> Diagnostic Medical Devices Regulation (EU) 2017/746	Adoption	Q2 2023
Report ex Article 54(4) of Medical Devices Regulation (EU) 2017/745: clinical evaluation consultation procedure and expert panels	Adoption	Q4 2023
Report to the European Parliament and to the Council on trends in the falsification of medicinal products and measures (Directive 2011/62/EU Article 3)	Completed	Q4 2023
Negotiation with the Parliament and Council of the proposal on Substances of human origin	Advancement of the inter-institutional negotiations	Throughout 2023
Advancement of the implementation of the Health Technology Assessment Regulation	Setting up the Methodology Sub-Group and the HTA stakeholder network	Q4 2023
Negotiation with the Parliament and Council of the proposal on the EMA fees	Advancement of the inter-institutional negotiations	Throughout 2023

General objective 2: Promoting our European way of life

Specific objective 2.3: Effective response coordination of serious cross-border health threats

Related to spending programme(s): EU4Health

Main outputs in 2023:

New policy initiatives

Output	Indicator	Target
Proposal for a Council Recommendation on Antimicrobial Resistance	Adoption	Q1 2023

External communication actions

Output	Indicator	Target
Press and media Communicate on actions being taken throughout the year	National print media coverage of EU's actions	Media coverage by at least 20 EU MS

Social media Continuous communication of actions throughout the year	Reach	Average a minimum of 140 engagements per tweet from SANTE accounts with #EUGlobalHealthStrategy, #AMR, #OneHealth or similar related (all engagements)
Website Update of related webpages	Increase in the number of visitors to the Cross- Border Healthcare web section	5% increase (Baseline 2022 – 15.290 entries / 28.465 page views *) <i>*Projection. Please take note that during 2022 DIGIT changed its analytics to a new platform and, concurrently, DG SANTE migrated to the cloud and all URLs changed. These 2 events may influence the accuracy of the 2022 analytics</i>
Lifelong vaccination multi media campaign:	Reach	50% of target audience
Global Health video and dissemination	Video views (engagement)	Average a minimum of 50K views per video, including paid-promotion
Antimicrobial resistance (AMR) multimedia campaign	Reach	Average a minimum of 100K views per video, including paid-promotion
One Health multimedia campaign:	Reach	Average a minimum of 50K views per video, including paid-promotion

Other important outputs

Output	Indicator	Target
Implementing / delegated acts to implement the new Regulation on cross-border health threats		
Implementing acts for preparedness reporting	Adopted	Q1 2023
early warning and alerts and for surveillance reporting on communicable diseases	Adopted	Q2 2023
Union prevention, preparedness and response plan drafted	Drafted	Q4 2023
New risk assessment system	Established	Q3 2023
Study on the coherence, complementarity and continued relevance of actions in the Council Recommendation on strengthened cooperation against vaccine-preventable diseases	Completion	Q3 2023

International relations		
Coordinate EU position in the negotiation of the international agreement on pandemic prevention, preparedness and response	Delivered	Throughout the year
Coordinate EU position and implement measures to strengthen WHO and the global health security architecture	Delivered	Throughout the year
Coordinate policies developed in cooperation with other relevant actors to strengthen the role of the EU in international relations:	Number of participation in OECD health committee meetings; contributions to WHO resolutions	Throughout the year
Bilateral relations		
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	1-2 meetings per year

General objective 2: Promoting our European way of life

Specific objective 2.4: More effective, accessible and resilient health systems

Related to spending programme(s): EU4Health and others

Main outputs in 2023:

External communication actions

Output	Indicator	Target
Social media	Increase engagement on Twitter	Average a minimum of 130 engagements per own tweet with #EU4Health or #HealthUnion
Website Update of related webpages	Increase in the number of visitors to the eHealth and European Health Data Space (EHDS) webpages	Retain baseline 2022 – 16.1076 entries / 27.3646 page views) <i>*Projection. Please take note that during 2022 DIGIT changed its analytics to a new platform and, concurrently, DG SANTE migrated to the cloud and all URLs changed. These 2 events may influence the accuracy of the 2022 analytics</i>

Other important outputs

Output	Indicator	Target
Negotiation with the Parliament and Council of the proposal on the European Health Data Space	Advancement of the inter-institutional negotiations	Throughout 2023
4th State of Health Cycle: Country Health Profiles	Publication	Q4 2023
Health System Performance Assessment Group report on “Value-based Healthcare”	Publication	Q4 2023
Health System Performance Assessment Group report on “Prevention”	Publication	Q1 2023
Launch of the next phase of development of the European Reference Networks	Launch of the Joint Action on integration of European Reference Networks in national health systems	Q4 2023
Study on the EU Health Policy Platform	Completion	Q2 2023