



Annual Activity Report

2020

DG Health and Food Safety (SANTE)

FOREWORD



The COVID-19 pandemic is unfortunately still with us. Together, we are working very hard on many fronts to tackle the challenges it continues to pose.

With that in mind, I cannot think of a better way to present the Annual Activity Report for 2020 than by paying tribute to the staff of DG Health and Food Safety (DG SANTE), whose dedication and professionalism have enabled the Commission to play such a substantial and effective role in fighting the virus since the very beginning of the pandemic.

The work of each and every staff member at DG SANTE has been instrumental in securing a coordinated response to the crisis across the Member States; in authorising and procuring the vaccines against COVID-19 and delivering other essential medical countermeasures; and in offering a joint set of tools to support Member States in deploying public health measures. All this was possible by ensuring efficient and effective coordination throughout the process with all relevant EU institutions.

In this endeavour, we have all had to cope with an unprecedented level of change for us all. We have had to deploy new resources, adopt new working arrangements, design and establish new processes, and keep refocusing the DG's efforts, as together we set about countering the pandemic's impact on people's health, lives and livelihoods in the European Union and beyond.

I would also like to emphasise how, while playing a central role in managing the health crisis, DG SANTE has also delivered on other priorities of the Von der Leyen Commission. The Pharmaceutical Strategy, Europe's Beating Cancer Plan, the EU4Health Programme and the Farm to Fork Strategy are key achievements in their own right and hugely important to the European Green Deal and promoting the European way of life.

Everyone at DG SANTE should be proud of the results achieved in 2020. Now we must look to the future. With the same dedication and professionalism, we can help the European Union emerge from the COVID-19 pandemic healthier, stronger and more united than ever.

Sandra GALLINA, Director-General of DG SANTE

Table of Contents

- THE DG IN BRIEF 4**
- EXECUTIVE SUMMARY..... 6**
 - A. Key results and progress towards the achievement of the Commission's general objectives and DG's specific objectives (executive summary of section 1). 6
 - B. Key Performance Indicators (KPIs)13
 - C. Key conclusions on Financial management and Internal control (executive summary of section 2.1)..... 14
 - D. Provision of information to the Commissioner(s) 14
 - E. Specific actions on COVID-1915
- 1. Key results and progress towards the achievement of the Commission's general objectives and DG's specific objectives 16**
- 2. Modern and efficient administration and internal control 45**
 - 2.1 Financial management and internal control45
 - 2.1.1 Control results.....45
 - 2.1.2 Audit observations and recommendations 57
 - 2.1.3 Assessment of the effectiveness of internal control systems..... 59
 - 2.1.4 Conclusions on the assurance61
 - 2.1.5 Declaration of Assurance.....61
- Declaration of Assurance 63**
 - 2.2 Modern and efficient administration – other aspects64
 - 2.2.1 Human resource management.....64
 - 2.2.2 Digital transformation and information management.....64
 - 2.2.3 Sound environmental management.....65

THE DG IN BRIEF

DG SANTE strives to protect **human, animal and plant health and animal welfare** and to promote a high level of **safety and sustainability along the food supply chain**.

Our mission supports the Commission's priorities for public health and food safety and sustainability as well as growth and competitiveness in two of the EU's most important economic sectors – health and food. Our activities are shaped by the Treaty on the Functioning of the European Union (TFEU) and principally linked to Articles 168 (public health), 43 (agricultural policy), 114 (internal market), and 13 (animal welfare).

DG SANTE contributes to two of the general objectives set out in President von der Leyen's Political Guidelines – **A European Green Deal** and **Promoting Our European Way of Life**. Health and safety are of paramount importance.

DG SANTE plays a leading role in managing **cross border threats to health** at EU level, including the COVID-19 pandemic, by coordinating and supporting action to prepare for and respond to such threats.

We also manage the EU health legislation, which includes – among others – the rules governing the authorisation of pharmaceutical products and medical devices, those applicable to tobacco control, to cross-border movements of patients, and those that allow cooperation and integrated work among Member States on e-health and rare diseases. Our activities in this area are both regulatory and non-regulatory, and supported by dedicated funds (the "Health Programme").

DG SANTE leads the Commission's action directed at ensuring the safety of the food supply chain and its transition towards a sustainable food system. In this area the EU is responsible for designing, implementing and enforcing a single, common regulatory framework, which aims to ensure food safety and to respond to threats to human, animal and plant health along the food supply chain. EU funds are provided to co-finance measures directed at preventing and countering animal and plant diseases, to increase food and feed safety, and to strengthen controls carried out by the Member States to ensure compliance with food chain requirements.

DG SANTE operates under the political leadership of the Commissioner for Health and Food Safety on the basis of multi-annual policies and financial frameworks. The 3rd Health Programme 2014-2020 provides funding for health policy and Regulation (EU) No. 652/2014 provides the financial framework for food safety, animal and plant health. Since April 2020, the Emergency Support Instrument (ESI) has financed measures such as vaccine advance purchase agreements, and procurement of medical equipment and therapeutics to support and complement Member States' efforts.

Until the end of 2020, DG SANTE worked closely with the **Executive Agency for Consumers, Health, Agriculture and Food (CHAFEA)**¹, which implements the **EU Health Programme** and the **Better Training for Safer Food initiative**. DG SANTE is a partner DG to the following EU decentralised agencies: the European Medicines Agency (EMA), the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC), the Community Plant Variety Office (CPVO) and the European Chemicals Agency (ECHA).

DG SANTE plans and reviews its main priorities and objectives annually, building its annual Management Plan around the resources available and any identified risks that may impact on its objectives. Bilateral meetings between the Director-General, individual Directorate and Unit managers, as well as weekly management meetings involving the Director-General and the Management Board are important monitoring activities.

On 1 September 2020, a new organisation chart entered into force to adapt the DG to the priorities of the von der Leyen Commission. In the second half of 2020, the Commission appointed a new Director-General, two new Deputy Directors-General and two new Directors. At the end of December 2020, DG SANTE had 770 staff (in 2019: 772).

DG SANTE pursues its policies with a focus on prudent management and protection of the EU's financial resources. The Director-General is the authorising officer by delegation and has sub-delegated budget implementation responsibilities to Directors and Heads of Unit. DG SANTE's budget in 2020 was dominated by the Emergency Support Instrument to fight the COVID-19 pandemic: commitments of EUR 3 277 million and payment credits of EUR 2 993 million, were almost seven times higher than in previous years. About 93% of the 2020 budget was implemented under direct management, mainly through grants and procurement while 7% was implemented through indirect management, mainly subsidy payments to EU decentralised agencies for their running costs.

Risk management helps establish and maintain specific internal control strategies focussing on the activities and domains representing the highest risks. As in previous years, DG SANTE's centralised on-the-spot controls played a prominent role in the financial control environment, verifying – where applicable – the eligibility of costs claimed at beneficiary level in Member States.

In 2020, DG SANTE's average residual error rate amounted to 0,8% leading to an estimated risk at closure of 1,6% and thus, did not exceed the materiality threshold of 2%. Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance.

¹ As of 2021, CHAFEA has been replaced by the European Health and Digital Executive Agency (HaDEA).

EXECUTIVE SUMMARY

This Annual Activity Report is a management report of the Director-General of DG SANTE to the College of Commissioners. Annual Activity Reports are the main instrument of management accountability within the Commission and constitute the basis on which the College takes political responsibility for the decisions it takes as well as for the coordinating, executive and management functions it exercises, as laid down in the Treaties².

A. Key results and progress towards the achievement of the Commission's general objectives and DG's specific objectives (executive summary of section 1)

DG SANTE has a key role to play in achieving two of the six priorities of the von der Leyen Commission. DG SANTE's role in promoting the good health of EU citizens saw it take centre-stage in coordinating **Europe's response to the COVID-19 pandemic**, while as the lead DG for the **Farm to Fork Strategy** for sustainable food, its work is central to the delivery of the European Green Deal. 2020 thus saw DG SANTE acting simultaneously on multiple fronts both to confront the immediate crisis, and to prepare the ground for the sustainable recovery that must follow.

1. Promoting our European Way of Life

In 2020, Europe was significantly impacted by the COVID-19 pandemic. The Commission deployed a strong and coordinated response to the health crisis, as well as to alleviate the impact on Europe's economy and society. **DG SANTE played the central role in coordinating and leading the EU's frontline response to this public health crisis**. Communication has been a fundamental element throughout the pandemic, including proactive actions aimed at promoting EU initiatives, as well as strong media relations and attempts to address misinformation during the "infodemic". The Coronavirus response website received more than 10 million visits. SANTE was also fully engaged in the development of the Commission's strategic communication plan on vaccines and vaccination.

The COVID-19 crisis required a significant reprioritisation and repurposing of SANTE's action in the area of public health from the beginning of 2020, so as to allow sustained efforts to manage the crisis and strengthen the Union's capacity to address both present and future threats to citizens' health.

A major deliverable of 2020 was the adoption of the **Pharmaceutical Strategy for Europe** (see further below), to address, amongst others, shortcomings along the pharmaceuticals supply chain which have been brought into focus by the ongoing crisis.

DG SANTE continued to deliver on its regulatory work in the area of public health. **93 new medicines** for human use were approved, over half of which (48) include a new

² Article 17(1) of the Treaty on European Union

active substance, work continued on the pending legislative initiative on health technology assessment (HTA), on the implementation and review of the health acquis and, importantly, on fostering integrated work with and among the Member States and supporting Member States' efforts to strengthen their national health systems.

Management of the COVID-19 crisis

SANTE played a central role in coordinating and leading the Union's and Member States' response to the COVID-19 crisis, in particular through sustained coordination with Member States (notably within the Health Security Committee, and the Council's Integrated Political Crisis Response (IPCR) mechanism) and the adoption of recommendations and guidance on public health measures, on testing, immunisation, and tracing apps. Significant measures included the Communication on Short-term EU health preparedness for COVID-19 outbreaks adopted on 15 July, the Commission Recommendation (EU) 2020/1595 of 28 October 2020 on COVID-19 testing strategies, including the use of rapid antigen tests, and the Communication of 2 December on Staying safe from COVID-19 during winter. Resources were redeployed across the DG, and some local support provided from other DGs, to reinforce the SANTE teams working on the COVID-19 response.

DG SANTE worked throughout in close cooperation with the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), and with its global partners, thus playing a key role in ensuring a response at Union level that is well coordinated with action taken by other institutions, at both European and global levels.

Medical products for COVID-19.



In 2020 much of DG SANTE's work in the pharmaceuticals domain was focused on **preventing shortages of medicines and medical devices during the crisis** due to problems in those products' supply chains. To ensure that regulatory requirements did not become a bottleneck and

hamper progress towards the development and authorisation of vaccines and medicines needed to address the pandemic, existing regulatory flexibilities were fully exploited, while not compromising the high standards of quality, safety and efficacy citizens expect. Thanks to this approach, in July 2020 the Commission was able to authorise the **first treatment for COVID-19**, Veklury (remdesivir). Then on 21 December Comirnaty, the **first vaccine against COVID-19**, was authorised.

The Vaccines Strategy adopted in June 2020 played a key role in securing access to vaccines for EU Member States via **Advance Purchase Agreements (APAs)**. DG

SANTE led the negotiations of these agreements, enabling the Commission to sign contracts with six companies giving access to 2.6 billion doses (as of March 2021)³. These very intense negotiations succeeded in securing the availability of a large portfolio of vaccine candidates, thus enabling Member States to start the rollout of the vaccination campaign across the EU before the end of 2020.

Once vaccines had been secured, it was crucial that Member States were ready at all levels for the roll-out. The Commission, led by DG SANTE and in cooperation with ECDC, has worked intensely with the Member States to make sure that sufficiently resourced vaccination services, logistics and (cold-chain) infrastructure were in place and that priority groups for vaccination had been defined. DG SANTE has also been leading on the launch of a large number of **joint procurement** procedures and **direct procurements via the Emergency Support Instrument**, including a procedure for the purchase of equipment specifically needed for COVID-19 vaccination.

COVID-19 and blood and organ donation

DG SANTE, in close collaboration with ECDC, has provided continuous expert guidance to the **Substances of Human Origin** sector to keep transplant and transfusion therapies safe from COVID, to avert a risk of shortages for plasma imported from the US to manufacture medicinal products, and to adapt the authorisation procedure for novel therapies, in particular to facilitate the use of plasma collected from recovered COVID patients as a treatment for COVID patients still in critical condition. DG SANTE was particularly active in formulating **guidance on collection and transfusion of recovered plasma**, and also provided EUR 35m in financial support from the Emergency Support Instrument to invest in plasma collection capacity.

European Health Union

The COVID-19 pandemic tested the EU's health systems as never before. Looking to the longer term, and based on lessons learned from COVID-19, on 11 November 2020,



the Commission put forward a set of proposals for building a **European Health Union** to strengthen the EU's health security framework, and to reinforce the crisis preparedness and response role of key EU agencies (ECDC and EMA). In addition to this and as a follow-up to the President's State of the Union

speech of 2020, DG SANTE also put forward the creation of a novel **European health emergency preparedness and response authority**.

³ This figure includes doses purchased under additional contracts finalised with the same companies in early 2021.

Engagement at global level

DG SANTE helped establish the **Access to COVID-19 Tools Accelerator (ACT-A)**, a global collaborative framework designed to accelerate progress in the development of vaccines, therapeutics and diagnostics with universal access. The European Union and its Member States, acting together as Team Europe, provided EUR 853 million of financial contribution to the COVAX Facility to purchase vaccines for 92 Low and Middle-Lower income countries.

DG SANTE was fully involved in the work of the **World Health Organization (WHO)** and coordinated its response to the COVID-19 pandemic with WHO. DG SANTE led the EU's close cooperation with the **Western Balkans and European Neighbourhood** policy countries to assist them in responding to the COVID-19 crisis.

Pharmaceutical Strategy for Europe and the review of the legislative framework

In 2020, DG SANTE developed a flagship Commission deliverable, a **Pharmaceutical Strategy for Europe**. This policy initiative includes 55 actions with ambitious deadlines, covering the whole lifecycle and value chain of medicines. It will ensure that we continue to deliver high quality, safe medicines and that the benefits of innovation reach patients equitably across the EU. It will guarantee that the EU remains an attractive place to invest, research and develop medicines, especially for areas of unmet medical needs.

One of the deliverables announced in the Strategy is the review of the regulatory framework that governs medicinal products in the EU; work started in 2020 to prepare the **evaluation of the rules applicable to medicinal products**, and an impact assessment that will consider options to address the shortcomings and strategic issues highlighted in the Strategy. The joint evaluation of the Regulations on **medicines for rare diseases and for children** was published in summer 2020, highlighting a number of issues to be addressed which are closely related to the areas of work outlined in the Pharmaceutical Strategy. An impact assessment process for the revision of the two regulations was launched in November 2020.

An impact assessment and revision process was also initiated in 2020 for EU legislation on **substances of human origin**, building on the evaluation published in 2019.

A new funding programme – EU4Health

2020 saw the launch in May of a Commission proposal for the most ambitious ever health funding programme, **EU4Health**. A provisional agreement on the programme, with a budget of EUR 5.1 billion, was reached by the European Parliament and the Council on 14 December 2020. The goal of the programme is to improve human health throughout the Union and ensure a high level of human health protection in all Union policies and activities. By funding Union added-value actions that complement the policies of the Member States, EU4Health will strengthen health systems' preparedness for, and responsiveness to, health crises, and improve their

resilience. Before the end of 2020, DG SANTE had initiated the preparation of strategic guidance as well as the first EU4Health work programme of direct health funding.

Diminishing the impact of cancer

DG SANTE continued work on **Europe's Beating Cancer Plan**, allowing its adoption in February 2021. The action plan addresses cancer in a modern and holistic way through its four pillars: (1) prevention; (2) early detection; (3) diagnosis and treatment; and (4) quality of life of cancer patients and survivors, all supported by research, innovation and digital technologies. After the launch of consultations on EU Cancer Day on 4 February 2020, intense and fruitful consultation activities took place, both with other Commission departments and with institutional actors and civil society, to ensure that the forthcoming initiative will mobilise the efforts of all relevant actors towards the objective of reducing the impact of cancer on people's health and on the economy. Appropriate linkages were established with all eligible EU funding mechanisms, including the EU4Health programme, and with the proposed mission on cancer in the future Horizon Europe programme. Several actions to improve cancer treatments are also foreseen in the Pharmaceutical Strategy, including the planned revision of the legislation on medicines for rare diseases and children which will investigate options to improve the availability of medicines for treating rare cancers in children.

DG SANTE also continued its global efforts to reduce tobacco consumption, which is the main risk factor in cancer.

More effective, accessible and resilient health systems

In November 2020, DG SANTE kicked off the third cycle of the ***State of Health in the EU*** project with the publication of the joint Commission-OECD publication *Health at a Glance: Europe 2020*. Among its main messages, the report highlights policy responses around Europe that have helped minimise the costs of the COVID-19 pandemic.

E-health

DG SANTE has a long-term commitment to maximise the potential of **e-health** to provide high quality healthcare and reduce inequalities in healthcare. A significant step towards the creation of a **European Health Data Space (EHDS)** was taken in February with the adoption of a European Strategy for Data, in which the Commission announced a series of legislative and non-legislative measures it will adopt. To this end, work also progressed in DG SANTE with the evaluation of the existing legislation governing e-health cooperation among Member States, and the publication of an inception impact assessment that outlines the main options for the establishment of the EHDS.

2. A European Green Deal

Sustainable food systems – the ‘Farm to Fork’ strategy

The adoption of the Commission’s **Farm to Fork Strategy** for a fair, healthy and environmentally friendly food-system, on 20 May 2020, has been a major achievement of DG SANTE, paving the way for its policies during this mandate. It is integral to the European Green Deal, as well as to the EU’s determination to achieve a greener and more resilient

Europe as we build back after the COVID-19 crisis. DG SANTE commenced work immediately on the most innovative initiative of the strategy – the creation of a **legislative framework on sustainable food systems and sustainable labelling** – as well as on the other initiatives that will contribute to the objectives of the strategy.



Actions for which preparatory work started or advanced in 2020 include the revision of the rules on sustainable use of **pesticides**, on **feed additives**, on **food labelling** (nutritional information, indication of origin, date marking), and on **food contact materials**. Following a successful media launch of the Farm to Fork Strategy in May and hundreds of articles in European media, the October Conference provided an excellent backdrop for widespread communication, with a 48 million potential daily reach. The Farm to Fork video has been viewed 120,000 times.

In 2020, DG SANTE advanced work on the two studies requested by the Council on **plant reproductive materials** and on **new genomic techniques**; the studies will enable informed consideration by the Commission on possible future initiatives in these areas to pursue the objectives of the Strategy.

An important aspect of the sustainability of EU food systems is animal welfare. DG SANTE finalised in 2020 the evaluation of the EU **Animal Welfare Strategy (2012-2015)**, started the preparatory work towards **the review of the animal welfare legislation** (animal welfare rules applicable to farming, transport, killing and slaughter), and started considering options on **animal welfare labelling**.

In 2020, DG SANTE also 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, to halve per capita food waste at retail and consumer levels by 2030, and to reduce food loss across the supply chain. DG SANTE is also working to ensure progress towards the specific targets set by the Farm to Fork Strategy of reducing by 50% the use and risk of chemical pesticides and by 50% the use of more hazardous pesticides by 2030.

Food and feed safety

DG SANTE remained active in ensuring that only **safe food and feed** are placed on the EU market. This important task is performed through a very substantial regulatory output for the authorisation of regulated products (e.g. certain foods and feeds and substances that may be found in them), and more generally the many acts through which DG SANTE sets out its risk management decisions (to **contain and address risks for human health**, and for **animal and plant health** along the entire agri-food chain). The containment of outbreaks of African swine fever and of highly pathogenic avian influenza continued to require sustained attention and action by the Commission.

In 2020, this included work to ensure that the enforcement of food and feed safety rules would not be disrupted by **BREXIT**, to ensure the smooth implementation of the Protocol on Ireland and Northern Ireland, and an important contribution to the negotiation of the Chapter of Sanitary and Phytosanitary (SPS) measures of the Trade and Cooperation Agreement (TCA) with the **United Kingdom**.

While DG SANTE was able to continue to deliver on its duties as regulator and risk manager (reacting to **food safety** issues, addressing outbreaks of **animal diseases and of plant pests**), the COVID-19 crisis has also affected work in this area. In particular, **DG SANTE's audit** activity was significantly impacted by the crisis. Of the 167 audits and similar controls initially planned in the food area, only 97 could eventually be carried out, and many of these had to be conducted remotely. Similarly, training activities under the Better Training for Safer Food were disrupted due to COVID-19.

International promotion of EU food safety standards

As in past years, DG SANTE worked with international partners to **promote the EU policy model and EU safety and quality standards**, to ensure our standards are respected and trade can take place. This was of particular importance to maintain trade flows in the early months of the COVID-19 crisis. DG SANTE worked to ensure policy coherence between our internal policy actions and external engagement on

the global stage. To this end, it actively sought to promote the shift to sustainable food systems in multilateral fora and at bilateral level, thus contributing to the objectives of the Farm to Fork Strategy and to the advancement of the EU's broader trade agenda.

B. Key Performance Indicators (KPIs)

KPI 1: Age-standardised five-year net survival of cervical, breast and colorectal cancer

Objective: Diminishing the incidence of cancer in Europe			
Result indicator 2.1.A: Age-standardised five-year net survival of cervical, breast and colorectal cancer			
Cervical, breast and colorectal cancer survival is one of the key measures of the effectiveness of health care systems in cancer care, reflecting both efficiency in early detection and the effectiveness of treatment			
Source of data: EUROCARE (Joint Research Centre) and CONCORD Programme, London School of Hygiene and Tropical Medicine			
Baseline (2014)	Interim milestone (2022)	Target (2024)	The latest data
Cervical cancer: 63% (EU average)	Increase	Increase, with at least 2/3 of Member States above baseline	n/a
Breast cancer: 83% (EU average)	Increase		
Colorectal cancer: 59% (EU average)	Increase		

Work is progressing as foreseen on data collection from the European Network of Cancer Registries as well as from several European projects on cancer survival rates. Given the time lag implied, the next results for this indicator will be available in 2022.

KPI 2: Estimated overall risk at closure

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		
Indicator 1: Estimated overall risk at closure based on the error rate found by DG SANTE's on-the spot controls (ex-post) of payments made (calculated as "estimated overall amount at risk at closure" / "total payments made")		
Source of data: Internal follow-up sheet, reported in AAR		
Baseline	Target (according to the control strategy approved by the DG)	The latest data
2018: 1,0% (M€4.4/M€441.3)	Less than 2%	2019: 0,5% (M€2.2/M€435.9) 2020: 1,6% (M€7,6/M€466,4)

DG SANTE carries out ex-post controls on a sample of payments made to Member States based on their cost declarations in the policy area "Food and Feed Safety". A key indicator of the legality of these payments is the estimated overall risk at closure which is calculated on the basis of the average error rate and the corrective measures taken, such as the recovery of over-payments.

In the policy area "Food and Feed Safety", DG SANTE's residual error rate in 2020 amounted to 0,8% resulting in an overall risk at closure of 1,6%. Thus, it does not exceed the materiality threshold of 2% and no reservation has to be made to the declaration of assurance. In the past years, DG SANTE has taken a series of mitigating actions which reduced the error rate to an acceptable level.

C. Key conclusions on Financial management and Internal control (executive summary of section 2.1)

In accordance with the governance arrangements of the European Commission, (the staff of) DG SANTE conducts its operations in compliance with the applicable laws and regulations, working in an open and transparent manner and meeting the expected high level of professional and ethical standards.

To ensure the achievement of policy and management objectives, the Commission has adopted a set of internal control principles, based on international good practice. The financial regulation requires that the organisational structure and the internal control systems used to implement the budget be set up in accordance with these principles. DG SANTE has assessed its internal control systems during the reporting year and has concluded that it is effective and the components and principles are present and functioning well overall, but some improvements are needed for minor deficiencies. These relate to ethics, staff allocation and professional development, functions that are only partially under DG SANTE management. In addition, further attention is warranted to improve senior management's guidance on "missions, objectives and tasks" and certain elements of DG SANTE's control activities. Furthermore, the updates of DG SANTE's IT security plans still need to be finalised in accordance with the corporate methodology. Please refer to AAR section 2.1.3 and Annex 8.2 for further details.

In addition, DG SANTE has systematically examined the available control results and indicators, including those for supervising entities to which it has entrusted budget implementation tasks, as well as the observations and recommendations issued by the internal auditor and the European Court of Auditors. These elements have been assessed to determine their impact on management's assurance about the achievement of the control objectives. Please refer to Section 2.1 for further details.

In conclusion, management has reasonable assurance that, overall, suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated; and necessary improvements and reinforcements are being implemented. The Director General, in her capacity as Authorising Officer by Delegation, has signed the Declaration of Assurance.

D. Provision of information to the Commissioner(s)

In the context of the regular meetings during the year between the DG and the Commissioner on management matters, the main elements of this report and assurance declaration have been brought to the attention of Commissioner Kyriakides, responsible for Health and Food Safety.

E. Specific actions on COVID-19

In 2020, Europe was strongly impacted by the COVID-19 pandemic. The Commission has proposed a strong and coordinated response to the health crisis as well as to alleviate the impact on Europe's economy and society. COVID-19 has also posed challenges as regards performance, control, audit and assurance in relation to the 2020 EU budget. In an exercise coordinated at corporate level, all Commission services have promoted the consistent and rigorous protection of the EU budget ensuring that appropriate mitigating measures were put in place.

Main steps taken to ensure sound financial management during the COVID-19 crisis were firstly, to replace on-the-spot controls by remote audits, and secondly, to discuss and decide at the highest hierarchical level and in close co-operation with central services how to speed up but still adequately control (joint) public procurement procedures for medical countermeasures given the extreme urgency and pressure to act in an uncertain environment. In addition, DG SANTE organised quality checks of medical goods prior to their direct delivery from the producer to the Member States. This prevented not only financial losses but, first and foremost, health issues had defective medical supplies been used in the fight against COVID-19.

1. Key results and progress towards the achievement of the Commission's general objectives and DG's specific objectives

General Objective 1: A EUROPEAN GREEN DEAL

In 2020, DG SANTE's work on safe and sustainable food contributed to kicking off the delivery of the European Green Deal, notably through the launch of the **Farm to Fork Strategy** and the first steps towards its implementation. The strategy guides our work towards improving the sustainability of the food chain both within the EU and at international level.

Safe food is essential for a healthy population and environment. In 2020, DG SANTE continued to manage the EU's food safety policy with a view to ensuring the protection of citizens, the smooth running of the internal market in this sector, and the international promotion of EU food safety and quality standards.

EU funding in the food chain area.

EU funding for food and feed safety is governed by Regulation (EU) No 652/2014. Expenditure covers animal and plant health measures, emergency measures for animal and plant disease outbreaks, training and official control activities, including the financing of EU Reference Laboratories (EURLs), and relations with relevant international organisations. The total budget of the Food Chain programmes (CFF) 2014–2020 was EUR 1.858,6 billion⁴.

In 2020, DG SANTE started work on the simplification of the financial management of veterinary and plant health eradication programmes using a new JRC-developed methodology that will make it possible to reduce the number of unit costs.

Working in partnership with the EU's decentralised agencies.

In the food chain area DG SANTE work is supported by four decentralised EU agencies: the European Food Safety Authority (EFSA), the European Chemical Agency (ECHA), the European Medicines Agency (EMA) and the Community Plant Variety Office (CPVO).

In 2020, EFSA continued to support SANTE's work to authorise regulated products, providing scientific opinions and technical reports to support the implementation of legislation on plant health, animal health and welfare, antimicrobial resistance and chemical contaminants. The Authority provided scientific support to the EU and Member States on outbreaks of animal diseases, and supported the Commission's activities in response to new multi-country foodborne outbreaks.

In 2020, ECHA issued opinions on active substances used in biocidal products and on EU authorisations for biocidal products. It also delivered opinions on classification and labelling for active substances used in biocides and pesticides.

⁴ See the latest [Food Chain Programme Statement](#).

EMA contributed to EU authorisations of new veterinary medicinal products, many of which are therapeutic innovations, by recommending several veterinary medicines for marketing authorisation.

The CPVO contributed to greater investment and innovation in plant breeding by granting plant variety protection at EU level and adopting measures for updating the system and improving its efficiency. The CPVO also promoted the EU's plant variety system at global level.

Specific Objective 1.1: Food and feed safety

Food and feed safety, animal health and welfare, and plant health contribute significantly to the European Green Deal. In 2020, DG SANTE ensured proper implementation – and where possible, simplification – of the extensive acquis in these areas, taking a “One Health” approach, i.e. integrating human and animal health, and environmental considerations.

The **food hygiene Regulations** (EC) 852/2004 and (EC) 853/2004 were revised to align them with new global standards as regards allergen control and food safety culture, and to facilitate food donation. The revision also introduced a new possibility for safe slaughter on farm, thus responding to both farmers' and society's demand for less transport of live animals to slaughterhouses and better protection of animal welfare. An evaluation was carried out on **food irradiation** rules.

Ensuring animal health and managing and isolating outbreaks of major animal disease.

In 2020, DG SANTE continued to manage the prevention, control and eradication of animal diseases transmissible to animals or to humans. On the preventive side, there has been a marked increase of areas officially free from certain zoonoses (Result Indicator 1.1.A), thanks to support provided to Member States in recent years.

Outbreaks of major animal diseases continued to occur in 2020. Two diseases, African swine fever (ASF), and highly pathogenic avian influenza (HPAI), required continuous efforts to ensure effective control and eradication, and the swift adoption by the Commission of regionalization measures to minimise impacts in non-affected regions.

In November, the discovery of SARS-CoV-2 (the virus that causes COVID-19 in humans) in mink farms in a number of Member States required actions to harmonise the national measures adopted in response to it, and to follow closely the risk posed for human health.

Information on the Union funding of animal health measures is included in part 2 below and in annex 7.

Preventing plant pests.

Globalisation has increased the risk of plant pest infestations. DG SANTE manages the EU plant health regime under the Plant Health Law (PHL) to protect crops, fruits, vegetables, flowers, ornamentals and forests from pests and diseases.

In 2020, DG SANTE prepared revised emergency measures against *Xylella fastidiosa* and Tomato Brown Rugose Fruit Virus (ToBRFV), derogations as regards the introduction of ash wood from Canada and the US and bonsai from Japan, and measures against *Agrilus planipennis* Fairmaire from Canada, the United States and Ukraine.



#planthealth



DG SANTE manages the mechanism for the notification of plant pest interceptions (e.g. Citrus black spot, *Spodoptera*) and outbreaks (e.g. *Xylella*, Pine Wood Nematode, *Anoplophora*, ToBRFV); in 2020 it introduced a

temporary ban on certain citrus fruit from Argentina due to the extremely high number of citrus black spot interceptions.

As announced in the Farm to Fork Strategy, the Commission also adopted measures to reinforce vigilance on plant imports, based on the assessment of their risk profiles.

Information on the Union funding of plant health measures is included in part 2 below and in annex 7.

The number of phytosanitary programmes successfully implemented in the Member States and the total number of phytosanitary programmes approved by the Commission (Result Indicator 1.1.B) has already passed the interim milestone foreseen for 2022.

Ensuring market access to safe substances and products.

Throughout 2020, SANTE and EFSA have collaborated closely to ensure the proper and timely implementation of the new Transparency Regulation⁵ entering into application in March 2021 through, amongst other measures, the adoption of a set of implementing acts.

⁵ Regulation (EU) No 2019/13815 on the transparency and sustainability of the EU risk assessment in the food chain will enter into application on 27 March 2021

Regulated products

In 2020, DG SANTE continued to assess and, where appropriate, authorise substances or products used in food and feed production. It also fixed limits to the presence of contaminants or residues of regulated substances in food and feed.

Maximum levels (MLs) have been established for a number of **contaminants** in food. The conditions of use of 15 **food additives** were amended and five **food flavourings** were withdrawn from the market. DG SANTE presented a proposal improving the specifications of Titanium Dioxide as a food additive, specifying for the first time the maximum percentage of nanoparticles allowed to be present in a food additive put on the market. Nine new **novel foods** and two traditional foods from non-EU countries were authorised, while the authorisations for four currently authorised novel foods were amended.

Five new active substances were approved for use in **plant protection products**, and the approval of six active substances was renewed. Three active substances were not approved, and the approval of six active substances was not renewed. For **pesticide residues**, the Commission adopted ten Regulations setting maximum residue levels (MRLs) for 45 substances, and reviewed MRLs for 14 substances. Three active substances were approved for use in **biocidal products** of different product-types, as well as eight EU authorisations of biocidal products or product families.

Around a hundred **feed additives** were approved following new applications or the re-evaluations of existing authorisations. On **residues of veterinary medicinal products in foodstuffs of animal origin**, the Commission adopted Regulations to set maximum residue levels for four substances.

In 2020, **one new GMO** was authorised for food and feed use.

The Commission continued in 2020 to address the recommendations made by the Court of Auditors in their 2019 report on chemical hazards in our food through a number of actions including on pesticide residue levels and food contact materials (see Annex 8).

Performing effective, efficient and reliable controls.

Official controls are performed by Member States to verify compliance with agri-food chain legislation. DG SANTE funded the work plans of EU Reference Laboratories that support enforcement work in this area, while activities aimed at training staff of the Member States tasked with official controls were suspended due to the COVID-19 crisis.

In 2020, DG SANTE pursued the enforcement of EU rules on food safety, animal health, plant health and animal welfare to ensure that the EU's high standards are not compromised, including through its **audit activity** in the Member States. The latter was significantly impacted by COVID-19-related travel restrictions, as planned controls had to be postponed to later in the year or altogether cancelled. Of the 167

audits and similar controls initially planned in the food chain area, 97 were eventually carried out in 2020, of which 61 remotely. DG SANTE verified that 62% of audit recommendations had been satisfactorily addressed by the Member States by the end of 2020 (Result Indicator 1.1.C).

DG SANTE contributed to the European Commission **action plan for better implementation and enforcement of single market rules**, which was adopted in March 2020.

Maintaining well-developed rapid alert systems.

Since 2020, notifications of non-compliance with agri-food chain requirements can be easily shared between network members in the electronic version of the Rapid Alert System for Food and Feed (iRASFF). This is an important achievement following the lessons learned from the fipronil incident.

DG SANTE continued to maintain and update the Animal Disease Notification System (ADNS) which handled the notification of over 16000 animal disease outbreaks by the Member States and neighbouring countries. Work progressed on the development of the future Animal Disease Information System (ADIS) including through regular meetings with the World Organisation for Animal Health (the OIE) with a view to allow ADIS to feed notifications directly into the OIE's World Animal Health Information System (WAHIS). The launch of ADIS in 2021 will complete the implementation of the recommendations made by the Court of Auditors in their 2016 report on the implementation of the EU's animal disease eradication and monitoring programmes (see Annex 8).

Enforcing EU food chain legislation

In 2020, acting upon the initiative of DG SANTE, the Commission started 49 **infringement proceedings** against Member States to ensure the transposition of 5 Directives⁶ and pursued 4 substantive infringement cases with regard to marketing requirements for mineral water, food hygiene, official controls and plant health.

In particular the Commission sent: a) a letter of formal notice to Bulgaria for failing to comply with EU rules on **marketing requirements for natural mineral and spring waters** in Directive 2009/54/EC on natural mineral waters⁷; b) a letter of formal notice to Romania regarding the exclusion of certain supplies of products of animal origin from the scope of Regulation (EC) No 853/2004 on **hygiene rules of food of animal origin**, which are accordingly governed by national law, without complying

⁶ 1. Commission Implementing Directive (EU) 2019/1813 of 29 October 2019 regarding requirements for the labelling, sealing and packaging of fruit plant propagating material and fruit plants intended for fruit production; 2. Commission Implementing Directive (EU) 2019/1985 of 28 November 2019 regarding the characteristics to be covered as a minimum by the examination and the minimum conditions for examining certain varieties of agricultural plant species and vegetable species; 3. Commission Implementing Directive (EU) 2020/177 of 11 February 2020 regarding pests of plants on seeds and other plant reproductive material; 4. Commission Implementing Directive (EU) 2019/990 of 17 June 2019 regarding the list of genera and species; 5. Commission Implementing Directive (EU) 2020/432 of 23 March 2020 amending Council Directive 2002/55/EC with regard to the definition of vegetables and the list of genera and species.

⁷ INFR(2020)4042.

with the conditions for exclusion from the scope of the EU Regulation⁸; c) a supplementary letter of formal notice to Czechia for failing to comply with EU rules on **official controls** performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules (Regulation (EU) 2017/625)⁹; d) a letter of formal notice to the United Kingdom for failing to comply with the EU rules concerning the **plant pests *Xylella fastidiosa* and *Ceratocystis platani***.¹⁰

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

As per President von der Leyen’s Mission Letter to Commissioner Kyriakides, in 2020 DG SANTE led the Commission’s work on the Farm to Fork (F2F) Strategy for sustainable food, coordinating the preparation of the Communication presenting the Strategy in May. At the heart of Europe’s Green Deal and of sustainable post-COVID-19 recovery, the F2F Strategy aims to accelerate and promote the global transition towards a sustainable food system and is central to the Commission’s agenda to achieve the United Nations’ Sustainable Development Goals (SDGs). The F2F Strategy is in synergy with the objectives and initiatives put forward under the Biodiversity Strategy, the new Common Agricultural Policy, the Methane Strategy and the new Circular Economy Action Plan.

A wide range of communication activities were deployed to support the launch of the Farm to Fork Strategy. The Farm to Fork conference in October was attended on-line by over 11,000 people and reached out to some 250,000 people on social media.

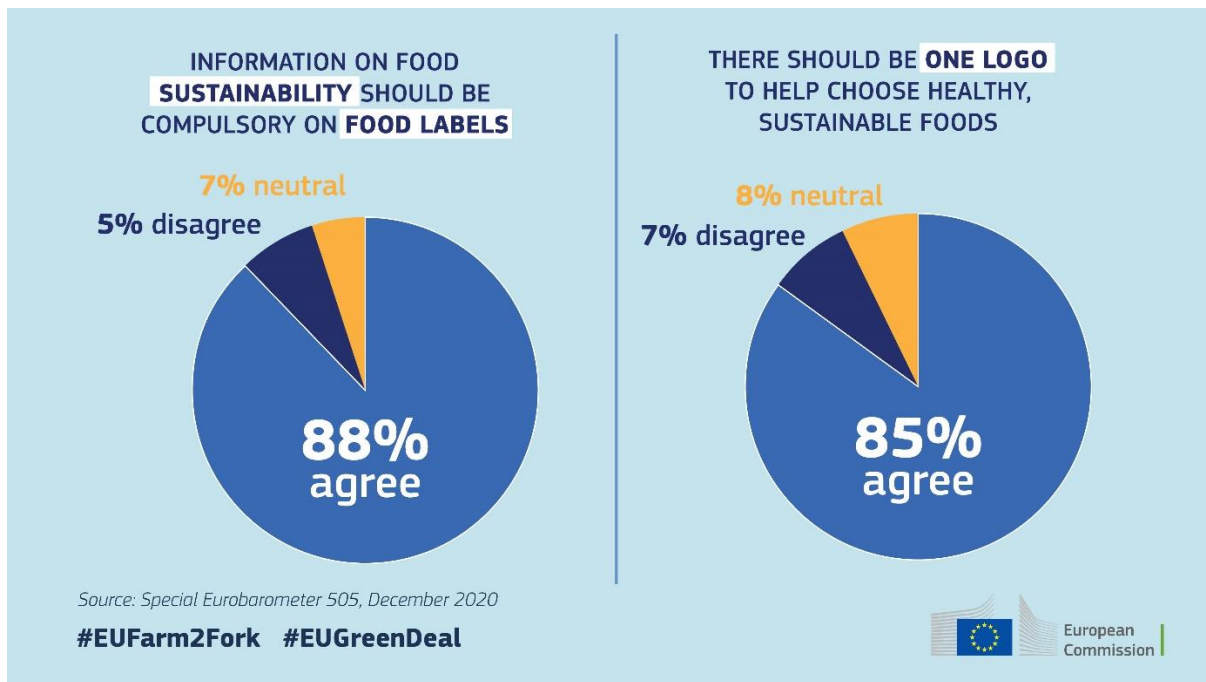
Throughout the year, DG SANTE participated at all levels in numerous public events and meetings of a wide range of stakeholders and Member State expert groups. DG SANTE organised a [Eurobarometer survey](#)¹¹ to collect citizens’ views and expectations on the sustainability of our food system.

⁸ INFR(2020)4041

⁹ INFR(2016)4222

¹⁰ INFR(2020)2283

¹¹ Special Eurobarometer 505 (December 2020), Making our food fit for the future – Citizens’ expectations.



Preparatory work on the flagship initiative of the strategy – the **legislative framework on sustainable food systems** – started in 2020 with the signature of an administrative arrangement with the JRC Policy Lab. Preparatory work also took place for one of the first deliverables of the Strategy in 2021, the development of the **Code of Conduct** for responsible business and marketing practices.

The F2F Strategy aims to promote a **global transition** to sustainable food systems. Numerous information sessions, dialogues and debates were held at international level along with exploratory talks in view of establishing possible partnerships with non-EU countries. Important work has been devoted to the drafting of a new Chapter on Sustainable Food Systems to be included in currently negotiated Agreements. Another important achievement was the inclusion of the sustainability of food systems in the Green Agenda for the Western Balkans allowing to merge in a single objective the perspective of EU-accession for concerned countries with their transition to a green economy.

This transition will be supported also by the future Common Agricultural Policy (CAP). In 2020, DG SANTE extensively contributed to the Commission's recommendations to the CAP National Strategic Plans (NSPs), especially in relation to the objectives of the F2F Strategy on pesticides, antimicrobial resistance, animal welfare, biosecurity, sustainable diets and food waste. In response to the recommendations of the European Court of Auditors in its Report on the sustainable use of plant protection products published in February 2020, DG SANTE drafted an action plan to address low enforcement of Integrated Pest Management (IPM) by Member States and identify the actions to be taken by the Commission and/or the Member States in line with subsidiarity principles. Four of these actions were completed in 2020.

Reducing dependency on and promoting the sustainable use of pesticides.

In 2020, DG SANTE continued working towards reducing dependency on pesticides and stimulating the take-up of low-risk and non-chemical alternatives for plant health protection. To this end, it pursued 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.

An evaluation of the sustainable use of pesticides Directive (SUD) together with an impact assessment of its planned revision was launched in May 2020. The aim is to deliver a legislative proposal in early 2022 to reduce the use and risk of chemical pesticides in line with the objectives of the Green Deal, Farm to Fork Strategy and Biodiversity Strategy.

The second report on the implementation of the SUD published in May 2020 concluded that despite weaknesses in National Action Plans, Member States had made progress with implementation, but noted that there remained significant potential for further risk reduction. The updated trends for both harmonised risk indicators were published on 27 August 2020 covering the period from 2011 to 2018.

Improving the efficiency and effectiveness of the pesticide legislation.

In 2020, DG SANTE started to implement the actions to improve the efficiency of the implementation of the pesticides legislation identified in the recent REFIT evaluation, some of which are also related to the actions announced in the Farm to Fork Strategy.

DG SANTE prepared technical guidance documents to facilitate the assessment of microorganisms used as plant protection products which are the most important candidate group for low-risk plant protection products. DG SANTE also prepared updated data requirements for application dossiers for microorganisms and plant protection products containing them. The first list of unacceptable co-formulants in plant protection products and implemented the relevant provisions of the Transparency Regulation for pesticides was finalised. DG SANTE contributed to the EFSA action plan for the further development of the methodology for cumulative risk assessment of pesticides residues and subsequent implementation. Activities were also launched to inform non-EU countries about the need to take environmental aspects into account when examining applications for import tolerances for substances no longer approved in the EU, as announced in the Farm to Fork Strategy.

Since February 2020, DG SANTE publishes all national notifications of emergency authorisations and the relevant guidance document for Member States has been updated. In October, DG SANTE mandated EFSA to verify whether the emergency authorisations granted by Member States in 2020 for neonicotinoids in sugar beet were appropriately justified.

Reducing the use of antimicrobials in animals to contribute to the fight against AMR.

In 2020, DG SANTE 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.

An important achievement was the adoption of rules on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria, which include AMR monitoring requirements for certain fresh meat imported into the EU in order to reduce AMR impact globally.

Providing for a wide range of concrete measures to fight AMR and promote prudent and responsible use of antimicrobials, the two recently adopted Regulations on veterinary medicinal products and on medicated feed will apply as of 2022. In 2020, DG SANTE progressed with the drafting of several of the key implementing acts in view of achieving the F2F target on **the sales of antimicrobials**.

DG SANTE delivered various new authorisations of **feed additives** with positive effects on animal welfare and health which can contribute to reducing the need for medicinal treatments with antimicrobials and consequently reduce the risk of AMR development.

DG SANTE also contributed to the definition and setting of recommendations for the reduction of the sales of antimicrobials for farmed animals and in aquaculture as part of its input to the draft National Strategic Plans for a reformed CAP.

An action plan was adopted in June 2020 to implement the recommendations of the Court of Auditors' 2019 report on addressing antimicrobial resistance (see Annex 8).

Fostering the use of innovative and more sustainable feeds.

In 2020, DG SANTE worked to facilitate the placing on the market of sustainable and innovative feeds to reduce the environmental and climate impact of livestock farming.

An impact assessment was launched to support **the revision of the feed additives legislation** aiming to facilitate the marketing of sustainable and innovative feed additives and to promote more sustainable livestock production in line with the European Green Deal and the Farm to Fork Strategy.

Extensive consultations have been held with the Member States and stakeholders to identify the best possible approach for a **revision of certain feed ban** provisions with a view to make better use of proteins and former foodstuffs produced in Europe. This included discussions to amend Commission Regulation (EC) No 999/2001 on Transmissible Spongiform Encephalopathies.

Reducing food loss and waste.

The Commission is committed to reaching the United Nations Sustainable Development Goal Target 12.3 to halve per capita food waste at retail and consumer levels by 2030, and to reduce food loss across the supply chain.

In this regard, DG SANTE contributed to the first International Day of Awareness of Food Loss and Waste, held on 29 September 2020. DG SANTE also organised two virtual meetings of the EU Platform on Food Losses and Food Waste and two webinars on food waste measurement.

In 2020, DG SANTE also worked on the revision of EU rules on date marking. To facilitate food redistribution, it provided an action grant in 2020 to support the European Food Banks Federation in strengthening and expanding its network in the EU.

Ensuring sustainable food production that improves the welfare of animals.

Animal welfare is an integral part of sustainable food production. In 2020, an evaluation of the EU Animal Welfare Strategy (2012-2015) was conducted and is scheduled for publication at the beginning of 2021. The publication of the study will address one of the three recommendations still to be implemented from the Court of Auditors' 2018 report on animal welfare in the EU (see Annex 8). The findings from the evaluation will feed into the revision of the EU animal welfare legislation by 2023. Since options for animal welfare labelling will also be considered under the Farm to Fork strategy, a dedicated sub-group on the matter has been established by the EU Animal Welfare Platform. In addition, DG SANTE has been working on the response to the European Citizens' Initiative "End the Cage Age", submitted to the Commission in October 2020, and has actively followed the work of the European Parliament's special Inquiry Committee on Animal Transport that was established in June 2020.

Fighting against food fraud.

In 2020, DG SANTE continued steering the EU Food Fraud Network and monitored the Administrative Assistance and Cooperation System. It took part in coordinated control activities with the Network and in joint operations with Europol targeting counterfeit and substandard food and beverages and illegal pesticides in transit. DG SANTE also intensified and widened its cooperation with OLAF.

DG SANTE commenced a new audit series to verify the implementation of the new requirement for Member States to put in place controls aimed at fraudulent or deceptive practices. DG SANTE carried out two pilot studies (Austria and Ireland) in 2020.

Empowering consumers to make sustainable and healthy food choices through the provision of food information.

In 2020, DG SANTE worked 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 aspects of food products.

In 2020, DG SANTE finalised the Report to the co-legislators on the use of additional forms of expression and presentation of the nutrition declaration, and the evaluation report of the Nutrition and Health Claims Regulation.

Following the adoption of the Farm to Fork Strategy, DG SANTE launched preparatory work for a proposal on harmonised mandatory front-of-pack nutrition labelling; setting nutrient profiles to restrict promotion of food high in salt, sugars and/or fat; extending mandatory origin indication to certain products; and revising rules on date marking to prevent food waste.

Moreover, in 2020 DG SANTE finalised a Notice to foster better understanding and application - by food business operators and competent national authorities - of the provisions on the origin indication of the primary ingredient, and launched the new Food Labelling Information System enabling the above actors, in particular SMEs, to retrieve the mandatory EU labelling indications in 23 EU languages for any selected food.

Supporting innovation in the food chain, especially via the promotion of novel food, plant reproductive materials and innovative techniques.

In 2020, DG SANTE pursued the implementation of the Plant Reproductive Material legislation on certification and marketing requirements, and of the Community Plant Variety Rights legislation. Applicable technical requirements were updated and work continued on the establishment of new rules for organic heterogeneous material.

The success of the Novel Foods Regulation has been confirmed by the large number of applications and notifications received, including for algae, new sources of plant proteins or insects. In 2020, in particular, the Commission clarified the status of Cannabidiol as food, thus allowing to resume the authorisation process for this substance as a novel food.

As part of its ongoing work to respond to the Council's Decision¹² regarding the status of new genomic techniques under Union law in light of the 2018 Court of Justice judgment¹³, DG SANTE prepared a study looking at the state of play of the implementation of and compliance with the legislation and of research and innovation in this area. The study also deals with safety aspects and potential benefits and concerns associated with novel genomic techniques (NGT) products and their applications.

¹² Council Decision (EU) 2019/1904.

¹³ Case C-528/16, Confédération paysanne and Others, Judgement of 25 July 2018.

Improving the regulatory framework on Food Contact Materials (FCM).

Food packaging plays a key role in the food system's sustainability. The preparatory work for the amendment of the recycling Regulation and individual authorisations of PET plastics recycling processes continued and work started on an Impact Assessment supporting the revision of the FCM framework legislation.

As regards the initiative on setting migration limits for certain metals from ceramic and vitreous food contact materials, the Commission contracted a study on its potential impacts, and those of the envisaged mitigating measures, that will feed into the Impact Assessment.

Specific Objective 1.3: International promotion of EU food safety standards

In 2020, DG SANTE worked with international partners to promote the EU policy model and EU safety and quality standards, to ensure our standards are respected and trade can take place. DG SANTE worked to ensure policy coherence between our internal policy actions and external engagement on the global stage.

Based on the ambitious international agenda embodied in the Green Deal and Farm to Fork Strategy, DG SANTE launched preparatory work to promote the shift to sustainable food systems in multilateral fora and at bilateral level. This work contributes to the EU's 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*.

Improving multilateral relations.

DG SANTE works closely with third countries and global partners in multilateral fora to ensure its standards are recognised, accepted and promoted at bilateral and multilateral level.

In 2020, DG SANTE continued to ensure strong EU influence on the work of the **World Organisation for Animal Health (OIE)** by coordinating the input of the Member States in OIE's international standard setting and by actively participating in relevant preparatory work. DG SANTE also supported specific OIE activities in the areas of animal health including zoonoses, animal welfare and veterinary public health both financially and through expert contributions.

DG SANTE contributed to the intersessional work under the **Convention on Biological Diversity (CBD)** and the **Cartagena Protocol on Biosafety**, including by preparing the Biosafety component of the post-2020 Global Biodiversity Framework and the post-2020 Implementation Plan and Capacity-building Action Plan of the Cartagena Protocol. Due to the pandemic, the Conference of the Parties to CBD (COP15) and the meeting of the Parties to the Cartagena Protocol (COP-MOP10) were postponed to next year.

In 2020, DG SANTE co-represented the EU at two meetings of the **World Trade Organisation Sanitary and Phytosanitary (SPS) Committee** to promote and defend

EU interests in the SPS area. Given the importance of the EU market and the EU's high sanitary and phytosanitary standards, WTO Members heavily scrutinised EU measures adopted in 2020 and raised eight new Specific Trade Concerns (STCs) against the EU in the SPS Committee.

In 2020, DG SANTE played a key role in the adoption of the World Health Assembly Resolution on strengthening efforts on food safety that, inter alia, sets the foundation for the development of a new WHO global strategy on food safety.

DG SANTE continued to represent the EU and actively participate in the **Codex Alimentarius Commission**. DG SANTE contributed to intersessional work of Codex committees by participating in 39 electronic working groups and chairing or co-chairing eight of those. EU positions for Codex committees were coordinated with Member States either electronically or in the Council preparatory meetings.

In the **International Plant Protection Convention (IPPC)**, DG SANTE continued to coordinate the EU input on the global plant health strategy, the development of international standards and guidelines for phytosanitary measures and gave a grant to support IPPC in its ePhyto, commodity standards and emerging risks activities. 2020 was the first International Year of Plant Health (IYPH) but its flagship events were postponed to 2021 due to the COVID-19 pandemic.

Improving bilateral trade relations.

In 2020, DG SANTE continued to engage with the EU's trade partners to ensure the relevant EU safety requirements are met to protect health and prevent trade disruptions.

In 2020, DG SANTE participated in the negotiation of the Chapter of Sanitary and Phytosanitary (SPS) measures of the Trade and Cooperation Agreement (TCA) with the **United Kingdom**. The Agreement provides for single export health certificates for all EU Member States thus ensuring the respect of the EU as single entity principle. It also ensures the recognition of established regionalisation measures for animal diseases and protected zones for plant pests, and provides for fast assessment and recognition of new requests.

On the preparedness side, in 2020 DG SANTE amended 24 acts to prepare future UK exports and imports of animals and sanitary and phytosanitary goods to/from the EU. It monitored the construction of border control posts (BCPs) in the most impacted Member States and prepared for the disconnection of the UK from all SANTE IT systems, networks and databases while providing full or partial access where exchanges of data are strictly necessary to comply with the obligations of the Protocol on the UK's withdrawal from the EU. All outstanding issues in the SPS area under the Protocol on Ireland and Northern Ireland (NI) have been finalised including the monitoring of the construction of four BCPs in NI and the organisation of virtual training classes for the new BCP staff.

DG SANTE contributed to and attended the yearly bilateral sub-committee meetings on food safety with **enlargement countries**.

Switzerland remained one of the most important trading partners for animals, plants and food products. Pending the agreement on the interinstitutional chapter, the extension of the agreement on trade in agricultural products to the whole food chain could not be finalised in 2020.

In 2020, negotiations for an SPS chapter with **ESA** (Eastern and Southern Africa) Countries¹⁴ made substantial progress with the overall objective to agree on an Economic Agreement Partnership.

DG SANTE suggested actions for the SPS annex of the **AfCFTA** (African Continental Free Trade Agreement) and to support African partners to adapt and build capacity on food safety and sanitary and phytosanitary (SPS) matters.

During 2020, DG SANTE continued its extensive contacts at technical and political level with the **US**, the EU's most important global agri-food trading partner. Currently, the EU is still excluded either wholly or partially from many important US agri-food markets due to sanitary and phytosanitary barriers and DG SANTE will remain committed in 2021 to tackling these barriers.

In 2020, DG SANTE continued its dynamic involvement in the implementation of the **EU-Canada** Comprehensive Economic and Trade Agreement (CETA) in the SPS area. The negotiations of Free Trade Agreements with **Australia** and **New Zealand** also continued to progress well.

Despite **Russia's** import embargo on the EU countries, Russia remains one of the EU's main trading partners. DG SANTE, in close cooperation with the Member States, continued to have a regular dialogue with the Russian authorities on a number of veterinary and plant health issues.

The **three Eastern Partnership countries** with whom the EU has separate Association Agreements in place pursued their work on the approximation to the EU *acquis* resulting in the transposition of SPS standards and rules, applicable in the EU, into their national legislation.

SPS relations with **China** were marked in 2020 by the updating of three Memoranda of Understanding. Two regionalisation projects have been proposed to China with the aim to strengthen cooperation on animal health and food safety.

Good progress was made on the mutual recognition project on regionalisation with Japan, in the context of the implementation of the **EU-Japan** Economic Partnership Agreement of February 2019, the largest EU agreement to have entered into force to date. In addition, a roadmap was agreed marking a pathway for mutual better market access.

¹⁴ Zimbabwe, Mauritius, Madagascar, Seychelles and Comoros.

In 2020, DG SANTE has actively participated in the legal scrubbing of the SPS and Dialogue Chapters of the EU-**Mercosur** Agreement, with a view to submission for adoption by the co-legislators in the second half of 2021. Concerning the bilateral relations with Mercosur member countries, the judgement of the EU Court of Justice of 8 July 2020 fully supported the Commission measures to withdraw certain Brazilian exporting establishments involved in fraudulent practices affecting the health of consumers.

In 2020, DG SANTE was actively involved in the implementation of both the EU-**Colombia, Ecuador and Peru** Comprehensive Trade Agreement and the EU-**Central America** Association Agreement.

In November 2020, DG SANTE organised the 9th meeting of the SPS committee of the EU-**Korea** Agreement. Two critical issues were on the agenda: the possible lifting of the ban on French and Irish beef, and further recognition of regionalisation. Both issues are still under discussion.

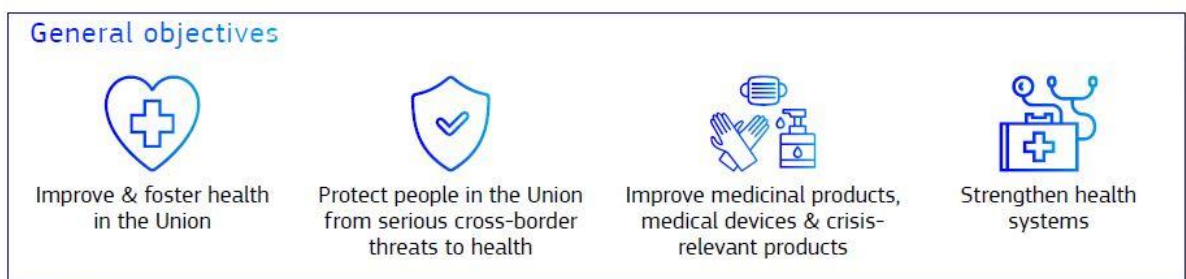
The first SPS committee under the EU-**Singapore** Free Trade Agreement (EUSFTA) in November 2020 was marked by the good quality of technical exchanges and cooperation despite the difficult circumstances caused by the pandemic.

DG SANTE has led FTA negotiations on the SPS chapter with **Indonesia** with substantial success in the first part of the year, as all the provisions will be in line with EU and international standard policies. Negotiations were halted due to a sudden ban by Indonesia on imports of EU alcoholic beverages, but have since been resumed and the next round will be held end of February 2021.

General Objective 2: PROMOTING OUR EUROPEAN WAY OF LIFE

In 2020, DG SANTE was at the heart of the Commission's response to the COVID-19 outbreak, which tested the EU's health systems as never before. DG SANTE led both the immediate health response – through the Strategy for COVID-19 Vaccines, nine joint procurements for medical countermeasures, as well as numerous initiatives and recommendations to coordinate responses both within Europe and internationally – and the equally important work to build more resilient and responsive health systems, in particular through Commission proposals for a European Health Union, a Pharmaceutical Strategy for Europe and a Europe's Beating Cancer Plan. These initiatives are backed by the ambitious EU4Health funding programme, and this new vision will also be reflected in other major actions over the coming years, in particular the European Health Data Space.

EU4HEALTH For a healthier and safer Union



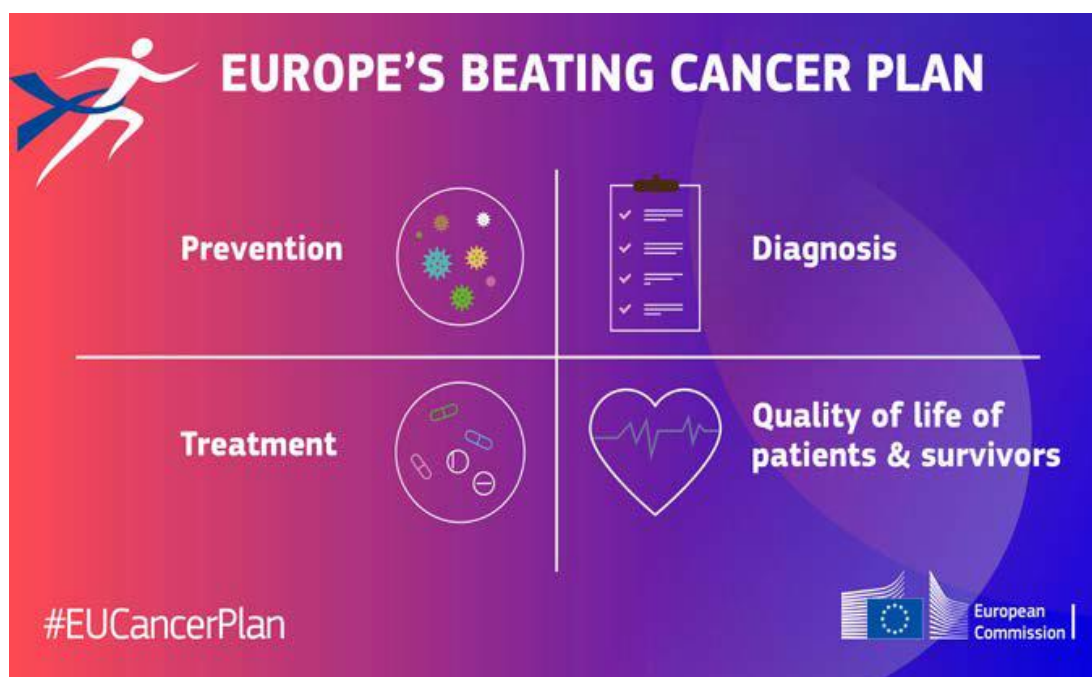
2020 saw the launch of the most ambitious ever EU health funding programme, **EU4Health**, with a budget of EUR 5.1 billion. DG SANTE prepared the EU4Health proposal, on which a provisional agreement was reached by the European Parliament and the Council on 14 December 2020.

EU4Health will pursue the following general objectives, following the One Health approach where applicable: improving and fostering health in the Union and reducing the burden of communicable and non-communicable diseases; protecting people in the Union from serious cross-border threats to health and strengthening the responsiveness of health systems and coordination among the Member States to cope with those threats; improving the availability, accessibility and affordability of medicinal products and medical devices as well as crisis-relevant products, supporting innovation regarding such products, and strengthening health systems by improving their resilience and resource efficiency. DG SANTE promoted the new programme, including press material, a new website and social media activity.

The ex-post **evaluation of the Third Public Health programme** was launched by the publication of the Roadmap on 20 October 2020.

DG SANTE contributed to the preparatory steps for **Horizon Europe**, the new Research and Innovation programme for which DG SANTE is co-leader with DG RTD of the Health cluster.

Specific Objective 2.1: Diminishing the impact of cancer in Europe



As tasked by President von der Leyen in her Mission Letter to Commissioner Kyriakides, DG SANTE worked on [Europe's Beating Cancer Plan](#). The objective of the Plan is to support the Member States and to supplement their national cancer control strategies. This will allow Europe to take the lead in the fight against cancer.

The Commission launched its consultation period for Europe's Beating Cancer Plan at an event in the European Parliament on 4 February 2020 (World Cancer Day). With more than 800 participants, including President von der Leyen, and personal testimonials from cancer patients and survivors, the event was widely covered by media in over 20 Member States and had a potential reach of 16 million social media users during the week. Following the launch, there was extensive public and

targeted consultation, including with the Member States, and the European Parliament, in particular through their Special Committee on Beating Cancer.

Tobacco: DG SANTE continued its global efforts to reduce tobacco consumption, which is the main risk factor in cancer. In 2020, tobacco control work focused on the implementation of the Tobacco Products Directive and the integration of tobacco control work as a cornerstone of the prevention axis of the new Cancer Plan. The ground work was done for the report on the application of the Tobacco Products Directive and for the future evaluation of the tobacco acquis. Due to COVID-19, the Conference of Parties of the WHO Framework Convention on Tobacco Control (FCTC) was postponed by one year to 2021.

The menthol ban came into effect in May 2020. The Joint Action on Tobacco Control I (to support Member States with the assessment of data on tobacco products and electronic cigarettes) was successfully closed and work on Joint Action II (with a wider focus and more policy-oriented around the full package of tobacco control actions) started. DG SANTE also provided support to DG TAXUD in preparation of the revision of the Tobacco Taxation Directive.

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

Pharmaceuticals Strategy

In 2020, DG SANTE developed a flagship Commission deliverable, a Pharmaceutical Strategy for Europe¹⁵. This policy initiative is a key pillar of the stronger European Health Union. It addresses access to affordable medicines and unmet medical needs, and proposes to create a future-proof and crisis-resistant framework which supports innovation, regulatory simplification, security of supply and combating shortages, ensures a strong voice for the EU globally, as well as responds to lessons learned from the COVID-19 pandemic. It includes 55 actions with important deliverables and ambitious deadlines, among which is a Commission proposal for the revision of the pharmaceutical legislation in 2022. These actions target the whole lifecycle and value chain of medicines, including research, industrial, competition, trade and environmental policies.

By boosting innovation for unmet needs, a patient-centred approach to clinical trials, and through its actions on access to affordable medicines, the strategy also supports the objectives of cancer prevention, diagnosis and treatment.

As part of the Pharmaceutical Strategy, DG SANTE also launched a study on shortages of medicines to identify root causes and propose solutions.

The press conference and technical briefing on the Strategy, accompanied by press and communication material (including a video), as well as extensive social media activity, generated significant media reaction with over 100 media outlets in 15 Member States.

¹⁵ European Commission, Pharmaceutical Strategy for Europe, (COM/2020/761 final)

Evaluation and review of orphan and paediatric medicines legislation

Delivering for patients with rare diseases and for children is another flagship initiative of the Pharmaceutical Strategy. [The results of the joint evaluation of the Regulations on medicines for rare diseases and for children](#) were published in summer 2020. This legislation was introduced to give a specific push to the development of medicinal products in these previously neglected areas marked by low commercial interest due to relatively small target populations and often more complex research.

DG SANTE published in November 2020 [an inception impact assessment on the revision of the two Regulations](#) by 2022. Citizens and stakeholders were asked to give their feedback on the proposed options that aim to improve the therapeutic landscape.

Review of European Medicines Agency (EMA) fees legislation

In 2020, DG SANTE initiated work on the impact assessment for the revision of the EMA fees system.

Implementation of the Clinical Trials Regulation

The Clinical Trials Regulation (EU 536/2014) is due to become fully applicable at the end of 2021, after the EU Clinical Trials Portal and Database, as part of the Clinical Trial Information System, achieves full functionality. In 2020, SANTE participated in the discussions around the development of the Clinical Trial Information System, including preparations for a go-live end of 2021. DG SANTE developed and published joint guidance for clinical trials during the COVID-19 pandemic and commenced work on rules for coordinated safety assessment under the Clinical Trials Regulation.

DG SANTE also facilitated an agreement among the Member States on adapting the application of the legislation on clinical trials with human cells genetically modified by means of retro/lentiviral vectors, on a common approach to deal with human cells modified by means of adeno-associated vectors, and on common principles to assess shedding from oncolytic viruses.

Falsified Medicines Directive

DG SANTE continued to help the Member States in implementing the new safety features on the packaging of prescription medicines.

BREXIT

DG SANTE continued to address the challenges posed by the withdrawal of the United Kingdom. The Commission adopted a BREXIT Notice on medicines that set the pathway for ensuring compliance with EU rules in this area, and DG SANTE addressed issues related to the implementation of the Ireland and Northern Ireland Protocol of the withdrawal agreement and access to databases managed by EMA and the Commission. DG SANTE supported the negotiations of the Trade Cooperation Agreement agreed between the EU and the UK (and its Annex on medicines).

International relations

In 2020, the EU and US confirmed their intention to extend the current product range of the Mutual Recognition Agreement from human medicines to veterinary medicines, and work progressed on the establishment of the conditions towards this objective.

Within the Good Manufacturing Practice (GMP) Protocol of the CETA with Canada, work progressed on the recognition of the inspections conducted by EU national competent authorities and Health Canada in third countries and on the inclusion of Active Pharmaceutical Ingredients (API) in the scope of the recognition. In addition, DG SANTE and EMA signed a Confidentiality Arrangement with Health Canada for the exchange of information on medicinal products.

DG SANTE continued to actively engage in the work of ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use), IPRP (International Pharmaceutical Regulators Programme), and in the work of the International Coalition of Medicines Regulatory Authorities, which stepped up its efforts to address the challenges posed by the COVID-19 pandemic.

Health Technology Assessment

Health Technology Assessment (HTA) informs decision makers on the formulation of safe, effective health policies that achieve best outcomes and value for money for patients, health professionals and health systems. The Commission proposal on Health Technology Assessment adopted in 2018 represents a key element of the Pharmaceutical Strategy.

Negotiations on the proposal were suspended in Q2 and Q3 of 2020 due to the pandemic, but resumed in Q4 and have since significantly advanced.

HTA coordination among Member States has been an important part of the responses to the current crisis. The European Network of HTA bodies (EUnetHTA), a co-funded Joint Action under the Health Programme, plays an active role in collecting scientific evidence at EU level to support national decisions on COVID-19-related measures. By the end of 2020, EUnetHTA had prepared and was regularly updating 18 rolling collaborative reviews for potential COVID-19 treatments and 2 collaborative reviews on the main testing methods for the identification of SARS-COV-2 (i.e. PCR, antibody testing). In addition, through the Joint Action, HTA organisations across the EU were able to share information, thus providing decision-makers with a timely synthesis of available evidence on the comparative effectiveness of therapeutic health technologies relevant to the management of the COVID-19 pandemic.

Medical Devices Regulation and In vitro diagnostic medical devices Regulation

In light of the COVID-19 outbreak, it was agreed to postpone the date of application of the Medical Devices Regulation for one year to May 2021. To mitigate the impact of the pandemic, DG SANTE produced a large number of guidance documents to

ensure that medical devices would continue to reach patients, for example, on requirements for ventilators and related accessories.

Marketing Authorisations of Medicinal Products, including the first vaccine against COVID-19

In 2020, the Commission authorised 93 new medicines for human use; over half (48) included a new active substance. There were 21 new medicines authorised for treatment of rare diseases, of which 3 were advanced therapy medicinal products. During the course of 2020 the Commission adopted more than a thousand decisions related to the marketing authorisation of medicines for human use, as well as 297 decisions relating to designations for orphan medicines.

Early in the year there was a rapid mobilisation of investment in the development of potential medicines to prevent and treat COVID-19. The flexibilities of the EU's regulatory framework allowed the development, authorisation and availability of vaccines to be accelerated, while standards for quality, safety and efficacy remained strict. EMA used its rapid review procedures to quickly deliver the assessments of vaccine applications. A dedicated group of experts in the COVID-19 EMA Pandemic Task Force gave scientific advice on clinical trials and product development. Rolling reviews allow data to be assessed as they become available from ongoing studies, before a formal application is submitted. That significantly shortened the normal assessment times of the formal submission, as most of the data can then be quickly reviewed, while maintaining the principles of quality, safety and efficacy. This required an unprecedented mobilisation of scientific resources from the EU Regulatory Network.

In July 2020 the Commission authorised the first treatment for COVID-19, *Veklury* (remdesivir), then on 21 December *Comirnaty*, the first vaccine against COVID-19. DG SANTE coordinated and accelerated the process that enabled the Commission to grant conditional marketing authorisation with record speed (in the case of vaccines, on the same day EMA transmitted its positive opinion). This allowed the start of the rollout of the vaccination campaign across the EU before the end of 2020.

A flexible and robust regulatory process as part of the EU Strategy for COVID-19 vaccines

Together with EMA and the network of medicines regulators, DG SANTE worked throughout 2020 on several initiatives to provide regulatory flexibility in light of the global pandemic, some of which relate to development and authorisation of COVID-19 vaccines and are part of the [Commission's vaccine strategy](#). To ensure that regulatory requirements do not become a bottleneck, existing flexibilities are fully exploited, without compromising the high standards of quality, safety and efficacy. Two important guidance documents were published [on regulatory expectations for human medicinal products during the COVID-19 pandemic](#), and [on labelling and packaging flexibilities for COVID-19 vaccines](#).

On 17 June 2020 the Commission proposed a regulation to derogate temporarily – and only for as long as COVID-19 is regarded as a public health emergency – from certain requirements provided for in the Union's legislation on GMOs, to facilitate clinical trials of COVID-19 vaccines that contain or consist of GMOs. The environmental impact assessment of such vaccines must still be carried out before a marketing authorisation is granted in the EU. The European Parliament and Council adopted [Regulation \(EU\) 2020/1043](#) in less than a month allowing for clinical trials with such vaccines to start in the EU without delay.

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

In 2020, DG SANTE was at the heart of the Commission's response to the COVID-19 outbreak, with coordination of Member States and information-sharing occurring primarily via the Health Security Committee (HSC) and the Early Warning and Response System.

Meetings of the HSC ensured the exchange of information on the epidemiological situation in the Member States and facilitated coordination of responses to the COVID-19 crisis. The Commission and the ECDC provided guidance on the use of the rapid antigen tests, vaccination, non-pharmaceutical interventions and other tools to help Member States to tackle the outbreak.

Once vaccines had been secured, it was crucial that Member States were ready at all levels for the roll-out. The Commission, led by DG SANTE and in cooperation with the ECDC, worked intensely with countries to make sure that sufficiently resourced vaccination services, logistics and (cold-chain) infrastructure were in place, and that priority groups for vaccination had been defined, along the lines set out in the [Communication on preparedness for COVID-19 vaccination strategies and vaccine deployment](#) published on 15 October. This included virtual **stress tests** to assess the level of preparations in the countries. DG SANTE has also been leading on the launch of a large number of joint procurement procedures, including for the purchase of the equipment specifically needed for COVID-19 vaccination.

In 2020 DG SANTE also continued to implement the Council Recommendation on strengthened collaboration against vaccine-preventable diseases in general, as well as its work with the Joint Action on Vaccination. 2020 also saw the implementation of the final two outstanding recommendations made by the Court of Auditors in their 2016 report on dealing with serious cross-border threats to health in the EU (see Annex 8).

Addressing shortages of medicinal products, medical devices, personal protective equipment and biocidals during the COVID-19 crisis

DG SANTE coordinated meetings which brought Commissioner Kyriakides and Commissioner Breton together with medicines and medical device supply chain stakeholders to determine how to prevent shortages of medicines during the COVID-19 crisis. The meetings ensured early identification of challenges faced by

manufacturers and their suppliers, distributors and healthcare professionals, specifically with regard to medicines and ancillary products used in the treatment of COVID-19. This provided valuable information to determine what actions needed to be prioritised, for example guidance to Member States on stockpiling, and ensuring export restrictions were lifted where required.

DG SANTE and EMA co-chaired meetings with national competent authorities to develop a reflection paper on forecasting demand data for medicines in the EU/EEA, to provide practical guidance for Member States to determine demand requirements, which could be aggregated at European level.

All of this work informed the Commission's adoption of a Communication on the rational use of medicines, a notice on regulatory flexibility and a legal proposal to reinforce the crisis preparedness and response role of EMA.

DG SANTE worked also to fight sudden export restrictions introduced by Member States and encourage solidarity across the EU so that medicines could be available where they were most needed.

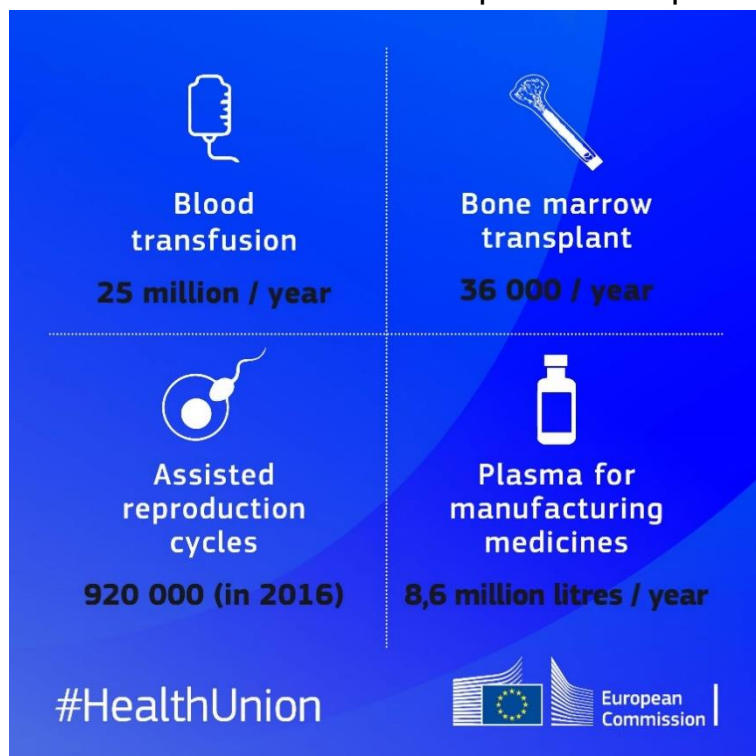
On the international scene, DG SANTE, working closely with the EU DEL in New Delhi, DG TRADE, DG GROW and the EEAS, played a vital role in the coordinated efforts of the Commission to obtain the lifting by India of a certain number of export restrictions on essential medical supplies and active pharmaceutical ingredients (including those used in paracetamol and some critical antibiotics) which had been imposed in response to the first wave of the COVID-19 pandemic in spring 2020. India gradually lifted all its export restrictions.

DG SANTE also acted quickly to address the emerging scarcity at the onset of the COVID-19 pandemic of disinfection products, which fall under the Biocidal Products Regulation. The DG collected weekly data from the relevant industry associations on the size of the problem and coordinated positions of Member States and ECHA. This led to general agreement for a pragmatic interpretation of the possibilities in the Biocidal Products Regulation to broaden the supply base. Other actions included information exchange on products authorised under national legislation that were effective against COVID-19 and ECHA advice on equivalence. The supply situation started to improve from the end of April, and regular follow-up with Member States and industry throughout the year helped to avoid renewed scarcity.

Substances of human origin (SoHO)

The supply of blood, tissues, cells and organs is crucial to support essential and often life-saving treatments and to allow patients to regain or retain an active and productive life. COVID-19 has underlined the need and urgency of revising the EU legislation on safety and quality in the sector, confirming different shortcomings identified in the 2019 evaluation. Throughout 2020, DG SANTE worked closely with ECDC to keep transplant and transfusion therapies safe from COVID, counter the SoHO supply risk, in particular for plasma imports from the US, and adapt the authorisation procedure for novel therapies.

This latter aspect is particularly relevant when assessing and authorising plasma collected from recovered COVID patients as a potentially effective therapy for COVID



patients in hospital. DG SANTE provided guidance on collection and transfusion of this plasma and is actively supporting national blood services to make this therapy available so that evidence can be gathered. This was achieved through the set-up of a common real-world data registry to monitor outcome (with DIGIT), organising dedicated research funding (with RTD) and providing EUR 35 million support (from the ESI) to invest in plasma collection capacity.

Health Union Package

Based on lessons learned from COVID-19, on 11 November 2020, the Commission put forward a set of [proposals for building a European Health Union](#) that would strengthen the EU's health security framework, and for reinforcing the crisis preparedness and response role of two key EU agencies, ECDC and EMA.

As part of the package and follow up to the President's State of the Union speech of 2020, DG SANTE also proposed the creation of a **European Health Emergency Preparedness and Response Authority (HERA)**.

Communication around the response package and the European Health Union was intensive and multi-channel: a new corporate webpage was developed, several factsheets, social media visuals and a video were prepared in close cooperation with DG COMM for the launch, which was accompanied by a press conference, press release and Q&A as well as social media activity and a technical briefing, resulting in significant press coverage.

DG SANTE also supported Member States by putting in place several joint procurements such as for personal protective equipment, therapeutics and laboratory equipment. These were accompanied by ESI-funded additional procurements which covered masks, the antiviral treatment remdesivir, intensive care unit training and antigen tests. In addition, DG SANTE collaborated with DG ECHO for the implementation of the ESI-financed mobility package, which supports the transfer of medical cargo, health workforce and patients.

DG SANTE led the work on several Communications and Recommendations for Member States, such as the [Communication on preparedness for further outbreaks](#), the [staying safe in winter Communication](#) and the [Rapid Antigen testing Recommendation](#). Joint Action Healthy Gateways have also been pivotal in providing Member States support and guidance on deployment of passenger locator forms at points of entry and work.

Throughout the year, DG SANTE played a leading role in preparing regular press and communication materials, as well as social media material and messaging, while responding on a daily basis to numerous media and citizens' enquiries.

ACT-A and COVAX. In 2020, DG SANTE was actively involved in defining and promoting a multilateral response to the coronavirus crisis. As part of the Coronavirus Global Response. DG SANTE helped establish the Access to COVID-19 Tools Accelerator (ACT-A), a global collaborative framework designed to accelerate progress in the development of vaccines, therapeutics and diagnostics with universal access. In September, the Commission also confirmed its participation in the COVAX Facility, the vaccines pillar of the ACT-A. Together with DG DEVCO, DG SANTE has been actively engaged with Gavi, the vaccine alliance, the Coalition for Epidemic Preparedness Innovations and the participating countries to set up COVAX governance and financial tools. The EU and its Member States, acting together as Team Europe, provided EUR 853 million of financial contribution to the COVAX Facility to purchase vaccines for 92 Low and Middle-Lower income countries.

DG SANTE was also actively involved in promoting ACT-A and COVAX in the Group of 20 (G20) under the Presidency of Saudi Arabia, and in the Group of 7 (G7) Health ministers.

World Health Organization (WHO): DG SANTE fully coordinated its response to the COVID-19 pandemic with WHO. DG SANTE continuously stressed the important role of the WHO in coordinating the response to the pandemic, and was supported in this by the EU Member States, in particular in G7 and G20 contexts.

DG SANTE organised the Commission input to support the EU Delegation in Geneva in developing common positions of the EU and its Member States in sessions of the WHO Governing bodies. It contributed to the EU-led preparation of the COVID-19 Response Resolution adopted by the 73rd World Health Assembly in May and the development of Council Conclusions on Strengthening the role of WHO adopted in November. During the 70th session of the WHO Regional Committee for Europe, Commissioner Stella Kyriakides and WHO Regional Director Hans Kluge made a joint statement on reinforced cooperation, emphasising among other things the need to strengthen health security against health emergencies.

The EU cooperated closely with the **Western Balkans and European Neighbourhood** policy countries to assist them in responding to the COVID-19 crisis. Western Balkans, Ukraine and Moldova were invited to participate as observers in the meetings of the EU Health Security Committee, and were also granted access to the Early Warning and Response System for information related to COVID-19. All

Western Balkans partners, as well as Iceland, Norway and Liechtenstein, joined the EU Joint Procurement Agreement for medical equipment in March and April 2020.

In the last quarter of 2020, in order to provide early access to COVID-19 vaccines for health care workers and vulnerable populations in Enlargement and Neighbouring countries, DG SANTE initiated discussions with EU Member States on the donation or re-direction of some doses procured by the EU Member States through the EU Vaccine Strategy.

Antimicrobial Resistance (AMR)

The Pharmaceutical Strategy for Europe acknowledges the importance of tackling the global health threat posed by AMR. It will address several challenges such as inappropriate use of antimicrobials, lack of economic interest in R&D, and access to and availability of new and old antibiotics. It proposes specific actions including the review of the pharmaceutical legislation to introduce measures to restrict and optimise the use of antimicrobial medicines and to explore new types of incentives for innovative antimicrobials.

Implementation of the European Action Plan against Antimicrobial Resistance continued albeit at a slower pace than anticipated because of the COVID-19 pandemic. The [Joint Action on Antimicrobial Resistance and Healthcare Associated Infection \(EU-JAMRAI\)](#) of 19 Member States and Norway, co-funded by the EU under the Health Programme, continued to make progress in supporting the “One Health” national action plans on AMR and actions on healthcare associated infections. Due to COVID-19 related work, the joint action partners obtained an extension of the action by 6 months until end February 2021.

DG SANTE led the EU input on the development of a new 5-year programme of action for the [Transatlantic Taskforce on Antimicrobial Resistance \(TATFAR\)](#). Due to COVID-19, the development of the work plan has been extended until end June 2021.

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

Health systems resilience was majorly tested in 2020 with the COVID-19 pandemic. As a result, in 2020, **for the first time, all 27 Member States received Country specific recommendations related to health systems resilience**. DG SANTE played a key role in facilitating this work. SANTE also drafted the health input to the European Semester country reports that were published end of February 2020.

SANTE continued its work to foster effective, accessible and resilient health systems, which is now even more urgent. Work continued to advance on addressing the recommendations of the Court of Auditors in their 2019 report on actions for cross-border healthcare, particularly in the areas of eHealth and rare diseases (see Annex 8).

The Recovery and Resilience Facility (RRF) will be used for investments and reforms addressing the challenges identified in the European Semester and recovery from COVID-19. The Commission issued specific RRF guidance for Member

States and DG SANTE's input to the European Semester enabled the Commission to address health-related country-specific recommendations; this is expected to generate requests from every Member State for some health-related RRF investment.

DG SANTE has collaborated with SG.RECOVER, DG ECFIN and DG EMPL to prepare country briefs for the Recovery and Resilience Facility, contributed to the Annual Sustainable Growth Survey, the Joint Employment Report and the Euro-area Recommendations.

Finally, DG SANTE made regular contributions to the preparatory work for InvestEU, such as the InvestEU Regulation and Investment Guidelines. DG SANTE has also attended meetings (together with DG ECFIN and DG EMPL) with the EIB and other potential Implementing Partners to discuss the financial products they are considering for InvestEU.

Country knowledge

In President von der Leyen's mission letter, Commissioner Kyriakides was requested to support Member States in their quest to improve the performance of their health systems, including by developing better information, expertise and best practice exchanges to inform policy-making at the EU and national level.



In response, DG SANTE continued its two-year knowledge-brokering cycle *State of Health in the EU*, which generates high-quality, evidence-based analysis and information on health systems performance in EU countries. It has been developed collectively by the Commission, the OECD and the European Observatory on Health Systems and Policies.

In November 2020, DG SANTE kicked off the third cycle of the *State of Health in the EU* project with the joint Commission-OECD publication *Health at a Glance: Europe 2020*. The thematic chapters of this report provided an in-depth analysis of European health systems' resilience to the COVID-19 pandemic and of the health impact of air pollution in Europe. The report also provides comparative analyses of the health status of EU citizens and the performance of EU health systems.

Strengthening Member States' tools to assess the performance of health systems

DG SANTE supports the development of expertise on health systems performance assessment (HSPA) via the **EU Expert Group on HSPA**, which it co-chairs. In 2020, the Group focused its work on identifying **tools and methods to assess health system resilience**, on which it published a report in December 2020. The amenable

mortality study final report was published in November 2020, presenting options for methodological improvements.

The Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases (SGPP) held ten meetings in 2020 and launched two joint actions with Member States, notably on mental health and on nutrition.

Patients' right to cross-border healthcare

EU citizens have the right to access healthcare in any EU country and be reimbursed for that care under Directive 2011/24/EU on cross-border healthcare (CBHC). The annual data collection exercise on cross-border patient mobility was carried out as planned, and DG SANTE also supported the work of National Contact Points (NCPs), organising regular meetings to encourage cooperation and exchange of good practices.

In April 2020, the Commission adopted guidelines on EU emergency assistance in cross-border cooperation in healthcare related to the COVID-19 crisis.

E-health

DG SANTE has a long-term goal to maximise the potential of e-health to provide high quality healthcare and reduce inequalities in healthcare. In line with the mission letter of Commissioner Kyriakides, DG SANTE continued in 2020 to work towards the creation of a European Health Data Space for cross-border access to health data for better healthcare, policy making and research and innovation. In the European Strategy for Data adopted on 19 February 2020, the Commission announced a series of legislative and non-legislative measures related to the European Health Data Space that it will adopt over the next two years.

DG SANTE continued preparatory work on the legislative proposal on the European Health Data Space that should be adopted in 2021. A supporting Joint Action was launched in 2020 with funding from the Health Programme. The Joint Action should facilitate cooperation among Member States' competent authorities and provide input to the work on the health data governance framework, infrastructure for the European Health Data Space, and health data quality.

With regard to COVID-19, DG SANTE in cooperation with DG CNECT and Member States set up an EU-wide digital infrastructure (European Federation Gateway Service, EFGS) to facilitate the exchange of information between national contact tracing and warning mobile applications. This means that citizens only need to install one app even if travelling across the borders of the Member States participating in the EFGS.

European Reference Networks

The 24 European Reference Networks for rare and complex diseases (ERNs), set up under the Cross-Border Healthcare Directive, bring together more than 900 highly specialised healthcare providers to improve diagnosis and treatment for patients

with these conditions across the EU. The ERNs are also focal points for knowledge generation, training and research on rare diseases.

In 2020 DG SANTE finalised the enlargement of the ERN's geographical scope with 250 affiliated partners of the ERN system. In addition, it conducted, together with the boards of the networks, the assessment of more than 800 new ERN member applications. Work continued on integrating the ERNs into the health systems of the Member States.

DG SANTE launched programmes in 2020 to develop ERN clinical practice guidelines and clinical decision support tools, and to facilitate short-term exchanges of health professionals among ERN members.

Building on the model of the European Reference Networks for rare diseases, the Commission launched a "COVID-19 Clinical Management Support System" to create rapid connections across the EU among the clinicians and the hospitals as reference centres dealing with COVID-19 patients.

2. Modern and efficient administration and internal control

2.1 Financial management and internal control

Assurance is provided on the basis of an objective examination of evidence of the effectiveness of risk management, control and governance processes.

This examination is carried out by management, who monitors the functioning of the internal control systems on a continuous basis, and by internal and external auditors. The results are explicitly documented and reported to the Director-General. The following reports have been considered:

- Annual reports on budget implementation drafted by the Authorising Officers by Sub-delegation, including their hand-over reports;
- Reports of the central financial cell on the results of the second-level ex-ante controls, on the recorded exceptions/non-compliance events or “confirmation of instructions” according to Article 92(3) of the Financial Regulation;
- Report of the Public Procurement Committee (“Comité des Marchés Publics”) on ex-ante controls of public procurement procedures;
- Audit reports and the annual activity report of DG SANTE’s on-the spot controls;
- Report of the Director in charge of Risk Management and Internal Control (RMIC) on the annual assessment of the internal control principles;
- Audit reports of the Commission’s Internal Audit Service (IAS) and its annual conclusion on the state of control in DG SANTE;
- Observations and recommendations reported by the European Court of Auditors;
- Reports on control results from the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA);
- Reports on control results from EU decentralised agencies to which DG SANTE is partner.

These reports result from a systematic analysis of the evidence available. This approach provides sufficient guarantees as to the completeness and reliability of the information reported and results in a complete coverage of the budget delegated to the Director-General of DG SANTE.

This section covers the control results and other relevant elements that support management’s assurance. It is structured into (a) Control results, (b) Audit observations and recommendations, (c) Effectiveness of internal control systems, and resulting in (d) Conclusions on the assurance.

2.1.1 Control results

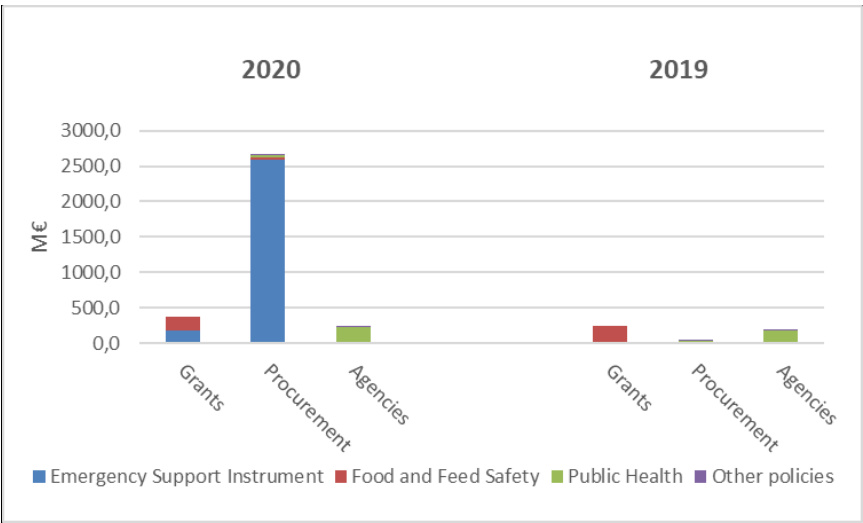
This section reports and assesses the elements identified by management which support the assurance on the achievement of the internal control objectives¹⁶. The DG’s assurance building and materiality criteria are outlined in Annex 5.

¹⁶ 1) Effectiveness, efficiency and economy of operations; 2) reliability of reporting; 3) safeguarding of assets and information; 4) prevention, detection, correction and follow-up of fraud and

Annex 6 outlines the main risks together with the control processes to mitigate them and the indicators used to measure the performance of the relevant control systems. As regards the specific reporting requirements stemming from the Financial Regulation¹⁷, in 2020, DG SANTE has no such cases to report.

The objectives, indicators and assessments in this section cover all expenditure and other significant non-expenditure items¹⁸. DG SANTE managed financial operations under two policy areas, Public Health and Food and Feed Safety, under direct management (93% of the total expenditure), mainly through grants and procurement. In addition, DG SANTE paid subsidies to agencies under indirect management (7%).

Figure 2.1 Allocation of DG SANTE’s 2020 expenditure (EUR 3 277 million)*



* Commitments made on the final available credits taking into account EFTA credits, budget amendments and/or budget transfers without credits co-delegated to other DGs.

! Emergency Support Instrument to address the COVID-19 pandemic

DG SANTE’s budget figures in 2020 were dominated by the Emergency Support Instrument¹⁹ to fight the COVID-19 pandemic: commitments of EUR 3 277 million and payment credits of EUR 2 993 million were almost seven times higher than in previous years (in 2019 DG SANTE committed EUR 482 million and paid EUR 436 million). The must-use commitment and payment credits were

irregularities; and 5) adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments (Financial Regulation Article 36.2).

¹⁷ Regulation (EU, Euratom) 2018/1046 on the financial rules applicable to the general budget of the Union, repealing Regulation (EU, Euratom) No 966/2012 (2012 Financial Regulation): Article 92.3 on cases of ‘confirmation of instructions’; Article 125.3 on cases of financing not linked to costs; Article 130.4 on Financial Framework Partnership Agreements exceeding the four-year duration; Article 181.6 on cases of flat rates exceeding 7% for indirect costs; Article 193.2 on cases of “Derogations from the principle of non-retroactivity.

¹⁸ These include only the significant amounts, i.e. assets (inventories exceeding EUR 5 million); no other items were significant, for example, revenue operations did not account for more than 5% of the total budget allocation in 2020.

¹⁹ Emergency support under Regulation (EU) 2016/369 - In mid-April 2020, the Council activated the Emergency Support Instrument (ESI) for the period February 2020 to January 2022.

implemented to 100% and 94% respectively. The payment credits were not implemented in full, as a high amount of pre-financing which was scheduled to be paid in December to a vaccine producer had to be postponed as conditions for payment were not fulfilled. The payment credits were carried over²⁰ to 2021.

Advance Purchase Agreements for vaccines (APA)

In 2020, DG SANTE concluded six Advance Purchase Agreements for vaccines worth EUR 2 484 million and paid EUR 2 372 million as pre-financing. Two additional procedures for APAs were launched in December 2020/January 2021 and are on-going.

Other measures under ESI

EUR 288 million were spent on a series of actions encompassing, for example, the purchase of face masks (EUR 29,5 million), the antiviral treatment Veklury/Remdesivir (EUR 70 million), services to support the interoperability between national tracing applications (EUR 10,0 million) and training in intensive care units (EUR 2,5 million). DG SANTE also awarded grants to increase Member States' capacity for COVID-19 testing (EUR 35,5 million) and for COVID-19 Convalescent Plasma Collection (EUR 35,7 million). In addition, EUR 100 million were earmarked for the purchase of rapid antigen tests and EUR 5 million for actions supporting the repurpose of medicines to treat COVID-19 patients.

Health programme – 2020 work programme²¹

Under the general objective 2 “Promoting our European way of life”, DG SANTE aims to complement, support and add value to the policies of Member States in improving the health of EU citizens and reducing health inequalities, encouraging innovation in health and increasing the sustainability of health systems²². Key priorities concern areas directly related to the COVID-19 pandemic (for example, vaccination, preparedness and integrated care), and others, such as antimicrobial resistance; digital health, including European Reference Networks; determinants of health such as nutrition, tobacco and alcohol consumption. In 2020, actions were reoriented to the largest extent possible towards combating the pandemic without having to terminate ongoing actions.

About 60% of the Health Programme budget for 2020 was transferred to CHAFEA. Around 40% was implemented by DG SANTE mostly using public procurement procedures, mainly for concluding framework contracts for IT products and services and for communication actions. Commitment credits

²⁰ Non-automatic carry over of payment credits in accordance with Article 12(2)(c) of the Financial Regulation

²¹ The Health Programme contributes to several specific objectives under the first and second general objective described in section 1; Regulation (EU)282/2014 of 11/03/2014 and annual work programme C(2020)368 of 28 January 2020.

²² [Latest Programme Statement on the Union action in the field of health \(Health Programme\)](#)

were almost fully consumed (99,4%); payment credits to 94,0%. The relevant internal control systems and results are described in Annexes 6.2 and 7.1.1).

Furthermore, in 2020, DG SANTE negotiated seven framework contracts for the supply of medical equipment and pharmaceuticals under the Joint Procurement Agreement with Member States to fight the COVID-19 pandemic. Under these contracts Member States have the possibility to place orders, but no obligation to do so. In 2020, the Commission itself has not acted as a buyer under these framework contracts.

Table 2.1 Overview table - DG SANTE's budget of 2020²³

Type of expenditure	Grants M€	Procurements M€	Admin. Credits M€	Budget transfer to CHAFEA M€	Subsidies to agencies M€	Total M€	Main internal control indicator(s)
Emergency Support Instrument	76,2	2.696,1				2.772,3	Estimated error rate < 2,0%
Food and Feed	194,4	32,6	0,7	19,0		246,7	Residual error rate: 0,9%
Public Health		24,6	0,7	40,5		65,9	Estimated error rate < 2,0%
Other policies*		4,1	5,6			9,7	Estimated error rate < 1,0%
CHAF-EA			5,9			5,9	ECA/IAS audits, SANTE supervision
EFSA					103,0	103,0	ECA/IAS audits, SANTE supervision
ECDC					62,5	62,5	ECA/IAS audits, SANTE supervision
EMA					58,9	58,9	ECA/IAS audits, SANTE supervision
ECHA-biocides					7,2	7,2	ECA/IAS audits, SANTE supervision
Global envelope for administration			0,2			0,2	Estimated error rate < 2,0%
Building expenditure etc, Ireland			4,9			4,9	Estimated error rate < 2,0%
TOTAL	270,6	2.757,4	18,0	59,5	231,5	3.337,0	
TOTAL excluding CHAF-EA**	270,6	2.757,4	18,0		231,5	3.277,5	
EC balance sheet category							MC
Assets – inventories of vaccines and antigen stocks for animal diseases							11,6

ad *: Co-delegations received from other DGs, including M€ 5,6 of administrative credits for CHAFEA

ad **: Total commitments made as per Annex 3 without credits transferred to CHAFEA

Food and Feed Safety expenditure

DG SANTE's work on safe and sustainable food makes an important contribution to the general objective 1 "European Green Deal". The by far largest share of the budget is spent to achieve specific objective 1.1 "Food and feed safety" to cover disease prevention (EUR 117 million were spent in 2020 on

²³ Commitments made on the basis of the final available credits taking into account EFTA credits, budget amendments and/or budget transfers without credits co-delegated to other DGs. Comparison to Annex 3: (a) Annex 3 shows the subsidies to EU decentralised agencies of EUR 224,4 million under "Public Health" and EUR 7,2 million under "Food and Feed"; (b) Annex 3 includes in administrative expenditure of Title 17 (EUR 11,9 million): subsidies to CHAFEA of EUR 5,9 million, the part of the expenditure for the building in Ireland on budget line 17.01 of EUR 4,9 million (an additional EUR 0,5 million are on budget line 26.01) and the administrative support credits on operational budget lines of EUR 1,4 million.

animal disease eradication, control and monitoring), and emergency measures (the 2020 expenditure directed EUR 57 million to contain mainly African swine fever and Avian Influenza). Smaller parts of the budget support specific objectives 1.2 “Sustainable food systems – the ‘Farm to Fork’ Strategy” and 1.3 “International promotion of EU food safety standards”. About 7% of the total Food and Feed budget, for the Better Training for Safer Food initiative, was implemented by the executive agency CHAFEA.

DG SANTE implemented its budget largely through grants to Member States based mainly on the co-financing of eligible costs. Provisions for the management of expenditure for the policy area Food and Feed in 2020 are set out in the Common Financial Framework (CFF)²⁴. Commitment and payment credits were almost fully consumed (99,2%). The main features of the corresponding internal control system are listed in Annex 6.1.1; the control results are explained in Annex 7.1.1.1.

Other policy areas

DG CNECT co-delegated EUR 2,8 million to DG SANTE under the CEF²⁵; EUR 1,0 million were co-delegated by DGs AGRI, ENV, MARE and TAXUD on operational budget lines for IT services, mainly related to the IT system TRACES.

In addition, EUR 3,7 million were co-delegated by DG AGRI and EUR 1,8 million by DG JUST on administrative budget lines to pay their respective shares of the subsidy to CHAFEA's running costs.

Commitment and payment credits were fully consumed. The internal control systems are described in Annexes 6.1.2 (procurement) and 6.2.1 (agencies).

Agencies

DG SANTE paid subsidies to finance – partially or in full – the operating budgets of the executive agency, CHAFEA, and four EU decentralised agencies (for more detail see Annexes 6.2.2 and 7.1.1.3).

Building expenditure for Grange, Ireland

EUR 4,9 million relate to the office building in Grange which is managed directly by DG SANTE (not by OIB or OIL).

The commitment credits were almost fully consumed (97%); the payment budget was implemented only to 74% in 2020, but as payments can still be made in 2021, the credits are expected to be used almost fully. The relevant internal control systems are described in Annexes 6.1.2 and 7.1.1.2 (procurement).

²⁴ Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material

²⁵ Connecting Europe Facility (CEF) programme

Balance sheet:

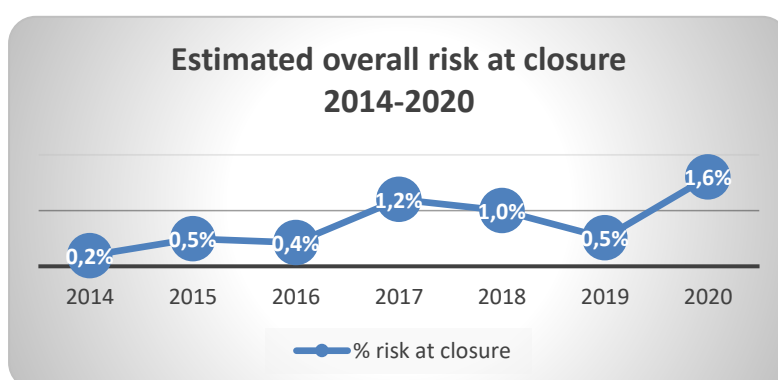
DG SANTE identifies current assets (inventories) of a total value of EUR 11,6 million pertaining to stocks of antigens for food and mouth disease (see section 2.1.1.3 below and Annex 7.1.3).

2.1.1.1 Effectiveness = the control results and benefits

2.1.1.1.1 Legality and regularity of the transactions

DG SANTE is using internal control processes to ensure the adequate management of the risks relating to the legality and regularity of the underlying transactions it is responsible for, taking into account the multiannual character of programmes and the nature of the payments concerned.

Figure 2.2



The coverage of the Internal Control Objectives and their related main indicators are described in greater detail in Annexes 6.1 and 7.1. One of the key performance indicators of the control objective "legality and regularity" is DG SANTE's estimated overall risk at closure based on the error rate found during DG SANTE's on-the spot controls. In the last seven years, it does not exceed the materiality threshold of 2% (materiality is assessed in accordance with Annex 5).

DG SANTE's portfolio consists of segments with a relatively low error rate: in 2020, DG SANTE's detected error rate during ex-post controls on grants in the Food Safety policy area amounted to 0,9%. In accordance with the control strategy, no ex-post audits took place on the procurement contracts in either policy area as these were mostly fixed price contracts. In one case, DG SANTE became aware of quality issues in medical goods it had purchased for direct delivery from the producer to the Member States. DG SANTE recalled the defective products and organised physical quality checks prior to further distribution to the Member States. Thanks to these rapid reactions, neither a health issue nor a financial loss was caused by the incident. Nevertheless, for procurement expenditure, a default error rate is set at just under 2% for the purpose of estimating the overall risk at closure in 2020.

The relatively low detected error rate in the Food Safety policy area is maintained since several years thanks to DG SANTE's mitigating actions, such as the clarifications of eligible costs in the legislation, the introduction of unit-costs and/or cost-ceilings in 2014 and the performance of the related control systems.

Due to closed borders and the sanitary containment in general, on-the-spot audits had to be suspended in mid-March 2020. The ex-post audits for which the fieldwork took place before mid-March 2020, could be finalised at the desk to the effect that a sufficient number of audit results was available for the declaration of assurance in the 2020 AAR. The planned audits that had to be postponed and could not be replaced by remote audits, were not expected to be finalised in 2020, and thus do not affect the 2020 audit coverage.

The analysis of all available control results (see Annex 7.1), the assessment of the weaknesses identified and that of their relative impact on legality and regularity, has not revealed any significant issues which could have a material impact as regards the legality and regularity of the financial operations. It is possible to conclude that the control objectives as regards legality and regularity have been achieved.

For the 2020 reporting year, the executive agency CHAFEA has itself reported reasonable assurance on the delegated budget managed by it on DG SANTE's behalf. CHAFEA has signalled no serious control issues and no reservation was made.

For all five EU decentralised agencies (EFSA, EMA, ECDC, CPVO, and ECHA for its biocides activities) for which DG SANTE was responsible in 2020, the Court of Auditors gave a positive declaration of assurance for the year 2019. The comments made by the Court do not call into question DG SANTE's reasonable assurance on the operating budget managed by the EU agencies. From its own monitoring and supervision work as a responsible DG, DG SANTE did not become aware of anything that would indicate that the reporting from the agencies would not be reliable. Consequently, in view of DG SANTE's residual responsibility for the management of the parts of the budget transferred to CHAFEA, as well as for the funds paid to the operating budgets of the agencies, DG SANTE concludes that there are no control weaknesses affecting the assurance building in terms of the control objective as regards legality and regularity.

The benefits resulting from the controls are not quantifiable. Examples of unquantified benefits are an increased quality of the results of co-financed programmes and procurement contracts as well as the prevention of conflict of interests, reduced risk of fraud and deterrent effects of DG SANTE's on-the-spot controls, the audits by the Court of Auditors and the Commission's Internal Audit Service (IAS).

In comparison to previous years, the amounts at risk at payment/closure and the estimated future corrections remain at a relatively low level. One reason is that despite the COVID-19 crisis, the control environment in the Food Safety policy area remained relatively stable with a detected error rate well below 2%. In the Health

policy area however, DG SANTE experienced a significant change in its control environment when it came to managing important parts of the Commission's health response to the COVID-19 pandemic. DG SANTE's expenditure in 2020 increased sevenfold compared to previous years: EUR 2 515 million of the Emergency Support Instrument were paid mainly to purchase medical counter measures and vaccines. In 2020, error rates are low, as 96% were paid as pre-financing. Error rates in the future final payments are deemed to remain at a low level as most of the purchases are based on fixed price contracts. Nevertheless, an estimated error rate of just under 2% was applied in the calculation of the risk at payment and at closure.

DG SANTE's relevant expenditure, estimated overall risk at payment, estimated future corrections and risk at closure are disclosed in Table 2.2 below. The estimated overall risk at payment for 2020 expenditure amounts to EUR 8,5 million representing 1,8% of the DG's total relevant expenditure for 2020. This is the AOD's best conservative estimate of the amount of relevant expenditure during the year not in conformity with the contractual and regulatory provisions applicable at the time the payment was made.

This expenditure will subsequently be subject to ex-post controls and a proportion of the underlying errors will be detected and corrected in subsequent years. The conservatively estimated future corrections for 2020 expenditure amount to EUR 0,9 million. This is the amount of errors that the DG conservatively estimates will be identified and corrected by controls planned to be carried out in subsequent years.

The difference between those two amounts results in the estimated overall risk at closure of EUR 7,6 million representing 1,6% of the DG's total relevant expenditure for 2020. In the context of the protection of the EU budget, the DGs' estimated overall risk at payment, estimated future corrections and risk at closure are consolidated at Commission level in the AMPR (see Table 2.2 below – estimated risk at closure).

Table 2.2 Estimated risk at closure

DG SANTE	"Payments made"	Minus new prefinancing	Plus cleared prefinancing	Relevant expenditure	Average Error Rate detected or equivalent (<i>weighted</i>)	Estimated risk at payment	Average Recoveries and Corrections (<i>adjusted</i>)	Estimated future corrections	Estimated risk at closure
	(in FY; M€)	(in FY; M€)	(in FY; M€)	(for the FY; M€)	AER %	(FY; M€)	AER %	(for FY; M€)	(FY; M€)
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)
				(2)-/(3)+/(4)		(5) x (6)		(5) x (8)	(7) - (9)
Food Safety (mainly grants)	218,6	-68,6	2,4	152,4	0,9%	1,3	0,5%	0,8	0,6
Health (mainly procurement)	12,2	-14,9	14,8	12,1	2,0%	0,2	0,0%	0,0	0,2
Subsidies to agencies	238,8	-238,8	185,8	185,8	0,5%	0,9	0,0%	0,0	0,9
Other (mainly procurement)	8,8	0,0	0,0	8,8	2,0%	0,2	0,0%	0,0	0,2
Emergency Support Instrument (mainly procurement)	2.514,8	-2.408,2	0,0	106,6	2,0%	2,1	0,0%	0,0	2,1
DG total	2.993,2	-2.730,5	203,0	465,7	1,8%	8,5	0,2%	0,9	7,6 1,6%
DG's subsidy to CHAFEA	11,4	0,0	0,0	11,4	0,5%	0,1	0,0%	0,0	0,0
DG's net' total, i.e. after deduction of the subsidies to CHAFEA	2.981,8	-2.730,5	203,0	454,3	1,9%	8,5	0,2%	0,9	7,5 1,7%

Notes to the table²⁶

²⁶ To column (1) Type of expenditure differentiated for DG SANTE's relevant portfolio segments, i.e. grants, procurement and subsidy payments to agencies.
 To column (2) Payments made or equivalent, e.g. expenditure registered in the Commission's accounting system, accepted expenditure or cleared pre-financing. This means after the preventive (ex-ante) control measures have already been implemented earlier in the cycle. In all cases of co-delegations (Internal Rules Article 3), "payments made" are covered by the delegated DGs. For cross-subdelegations (Internal Rules Article 12), they remain with the delegating DGs.
 To column (3) New pre-financing actually paid by the department itself during the financial year (i.e. excluding any pre-financing received as a transfer from another department). "Pre-financing" is covered as in the context of note 2.5.1 to the Commission annual accounts (i.e. excluding "Other advances to Member States" (note 2.5.2) which is covered on a purely payment-made basis). "Pre-financing paid/cleared" are always covered by the delegated DGs, even for cross-subdelegations.
 To column (4) Pre-financing actually cleared during the financial year (i.e. their 'delta' in the financial year 'actuals', not their 'cut-off' based estimated 'consumption').
 To column (5) For the purpose of equivalence with the European Court of Auditors' scope of the EC funds with potential exposure to legality & regularity errors, the Commission's concept of "relevant expenditure" includes the payments made, subtracts the new pre-financing paid out, and adds the previous pre-financing actually cleared during the financial year. This is a separate and 'hybrid' concept, intentionally combining elements from the budgetary accounting and from the general ledger accounting.
 To column (6) In order to calculate the weighted Average Error Rate (AER) for the total relevant expenditure in the reporting year, the detected error rates have been used – or an equivalent. For low-risk types of expenditure, where there are indications that the equivalent error rate might be close to 'zero' (e.g. administrative expenditure, operating subsidies to agencies), it is nevertheless recommended that 0.5% be used as a conservative estimate.

2.1.1.2 Fraud prevention, detection and correction

DG SANTE has developed and implemented its own anti-fraud strategy since 2013, on the basis of the methodology provided by OLAF. The strategy and its action plan were last updated in July 2017 covering the years 2017 to 2020. It is monitored and reported to the management twice a year.

In 2020, due to the difficult working conditions during the COVID-19 crisis, only about 88% of the actions were implemented as some of the usual awareness raising actions could not take place as planned. They will resume in 2021. Moreover, in addressing the COVID-19 pandemic in the frame of the Health policy, DG SANTE faced significant changes in its control environment and became aware of new risks and fraud patterns in its new activities. Therefore, the planned update of the anti-fraud strategy has been postponed to 2021 (more detail on the main actions taken and on indicators is included in Annex 7.1.2).

DG SANTE also contributed to the Commission anti-fraud strategy by further developing the existing channels for exchanging fraud related information with OLAF, especially in the area of food fraud. In 2020, DG SANTE became aware of allegations of fraud in connection with the purchase of medical countermeasures, but without having an effect on DG SANTE's budget. DG SANTE was in close contact with OLAF to exchange information. Upon completing its selection activities, OLAF decided not to open a case as the suspicions of fraud were insufficient. All follow-up actions to implement OLAF recommendations from previous OLAF cases were closed since 2013; no new recommendation has been issued since.

On the basis of the available information, DG SANTE has reasonable assurance that the anti-fraud measures in place are effective overall.

2.1.1.3 Other control objectives: safeguarding of assets and information, reliability of reporting

In its balance sheet, DG SANTE identified current assets (inventories) of a total value of EUR 11,6 million at 31 December 2020. The assets pertain to antigen stocks for food and mouth disease in order to carry out emergency vaccination. No other

To column (8) Even though to some extent based on the 7 years historic average of recoveries and financial corrections (ARC), which is the best available indication of the corrective capacity of the ex-post control systems implemented by DG SANTE over the past years, the DG adjusted this historic average from 1,67% to 0,2%. The figure 0,2% only includes recoveries and corrections based on ex-post controls while the historic average also includes differences between the registered cost-claim/invoice and the actual payments made that are not corrections stemming from ex-post controls.

To column (9) Any ex-ante elements, one-off events, (partially) cancelled or waived recovery orders, and other factors from the past years that would no longer be relevant for current programmes (e.g. higher ex-post corrections of previously higher errors in earlier generations of grant programmes, current programmes with entirely ex-ante control systems) would be adjusted in order to come to the best and most conservative estimate of the ex-post future corrections to be applied to the reporting year's relevant expenditure for the current programmes.

vaccines or antigens were in stock at the end of 2020. More detail is described in Annex 7.1.3.

The main aim of accounting controls is to assure the quality and reliability of the accounts and underlying transactions through methodical checks on the accounting records (data) and timely communication and correction of the errors. The Court of Auditors carries out annual audits on DG SANTE's accounts. In the past few years, no observation was made that would affect the vaccines stocks.

In conclusion, DG SANTE considers the current control arrangements for accounting and financial reporting to be sufficient. They work in practice as intended. Proper safeguarding of the DG SANTE inventories was ensured throughout the year as stated in the reports received from the contractors.

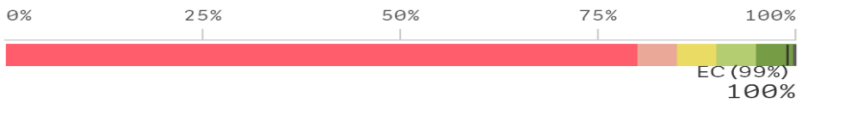
2.1.1.2 Efficiency = the Time-to-... indicators and other efficiency indicators

The main efficiency indicators monitored in 2020 focussed on the timeliness of procedures. Most importantly, DG SANTE did not face any undue delays with regard to the legal deadlines fixed for the 2020 animal disease eradication programmes in the policy area Food Safety or in relation to subsidy payments to agencies.

In addition, DG SANTE ensured efficient processing of payments within the legal deadlines. Supported by electronic workflows with automatic reminders of payments due, DG SANTE was able to increase the efficiency of its payment file handling. The timeliness of payments to Member States for grants in the policy area Food and Feed has much improved in comparison to the last two years thanks to a range of the corrective actions taken.

In 2020, efficiency gains were also realised thanks to the full use of the Public Procurement Management Tool and the qualified electronic signature technology that DG SANTE started to use in mid-2020 to replace the hand-written signatures of procurement contracts and grant agreements (for more detail see Annex 7.2.4). Both tools were indispensable to manage the additional workload and difficult working conditions brought about by the COVID-19 pandemic.

In 2020, DG SANTE's indicator of timely payments (100% of payments made on time in amount) is higher than the Commission average of 99%.

Timely Payments	DG Score	EC Score
	100%	99%

The good result was possible thanks to performant monitoring of payment time limits. To be noted that DG SANTE processed several pre-financing payments of very large amounts under the Emergency Support Instrument (for more indicators see Annex 4).

2.1.1.3 Economy = the estimated cost of controls

The main economy indicators monitored in 2020 focussed on the resources employed for internal control activities. They encompass DG SANTE's staff carrying out the monitoring tasks through the different stages of the control processes as defined in Annex 6. The costs are calculated on an all-cost basis without including an overhead rate. They are based mainly on estimates made in the 2020 Unit Management Plans of March 2020 approved by the then Director-General. The cost of control relative to the Emergency Support Instrument (ESI credits) are estimated ad hoc as they were not foreseen in the Management Plan (for more detail on the indicators see Annex 7.2).

Table 2.3 Economy = the cost of controls

Cost of controls as % of annual payments	Targets	2020		2019		2018	
		Payments	Cost of controls	Payments	Cost of controls	Payments	Cost of controls
		M€	%	M€	%	M€	%
Grants in the Food Safety policy area	1%	188,8	1,6%	211,9	1,5%	218,7	1,4%
Public procurement and other grants (including ESI)	< 10%	2 565,5	0,2%	36,5	6,9%	39,2	6,2%
Subsidy payments to agencies	< 1%	238,8	0,4%	187,5	0,5%	181,3	0,6%

The main cost-drivers in grant management in the Food Safety policy area are the relatively high number of files, their diversity and complexity in both technical and financial aspects.

Public procurement procedures are highly regulated, and compliance and good quality must be ensured in each process. For many years, DG SANTE purchases services in new fields and technically complex environments entailing a relatively high workload for drafting tender specifications. Contract values are usually relatively small which increases the indicator "cost over payments made". In 2020 however, EUR 2 515 million payment credits of the Emergency Support Instrument (ESI) were allocated to DG SANTE ad hoc to support Member States in the health response to the COVID-19 crisis. Most of the money was spent on advance purchase agreements for vaccines. In addition, DG SANTE ran a number of Joint Procurement procedures with Member States to purchase a range of medical countermeasures. The related procurement procedures were prepared ad hoc, under high political pressure and extreme urgency. Although the workload was intense for many colleagues, the indicator "cost over payments made" remains very low given the high amounts involved.

Cost drivers in indirect management for the subsidy payments to agencies are mainly the intense annual exercises of drafting the Commission opinions on the agencies' Strategic Programming Documents (SPDs), DG SANTE's preparation for and attendance of Management Boards and, where applicable, Audit Committees, and the follow-up of the regular external evaluations of the agencies.

2.1.1.4 Conclusion on the cost-effectiveness of controls

Based on the most relevant key indicators and control results, DG SANTE has assessed the effectiveness, efficiency and economy of its control system and reached a positive conclusion on the cost-effectiveness of the controls for which it is responsible.

DG SANTE considers that its control strategy for grants, public procurement and subsidy payments to agencies is cost-effective overall, given the main cost drivers, and the efforts already taken over several years to reduce the cost of controls, without compromising the effectiveness of controls. While in the Food Safety policy area budget implementation tasks have been affected only moderately by the COVID-19 pandemic, and on-the-spot controls could be replaced by remote audits, the health policy area faced a step-change: in addition to the Health programme, with its annual budget of about EUR 66 million, DG SANTE implemented EUR 3 277 million, including the Emergency Support Instrument (ESI). Several public procurement procedures had to be prepared ad hoc, under high political pressure and extreme urgency to support the Commission's contribution to the crisis response. Faced with these exceptional circumstances, DG SANTE co-operated closely with other DGs and horizontal services at the highest hierarchical level to speed up procedures and decide on derogations from rules and procedures.

2.1.2 Audit observations and recommendations

This section sets out the observations, opinions and conclusions reported by auditors – including the limited conclusion of the Internal Auditor on the state of internal control. Summaries of the management measures taken in response to the audit recommendations are also included, together with an assessment of the likely material impact of the findings on the achievement of the internal control objectives, and therefore on management's assurance. More detail on the audits and DG SANTE's follow-up is included in Annex 8.

2.1.2.1 European Court of Auditors

(1) 2019 DAS – compliance audit

In November 2020, the Court published its annual report (2019 DAS) on the implementation of the 2019 budget. The structure of the Court's annual report is adapted to the budget headings of the Multi-annual Financial Framework (MFF) 2014–2020. DG SANTE is part of the policy chapter "Security and Citizenship". In its report, the Court did not address a finding directly to DG SANTE.

(2) Court's review of the COVID-19 health response

On 18 January 2021, the Court published its review on the EU's initial contribution to the public health response to COVID-19. The review covered only actions taken from 3 January to 30 June 2020 and highlights some of the challenges faced by the EU in its support to Member States' public health response to the pandemic given the scale and speed of the required actions.

The Court did not make recommendations but acknowledged that it was a challenge for the EU to complement rapidly the measures taken within its formal remit as public health is primarily a national competence. With regard to the Commission's financial support to vaccine development, the Court highlighted that the Commission mitigated the inherent risk linked to vaccine development by investing in a range of vaccine technologies and companies. The strategy included funding research on vaccine hesitancy as well as fighting disinformation, which could harm the success of mass immunisation campaigns.

(3) Court's special reports

In 2020, DG SANTE was associated to two performance audits: one on the protection of wild pollinators (SR 2020/15) and one on EU decentralised agencies (SR 2020/22). More information is provided in Annex 8.1.1.

Two recommendations were addressed to DG SANTE to improve the protection of wild pollinators in the pesticides risk assessment process. DG SANTE plans to implement the recommendations by the end of 2022 in close co-operation with EFSA and the Member States.

In September, the Court published the performance audit "Future of EU agencies – potential for more flexibility and cooperation" and addressed several recommendations to the Commission central services and to the agencies as a whole. No issue was addressed directly to DG SANTE. Given its work with five EU decentralised agencies, DG SANTE followed the audit closely and will stay abreast of the developments to implement the Court's recommendations.

2.1.2.2 Internal Audit Service

The IAS contributed to DG SANTE's Annual Activity Report for 2020 by submitting a "limited conclusion on the state of internal control" in February 2021. Based on the audit work performed in the period 2018 to 2020, the IAS points to four open recommendations rated 'very important', and as a result concludes that "the internal control systems in place for the audited processes are effective, except for the observations giving rise to the 'very important' recommendations". These recommendations relate to firstly, DG SANTE's IT tool TRACES²⁷ for which DG SANTE enhanced its IT governance and certain IT security aspects, secondly, DG SANTE's Health and Food Audits and Analysis Directorate in which work is on-going to

²⁷ Trade Control and Expert System (TRACES) established by Commission Decision 2004/292/EC pursuant to Council Directive 90/425/EEC

improve the staffing of activities and time reporting and performance monitoring, and thirdly, DG SANTE's financial management of food and feed programmes (including emergency measures) – in particular the unit-cost methodology which is being overhauled. The very important recommendations and DG SANTE's actions are explained in Annex 8.1.2.

DG SANTE believes that the mitigating measures already in place do not put the effectiveness of DG SANTE's internal control system into question and that the identified weaknesses do not warrant a reservation to the annual declaration of the Director-General of DG SANTE.

2.1.2.3 Conclusion on audit results and follow-up

DG SANTE addresses all audit recommendations by proportionate action plans and monitors their implementation regularly. The Director in charge of Risk Management and Internal Control (RMIC) reports on the progress made twice a year, firstly, in the context of the mid-term report on internal control, and secondly, during the annual activity reporting. DG SANTE's implementation of audit recommendations is in general assessed as positive: auditors find DG SANTE's actions appropriate and do not report any improper delays.

None of the issues raised by the auditors met the materiality criteria set out in Annex 5: no critical recommendation was made; no significant repetitive error or material deficiency in the internal control systems of DG SANTE was highlighted. The issues addressed by the Court of Auditors or the weaknesses pointed out in the IAS audits do not point to significant quantifiable errors. Furthermore, DG SANTE is confident that the elements identified could not seriously damage the reputation of the Commission. Therefore, the identified weaknesses are not likely to have a bearing on the content of the annual declaration of the Director-General of DG SANTE.

2.1.3 Assessment of the effectiveness of internal control systems

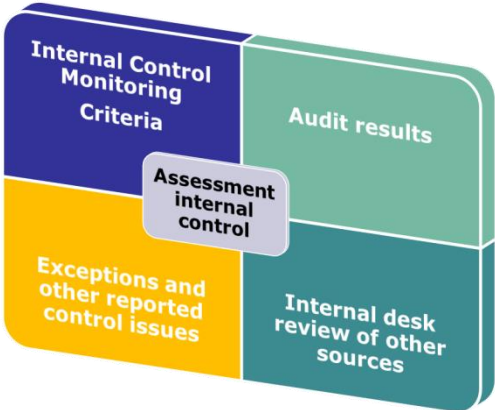
The Commission has adopted an Internal Control Framework based on international good practice, to ensure the achievement of its policy and management objectives. Compliance with the internal control framework is a compulsory requirement.

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 and has due regard to the risks associated with the environment in which it operates.

In its internal control system, DG SANTE embedded continuous monitoring measures to ensure that its management and internal control framework is effective. DG SANTE management assessed the effectiveness of its internal control system and its results following the methodology proposed in the "implementation guide of the internal control framework of the Commission".

The assessment findings are evaluated and any deficiencies are communicated and corrected in a timely manner, with serious matters being reported as appropriate.

The main sources of information and details of the assessment are described in Annex 8.2. DG SANTE assessed its internal control system during the reporting year and concluded that it is effective and that the components and principles are present and functioning well overall, but some improvements are needed for minor deficiencies. These relate to ethics, staff allocation and professional development, functions that are only partially under DG SANTE management. In addition, further attention is warranted to improve senior management’s guidance on “missions, objectives and tasks” and certain elements of DG SANTE’s control activities. Furthermore, the updates of DG SANTE’s IT security plans still need to be finalised in accordance with the corporate methodology.



Further to a restructuring exercise that started in 2019 to adapt DG SANTE’s organisation to the priorities of the von der Leyen Commission, the new organisation chart entered into force on 1 September 2020. In late September 2020, the Director-General left DG SANTE and handed her tasks over to the acting Director-General who became the new Director-General and Authorising Officer by delegation on 16 October 2020. In the second half of 2020, DG SANTE also welcomed two new Deputy Directors-General and one new Director. The handover processes went smoothly (for more detail see Annex 8.2.1).

Throughout the year, the functioning of the internal control system was closely monitored by the systematic registration of so-called "exceptions", non-compliance events and internal control weaknesses. In each case, the underlying causes behind the exceptions and weaknesses are analysed and drawn to the attention of or submitted for approval by the Director-General. In 2020, several possible derogations were discussed with the horizontal services at Director-General level to ensure adequate control and transparency when speeding up procurement procedures to an extent that entailed non-compliances with the Financial Regulation and the Joint Procurement Agreement.

DG SANTE made proper use of exception reporting in procurement procedures for medical countermeasures and vaccines, when facing extreme urgency and numerous uncertainties as to the needs in Member States and the supplies on the market. To assure the successful purchase of urgently needed goods, several non-compliances with the Financial Regulation were recorded, for example, amending tender specifications after their publication to react to rapid changes in the product specifications and needed quantities, and granting extra time to bidders to provide supporting documents for the selection criteria. Furthermore, DG SANTE used a certain amount of flexibility when it came to handling procurement procedures

divided into several lots and when implementing multiple framework contracts in cascade.

DG SANTE also applied some derogations to the Joint Procurement Agreement (JPA) to speed up the conclusion of seven framework contracts for the supply of medical countermeasures. Each derogation was brought to the attention of the participating Member States and met their approval.

In addition, in agreement with DG BUDG, DG SANTE anticipated the new mechanism of the Emergency Support Instrument (ESI) before it was operational. A direct purchase contract for face masks was signed under the Health programme rather than a framework contract under the Joint Procurement Agreement. Due to the extreme urgency to sign the contract within a few days of receipt of the offer, there was no time to conclude a framework contract followed by specific purchase contracts of the Member States. DG SANTE kept the Member States informed at every stage of the procedure.

Throughout 2020, DG SANTE faced an exceptionally high workload with a series of access to documents requests related to its procurement and grant procedures. Special care was taken to safeguard confidential commercial information, and prevent leaks. DG SANTE followed its well-established procedures and no control issue came to the attention of management. The Ombudsman sent DG SANTE an informal recommendation to settle an access to documents request, but did not open a case.

In conclusion, no instances of ineffective controls came to management's attention that would have exposed the DG to serious risks. Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance.

2.1.4 Conclusions on the assurance

This section reviews the assessment of the elements already reported above (in Sections 2.1.1, 2.1.2 and 2.1.3), and the sub-conclusions already reached. It draws an overall conclusion to support the declaration of assurance and whether it should be qualified with reservations.

The information reported in section 2.1 stems from the results of management and feedback received in audit reports listed above. These reports result from a systematic analysis of the evidence available. This approach provides sufficient guarantees as to the completeness and reliability of the information reported and results in a full coverage of the budget delegated to the Director-General of DG SANTE.

In 2020, DG SANTE's on-the-spot control function was able to conduct remote audits when the COVID-19 pandemic prevented traveling. Audits could be finalised at the desk to the effect that sufficient information was available for the declaration of assurance in 2020.

The average residual error rate of 0,8% and the overall risk at closure of 1,6% did not exceed the materiality threshold of 2%. Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance. Taking into account the conclusions of the review of the elements supporting assurance and the expected corrective capacity of the ex-post controls to be implemented in subsequent years, DG SANTE assesses that it has an effective, efficient, robust and reliable internal control system at its disposal.

Despite numerous changes in procedures and deviations from rules to gain more flexibility in urgent procurement procedures, the discussions at the highest hierarchical level, including the horizontal services in the Commission, helped ensure sound financial management.

None of the issues raised by internal and external auditors met the qualitative materiality criteria: based on the audit engagements performed, their objectives and scope, no critical recommendation was made; no significant repetitive error or material deficiency in the internal control systems of DG SANTE was highlighted; neither were elements identified that could seriously damage the reputation of DG SANTE.

Therefore, the identified weaknesses are not likely to have a bearing on the content of the annual declaration of the Director-General and thus, it is possible to conclude that the internal control system provides sufficient assurance with regard to the achievement of the other internal control objectives and no reservation to the declaration is warranted.

Overall Conclusion

In conclusion, management has reasonable assurance that, overall, suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated; and necessary improvements and reinforcements are being implemented. The Director General, in her capacity as Authorising Officer by Delegation has signed the Declaration of Assurance.

2.1.5 Declaration of Assurance

I, the undersigned,

Director-General of Health and Food Safety

In my capacity as authorising officer by delegation

Declare that the information contained in this report gives a true and fair view²⁸.

State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the self-assessment, ex-post controls, the work of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for years prior to the year of this declaration.

Confirm that I am not aware of anything not reported here which could harm the interests of the institution or those of the Commission”.

Brussels, date 30 March 2021

(e-signature)

Sandra GALLINA

Authorising Officer by Delegation

²⁸ True and fair in this context means a reliable, complete and correct view on the state of affairs in the DG/Executive Agency.

2.2 Modern and efficient administration – other aspects

2.2.1 Human resource management

Since the beginning of 2020, the COVID-19 virus dominated activity in DG SANTE, in particular in the Health domain. Crisis management procedures were installed and arrangements for extensive teleworking implemented. This situation is expected to continue through an important part of 2021.

Nevertheless, DG SANTE continued its internal reorganisation as planned to ensure better preparedness for tackling the challenges emanating from the ambitious work programme of the von der Leyen Commission. However, the unforeseen policy changes, which occurred during the year as a result from the COVID-19 crisis, have again imposed rethinking of the DG SANTE organisation and distribution of tasks.

Despite the difficult working context, the pace of recruitment was accelerated to ensure rapid reinforcements, firstly, to assist the teams in the frontline of managing the crisis, and secondly, to prepare for implementing the important budget increase for Health in the context of the 2021-2027 Multi-annual Financial Framework. More information is available in Annex 9.

Considering the exceptional circumstances overall, staff seemed to have coped well with the new ways of working. Although the figures of the December survey on the issue show some concern as the percentage of staff signalling difficulties in coping with the situation rose from 5% to 10%, the staff engagement index for 2020 amounts to 72% and exceeds both the Commission average of 69% and DG SANTE's 2019 staff engagement index of 69%. Nevertheless, the data need to be looked at in the context of some survey fatigue as the staff participation rate decreased from 35% in May to 25% in December.

2.2.2 Digital transformation and information management

The principles of the Commission's digital strategy form the cornerstone of all new digital solutions developed by DG SANTE. Several systems provide fully automated activities, full electronic case handling and electronic signatures respecting the highest level of security and privacy and making use of reusable solutions. Examples are the European Federation Gateway Service (EFGS), the e-Health Digital Service Infrastructure (eHDSI) and TRACES. In 2020, DG SANTE also contributed actively to the corporate digital modernisation strategy focused on identifying synergies across the Commission. DG SANTE led the initiative "Health Policy Agencies Collaboration (HPAC)" focusing on solving common digital challenges for both DG SANTE and the health policy decentralised agencies.

When the COVID-19 pandemic became a priority, DG SANTE developed a number of systems in record time and provided adequate operational solutions (including EFGS, COVID-19 Clearing House and Convalescent Plasma – CCP). Furthermore, truly and fully paperless remote work became possible for the whole DG, allowing

the high degree of collaboration and procedure development during the COVID-19 crisis.

Data, information and knowledge management

During 2020 SANTE prepared for the development of its first **Data Strategy** and an annual **data work plan**. Due to the COVID-19 pandemic, the development of the data strategy had to be postponed to 2021. DG SANTE identified immediate needs of priority policy initiatives related to the COVID-19 crisis as well as to the Europe's Beating Cancer Plan, the Farm to Fork Strategy, and the Pharmaceuticals Strategy. DG SANTE developed a COVID-19 knowledge hub serving as a one-stop shop for all related data and information held in the Commission and EU agencies.

DG SANTE is following the Environment Knowledge Community (EKC) for the purpose of the European Green Deal contributing to areas of relevance for the Farm to Fork Strategy and participating in its biodiversity working group.

Data protection

As in previous years, DG SANTE followed the five objectives specified in the Commission's Data Protection Action Plan (C(2018)7432). In particular, DG SANTE completed the conversion of all legacy notifications related to processing operations already in place before the entry into force of Regulation (EU) 2018/1725 to records.

As a frontline DG in the fight against the COVID-19 crisis, DG SANTE managed many related files, several with important data protection implications (EU COVID-19 Convalescent Plasma Platform, European Federation Gateway Service (EFGS), vaccination certificates). More information is included in Annex 9.

2.2.3 Sound environmental management

DG SANTE has sites 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 itself manages the day to day running of the site in Grange, Ireland, which is 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.

Due to the COVID-19 pandemic, initiatives were not carried out as planned. As the building was closed most of the year, lighting was reduced to the minimum necessary and heating was programmed only to kick-in when internal temperatures dropped below 15°C. Nonetheless, with regard to water consumption, infrared taps were installed throughout the Grange building, which also avoids the need to touch the tap. More information is available in Annex 9.