



Management plan 2022

DG Health and Food Safety (SANTE)




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INTRODUCTION

For almost two years now, the activities of the European Union – including of the Directorate-General for Health and Food Safety (DG SANTE) – have rightly centred on resolute action to overcome the COVID-19 pandemic and protect our citizens' health and welfare. The pandemic is still with us and we must continue tackling it. In 2022, DG SANTE will carry on implementing its core mission to strive to protect **human, animal and plant health**, 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**. Indeed, the work of DG SANTE is by definition highly impacted by external factors such as human and animal pandemics.

With this in mind, we intend to make 2022 another **year of delivery** – in which we continue to take actions supporting the sustainable **recovery** of the Union whilst at the same time focusing on the achievement of this Commission's political priorities. DG SANTE will continue working with Member States on all fronts to tackle the COVID-19 pandemic. As President von der Leyen announced in her 2021 State of the Union address, DG SANTE will contribute to the efforts to speed up global vaccination and vaccination efforts in Europe against COVID-19 and work on pandemic preparedness, in full coordination with the newly created HERA.



In parallel, 2022 will see us pursue our contribution to the Commission's **headline ambitions**. In health, this will mean a continued focus on building a strong **European Health Union**, borne out of the lessons learned from the COVID-19 pandemic and strengthening the “European way of life” (General Objective 2 of this plan). We will deliver important flagship initiatives under the **Pharmaceutical Strategy for Europe**, such as the proposed revisions of the **general pharmaceutical legal framework**¹ and legislation on **medicines for children** and **rare diseases**. The **European Health Data Space** will be launched at the beginning of the year. Implementation of **Europe's Beating Cancer Plan** will advance at full speed, and include an update of the Recommendation on cancer screening . The entry into force of three legislative initiatives on crisis preparedness and response will complete the main elements of the Health Union in 2022.

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 our health systems. DG SANTE will also continue rolling out the new legal framework on **medical devices** and **in vitro diagnostic medical devices** effectively.

The COVID-19 pandemic has highlighted the increasing urgency of efforts to fight **antimicrobial resistance** (AMR), through initiatives such as the EU's “One Health Action Plan”, and actions under our food safety, health and sustainability policies. In 2022, we will

¹ Initiatives that are part of the Commission Work Programme 2022 are marked with the icon .

make a proposal for a Council Recommendation to strengthen the anti-AMR instruments currently in place and boost the overall EU action on antimicrobial resistance.

DG SANTE's activities on food safety and sustainability will also focus on the Commission's priorities. 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 its first fruits in 2022, with the delivery of several legislative proposals. These relate to the revision of the Directive on the **sustainable use of pesticides** , along with the revision of the legislation on feed additives, marketing standards for **seeds and forest reproductive material** , and **food information to consumers**.

Under the Farm to Fork Strategy, DG SANTE will also continue preparing the future legislative framework on **sustainable food systems** – due by 2023. At the same time, we will work on sectorial legislative initiatives, notably aimed at setting mandatory **EU food waste reduction targets** and preparing the revision of existing legislation on **animal welfare** and on **food contact materials**. DG SANTE will pursue its policy action on **new genomic techniques** in view of a possible legislative initiative.

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 2021, 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.

In 2022, DG SANTE will also deliver on the Council's requests under **Article 241 TFEU** to prepare a study on the Union's situation regarding placing on the market and use of **Invertebrate Biological Control Agents**.

At **international level**, DG SANTE will promote global health cooperation, including the global response to the COVID-19 pandemic and the ACT-A platform, transformation towards sustainable food systems and other EU priorities as well as global solutions with its trade partners and within international fora. In 2022 we expect the lessons learned from the pandemic and the recommendations of independent panels to translate into vital steps to strengthen the global health security architecture. This will involve negotiations on a potential international **agreement on pandemic prevention, preparedness and response**. DG SANTE will also actively contribute to the discussions on improving the global health security architecture and strengthening the role of the World Health Organisation (WHO). We will advocate the EU's **"one health" approach** and a global agreement on AMR, 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. Against this background, DG SANTE will contribute to a **report assessing the rationale and legal feasibility of applying EU health and environmental standards** to imported agricultural and agri-food products, whose findings will underpin the future roll-out of the Farm to Fork Strategy at international level.

DG SANTE's work attracts strong interest from citizens, interest groups, professional organisations, as well as MEPs, Member States and non-EU authorities. This is why the 2022 communication strategy will be extended to **citizens-oriented communication campaigns on key priorities**, in addition to the usual media and stakeholder engagement actions. Special attention will also be given to the follow up to the Conference on the Future of Europe. Similarly, DG SANTE will with DG INTPA co-lead the relaunched Global Health Policy Forum representing an ongoing dialogue with civil society organisations, informing global health policy.

In short, this management plan outlines DG SANTE's political priorities and planned initiatives for 2022. 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 2022

General Objective 1: A EUROPEAN GREEN DEAL



In 2022, DG SANTE's work on safe and sustainable food will make a key contribution to the European Green Deal particularly by delivering the first legislative proposals under the Farm to Fork Strategy (F2F), most notably the **revision of the Directive on the sustainable use of pesticides**, as well as the revisions of the legislation on **feed additives, marketing standards for seeds and forest and plant reproductive materials** and of the **Regulation on the provision of food information to consumers**.

DG SANTE strives to ensure food and feed safety and sustainability against the backdrop of external factors such as the increased polarisation and politicisation of discussions around these themes. In particular, upholding science- and evidence-based decisions and avoiding further compartmentalisation of the single market represent important challenges in the accomplishment of the DG's mandate.

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 (CPVO), 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). Collectively, they offer a wealth of scientific resources, expertise and network opportunities to support scientific evidence-based policymaking. Collaboration amongst agencies and between the latter and DG SANTE is crucial in the light of the "one substance – one assessment" principle featuring in the Chemicals Strategy.

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 2022 budget for the food chain strand under the SMP is EUR 225.8 million.

In 2022, 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 particular the veterinary programmes and phytosanitary survey programmes, actions relating to official controls such as EU Reference Laboratories and EU Reference Centers for animal welfare, and the Better Training for Safer Food programme. In addition, in 2022 DG SANTE will produce a report on the conclusions of the evaluation of the 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, and to simplify it where possible. It takes a “One Health” approach to preparedness and prevention, integrating human, animal 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 moving 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 2022, DG SANTE will continue to ensure the smooth implementation of the new **EU Animal Health Law (AHL)**, applicable as of 2021, and to adapt the EU legal framework 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 system under the **Plant Health Law (PHL)** to protect crops, fruits, vegetables, flowers, ornamentals and forests from pests and diseases. This law includes provisions on moving plants and plant products within the EU, and strict rules for imports of plants and plant products that might host dangerous pests.

In 2022, DG SANTE will prepare a series of acts under the PHL 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.

DG SANTE works proactively to **detect early, notify, contain and eradicate pests** found in the EU. Prevention, preparedness and management of plant health crises will remain a core part of our work in 2022, as well as the management of interceptions/outbreaks. 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 2022, the estimated budget for implementing national veterinary programmes is EUR 107 million and for

phytosanitary programmes it is EUR 20 million. EU funds will also be available during crises to co-fund emergency measures to quickly eradicate and prevent disease spread. The estimated budget for those is EUR 19 million in 2022.

Ensuring market access to safe substances and products. DG SANTE is responsible for the General Food Law Regulation, ensuring a high level of protection of human health and consumers' interests, based on the risk analysis principle. DG SANTE adopts risk management decisions to place substances for food and feed related uses on the market, 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, Biodiversity, the Zero Pollution and the Chemicals Strategies. In relation to the latter, DG SANTE's work on endocrine disruptors, cumulative effects of chemicals, and the inter-agency collaboration in the light of "one substance one assessment" will be part of the DG's work for 2022.

Further to the entry into application of the Transparency Regulation in March 2021, in 2022 the DG pursue the development of a general plan on risk communication to ensure a coherent risk communication framework throughout the risk analysis process, combined with open dialogue amongst all interested parties. 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 2022, DG SANTE will continue to authorise a range of substances whose safety has been positively assessed.

These authorisations include new substances and new uses of already authorised substances used as food additives and flavourings (around ten), novel foods (around 25) and traditional foods from non-EU countries (around three), and substances used in plastic food contact materials (around eight).

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. In this context, it will pursue preparatory work on 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 in **plant protection products and biocides** will be proposed on the basis of safety evaluations. These will include decisions on low-risk active substances. In 2022, in the area of plant protection products, around seven decisions on new active substances are expected, as well as around 11 decisions on the renewal of currently approved active substances, and around 10 decisions on basic substances. Toward the end of 2022, DG SANTE will have to prepare a Commission decision on whether the approval of **glyphosate** can be renewed, which will entail a significant communication effort. As such, a dedicated communication plan will be designed combining proactive and reactive media activities.

For biocidal products, around 21 decisions on the approval of existing (15) and new (six) active substances, six decisions on the renewal of approval of active substances and around 50 decisions on EU-wide authorisations for biocidal products are expected.

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. SANTE will present draft proposals for decisions on around 55 MRL applications for specific crop-commodity combinations and for the full review of around 27 active substances, as well as Regulations lowering MRLs for about 20 substances following non-renewal decisions and expiry of approvals of active substances.

Maximum levels for **contaminants in food and feed** will also be set based on EFSA opinions. In 2022, it is foreseen to set or review maximum levels for several contaminants. These actions will also feed into the prevention pillar of the Europe's Beating Cancer Plan.

Moreover, DG SANTE will continue to process **genetically modified food and feed** applications based on EFSA opinions.

For **veterinary medicines**, in 2022, DG SANTE will handle around 12 new authorisations, around three referral procedures, around two renewals of marketing authorisations and about five to ten procedures for setting MRLs for veterinary medicines. On residues, several delegated and implementing acts will be adopted to ensure a smooth functioning of the Official Controls Regulation and import conditions.

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.

In January 2022, the Regulation (EU) 2019/6 on **Veterinary Medicinal Products** and Regulation (EU) 2019/4 on **Medicated Feed** will apply. DG SANTE will continue to prepare the related tertiary legislation, necessary to their full implementation. A report on a feasibility study of an active substance based review system ('monographs') and other potential alternatives for the environmental risk assessment of veterinary medicinal products will be prepared.

DG SANTE contributes to a high level of food safety through better **food hygiene** and control of biological hazards. In 2022, it will continue adapting the relevant legal framework.

Finally, DG SANTE monitors the occurrence of cross-border food-borne incidents and coordinates their sound and swift management by Member States when necessary. In 2022, particular attention will be paid to incidents linked to the use of Ethylene Oxide in food and food ingredients placed on the EU market.

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. The safety of the food chain relies on business operators acting responsibly and in line with food law requirements. Member States' authorities monitor and enforce these requirements by performing official control activities, as required by the **Official Control Regulation (OCR)**.

In 2022, DG SANTE will further complement and update the legal framework on official controls, particularly as regards the rules on border checks on goods, and will continue to work on guidance for a more harmonised implementation of the legislation. In this context, the DG will manage the "Green line Regulation" (Cyprus settlement case).

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 2022 includes 283 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 173 audits and similar controls, and 110 analyses. During 2022, DG SANTE will use a combination of **on-the-spot missions** and **remote assessment tools** to conduct the audits and similar controls.

The **EU Reference Laboratories** (EURLs) contribute to better implementation of EU legislation in the agri-food chain and the credibility of the food production system. EURLs will support the Commission and national reference laboratories, helping to provide state of the art analytical and diagnostic services to national authorities and enforcement bodies. The 2022 budget for the EURLs is EUR 21 million.

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. They aim to identify problems early and allow rapid information sharing, response and effective cooperation. Each year, there are about 15.000 notifications in the Rapid Alert System for Food and Feed (RASFF) network, 2000 requests for assistance and cooperation between Member States concerning non-compliances of which 300 are fraud-suspicion related, and 2 million documents in TRACES, the platform for sanitary and phytosanitary certification.

The DG will launch a 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 is being implemented in policy areas in which it was previously not yet active: plant health, animal health and animal welfare.

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 parallel, at the initiative of the Member States, a reflection on a possible strategy on digitalisation in the veterinary and food chain controls will be undertaken.

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, the main DG SANTE deliverable under this Specific Objective is the adoption of a **new legislative framework on sustainable food systems** by 2023. Led by DG SANTE in association with DG AGRI, ENV and MARE, this flagship action will translate the new concepts, objectives and parameters of food systems' sustainability in a framework legislation. In 2022, DG SANTE will launch an impact assessment, and organise a broad public consultation. 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 will represent an important challenge for DG SANTE.



Moreover, the DG will work towards developing a **monitoring framework** for the Strategy by setting up a methodology and indicators in view of the Strategy review in mid-2023. It will coordinate the development of the framework in collaboration with DG JRC, ESTAT, EEA, and other relevant DGs.

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

A **multi-media campaign** targeting young people and families will be launched to engage on sustainability issues to show how the EU addresses specific concerns on areas like pesticides and the environment. The campaign will also be used to show how F2F will help producers make the transition. In October, DG SANTE will also organise the **third annual conference** on the Strategy with wide-ranging communication and reach-out efforts, including science days on sustainable food systems.

At cross-policy level, in 2022 DG SANTE will continue to work with DG AGRI on the assessment of National Strategic Plans (NSPs) for the Common Agricultural Policy (CAP).

Reducing dependency on and promoting the sustainable use of pesticides. DG SANTE works towards reducing dependency on pesticide and stimulating the take-up of low-risk and non-chemical alternatives for plant health protection. To this end, it will pursue actions to achieve the F2F target of reducing by 50% the use and risk of chemical pesticides and by 50% the use of more hazardous pesticides by 2030.

In 2022, DG SANTE will finalise a proposal for the revision of the **Sustainable Use of Pesticides Directive (SUD)** 🏛️, the first SANTE legislative proposal to be delivered



under the F2F. The revision aims 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.

A pesticides **communication package** will be prepared for the revision of the Sustainable Use of Pesticides Directive (SUD), building a narrative that brings together the different elements proposed by F2F and beyond. The proposal will also feature extensively in the multimedia campaign mentioned above.

In addition, DG SANTE will continue working to improve the existing **indicators** for changes in the use and risk of chemical pesticides.

DG SANTE will continue targeted **audits** concerning the SUD and the authorisation, marketing and use of pesticides in Member States. It will continue to work with and support Member States in the implementation of the SUD, including through BTSF trainings to exchange best practices specifically on Integrated Pest Management (IPM).

In addition, in 2022 DG SANTE will complete the adoption of a number of Implementing Regulations adapting the data requirements, uniform principles for evaluation and decision-making criteria for micro-organisms in plant protection products. The aim is to facilitate the placing on the market of alternatives to chemical pesticides. DG SANTE also intends to adopt an implementing act which will set out details for the records of pesticide use to be kept by professional users. This will facilitate monitoring of pesticide use, the collection of harmonised use data and the development of further risk indicators under the SUD.

Improving the efficiency and effectiveness of the pesticide legislation. DG SANTE will work 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 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 uphold the use of low-risk substances and alternatives to pesticides 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 set in motion 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 2022 DG SANTE will continue to prepare and adopt the tertiary legislation necessary to enable the application of these Regulations as of 2022. The adoption of tertiary legislation featuring core measures to fight AMR, such as the adoption of a list of antimicrobials to be reserved for use in human medicine, and those with an international dimension (e.g. implementation of Article 118 of the veterinary medicinal products Regulation), will represent a challenge.

DG SANTE will continue to promote vaccination, animal husbandry and feeding systems, which support good animal health and welfare to reduce the need for antimicrobials.

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**. Based on the evaluation of the feed additives legislation, an impact assessment will be completed by February 2022 and followed by the adoption of a legislative proposal by mid-2022.

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 2022, DG SANTE will help drive and reinforce action at national level, guided by the recommendations of the re-established **EU Platform on Food Losses and Food Waste**, whose mandate has been extended until 2026. 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**, food waste will feature prominently in the multimedia campaign and the work of the Platform will be promoted extensively.

On the legislative side, in 2022, DG SANTE will propose a revision of the EU rules on date marking ('use by' and 'best before'). In addition, the DG will launch an impact assessment and a stakeholder consultation to prepare the proposal for a Directive setting **legally binding EU food waste reduction targets** to be adopted in 2023.

In addition, DG SANTE will support Member States in the implementation of the new EU provisions on measurement methodology in cooperation with ESTAT, and will oversee the implementation of the JRC-managed EP pilot project on the European Consumer Food Waste Forum.

Finally, cooperation with international organisations such as Food and Agriculture Organization and the UN Environment Programme will be pursued in the context of monitoring SDG Target 12.3 and of the third International Day on Food Loss and Waste (29 September 2022).

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 2022, DG SANTE will finalise the **evaluation**² of the existing animal welfare *acquis* and prepare for the **revision** of the EU animal welfare legislation, including launching an impact assessment covering animal welfare at farm level, during transport, at the time of killing, animal welfare labelling and the phasing out of cages, as announced in the Communication responding to the European Citizens' Initiative "End the Cage Age". It will also complete two new series of animal welfare **audits** in Member States to ensure the welfare of calves transported on long distances and of animals transported by sea vessels.



DG SANTE's management of the **EU Animal Welfare Platform** links directly to the above, in particular as regard the work of the envisaged Platform subgroups on pigs, poultry, dairy cows, transport, slaughter/killing and animal welfare labelling, that will provide input for the revision of the animal welfare legislation.

Furthermore, DG SANTE will follow-up to the **conclusions of the European Parliament ANIT Committee**, considering them as part of the work on the preparation of tertiary legislation on the transport of animals by sea, and on the planned revision of the animal transport Regulation.

² Evaluations referred to in this Management Plan are also referred to in the dedicated interinstitutional EU studies database, containing the full list of ongoing evaluations and related studies.

In 2022, DG SANTE will continue to ensure the supervision of the **Animal Welfare Reference Centres**. It will also manage the follow-up of two **pilot projects** on laying hens and dairy cows, and launch two new pilot projects on stunning methods for pigs and on the monitoring of pig tail-docking indicators at slaughterhouse.

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 2022 to provide Member States with intelligence on agri-food fraud matters and plan 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 in absence of appropriate reaction may propose special import conditions, heightening checks for specific commodities or suspending access to the EU market. DG SANTE will also aim at setting up an EU platform devoted to agri-food frauds to **protect whistle-blowers**.

Finally, the Official Control Regulation (EU) 2017/625 introduced a new provision, which foresees that Member States should put in place **controls aimed at identifying and following-up fraudulent or deceptive practices**. DG SANTE will carry out two fact-finding studies of Member States in the first semester 2022 in order to collect further information on the implementation of the above provision. The outcome of this project will be summarized in an overview report in the second semester 2022 and will form the basis for the preparation of a guidance document to assist Member States in the implementation of the new requirements.


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, which will be promoted through labels and digital tools.

Based on an external study to be also delivered in 2022, DG SANTE will finalise the impact assessment in view of the legislative proposal on the **revision of the Regulation on food information to consumers (FIC)** to be adopted by end 2022. The revision will cover front-of-pack nutrition labelling/nutrient profiles, origin labelling, date marking (see also section of Food Loss and Waste) and, following the adoption of the Europe Beating Cancer Plan in February 2021, the labelling of alcohol. As a main deliverable under F2F, the FIC revision will benefit from extensive communication actions notably targeting media.

Moreover, preparatory work will continue on the **sustainability labelling initiative** that will be part of the general framework legislation for a sustainable food system planned for end of 2023. In particular, an impact assessment will be conducted in close collaboration with the JRC.

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 on food 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 requests for authorisations of insects, plant-based proteins and algae-derived products as novel foods in Europe, based on EFSA's scientific advice.

DG SANTE will finalise the impact assessment and the subsequent proposal for a revision of the legislation on **marketing standards for seeds and forest and plant reproductive material** . Meanwhile, DG SANTE will also ensure proper and timely implementation of the 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).

Moreover, DG SANTE will carry out a study on the Union's situation regarding placing on the market and use of **Invertebrate Biological Control Agents** (IBCA), as requested by the EU Council under Article 241 TFEU.

In addition, DG SANTE will pursue preparatory work in relation to the policy action on **new genomic techniques**, including carrying out a public consultation and advancing on the preparation of the impact assessment in view of a legislative proposal. The sensitivity of this file warrants transparent communication and engagement with stakeholders, which will continue throughout 2022. Moreover, DG SANTE will prepare a Commission report regarding Member States' experience with the contained use of genetically modified microorganisms in 2019-2021.

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 the launch of 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.

Linked to the Commission's work on the European strategy on plastics, DG SANTE will continue to prepare, with a view to ultimately adopt in 2022, decisions for around 200 authorisations of mechanical **PET plastic recycling processes** after the adoption of the related targeted amendment of plastics recycling legislation in early 2022. This will facilitate the uptake of recycled plastics by the food packaging industry, which accounts for a major part of plastic packaging and represents a significant contribution to the Circular Economy.

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. In this context, following a request by the EU Council and the European Parliament, in 2022 DG SANTE will produce, in cooperation with DG AGRI, TRADE and ENV, a **report assessing the rationale and legal feasibility of applying EU health and environmental standards** (including animal welfare standards as well as processes and production methods) to imported agricultural and agri-food products, as well as identifying the concrete initiatives to ensure better consistency in their application, in conformity with WTO rules.

Improving multilateral relations. The EU is the largest exporter and second largest importer of food in the world with a well-recognised and respected framework of food safety legislation. In 2022, DG SANTE will promote and support relevant initiatives – e.g. the development and implementation of new food safety strategies – of the Food and Agriculture Organisation (FAO), the World Health Organisation (WHO) and other UN agencies, and will engage with them in the development of sustainable food systems. Following the 2021 UN Food Systems Summit, DG SANTE will be actively involved in the follow-up and relevant coalitions.

In the context of the **World Trade Organization** (WTO), DG SANTE will contribute to the preparation of meetings 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 continue to advocate the need for mainstreaming food sustainability aspects in all relevant WTO fora. 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 or on the new EU rules on plant health and veterinary medicines in the area of AMR. 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** (OIE), DG SANTE defends the EU's high animal health and welfare standards and works to influence and promote international

standards. In 2022, 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 antimicrobial resistance, sustainability, alcohol labelling, tackling food fraud, the recognition of equivalence of national food control systems and bringing sustainability aspects into the Codex work program.

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 towards the Conference of the Parties of the Convention on Biological Diversity (COP) and the meeting of the Parties of the Cartagena Protocol (COP-MOP), to be held in April-May 2022. 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.

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 2022, 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. The EU's external trade requires strong engagement with trade partners to ensure the relevant safety requirements are met to protect health and prevent trade disruption. Trade policy 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. SANTE will continue to cooperate with partners in a horizontal way, through trade agreements, the Partnership instruments and training programmes.

In this area, ensuring smooth trade relations with the UK whilst 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. To continue our international outreach, a specific programme on F2F financed under the Partnership Instruments, will be launched in 2022 over a period of 18 months, with six regional and four country to country events organised in Asia, Latin America and EU Southern Neighbourhood Countries.

DG SANTE will continue leading negotiations on **SPS and Sustainable Food Systems Chapters** in the Free Trade Agreement negotiations underway, or planned, e.g. Australia, New Zealand, Indonesia, Chile, Tunisia, Morocco, Eastern and South African countries (ESA).

Moreover, the DG will continue to pursue good **bilateral SPS relations** with key commercial partners. DG SANTE will notably manage and **implement existing agreements**, such as the EU-UK Trade and Cooperation Agreement, Eastern Partnership agreements, and agreements with Canada, Singapore, Vietnam, Japan, and Central American and Andean countries. 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 (e.g. Russia); conduct activities on **equivalence determination and related activities** (Japan, Australia, USA); 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**. It will contribute to the implementation of the Green Agenda for Western Balkans (in particular, actions aiming to establish sustainable food systems in the region); 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.

On the **neighbourhood policy**, the DG will implement the Association Agreements and Deep and Comprehensive FTAs, including support and monitoring of the legislation approximation process (Ukraine, Georgia, Moldova). 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 2022, 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 deal with public health crises and cross-border threats to health, including continued response to the current COVID-19 outbreak, through working with the Health Security Committee and a new legislative Health Security Framework for a longer-

term better preparedness. DG SANTE will also continue its work on the implementation of Europe's Beating Cancer Plan and the Pharmaceutical Strategy for Europe, and will launch the European Health Data Space.

DG SANTE will strengthen its approach to supporting the Member States in achieving the United Nation Sustainable Development Goals, namely the objective of reducing the burden of non-communicable diseases. The initiative "Healthier together – EU Non-Communicable Diseases", launched in December 2021, will help Member States and stakeholders address major causes of mortality and morbidity, such as cardiovascular diseases, diabetes, chronic respiratory diseases, mental health and neurological disorders, as well as health determinants. It will complement and be coordinated with Europe's Beating Cancer Plan.

While focusing on promotion and prevention, it will also support better knowledge and data, screening and early detection, diagnosis and treatment management, and quality of life of patients.

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

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.

International cooperation. DG SANTE will actively promote priority topics in **multilateral cooperation** spanning from pandemic preparedness and response, support to overcome the current pandemic, building back better from the pandemic, improving the global health security architecture and promoting antimicrobial resistance. We will closely cooperate with our international partners. Strengthening the role of the World Health Organisation, 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 World Health Organisation and the United Nations.

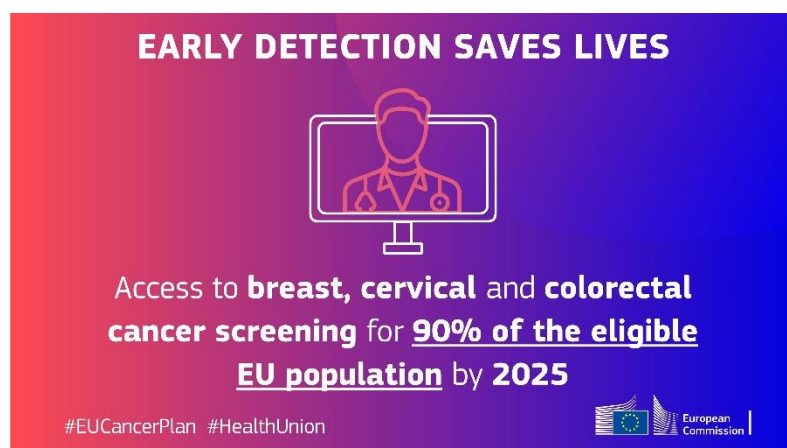
DG SANTE will also actively contribute to the discussions on ways to strengthen the role of the EU in global health in the context of the multipresidency initiative under the lead of the EU Presidencies of the Council, France and the Czech Republic.

DG SANTE will provide leadership at the Framework Convention on Tobacco Control, promote our pharmaceutical regulatory standards and cooperate with the Organisation for Economic Cooperation and Development (OECD). In addition, international cooperation is part of the implementation of specific policies, as presented below.

DG SANTE will also further strengthen its cooperation with the WHO European Region on important areas such as health security, antimicrobial resistance, cancer, mental health, sustainable food systems, health systems development, one health and support related to non-EU neighbouring countries.

In **bilateral cooperation**, DG SANTE will actively support the uptake of the EU health *acquis communautaire* in the Western Balkans. DG SANTE will increase cooperation on health matters of mutual interest with Turkey and Canada through the organisation of High Level Dialogues.

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** to support Member States to improve cancer prevention and care. In 2022, the Plan's implementation will be in full swing. Significant actions will be implemented through a number of EU4Health funded projects and Joint Actions by the Member States and with stakeholders, including the launch of an EU network on Youth Cancer Survivors. DG SANTE is co-leading the Horizon Europe Cancer Mission with DG RTD to ensure synergies with the Cancer Plan. In 2022, DG SANTE will put forward the **Commission proposal to update the Council Recommendation on cancer screening** 📄, which currently covers breast, colorectal



and cervical cancer. The proposal will ensure the Council Recommendation reflects the latest available scientific evidence, and will explore the extension of cancer screening to prostate, lung and gastric cancer, and other cancers if supported by scientific evidence. An EU-wide **media and influencer**

campaign targeting youth which underlines the importance of screening, will be launched in September 2022. Synergies will be established in the field of health promotion and disease prevention with the work on other non-communicable diseases and their determinants (such as tobacco, alcohol, nutrition and physical activity). The Commission will develop a Cancer Inequality Registry to help identify trends, disparities and inequalities between Member States and regions. An **event on World Cancer Day** will take stock of the Cancer Plan deliverables so far.

Tobacco control. DG SANTE has long engaged in efforts in the EU and globally to reduce tobacco consumption, which is the main risk factor in cancer. In 2022, DG SANTE will embark on a **review of the tobacco control legislation** – the Tobacco Products Directive and the Tobacco Advertising Directive – in line with the ambition of creating a ‘Tobacco-Free Generation’, where less than 5% of the population uses tobacco by 2040, as set out in Europe's Beating Cancer Plan. In parallel, as also indicated in the Cancer Plan, DG SANTE

will work on a **proposal for the revised Council Recommendation on smoke-free environments**. 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. In 2022, DG SANTE will prepare a report on substantial change of circumstances for heated tobacco products. If such change of circumstances is established, DG SANTE will follow, as foreseen under the Tobacco Products Directive, with preparing a draft delegated act, which will render these products less attractive.

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

Pharmaceutical Strategy for Europe. The strategy³ 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 actions under the EU Strategic approach⁴ to pharmaceuticals in the environment to reduce their environmental risk, address pollution from pharmaceutical residues and promote greener manufacturing, use and disposal.

In 2022, a major action of the Strategy will be the proposal for the **revision of the general pharmaceutical legal framework** 🏛️, which aims to improve access to 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. A communication campaign around the aspects of accessibility and availability of medicines will be launched.

In 2022, DG SANTE will also propose the revision of the EU legislation on **medicines for children and rare diseases** 🏛️ to

address a number of shortcomings in the functioning of the existing framework detected during an evaluation⁵. The proposed revision will aim at supporting the development of products in areas of high unmet needs for patients and also ensure their timely access and affordability. Furthermore, it will ensure that the legislation is fit to keep the pace with

³ [Commission Communication on a Pharmaceutical Strategy for Europe COM\(2020\) 761 final.](#)

⁴ <https://ec.europa.eu/environment/water/water-dangersub/pharmaceuticals.htm>.

⁵ https://ec.europa.eu/health/human-use/paediatric-medicines/evaluation_en.

technological and scientific development. Finally, it will streamline and simplify existing procedures.

Further key actions in 2022 by DG SANTE under the Pharmaceutical Strategy include:

- Availability: follow-up to the shortages study and to the structured dialogue on security of supply;
- Affordability: DG SANTE will continue to implement the Strategy's affordability agenda, together with the Council presidencies, in the group of Competent authorities on Pricing and Reimbursement and public healthcare payers;
- Pilot projects: Support to pilot projects regarding the repurposing of medicines and the market launch of newly authorised medicines in the EU.

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 2022, the DG will continue to authorise new medicinal products and modifications of already authorised products (on average, there are more than 1 200 implementing decisions per year).

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, possible regulatory actions and related communication). A joint action under EU4Health aimed at increasing availability of medicines, preventing shortages and ensuring security of supply, will support Member States for the next years.]

The **Clinical Trials Regulation** will become fully applicable in February 2022. DG SANTE will continue to monitor the implementation and application of the Regulation. Audits in this area will be formally launched in 2022, both in Member States and in third countries. DG SANTE will also continue to monitor the implementation of the **Falsified Medicines Directive**.

Review of the legislation organising the fees to be paid to the European Medicines Agency (EMA). In 2022, the Commission will propose to revise the current system of fees which finances, among other sources of revenue, the functioning of the European medicines agency and the network of national agencies involved in the authorisation of medicines across the EU.

International cooperation in the area of pharmaceuticals. DG SANTE will continue its bilateral relations with key strategic partners and its engagement in international regulatory convergence fora, such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), promoting high level global standards of quality and safety and encouraging non-EU countries to apply them, as well as in the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme).

DG SANTE will continue to monitor the **implementation of the mutual recognition agreement with the US** and will start work to extend the scope of the agreement to include veterinary medicines, vaccines and blood-based medicines.

In this area, ensuring smooth trade relations with the UK whilst preserving EU interests and implementing the Northern Ireland protocol is an additional challenge.

Health Technology Assessment (HTA). In 2022, the focus will be the effective implementation of the HTA legislation adopted in 2021. Main priorities will be to set up the Coordination Group and subgroups; and start preparing a number of essential implementing acts defining procedures for joint work, including rules for conflict of interest, involvement of stakeholders as well as cooperation with the European Medicine Agency; to set up the stakeholder forum and to start developing the IT tools set out in the Regulation. DG SANTE will ensure timely input for the production of scientific methodologies necessary for the implementation of the Regulation and continuity of EU cooperation on HTA until the Regulation becomes applicable in late 2024.

Medical Devices and in vitro diagnostic Medical Devices. DG SANTE's will continue to effectively implement the new legal framework on **Medical Devices** (MD) and **in vitro diagnostic Medical Devices** (IVD) in line with the Commissioner's mission letter. A special focus in 2022 will be to ensure a smooth entry into application in May 2022 of the In Vitro Diagnostic Medical Devices Regulation (IVDR). The Commission will support the adoption of the proposed amendment of IVDR by the Council and the European Parliament as early as possible in 2022. Specific communication actions will target media and stakeholders at the time of the entry into application. DG SANTE will ensure continued monitoring of the market, to avoid shortages and conduct regular surveys with manufacturers and notified bodies (MDs and IVDs). DG SANTE already plays a pivotal role in the joint assessment process of notified bodies and, in order to support sustainability of the system, DG SANTE will launch in 2022 a project to address the identified challenges related to the lack of notified body capacity (MDs and IVDs). DG SANTE will also launch the call for and finalise the evaluation of the **EU Reference Laboratories** to be designated under IVDR. DG SANTE will also make necessary efforts to secure a smooth transfer of the expert panels for clinical investigations to EMA.

DG SANTE will continue the development of the highly complex database **EUDAMED**. Focus will be to finalise the development of the remaining three modules necessary to respond to the requirements set out in the MDR.

A number of implementing acts are planned for adoption in 2022, in order to ensure effective implementation of MDR and IVDR, notably on common specification for products without medical purpose; common specifications for IVDs, rules for unique identifiers for highly individual devices and harmonised standards for medical devices.

DG SANTE will continue to chair and manage the **Medical Device Coordination Group** and its 13 Working Groups to agree on guidance documents necessary for proper implementation and to facilitate coordination and exchanges according to MDR, including in the area of vigilance and market surveillance.

DG SANTE will continue to engage in **international discussions** regarding medical devices, including multilateral discussions within the International Medical Device

Regulatory Forum (IMDRF), and bilaterally, notably with the US, Turkey and Australia and also continue to monitor the bilateral relations with Switzerland. In 2022 DG SANTE will start preparing for the Presidency of the IMDRF which the EU will hold in 2023.

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.

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. In the discussion on improving the global health security architecture the DG will in particular contribute to the discussions to strengthen the World Health Organization to enable it to fulfil its mandate and meet the expectations of the global community,

Along with targeted amendments to the International Health Regulations, initiatives to better implement the International Health Regulations and other necessary measures to improve core capacities to address health emergencies, negotiations on a new **international agreement on pandemic prevention, preparedness and response** will be essential to avoid future pandemics. Following the decision adopted at the special session of the World Health Assembly on 1 December 2021 to launch the process to develop an international agreement on pandemic prevention, preparedness and response, DG SANTE will lead the Commission's work on the new agreements.

Preparedness and Response. 2022 will see the further strengthening of the European Health Union and the EU's resilience to cross-border threats⁶. DG SANTE will implement the **Regulation on serious cross-border threats to health**⁷, expected to be adopted by the co-legislators in early 2022, 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. These tools are the main mechanisms used in the coordination of response to Covid-19, which will continue to be heavily relied upon in 2022. DG SANTE will continue organising the work of the EU Health Security Committee and the policy development around the Joint Procurement Agreement. Furthermore⁸, DG SANTE will

⁶ COM(2020) 724 final, https://ec.europa.eu/info/sites/info/files/communication-european-health-union-resilience_en.pdf.

⁷ COM(2020) 727 final, https://ec.europa.eu/info/sites/info/files/proposal-regulation-cross-border-threats-health_en.pdf.

⁸ As of 1 October 2021, future joint procurement procedures under the Joint Procurement Agreement for medical countermeasures are managed by HERA. Therefore, while DG SANTE will continue to be in charge of the Joint Procurement Agreement assessment and the management of existing framework contracts, HERA will launch future joint procurement

ensure the follow-up of the **strengthened mandates of the European Centre for Disease Prevention and Control**⁹ (ECDC) and the **European Medicines Agency**¹⁰ (EMA), also expected to be adopted by the co-legislators in early 2022. DG SANTE will work closely with these agencies and with the **EU Health Emergency Response Authority (HERA)**, to ensure complementarity of the work of the EMA, ECDC, and HERA. The Covid-19 response will likely continue to be the main public health priority in 2022.

Vaccination. Vaccination is one of the most powerful and cost-effective public health measures at our disposal. In 2022, DG SANTE will build upon the great success of the EU Strategy for COVID-19 vaccines¹¹, whereby 68 per cent of the total EU population was fully vaccinated by the end of 2021. In 2022, regulatory actions and policy-related activities to support the development, authorisation and close monitoring of COVID-19 vaccines and therapeutics will continue to be a priority for DG SANTE. DG SANTE will continue its work to support access to **COVID-19 vaccines**, and support Member States in ensuring successful deployment and sufficient uptake of such vaccines, in line with the Commission Communication on Preparedness for COVID-19 vaccination strategies and vaccine deployment¹².

DG SANTE will also continue the work to deliver on actions from the roadmap implementing the Commission Communication and Council Recommendation on strengthened cooperation against **vaccine-preventable diseases** including the joint EMA-ECDC vaccination monitoring platform to be fully operational, beyond COVID-19 vaccines and completion of the work of the Joint Action on vaccination. As part of EU4Health, an **EU Immunisation Initiative** is being set up, building on the Commission's efforts on vaccination so far and taking the experience from the COVID-19 pandemic into account.

The EU is the region in the world with the lowest **confidence in the safety and effectiveness of vaccines**. As highlighted in 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 that surround them, particularly important in the context of the COVID-19 vaccine uptake.

A vaccine misinformation counter-initiative will be launched under EU4Health, including new data on vaccine confidence, promotion of reliable information through the European

procedures and finalises ongoing procedures for Covid-19 therapeutics as well as for pandemic vaccines

⁹ COM(2020) 726 final, https://ec.europa.eu/info/sites/info/files/proposal-mandate-european-centre-disease-prevention-control_en.pdf.

¹⁰ COM(2020) 725 final, https://ec.europa.eu/info/sites/info/files/proposal-mandate-european-medicines-agency_en.pdf.

¹¹ [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.](#)

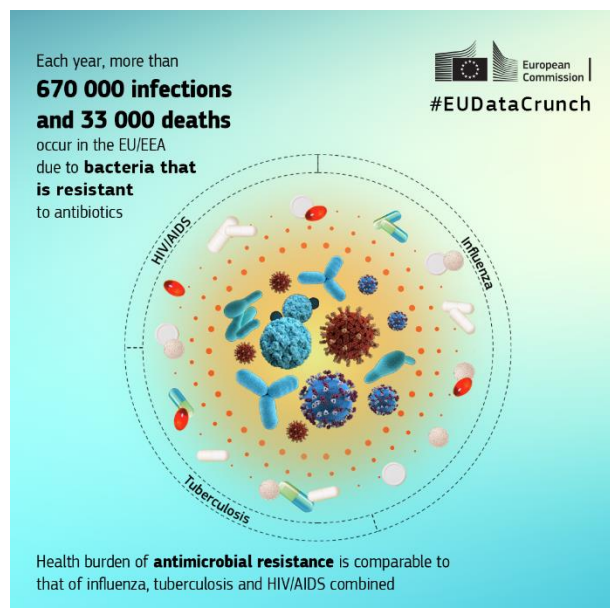
¹² [Communication from the Commission to the European Parliament and the Council: Preparedness for COVID-19 vaccination strategies and vaccine deployment, COM\(2020\) 680 final.](#)

Vaccination Information Portal and resources to educate teenagers and teachers of the importance of childhood, routine and catch-up vaccination.

Together with the European Centre for Disease Prevention and Control and the European Medicines Agency, DG SANTE will contribute to fulfil the urgent need for post-marketing authorisation studies assessing the safety and the effectiveness of **COVID-19 vaccines**.

DG SANTE will also promote the **“One Health”** approach within multilateral fora at the UN, WHO, OIE, FAO, Codex, G7 and G20 level, in the areas of antimicrobial resistance and for the prevention of future pandemics, and continuing its work at the Transatlantic Taskforce on Antimicrobial Resistance – TATFAR. A number of One Health audits are planned on rabies and avian influenza controls and on AMR systems, and in our analysis of Member States’ contingency plans the DG will explore the communication between human and animal health authorities.

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 and will take forward work with our international partners to advocate for its inclusion in the Pandemic Agreement. In 2022, DG SANTE will pursue the implementation of the 2017 AMR action plan and publish biannual progress reports. DG SANTE will manage and revamp the AMR One Health Network with Member States, in order to formalise the Network, and extend participation to stakeholders. DG SANTE will adopt in 2022 a **new proposal for Council Recommendation**, which will strengthen ongoing activities of the EU One Health AMR Action Plan and add a number of new impactful activities in order to reach concrete outcomes in reducing the spread of AMR. It will be based on a review by DG SANTE of 2017 EU AMR Action Plan, and national Action Plans. DG SANTE will further harness new instruments brought along as a result by COVID-19 to boost the efforts to combat AMR, such as under the strengthened health security framework and the mandates of ECDC and EMA, in cooperation with HERA, including opportunities under the EU4Health programme, notably a new **Joint Action on AMR**. Communication actions will support the above-mentioned initiatives, for instance during the European Antibiotics Awareness Day. Finally, supporting the objectives of the AMR policy from the medicines perspective is one of the flagship actions under the Pharmaceutical Strategy for Europe and is considered in the ongoing review of the pharmaceutical legislation.



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 2022. 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 in the wake of the COVID-19 crisis.

Digital health. In 2022, DG SANTE will put forward a legislative proposal on the **European Health Data Space**, accompanied by a Commission Communication, to 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 (secondary use of health data), while preserving trust and security. Preparatory work will start on the implementation concerning standardisation on interoperability, data quality and Artificial Intelligence.

A campaign using a broadcaster such as Euronews will be used to target the industry, healthcare providers and researchers.



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**, but also of images, laboratory results, discharge reports and patients' access

to their health data in the language of the country of destination. It will also continue the work on preparing for standardisation of Electronic Health Record Exchange Format (in collaboration with DG CNECT) and for tele-health and m-health.

On secondary use of data, DG SANTE will continue the work on a framework for a governance for access to data, data quality and AI, as well as the technical infrastructure, including through a **pilot project for infrastructure for the secondary use of health data**. DG SANTE will also support and coordinate the work of the Joint Action towards the European Health Data Space (TEHDaS).

DG SANTE will support the functioning of the **eHealth Network**; including on COVID-19 related actions, in particular the **interoperability of contact tracing and warning apps** and the **EU Digital Covid-19 Certificate** (EU DCC), in close collaboration with DG JUST and DG CNECT.

Health systems. DG SANTE will continue to generate country-specific and cross-country knowledge on health systems, in particular through the launch of the 4th cycle of the **State**

of the Health in EU with OECD and the Observatory on health systems with a focus on digitalising its content, and continuing to produce the reputable Health at Glance in the EU and Country Health Profiles publications. A joint action on health workforce planning and forecasting and a project on developing a methodology for resilience testing in health systems will be launched under EU4Health.

Work is also ongoing to support the implementation of best practices to tackle the pandemic's **mental health** impact.

DG SANTE will contribute to the revamped **European Semester process** by providing detailed country-specific analyses on health systems

In 2022, DG SANTE will continue to work with the **Steering Group on Promotion and Prevention** (SGPP) in the identification and scaling-up of best practices on health promotion and disease prevention. DG SANTE will revise the SGPP mandate to improve its effectiveness and include communicable disease interventions for instance on antimicrobial resistance, HIV and vaccination, in close cooperation with and to complement the work of the Health Security Committee.

DG SANTE will continue to host two **Scientific Committees**, on consumer safety (SCCS) and on health, environmental and emerging risks (SCHEER). A priority SCHEER opinion on Potential health effects of exposure to electromagnetic fields is planned to be published in 2022¹³. This opinion will review the latest scientific evidence available with regard to radio frequency 100 kHz to 300 GHz, which could trigger a proposal for an amendment to the Annexes of Council Recommendation of 12 July 1999 on the limitation of exposure of the general public to electromagnetic fields (0 Hz to 300 GHz), bringing the Council Recommendation in line with the latest available scientific knowledge.

Substances of human origin (SoHO). Following the evaluation of the EU legislation on the safety and quality of **blood, tissues and cells (Directive 2002/98/EC and Directive 2004/23/EC)**, DG SANTE will propose a revision of the legislation in 2022. 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' right 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 **Directive 2011/24/EU on Cross-border Healthcare** (CBHC), which sets out the legislative provisions in this regard. In 2022, DG SANTE will conclude the **Evaluation of the CBHC Directive**.

¹³ [scheer_q_023.pdf \(europa.eu\)](#).

European Reference Networks (ERN) for **rare and low prevalence complex diseases** bring together more than 900 highly specialised healthcare providers to improve the diagnosis and treatment for rare diseases patients in Europe. DG SANTE, working with HaDEA, will launch new grants under EU4Health for coordination activities and operation of all ERNs.

PART 2. Modernising the administration: main outputs for 2022

The internal control framework¹⁴ supports sound management and decision-making. It notably ensures that risks to the achievement of objectives are taken into account and reduced to acceptable levels through cost-effective controls.

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

A. Human resource management

DG SANTE will need to recover from the unprecedented impact of the COVID-19 pandemic on its work programme and workload. Many new policy initiatives, which were initiated in 2021 to follow up on the lessons learned from the COVID-19 pandemic, will need to be taken forward and implemented. Moreover, the important budgetary increase for health expenditure, and the creation of the new Health and Digital Executive Agency (HaDEA) for which SANTE is the lead parent DG, will need to be integrated into the DG's working structures. Also the coming into force of the European Health Emergency Preparedness and Response Authority (HERA) requires a redistribution of tasks within DG SANTE.

The DG HR staff survey results, which are expected in spring 2022, will be carefully examined. In the light of the new Commission HR strategy, DG SANTE will develop its local HR strategy focussing on HR domains where specific action at DG SANTE level is required. DG SANTE will continue following and implementing corporate HR policies, including actions related to equality, diversity and inclusion.

In the context of the revised working time and teleworking arrangements, special attention will continue to be given to the gradual return to the office of staff. The organisation of induction days for newcomers will be resumed and the organisation of Directorate and Unit events will be encouraged and promoted.

As regards the recruitment of female managers, DG SANTE has reached the 50% target. In order to keep the pace and ensure a sufficient instream of female managers, DG SANTE will continue its efforts to accompany interested female colleagues towards becoming middle managers. For example, DG SANTE will continue to make use of appointments to junior management positions in order to allow potential future managers to put into practice their learnings from management trainings.

¹⁴ [Communication C\(2017\)2373 - Revision of the Internal Control Framework](#).

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 2022:

Output	Indicator	Target
Recruitment of new female middle managers	Number of appointments validated	2 appointments validated by end 2022
Back to the office events at DIR and Unit level	All actions implemented	31/12/2022
DG SANTE staff engagement index	DG SANTE staff engagement index as communicated by DG HR	Above Commission average
DG SANTE Local HR Strategy 2022-2025	Validation by the DG of the HR strategy	01/07/2022

B. Sound financial management

DG SANTE uses the organisational structure and the internal control systems suited to achieving its policy and internal control objectives in accordance with the internal control principles set by the Commission¹⁵. 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 two 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 internal control strategy, in its latest version of December 2017, is an evolving document and will be updated in 2022 to reflect the organisational and procedural changes that have been implemented in 2020 and 2021 further to the COVID-19 pandemic and the decisions taken in the context of the Multi-annual Financial Framework 2021 to 2027. Of particular importance will be the supervision of budget implementation tasks transferred to the Health and Digital Executive Agency (HaDEA), and the taking up of the shared resources management for the Health Emergency Preparedness and Response Authority (HERA). DG SANTE's administrative priority in 2022 will be establishing Memoranda of Understanding with HaDEA and HERA with the aim to manage resources in accordance with the principles of sound financial management. 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

¹⁵ Commission Communication (2017) 2373 on the revision of the Internal Control Framework.

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 2022, DG SANTE will again 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 2022:

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
	Time-to-pay	Remains >95% of payments (in value) 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	30/09/2022

C. Fraud risk management

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

In 2022, DG SANTE will organise an increased number of awareness raising activities, a re-launch of DG SANTE's inter-agencies' task force, broader fraud detection capabilities in

budget implementation, stronger cooperation with OLAF and a high implementation rate of measures foreseen in the anti-fraud action plan for 2022. These 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.

Some actions are already well embedded in existing procedures. The internal control officer monitors the implementation of the anti-fraud action plan and reports the results to DG SANTE management twice a year, i.e. in February and again in 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) ¹⁶ aimed at the prevention, detection and correction¹⁷ of fraud.

Main outputs in 2022:

Output	Indicator	Target
Training and awareness raising in DG SANTE and through promoting ethics training	Annual implementation rate of awareness activities	>90%
Actions linked to handling "conflict of interest" in agencies, scientific committees and expert groups	Annual meeting of the SANTE inter-agencies task force on independence	1 meeting per year, usually in September, 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 2022
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 2022	% implementation of actions planned for 2022 as per the anti-fraud strategy	At least 90%

D. Digital transformation and information management

Following 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 solutions portfolio. At the same time, the DG will change our approach to delivering and procuring IT solutions and services in order to be more reactive, agile and

¹⁶ 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'.

¹⁷ Correction of fraud is an umbrella term, which notably refers to the recovery of amounts unduly spent and to administrative sanctions.

business oriented. This approach aligns with the new corporate 'dual-pillar' approach whereby there is a push away from traditional in-house adapting and building of software to respond to existing business processes and a move towards aligning our business processes to proven market solutions using off-the-shelf solutions or existing reusable solutions, enriched with low code and cloud based tools.

Details of the digital transformation and information management in DG SANTE are defined in DG SANTE's IT Master Plan. It is an important instrument to oversee the annual digital and data investments in DG SANTE, including an alignment with the digital strategy and corporate governance on IT and Data. The IT 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 adopted the 2022 IT Master Plan on 13 December 2021 and in 2022 will receive reports on its implementation on a regular basis.

Pilot projects on the European Health Data Space will aim to provide a test bed to demonstrate the potential for a cross-country infrastructure enabling the secondary use of health data with all of the challenges that come with securing, accessing and protecting citizen data.

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 also aims to follow a number of the work streams organised by DG DIGIT relating to help modernise the way the DG works including:

- Data cluster;
- Stakeholder management cluster (to facilitate efficient management and follow-up of stakeholders across various business settings, e.g. managing experts);
- Secure exchange cluster (reuse of corporate building blocks like EU Send and EU Sign).

The COVID-19 pandemic was a catalyst for digital transformation across the Commission. In 2022, DG SANTE will aim to use the new sets of collaborative tools made available under the corporate roll-out of Microsoft Teams and its associated set of tools. In particular DG SANTE will take advantage of the new set of 'low code' options made available through the use of tools such as 'Microsoft Power BI' which will help empower staff to discover their own insights from data in much the same way that they use now Excel to create tables and charts. To complement this initiative, DG SANTE will extend its support and consultancy for using these new tool sets to help policy and business units to make data driven decisions. Further pilot projects will also be launched by identifying policy initiatives and emerging needs where large raw data sets could help influence decisions and policy making (for example, Animal Welfare Platform or other Farm to Fork related solutions).

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 eUI¹⁸ corporate building block to ensure longevity of the solution and reduce the related supporting maintenance costs.

Data protection

In 2022, 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 principle of 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, including promoting and monitoring such implementation in document management.

In 2022, the data strategy will be defined, taking also into account needs for the interim data catalogue, publication of data and possible integrations of IT systems with Hermes-Ares-NonCom (HAN) via Hermes-Repository-Services (HRS).

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 2022:

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 ¹⁹	50%
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%
The interim corporate data catalogue reflects the current key data assets of DG SANTE, improving transparency, sharing and reuse of Data across the EC.	Percentage of SANTE key data assets reviewed and included in the interim solution	100%

¹⁸ User Interface.

¹⁹ Follow-up indicator from SANTE's multi-annual strategic plan 2020-2024.

Output	Indicator	Target
Setting up and implementing a digital and data strategy board to review and endorse actions	Annual IT MP replaced by an all-encompassing digital and data annual plan to address both individual and horizontal needs	<ul style="list-style-type: none"> - Board to meet twice per year - Annual plan due Q4 2022
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	<ul style="list-style-type: none"> - 100% newcomers; - 20% of all staff
Increase in the number of data sets made available by the open data portal	Number of public solutions published via open data portal	- 15
More accessible IT solutions	Number of solutions migrated to e-UI and accessibility tests	- 5
Increase in awareness of staff on data protection compliance ²⁰	Percentage of staff attending awareness raising activities	<ul style="list-style-type: none"> - 100% newcomers; - 20% of all staff

E. Sound environmental management

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 itself manages the day-to-day running of the site, are fully integrated into EMAS (Commission's Eco-Management and Audit scheme).

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

In 2022, the priority will be to appoint ECORs (EMAS correspondents) for Brussels and Luxembourg to facilitate communication and awareness raising about actions aimed at reducing our environmental footprint. An EMAS site coordinator is already in place in Grange.

Also in 2022, 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 ensure that the Commission targets set for 2022 will be achieved, with reduced consumption of both utilities and resources, and reduced emissions and waste.

Green public procurement will continue to be a cornerstone of the DG's procurement activities. In addition, with the benefit of infrastructure put in place during the COVID-19 pandemic, efforts will be made to reduce the number of mission days per person for the DG as a whole.

²⁰ Follow-up indicator from SANTE's multi-annual strategic plan 2020-2024.

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 2022:

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 ²¹ where appropriate.	Number of staff awareness actions	3 actions
	% of staff informed/participated	85%
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 ²² 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	3 actions
	% 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 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 2022)

²¹ See OIB – Environmental Building Performances for Brussels and OIL- Environmental Building Profiles for Luxembourg.

²² 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 ²³ 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 in 2021 with 9 additional rooms in Brussels and 5 in Grange. With the 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) ²⁴), 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 (% means of transportation used)	Reduce DG's CO ₂ emissions from missions ²⁵ (%)
	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

²³ VC (Videoconferencing) room.

²⁴ data provided by HR.D.02.

²⁵ 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	3 new contracts in 2022
	Number of GPP-relevant contracts with green criteria	3 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

F. 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 SMP

In view of the Single Market Programme (SMP 2021-2027), a full revision of the financing system for EU support to Member States in the framework of veterinary programmes and emergency measures was launched in 2020 with the JRC. The revision will continue throughout 2022 and be based – inter alia – on the methodology developed by the JRC and in close co-operation with HaDEA who implements the animal disease eradication programmes. The use of unit-costs and lump-sums is at the heart of the revision aiming 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) In January 2020, DG SANTE centralised its financial planning and monitoring tasks, i.e. the coordination of the adoption of the annual work programmes/financing decisions for the operational budget. DG SANTE is involved in discussions and workshops for the development of a common corporate initiative to address the problems of programming, planning and forecasting. The “EC Multi-annual Programming and Planning solution”, developed by DGs DIGIT and BUDG, is expected to provide:

- A ‘Financial Forecasting’ solution for the high level forecasts that are required for central financial management;

- A 'Multi-annual Programming & Planning' for programme planning and implementation. Further to additional workshops and tests and the establishment of the Programme charter and Governance in 2021, the 2022 work plan and roll-out roadmap will be implemented in 2022.