European Commission

Management Plan 2020

DG Health and Food Safety (SANTE)

Contents

INTRODUCTION

DG SANTE strives to protect human, animal and plant health, promote a high level of food and animal feed safety, contribute to the Union's efforts to ensure sustainable food systems and enable the health and food sectors to achieve their full economic potential.

This Management Plan outlines the DG's political priorities and planning assumptions for 2020. It follows the priorities outlined in DG SANTE's Strategic Plan for the 2020-2024 cycle, which was developed on the basis of President von der Leyen's Political Guidelines and six headline ambitions, and her mission letter to Commissioner Kyriakides. The Strategic Plan translates SANTE's priorities into concrete and operational strategies that will shape its work during this Commission's mandate. It also looks at ways to modernise the way the DG's administration functions and improve efficiency and sustainability.

The strategy is expressed through General Objectives (the Commission's headline ambitions) and Specific Objectives (reflecting the specific contribution of DG SANTE) and includes indicators and targets to allow performance to be tracked.

Part 1 of this Management Plan sets out how DG SANTE will contribute to two General Objectives – (1) A European Green Deal and (2) Promoting our European way of life. Part 2 clarifies how DG SANTE will continue to modernise the administration in 2020 to achieve the greatest possible levels of efficiency and sustainability.

DG SANTE's core work in 2020 will continue to focus on implementing the community acquis related to health and food safety. It will also make an important contribution to the EU's response to the ongoing COVID-19 pandemic.

DG SANTE is committed to the principles of Better Regulation and to fostering simplification of its vast legislative acquis. The most relevant evaluation and impact assessment work is identified in this Management Plan.

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

General Objective 1: A EUROPEAN GREEN DEAL

DG SANTE's work on safe and sustainable food will make an important contribution to the European Green Deal. Safe food is essential for a healthy population and environment. The EU's food safety policy ensures the internal market in this sector runs smoothly and that citizens are well-protected and confident to engage. EU food safety and quality standards are an internationally recognised and respected "trademark". We work to improving the sustainability of the food chain both within the EU and at international level.

EU funding in the food chain area is governed by the **Common Financial Framework 2014–2020** (CFF, Regulation (EU) No 652/2014). Expenditure covers animal health and plant health measures, emergency measures linked to animal and plant disease outbreaks, official controls and relations with relevant international organisations. The total budget of the CFF is EUR 1.892 billion (circa EUR 270 million per year). The CFF finances actions under the specific objective 1.1 in relation to food and feed safety.

In 2020, **veterinary measures** (animal health) are expected to remain the largest share of the food chain budget. They will mostly cover disease prevention through veterinary programmes, emergency measures, crisis management and permanent availability of strategic vaccines in EU funded vaccine banks.

For plants, **phytosanitary measures** are becoming increasingly important due to increased globalisation and trade and new threats. For 2020, the CFF will continue to cover phytosanitary survey programmes and phytosanitary eradication and emergency measures.

DG SANTE will continue to support the Member State's **official control activities** in animal health, plant health and food safety through EU databases, alert and notification tools, activities carried out by the EU Reference Laboratories (EURLs), implementation of the Better Training for Safer Food (BTSF) programme, and management of two Member State networks (for officials responsible for the multi-annual national control plans and national audit systems). DG SANTE will continue to verify, through audits, the performance of official controls in Member States and third countries exporting to the EU.

The **2021-2027 Multiannual Financial Framework** (MFF) is essential to deliver the European Green Deal agenda. The **Single Market Programme** (SMP) will govern activities on food and feed safety for the 2021-2027 period. Food safety programmes are key to

ensure a high level of human, animal and plant health and safe food, and improve animal welfare and the quality of official controls. In 2020, DG SANTE will draw up work programmes, guidelines and standard operating procedures to help complete the inter-institutional process and establish the food and feed strand of the SMP.

Working in partnership with the EU's decentralised agencies. DG SANTE's work is supported by five decentralised EU agencies: the Community Plant Variety Office (CVPO), the European Food Safety Authority (EFSA), the European Agency for Medicines (EMA), the European Centre for Disease Prevention and Control (ECDC), and the European Chemicals Agency (ECHA). Collectively, they offer a wealth of scientific resources, expertise and network opportunities to support evidence-based policy making.

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. DG SANTE aims to ensure proper implementation of the extensive legislation in food and feed safety and animal and plant health, and to simplify it where possible. It takes a "One Health" approach to preparedness and prevention, integrating human, animal and environmental health, food and feed safety wherever applicable. Food and feed safety is often directly linked to public health.

Ensuring animal health and managing and isolating outbreaks of major animal disease. DG SANTE manages measures to prevent, control and eradicate animal diseases transmissible to animals or humans, and requirements for moving animals and animal products into the EU. One of the most important tasks is ensuring the EU can rapidly isolate and eradicate **outbreaks of major animal diseases**, such as African swine fever and highly pathogenic avian influenza.

A new **EU Animal Health Law** (AHL) will apply from 21 April 2021. In 2020, DG SANTE will ensure the remaining tertiary legislation needed to implement this Law is adopted.

At the same time, we will continue to adapt the EU legal framework to reflect the evolving disease situation and provide financial support for measures implemented in EU and neighbouring non-EU countries, taking into account the Global Framework for the Progressive Control of Transboundary Animal Diseases (GFTADs).

For 2020, the Commission received 147 applications for **veterinary programmes** to tackle animal diseases - 146 have been approved for funding (at the time of writing). These programmes target transmissibleanimal diseases, which are often epidemic and can have a direct impact on public health and can trigger significant economic costs.

Preparedness and early response will be strengthened and supported by other relevant instruments - including audits by DG SANTE, EU Veterinary Emergency Team (EUVET) missions, BTSF training courses, and EU Reference Laboratories and Centres (EURLs and EURCs).

EU support for animal disease eradication, control and monitoring programmes accounts for the largest proportion of spending under the CFF food safety programme. The budget for implementing national veterinary programmes in 2020 is EUR 116.4 million. EU funds will also be available during crises to co-fund emergency measures to quickly eradicate and prevent disease spread. The budget for these is EUR 20 million in 2020.

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. This law includes rules on moving plants and plant products within the EU, and a strict regime for imports of plants and plant products that might host dangerous pests. In 2020, DG SANTE will adopt some additional tertiary legislation to ensure the new Plant Health Regulation is implemented smoothly. We will also use the first-ever International Year of Plant Health to raise awareness of EU plant health rules and their role in preventing plant disease and promoting biodiversity.

DG SANTE works proactively to **detect early, notify, contain and eradicate pests** found in the EU. Prevention, preparedness and management of plant health crises will remain a core part of our work in 2020. In line with the new plant health regime, detailed containment measures will be put in place for all regulated quarantine pests that cannot be eradicated.

DG SANTE will also continue to manage interceptions/outbreaks (e.g. Citrus black Spot, Xylella, Pine Wood Nematode, Anoplophora, Spodoptera) by adapting specific measures to the evolving situation. We will update the lists of quarantine pests, regulated non-quarantine pests, permanent import requirements, and protected zones. A comprehensive review of the legislation on *Xylella Fastidiosa* will be adopted and DG SANTE will also evaluate Member States' requests to co-finance the implementation of EU emergency and eradication measures. Requests for co-financing emergency measures may go up to EUR 40 million.

National survey programmes for plant pests support the earliest possible detection and eradication of about 50 of the regulated quarantine pests on EU territory. In 2020, SANTE will prepare surveys with a view to the new Single Market Programme and process applications for 2021, and the final reports for 2019 surveillance activity. The budget in 2020 for implementing plant health survey programmes is EUR 13.8 million.

Ensuring market access to safe substances and products. SANTE is responsible for risk management decisions and risk communication for placing substances for food related uses on the market. In 2020, DG SANTE, in cooperation with EFSA, will carry out preparatory work for implementing the **Transparency Regulation** - which will considerably change the landscape for EU risk assessment in the food chain. The main priorities are: adapting the Commission rules in different sectors of the food chain to prepare for early and transparent publication of the data that underpins requests for market authorisations; adapting and drafting Commission and EFSA guidance; rollout of the Food System Common Authorisation

Process to submit authorisation and approval dossiers/applications in electronic format across all food sectors (except for plant protection products) and preparing the conduct of fact-finding missions in testing facilities. All this will be done in close collaboration with EFSA, Member States and stakeholders.

DG SANTE oversees the **authorisation and approval processes for substances** used in food and feed production and processing. In 2020, we will continue to authorise a range of substances whose safety has been positively assessed. If their safety for health/the environment is not established, newly requested authorisations will be denied and existing ones will be withdrawn or not renewed.

These authorisations include: new substances and new uses of already authorised substances used as food additives (about 10 legislative amendments authorising new additives and extending the uses of already authorised additives per year), food flavourings (about 3 amendments authorising new flavourings and amending the use of those already authorised per year), novel foods (over 80 applications and notifications expected in 2020), and substances used in plastic food contact materials (about 15 substances added yearly to the list of authorised substances, or their use extended).

DG SANTE will also authorise health claims, generic descriptors, nutrition claims, vitamins and mineral substances as per legal obligations. Regarding the addition of substances other than vitamins and minerals in food, DG SANTE will continue to examine their safety, whenever necessary, and adopt the necessary measures to ban or restrict their use based on EFSA scientific assessment.

New approvals and renewals of previously approved active substances in plant protection products and biocides will be proposed on the basis of safety evaluations. These will include decisions on low-risk active substances. In 2020, we expect around 10 decisions on new active substances, around 20 proposals for renewal/non-renewal of approval of active substances, and around five proposals for approval/non-approval of basic substances. DG SANTE will also increase overview of Member States' activities on emergency authorisations. In biocides, around 15 decisions on existing and new active substances and around 20 decisions on authorisations for biocidal products are expected.

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

SANTE will present draft proposals for around 70 routine MRL applications for specific crop-commodity combinations and for the full review of around 25 active substances, as well as Regulations lowering MRLs for about 20 substances following non-renewal decisions and expiry of approvals of active substances. Maximum levels for contaminants in feed and food will also be set via Commission Regulations based on EFSA opinions. In 2020, it is

foreseen to set maximum levels for acrylamide, MCPD-esters, cadmium and lead. Discussions will begin or continue to set maximum levels for other contaminants such as quinolizidine alkaloids, arsenic and perfluoroalkylated substances.

Moreover, DG SANTE will continue to process GM food and feed applications (37 pending in EFSA) based on favourable opinions by EFSA.

For veterinary medicines, in 2020, we will handle new authorisations (around 12), referral procedures (around 6), renewals of marketing authorisations (20 procedures) and about 4 to 8 procedures for setting MRLs for veterinary medicines.

We will propose re-evaluations of authorisations, new authorisations, modifications of authorisations and renewal of authorisations of feed additives based on the outcome of safety evaluations (over 50 implementing regulations approving some 80 feed additives and 10 amendments of existing authorisations are expected in 2020), including confidentiality decisions. This will cover some essential elements, including vitamins, amino acids, trace elements, some microorganisms aimed at boosting the reduction of the use of antimicrobials, as well as new substances to mitigate the impact of animal breeding in the environment.

At the same time, we will do considerable preparatory work for the tertiary legislation needed to implement the new EU Regulations on veterinary medicinal products and medicated feed, to apply from 2022 onwards.

DG SANTE will actively support the identification and prioritisation of relevant needs related to research and innovation, and will seek to incorporate them into the activities of Horizon 2020 and the forthcoming Horizon Europe.

Performing effective, efficient and reliable controls. Strict enforcement of the EU's rules on food safety, animal health, plant health and animal welfare is essential to ensure that our high standards are not compromised.

In 2020, DG SANTE will ensure continued and smooth implementation of the new **Official Controls Regulation** (OCR). It will adopt additional tertiary legislation, including on official certificates for movements within and entry into the EU territory, jointly with the Animal Health Law.

We will continue to carry out controls including **audits**, in both EU and non-EU countries exporting to the EU, to verify that the EU's high food safety standards are complied with. Audits are explicitly mentioned in Commissioner Kyriakides' Mission Letter as a crucial tool to implement and enforce the EU's extensive and mature legal framework on food safety.

Due to the COVID-19 crisis, many audits which were initially planned for 2020 have been postponed or cancelled. The revised programme for 2020 includes 117 in the area of food safety and quality, animal health, animal welfare and plant health in both EU and non-EU

countries. However, there may be further cancellations or postponements due to COVID-19 pandemics and DG SANTE is exploring to what extent some audits can be done remotely.

In 2020, DG SANTE will develop its control plan for 2021-2025 and adopt its programme of controls in Member States as an implementing act for the first time, in line with the new Official Controls Regulation. DG SANTE will prepare the Commission's report on the operation of official controls in Member States for the period 2017-2018. DG SANTE will continue to manage **enforcement cases and the safeguard cell** (SGC) for EU and non-EU countries.

DG SANTE will exchange **with Member States** to ensure coordination and consistency in applying the official controls legislation, bring forward enforcement matters and find concrete solutions. This takes place in High Level meetings between SANTE and Member States' authorities, technical meetings and the "Better Training for Safer Food" (BTSF) initiative. Around 160 BTSF training courses on EU legislation were planned for Member State staff responsible for official controls, but since the programme was put on hold on 6 March 2020 due to COVID-19, a number will be cancelled or postponed. It will resume when the epidemiological situations allows safe travel for participants and trainers. The 2020 budget for BTSF is EUR 19 million. DG SANTE will continue to manage the BTSF Academy e-learning platform.

SANTE manages two Member State networks - the Multiannual national control plans (MANCP) and the National Audit System (NAS) networks. They aim to enhance official control systems in Member States. In 2020, 5 plenary meetings and 4 subgroup meetings are planned.

In the context of Brexit, the correct application of controls on imports into **Northern Ireland** from Great Britain (or other non-EU countries) after the transition period ends must continue to be ensured.

The EU Reference Laboratories (EURLs) contribute to better implementation of EU legislation in the agri-food chain and the credibility of the food production system. EURLs will support the Commission and national reference laboratories, helping to provide state of the art analytical and diagnostic services to national authorities and enforcement bodies. The 2020 budget for the EURLs is EUR 19 million.

Maintaining well-developed rapid alert systems. Crisis management in the food and feed sector is supported by a number of well-established tools, notably the EU's rapid alert systems. They aim to identify problems early and allow rapid information sharing, response and effective cooperation. Each year, there are about 7000 notifications in the RASFF network, 300 suspected cases of food fraud and 1500 cases of non-compliance, 2 million certificates in TRACES.

Effective official controls depend on DG SANTE's implementation and management of the Integrated Management System for Official Controls (IMSOC) - established by the new OCR - and integrating the existing Trade Control and Expert System (TRACES) and EU alert

systems (RASFF and EUROPHYT) into IMSOC. This will ultimately simplify border controls and allow full paperless procedures.

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

As tasked by President von der Leyen in her Mission Letter to Commissioner Kyriakides, DG SANTE leads on the new Farm to Fork (F2F) Strategy for sustainable food, which lies at the heart of Europe's Green Deal. The Communication presenting the F2F Strategy will be the main DG SANTE deliverable under this Specific Objective. Its overall aim is to accelerate the transition towards a sustainable food system. This should have a neutral or positive environmental impact, be able to adapt to climate change and contribute to climate change mitigation, ensure food security and public health, make healthy diets the easy choice and generate fair economic returns in the supply chain.

Following the Communication's publication, DG SANTE will begin preparatory work on a policy framework for sustainable food systems, underpinned by evaluations and impact assessments where necessary. It will strive to ensure coherent implementation of the Strategy across different policy areas and full buy-in by stakeholders, Member States, trade partners and international organisations. DG SANTE will also organise the first annual conference on the F2F Strategy and implement a wide ranging communication effort, including a high visibility event on World Food Day (16 October). It is a main contributor to the corporate communication campaign on the Green Deal.

SANTE will also contribute to the Commission's guidance to Member States for preparing the National Strategic Plans (NSPs) under the Common Agricultural Policy. In particular, it will contribute to the SWOT analysis linked to pesticides, animal welfare and antimicrobials and as a first step, support preparation of the NSPs at technical level. This aims to ensure the NSPs make an effective contribution to the Commission's objectives and improve policy consistency across the environment, public health, animal health, plant health and animal welfare objectives.

At the same time, DG SANTE will work to modernise EU legislation and reduce its burden. Several reports on REFIT evaluations were published with the strategy, notably those on the Regulation on nutrition and health claims, and the legislation on pesticides and their residues. Others, such as the evaluation of the Food Contact Material (FCM) legislation and of the legislation on feed additives will continue in 2020 and will feed into the subsequent implementation of the F2F Strategy.

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

In 2020, DG SANTE will also work on the revision of the Sustainable Use of Pesticides Directive (SUD) based on an ex-post evaluation to be conducted back–to-back with an impact assessment of possible options for change. The revision aims to reduce the risks and impacts of pesticide use on human health and the environment and improve the availability and usability of sound data and statistics on the use of pesticides in the EU and reinforce evidence-based policymaking.

It will also facilitate placing on the market of plant protection products containing biological active substances and substituting pesticides containing hazardous substances. On the latter, it will do further evidence gathering and impact assessment work where necessary. In addition, DG SANTE adopted as part of the F2F Strategy package, the second SUD implementation Report to the Council and the Parliament, and will start work to improve the existing indicators established under the SUD.

DG SANTE will continue targeted SUD-related audits in Member States and organise 'Better Training for Safer Food' training to exchange best practices specifically on implementation of Integrated Pest Management (IPM) - the cornerstone for low-pesticide-input pest management, for which general principles are laid down in the SUD. We will also continue to work with Member States to deliver actions identified in the implementation plan on sustainable plant protection.

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

We will also complete the preparatory work to adapt data requirements and guidance on assessment methodologies for microorganisms to facilitate their market access as low-risk active substances. We will adopt the first list of prohibited co-formulants, and continue to work with EFSA and the Member States to further develop the methodology for cumulative risk assessment of pesticides residues. And we will take into account environmental aspects when assessing requests for import tolerances for pesticide substances no longer approved in the EU and using diplomacy, trade policy and development support instruments to promote the phasing out, as far as possible, of such pesticides and to promote low-risk substances and alternatives to pesticides globally.

Reducing the use of antimicrobials in animals to contribute to the fight against AMR. DG SANTE will capitalise on the recently adopted EU Regulations on veterinary medicinal products and medicated feed to set in motion actions to achieve the F2F target

of reducing the overall EU sales of antimicrobials for farmed animals and aquaculture by 50%, by 2030. In particular, DG SANTE will prepare the tertiary legislation necessary to implement these Regulations, to enable their application as of 2022.

DG SANTE will continue to promote vaccination, animal husbandry systems and feeding regimes which support good animal health and welfare to reduce the need for antimicrobials. The results of the evaluation of the Feed additives legislation will be accounted for in light of the "One health" approach. DG SANTE will also pursue the implementation of the 2017 AMR action plan.

Revision of the legislation on AMR monitoring in foods, included imports, has also been initiated, based on a recent EFSA opinion. It will need to be completed by mid-2020 to allow monitoring to start in January 2021 for the next seven years.

Fostering the use of innovative and more sustainable feeds. To reduce the environmental and climate impact of animal production, DG SANTE strives to facilitate the placing on the market of sustainable and innovative feed additives. We will complete the evaluation of the feed additives legislation by the end of 2020 to assess its fitness for purpose, and launch an Impact Assessment in parallel. A possible review of the feed ban linked to BSE-eradication will also be explored.

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 reduce food loss across the supply chain. In 2020, DG SANTE will help drive and reinforce action at national level, notably to curb consumer food waste, guided by the recommendations of the EU Platform on Food Losses and Food Waste, which will meet twice during the year.

In order to mobilise players and promote evidence-based best practice, DG SANTE will establish a new one-stop, digital resource center, the EU Food Loss and Waste Prevention Hub, for information on food waste prevention initiatives, results, tools and EU funding opportunities.

Moreover, cooperation with international organisations such as FAO and the UN Environment Programme will be pursued in the context of monitoring SDG Target 12.3 and the launch of the first International Day on Food Loss and Waste (29 September 2020).

Following the introduction of an EU measurement methodology, DG SANTE will work closely with other Commission services and Member States to implement food waste prevention measures and start preparatory work to set legally binding food waste prevention targets. It will also carry out consumer research on date marking and launch an impact assessment with a view to eventually proposing revised EU rules to prevent misunderstanding and misuse of these tools in the supply chain. Finally, SANTE will contribute to investigating the extent and causes of food losses in primary production.

Ensuring a sustainable food production that improves the welfare of animals. Good treatment of animals is an integral part of sustainable food production. In 2020, DG SANTE will ensure follow-up of the European Court of Auditors 2018 recommendations and the EU Parliament resolution[1] by completing the evaluation of the EU Animal Welfare Strategy 2012-2015.

We will launch specific animal welfare actions foreseen in the F2F Strategy. This includes a Fitness Check of the animal welfare legislation, taking into account the latest scientific evidence and evolution of societal expectations and consumers' demands. The evidence collected will inform further reflection on available options to improve the current legislative framework. Scientific evidence will be updated with EFSA's assistance. The Commission will also consider options for animal welfare labelling as a means to contribute to sustainable food consumption.

DG SANTE will manage the EU Animal Welfare Platform, and implement and follow-up regular enforcement activities on animal transport and the welfare of pigs. It will ensure coordination of the network of Animal Welfare Reference Centres. It will also manage two major pilot projects linked to animal welfare - on laying hens and dairy cows.

The decision of the European Parliament to establish a Committee of Enquiry on animal transport will imply considerable input from DG SANTE during the 12 months of its operation – from September 2020. The remit of the Committee is to investigate alleged

[1] European Parliament resolution of 14 February 2019 on the implementation of Council Regulation (EC) No 1/2005 on the protection of animals during transport within and outside the EU (2018/2110(INI))

failure to enforce EU legislation on animal welfare during transport by both Commission and Member States.

Fighting against food fraud. Combating food fraud is essential to protect the safety and quality of EU food products, to protect consumers and ensure sustainable food systems.

The EU Food Fraud Network will continue to coordinate responses to suspected food fraud. DG SANTE will continue to work with Member States, other relevant DGs, OLAF, EUROPOL and INTERPOL to ensure better cooperation and coordination of national investigative services, and to ensure effective data analysis and intelligence sharing at EU level.

Empowering consumers to make sustainable and healthy food choices through the provision of food information. DG SANTE will work to improve consumer information, notably by looking at ways to address demands for more visible and complete information, especially on the health benefits and sustainability of food products.

We will continue working on the implementation of Regulation (EU) No 609/2013 on foods for specific groups. In this context, DG SANTE will continue working on the preparation of a delegated act on compositional requirements for baby food.

In food labelling, DG SANTE will launch an Impact Assessment on Front of Pack/nutrient profiles/origin labelling of certain products with a view to a subsequent legislative proposal. However, until then, notified national measures on mandatory origin labelling will continue to require substantial follow-up.

Moreover, DG SANTE will ensure proper response, including EU wide measures, to the European Citizens' Initiative 'Eat original - Unmask your food', and launch preparatory work for an impact assessment on sustainable food labelling.

Finally, DG SANTE will ensure implementation of the rules on food information to consumers (Regulation 1169/2011). It will continue to operationalise a Food Labelling Information System encompassing all EU and national mandatory labelling indications to support food business operators.

Supporting innovation in the food chain, especially via the promotion of novel food, plant reproductive materials and innovative techniques. DG SANTE will continue to capitalise on Horizon 2020 results and will facilitate new opportunities under Horizon Europe to deliver new knowledge and data to support the F2F Strategy on food waste, find alternatives to antimicrobials and synthetic chemical pesticides and improve access to healthy diets.

In the field of novel food, authorisation applications processed by DG SANTE (see Specific Objective 1.1 – Market access for safe substance) will include requests for authorisations of insects, plant-based meat and algae-derived products as novel foods in Europe following the scientific advice of the European Food Safety Authority.

On seeds and plant reproductive material, DG SANTE will ensure proper and timely implementation of the Plant Reproductive Material legislation, certification and marketing requirements and the Community Plant Variety Rights legislation, including the work carried out by the CPVO. DG SANTE will continue to register new improved plant varieties in the Common Catalogues for marketing throughout the Union.

In addition, DG SANTE will work on two studies to follow up the Council's request under Article 241 TFEU. One will focus on the Union's options to update the existing legislation on the production and marketing of plant reproductive material. The other (to be completed by end April 2021) will focus on the status of new genomic techniques under EU law following the ruling of the EU Court of Justice. The Commission will also report on Member States' experience of the contained use of genetically modified microorganisms in 2020.

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

Food packaging plays a key role in food systems' sustainability. DG SANTE will continue to revise the Food Contact Materials framework legislation, conducting in parallel its evaluation and the launch of the corresponding Impact Assessment process. In the run-up to the revision of the Food Contact Materials legislation, we will pay special attention to the reduction of citizens exposure to endocrine disruptors.

In parallel, the Commission will further explore how to best address the migration into food of various heavy metals from ceramic and vitreous food contact materials. A study supporting the Impact Assessment will be launched in 2020, enabling the consideration of health-protective measures to reduce consumers' exposure to heavy metals.

Linked to the Commission's work on the European strategy on plastics, DG SANTE will continue to prepare, with a view to ultimately adopt, Decisions for around 140 authorisations of mechanical PET plastic recycling processes and related targeted amendment of plastics recycling legislation. This promotes the uptake of recycled plastics by the food packaging industry, which accounts for a major part of plastic packaging.

Specific Objective 1.3: International promotion of EU food safety standards

DG SANTE will enhance its work 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 steers the Commission's position and coordinates Member State input to ensure policy coherence between our internal policy actions and external engagement on the global stage.

The Green Deal and Farm to Fork call for an ambitious international agenda. DG SANTE will foster international discussions to promote the shift to sustainable food systems in multilateral fora and at bilateral level. This work will contribute to the EU 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. The EU is the largest exporter and importer of food in the world with a well-recognised and respected framework of food safety legislation. In 2020, DG SANTE will continue to promote food safety and quality standards, and the new F2F Strategy through its work in multilateral fora. It will also promote and support existing and new relevant initiatives of FAO, WHO and other UN agencies with specific attention on the 2021 UN Food Systems Summit.

In the context of the **World Trade Organization** (WTO), DG SANTE will contribute to the preparation of meetings of the WTO governing bodies and seek to seize other opportunities to promote the EU regulatory system. At meetings of the WTO SPS Committee, DG SANTE will promote and defend EU interests in the field of sanitary and phytosanitary measures and defend EU legislation on food safety, animal health and plant health that is increasingly challenged by non-EU countries. In particular, it will continue to address the criticisms on EU policy on pesticides, which are expected to increase following the adoption of the Farm to Fork Strategy, or on the new EU rules on plant health and veterinary medicines. DG SANTE will also continue its work in the context of the WTO Committee on Technical Barriers to Trade (TBT) in certain policy areas, such as food labelling, halal meat and animal welfare.

In the **World Organisation for Animal Health** (OIE), DG SANTE defends the EU's high animal health and welfare standards and works to influence and promote international standards. In 2020, DG SANTE will continue to coordinate EU positions within the **Codex Alimentarius** and lead or contribute actively to Codex work in priority areas to promote food safety at international level and ensure as far as possible that EU legislation and Codex standards are aligned. Special attention will be paid to priority or sensitive dossiers such as the revision of the code of practice to minimise and contain AMR and new guidance on integrated surveillance on AMR by the AMR Task Force; the prevention and control of food fraud; the adoption of Codex Maximum Residue Limit (MRLs) for pesticide residues and veterinary medicinal products; and the development of guidelines on front-of-pack labelling and nutrient profiles. The EU will continue scrutinising the provisions on food additives under discussion to ensure they fulfil the strict EU criteria and lead the important work on the technological justification of certain additives used in foods for infants. For the Codex Committee on contaminants in food the EU positions will be defended, including for cadmium in chocolate and aflatoxins in cereals and cereal products.

DG SANTE will actively participate and contribute to the intersessional activities under the **Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety.** EU positions and statements will be coordinated and used for negotiations towards the Conference of the Parties of the Convention on Biological Diversity (COP) and the meeting of the Parties of the Cartagena Protocol (COP-MOP), to be held early 2021. DG SANTE will also contribute to the biosafety component in the post-2020 global biodiversity framework. In the **International Plant Protection Convention** (IPPC), DG SANTE will continue to coordinate the EU input on global plant health strategy, including the IPPC Strategic Framework for 2020-2030 and 2020 Ministerial declaration, the development of

international standards and guidelines for phytosanitary measures and will actively participate in the events linked to the International Year of Plant Health.

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

The EU is one of the world's largest exporters of seeds. International policies on seeds are important for jobs, food security, to adapt to climate change and ensure sustainable agricultural production. In 2020, DG SANTE will continue to work towards international harmonisation and governance in the area of seeds and in particular towards implementing the **OECD Seed and Forest Schemes** strategies. It will work to improve cooperation and guidance within the **International Union for the Protection of New Varieties of Plants** (UPOV), and improve access to plant genetic resources and sharing in the context of **International Treaty on Plant Genetic Resources for Food and Agriculture** (ITPGRFA).

DG SANTE will seek to strengthen relationships with the **African Union** in the context of our contacts in international organisations. The EU is uniquely well-positioned to assist the African Union, the Regional Economic Communities and African countries to build up a better continental integrated SPS regulatory framework and the implementation of international SPS standards. This will be translated into fair trading relations with Africa, to support opportunities for sustainable food systems in Africa. It will also allow safer products to better reach the EU markets.

Regarding WHO, DG SANTE will engage in implementation of the WHA Resolution on strengthening food safety, prepared under EU leadership. It will contribute to the development of a new WHO strategy on food safety (expected adoption in 2022) and sustainable financing of scientific advice or the engagement of WHO in the development of sustainable food systems. DG SANTE will engage in discussions at WTO level on the commercial aspects of promoting sustainable food systems.

Improving bilateral trade relations. The EU's external trade requires direct engagement with trade partners to ensure the relevant safety requirements are met to protect health and prevent trade disruption. The main activities planned for 2020 are to negotiate safe, secure and harmonised export conditions for EU products with non-EU countries and to manage, monitor and implement existing agreements. Ensuring trading partners will adopt proportionate measures respecting international principles in reaction to occurrences of animal diseases in particular (regionalisation) is also expected to remain a significant challenge. SANTE will work on the cooperation with trade partners in a horizontal way, through the Partnership instruments and training programs.

In this area, ensuring smooth trade relations with the UK whilst preserving EU interests is an additional challenge. Non-EU country relations need to be established with the United

Kingdom before the end of the transition period (currently 1 January 2021), when it leaves the internal market.

We will also promote the F2F Strategy internationally – seeking to build "green alliances" with like minded non-EU countries - and advocate for a global agreement on AMR. It will engage with major global players and strategic partners to achieve the objectives of the WHO global action plan on AMR.

DG SANTE will lead negotiations on **SPS chapters** in the Free Trade Agreement negotiations underway, or planned, e.g. Australia – New Zealand (deadline end 2020), Indonesia, Chile, Eastern and South African countries (ESA). It will monitor the ratification process of the EU-Mercosur Agreement and prepare for the entry into force of recently ratified agreements (Vietnam and Singapore). It will contribute to the post-Brexit negotiation of the Agreement with the United Kingdom through the preparation of SPS requirements for trade in agri-food products, and seek to update the EU-Switzerland SPS Agreement to possibly extend its scope to include the entire food safety area. For agreements in force, DG SANTE will manage and ensure enforcement of those linked to the Eastern Partnership, the EU-Canada Comprehensive Economic and Trade Agreement (CETA), EU –JAPAN Economic Partnership Agreement (EPA), the Partnership Agreement with New Zealand and the agreement with Chile.

DG SANTE negotiations are based on the concept of ensuring fair and balanced market access, with the EU considered as a **single entity** for export, rather than a collection of 27 individual Member States assessed independently. In practice, this means striving for the EU trading partners to accept EU-wide applications for export, and to carry out audits based on visits to a representative sample of Member States.

DG SANTE will also aim for successful negotiations of **enlargement related dossiers**. In particular, DG SANTE will screen for candidate countries and set benchmarks (North Macedonia, Albania), assess the fulfilment of the latter (Montenegro, Serbia and Turkey), and manage the "Green line" Regulation in the context of the Cyprus settlement case. It will also contribute to implementing the Green Agenda for Western Balkans and to actions aiming to establish sustainable food systems in the region. Furthermore, it will implement a capacity building project for veterinary services in the Western Balkan countries, set up with support of DG NEAR.

DG SANTE will continue to pursue better **bilateral SPS relations** with key commercial partners, notably maintaining the technical dialogue with Russia and Eurasian Economic Union countries, and implementing and revisiting the MoU with China. With regard to mutual recognition, DG SANTE will pursue the completion of the EU-Australia mutual equivalence recognition project for beef and pork, the EU-Japan mutual recognition project on regionalisation, and launching the EU-China project on regionalisation.

General Objective 2: PROMOTING OUR EUROPEAN WAY OF LIFE

In 2020, DG SANTE is working with Member States on all fronts to tackle the COVID-19 outbreak. The first priority is to guarantee the health and safety of European citizens, protecting people from the spread of the virus, supporting the health systems and health workers and facilitating the supply of protective and medical equipment across Europe while working towards the development and equitable distribution of COVID-19 treatments, vaccines and diagnostics.

Guaranteeing access to high-quality health care is a key objective of social protection systems in EU countries. For many citizens, health and healthcare are a fundamental part of how they understand their social fabric and the European way of life. The European Pillar of Social Rights stresses the right to timely access to affordable, preventive and curative health care of good quality in Principle 16[2]. The EU promotes cooperation among EU countries in this area focusing in particular on access, quality, resilience and sustainability of health systems, and the coordination of responses to cross-border health threats, such as the COVID-19 pandemic. In the field of medicinal products where there is a well-developed EU regulatory framework, DG SANTE ensures the functioning of the internal market where medicines meet the requirements relating to safety, quality and effectiveness.

EU funding for health: In 2020, DG SANTE will continue to manage the final accounting and reporting of the outgoing primary funding mechanism for action on health, the 2014-2020 Health Programme and deliver the ex-post evaluation of the third Health programme, while focusing on the adoption by the co-legislator of the new EU4Health Programme[3].

The proposal for a new, much strengthened, Programme, which represents a turning point in EU funding in the area of health, replaced the original proposed Health strand in the ESF+ programme. The broader objectives of the new Programme take into account the first lessons learnt from the COVID-19 crisis and seek, on the one hand, to improve health crisis preparedness and coordinated management and improve the availability and affordability of medicines, medical devices and other crisis relevant products, and, on the other hand, to strengthen health systems and the healthcare workforce in the Member States by addressing the long-term challenges that health systems, patients, and society as a whole, are facing. The programme will also fund actions to implement the Cancer Action Plan and the Pharma Strategy that the Commission will adopt at the end of this year.

Actions under the Programme will be implemented in keeping with the 'One Health' approach wherever relevant, in acknowledgement of the interconnection between human health and animal health and more broadly with the environment, and will also support

[2] The European Pillar of Social Rights in 20 principles

[3] REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the establishment of a Programme for the Union's action in the field of health –for the period 2021-2027 and repealing Regulation (EU) No 282/2014 ("EU4Health Programme") https://ec.europa.eu/info/sites/info/files/com_2020_405_en_act_v11.pdf

Member States in achieving the health-related United Nations Sustainable Development Goals (SDGs).

In 2020, DG SANTE will prepare strategic guidance as well as the first "EU4Health" work plan to direct health funding in the most effective and efficient way under the new Programme. Where needed for the implementation of the Programme, new legislation will be proposed.

For the implementation of the new programme, DG SANTE will work on maximising coordinated action with other Union funds and instruments available in the area of health. Synergies will be sought with the health cluster of the Horizon Europe research programme, including its Cancer Mission, with the European Social Fund Plus (ESF+), the European Regional Development Fund, the Digital Europe Programme, and the Connecting Europe Facility 2. Working across programmes, and having shared objectives between policies will be key considerations to channel health funds across policies and support the achievement of their objectives effectively. An important part of this work will be to collaborate with other DGs (CNECT, ECFIN, ECHO, EMPL, REFORM, REGIO, RTD) and the European Investment Bank, as well as to define consultation processes for cooperation and exchange between health authorities, and the civil society health constituency.

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 will put forward Europe's Beating Cancer Plan to support Member States to improve cancer prevention and care, which will allow Europe to take the lead in the fight against cancer. In 2020, DG SANTE will prepare and adopt the Cancer Plan, which is a key priority for Commissioner Kyriakides. It will include actions at EU and national level needed to deliver on beating cancer along the following four cornerstones: prevention, early diagnosis, treatment, and survivorships. A close link will be established with the research mission on cancer in the future Horizon Europe programme.

Consultation on the Action Plan involves all concerned actors, from public authorities to citizens. The launch event at the European Parliament on 4 February 2020 (World Cancer Day) began a large consultation process which requires dedicated communication channels with stakeholders and citizens, including citizens' dialogues in Member States and sustained communication activities throughout 2020.

Cancer is a disease which deeply affects large parts of society and DG SANTE is determined to take full account of stakeholder views in 2020. The work in this regard will encompass a Roadmap consultation; a public consultation closed on 21 May; and targeted consultations running until the third quarter of 2020. Almost 2 500 replies were received so far showing the large public interest in the Cancer Plan. The outcomes of close and regular consultation with a number of key stakeholders – such as the European Parliament, the Member States, the Cancer Mission Board and health professionals – will also feed into the Cancer Plan. The

European Week Against Cancer was used as an occasion to further promote the Commission's work via social media.

The Cancer Plan will also build upon DG SANTE's work on health systems and investments for health. Important issues include (i) access to cancer services and to innovative medicines for cancer; (ii) continuity of care, with integrated approaches for diagnosis, treatment and follow-up care; (iii) health workforce (new roles, training and up-skilling of health professionals); and (iv) investments (in infrastructure, innovative technologies, new care models and health workforce skills).

In 2020, DG SANTE will also continue its current work on the development of cancer guidelines and cooperate with national and regional authorities through the European Network of Cancer Registries (ENCR). DG SANTE will pursue cooperation with the JRC as well as relevant EU agencies and international bodies to gather epidemiological data on cancer and chronic diseases to support health policy decisions at EU level and by the Member States. The focus will be on health determinants, including environmental and climate-related ones. DG SANTE will cooperate with DG CLIMA and the European Environment Agency to build a virtual observatory on health impact of climate changes.

Tobacco

DG SANTE has long engaged in the global efforts to reduce tobacco consumption, which is the main risk factor in cancer. DG SANTE will continue to implement EU legislation and global initiatives aimed at reducing the consumption of tobacco. In 2020, tobacco control work will focus on the integration of tobacco control work as a cornerstone of the prevention part of the new Cancer Plan; on laying the preparatory and ground work for the May 2021 report on the implementation of the Tobacco Products Directive and of the future evaluation of the tobacco acquis, and managing a number of studies, (on the application of the Tobacco Products Directive 2014/40/EU, on consumer preference and perception of specific categories of tobacco and related products and on smoke-free environments and on advertising of tobacco and related products); and on the preparation of and participation in COP9 of the Framework Convention on Tobacco Control (FCTC).

The menthol ban came into effect in May 2020. Last year saw the launch of the track-and-trace system on cigarettes and roll-your-own tobacco products, and the system is expected to be fully operational this year. 2020 has also seen the adoption of audit guidelines. The closure of the Joint Action on Tobacco Control I (to support Member States with the assessment of data on tobacco products and electronic cigarettes) is expected for October 2020 and Joint Action II (with a wider focus and more policy-oriented around the full package of tobacco control actions) is expected to start before the end of 2020. DG SANTE is also highly engaged regarding input to changes to the tobacco taxation directive.

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

Pharmaceuticals Strategy: In line with the Mission Letter to Commissioner Kyriakides, in 2020, DG SANTE will develop a Pharmaceutical Strategy to help ensure Europe has a supply of affordable medicines to meet its needs, while continuing to support Europe's pharmaceutical industry to ensure it remains an innovator and world leader. The strategy will build on an evidence-based assessment of the existing regulatory framework and policy, aiming towards a system that is future-proof and that consistently addresses all levels of the value chain, from R&D to authorisation and access of patients to medicines. It will take into account scientific and technological advances and the necessity to ensure environmental sustainability. The unprecedented COVID-19 pandemic is an example of the public health response needs and potential impacts. It demonstrates the need to have a future-proof and crisis-proof system to ensure timely access to safe, quality and efficacious medicines under all circumstances.

The main milestones in 2020 include the publication of the Pharmaceutical Strategy Roadmap; the related public consultation in Q3; a public launch of the Strategy in Q4; as well as an impact assessment for a legislative proposal on EMA fees by the end of the year. The completion of the evaluation of orphan and paediatrics regulations will be another important deliverable in 2020. The consultation process will be promoted and communication will be adapted to the main objectives of the strategy and take account of the COVID-19 context.

Preparatory work will also take place during 2020 in view of delivering in 2021 an evaluation of the pharmaceutical legislation's strengths and weaknesses, to prepare possible options for legislative change[4], and a study on shortages in 2021.

Audits are an important element of maintaining quality control for pharmaceutical products. In 2020, DG SANTE will undertake audits in third countries on Good Manufacturing Practice (GMP) for active pharmaceutical ingredients (APIs) for human medicinal products. These audits concern non-EU countries applying to be listed (or already listed) as equivalent and focus on control and enforcement activities, aiming at ensuring a level of protection of public health equivalent to that in the EU and seeking a level playing field. In 2020, DG SANTE will continue its bilateral relations with key strategic partners focusing, amongst others, on making the case for these audits.

In terms of multilateral collaboration in 2020, DG SANTE, as a Founding Member in the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), will put forward proposals for further harmonisation work, such as a revision of the ICH Q7 guideline (GMP for APIs). Furthermore, DG SANTE will continue to advocate for the EU to be recognised as a single entity due to its common legal framework on pharmaceuticals, i.e. as a regional regulatory system composed of the national

[4] Directive 2001/83/EC and Regulation (EC) No 726/2004

regulatory authorities of the members of the European Economic Area, the European Commission and the European Medicines Agency.

A study is also ongoing, focusing on legislative alignment checks of the EU public health acquis for non–EU countries. The final report of the study on accessibility of pharmaceutical care and sustainability of pharmaceutical spending for the past ten years is expected this year as well.

Shortages of medicines: Pressure has significantly increased in relation to the problem of shortages of medicines. In 2020, DG SANTE will launch a study on shortages of medicines to identify the root cause of shortages and assess possible solutions. As regards the EU dependency to active substance sourced from third countries, we will work with DG GROW to create a pharmaceutical value chain alliance. This would gather EU producers (from raw materials, APIs to finished dosage forms) and other stakeholders with the objective of strengthening the capacity of production and reduce shortages of medicines in the EU.

Evaluation and review of orphan and paediatrics: Another important deliverable in 2020 is the completion of the joint evaluation of the Paediatric regulation and the regulation on Medicines for Rare Diseases (Orphan medicines) and the initiation of the Impact Assessment study in the fourth quarter of 2020.

Review of EMA fees legislation: DG SANTE published the outcome of the evaluation on EMA fees in September 2019, together with an inception impact assessment. The impact assessment study - to be launched in 2020 - will assess policy options and calculate fee and remuneration amounts for the legal proposal and will estimate the effect on the European Medicines Agency and National Competent Authorities.

A report to the co-legislator on the experience acquired as a result of the procedures for authorisation and monitoring of medicinal products for human use will also be prepared in 2020.

Implementation of the Clinical Trials Regulation: In 2020, DG SANTE will prepare the implementation of the new Clinical Trials Regulation. We will continue work closely with EMA and the EU Member States to ensure progress in the implementation of the legal obligations stemming from the above-mentioned Regulation which represent major changes for the pharmaceutical sector. In particular, DG SANTE will continue to monitor the development of the clinical trials portal and EMA will launch an audit of the system in December 2020. DG SANTE will also continue to develop harmonised templates and to update its question-and-answer document to ensure harmonised implementation of the new Regulation.

Falsified Medicines Directive: DG SANTE will also continue to advance the implementation of the Falsified Medicines Directive. The EU authentication system to fight

falsified medicines was launched in February 2019, however some challenges persist and continue to require monitoring.

Implementation of the mutual recognition agreement with the US: DG SANTE will continue to work on the implementation of the mutual recognition agreement with the US to extend the scope of the agreement on veterinary medicines, vaccines and blood-based medicines.

Other non-legislative actions: In 2020, DG SANTE will also continue non-legislative action (together with EMA) to optimise the implementation of the Advanced Therapy Medicinal Products (ATMP) Regulation and Paediatric legislation, as well as work on the implementation of the AMR action plan in particular with regards to the development of new antibiotics and consideration of new business models, as well as the implementation of the Commission Communication setting up the EU Strategic Approach on pharmaceuticals in the environment.

Health Technology Assessment: The Commission proposal on Health Technology Assessment adopted in 2018 remains an important priority of DG SANTE. The proposal is expected to contribute to the overall objective outlined in the mission letter to ensure "the supply of affordable medicines" and "support the European pharmaceutical industry to ensure that it remains an innovator and world leader".

The priority in 2020 will be to advance as much as possible the negotiations in the Council with a view of achieving a general approach and start trilogues. The aim is to achieve the adoption of a new legal framework with added value during the first half of the current Commission mandate. The COVID-19 outbreak is having an impact on the negotiations, which might be subject to delays.

HTA coordination among Member States is proving to be important in the current crisis situation and must continue. The European Network of HTA bodies is currently playing an active role in gathering scientific evidence at EU level in order to support national decisions for COVID-19-related measures.

Medical Devices: DG SANTE is fully committed to the effective implementation of the new legislative framework of medical devices, Regulations (EU) 2017/745 (Medical Devices Regulation; MDR) and (EU) 2017/746 (In Vitro Diagnostics Regulation; IVDR) which entered into force in May 2017. Initial planning for dates of application were May 2020 for MDR and May 2022 for IVDR. The implementation of both Regulations is a significant challenge for national competent authorities, stakeholders and the Commission. The Commission and Member States have been collaborating closely and working very hard in this context and a lot of progress has been achieved. In light of the COVID-19 outbreak, on 03 April 2020, the Commission adopted a proposal for a postponement of the date of application of MDR for one year, i.e. May 2021 instead of May 2020 in order to enable prioritisation of resources against COVID-19. The proposal was adopted by the Council and the European Parliament on 23 April 2020 (Regulation (EU) 2020/561). Other actions on medical devices are also

being developed to address the current COVID-19 crisis, including a Recommendation on market surveillance; implementing act on standards, making some COVID-19 standards freely available; guidance on medical devices in the context of COVID-19; the steering group on performance of diagnostic tests and other work with JRC on testing.

DG SANTE is working together with Member States and relevant stakeholders to ensure effective implementation of MDR by May 2021. Work in this regard will include:

- Development of EUDAMED database (endorsement of guidance documents, and statements, regular updates, implementing act etc.)
- Actions related to the placing of safe devices on the market (CIRCA BC platform for exchange of information on national derogations, regular reporting from notified bodies etc.)
- Actions related to clinical evaluation endorsement of guidance documents on clinical evidence for legacy products and well-established technologies and their equivalence;
- Establishing the Expert Panels involved in the assessment of some critical medical devices, including the nomination of experts, training, IT structure in the absence of EUDAMED, web page, all in close cooperation with JRC;
- Adoption of Implementing Acts, e.g. on reprocessing, standardisation, non-medical devices.

DG SANTE will also organise and participate in joint assessments of notified bodies to ensure the satisfactory implementation of the new medical devices regulation (MDR). The Commission is determined to put the new system to work and DG SANTE will play its full role to that effect in close collaboration with Member States.

In order to implement the in vitro diagnostics regulation (IVDR), which will apply as of May 2022, a number of implementing acts will be adopted in 2020. These will include: (a) the tasks and criteria of EURLs; (b) the structure and level of fees to be levied by EURLs; (c) designation of the laboratories by name and competence area/category of device. The work on EURLs is conducted in close cooperation with JRC (based on an administrative agreement still to be signed).

DG SANTE will also continue work within international pharmaceutical fora to promote the EU regulatory model and support the EU trade agenda in the area of pharmaceuticals and medical devices. This includes work on the implementation of trade agreements with the US, Canada and Japan, bilateral regulatory dialogues with India and China and within related multilateral fora.

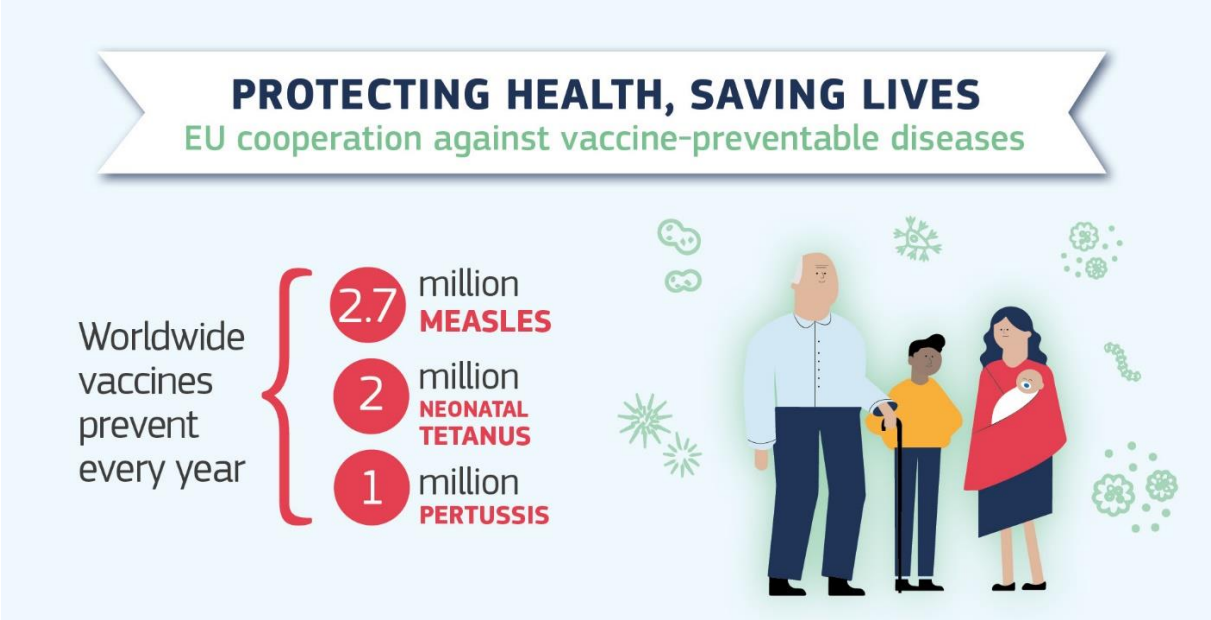
Specific Objective 2.3: Effective response coordination of serious cross-border health threats

The spread of COVID-19 in the first half of 2020 demonstrated that epidemics and infections represent a serious health and security risk, with a devastating impact on human health, many lives lost, and a direct economic cost. They must be contained and well-

managed. Resilience, i.e. the ability to respond to shocks, including crisis preparedness, prevention and response capacity in the field of human, animal and plant health and food safety will remain a top priority during this Commission mandate.

DG SANTE, along with other Commission DGs, is fully involved in the multilateral response to the COVID-19 crisis and continues to stand alongside the United Nations, the World Health Organisation, G7 and G20 to step up a forceful and coordinated global response to the pandemic. In 2020, DG SANTE's priority in this area will be the management of response coordination. This will include using enhanced operation procedures which provide a central coordination point for the emergency response; ensures information management and effective communication; and provides an overview of data, information and public health measures already taken or planned. At time of writing, DG SANTE has launched four joint procurement procedures to respond to Member State needs in relation to COVID-19 (with additional procurement procedures likely to be launched); participated in a "clearing house" to monitor stocks, production and imports of Personal Protective Equipment and medical equipment; issued guidance on enhancing existing EU emergency assistance in cross-border cooperation, as well as recommendations on testing strategies, community measures, health systems resilience, and on the rational use of medicines based on input by the ECDC, EMA and the advisory panel on COVID-19. DG SANTE will take stock of the crisis response and together with Member States and the European Parliament draw the lessons, taking also into account the outcome of the recent ex-post evaluation of the ECDC. This could include improving health systems' resilience, cross-border cooperation, and preparedness and response in the EU for future outbreaks, working in close concertation with ECDC.

Vaccination: Vaccination is one of the most powerful and cost-effective public health measures. Nevertheless, the EU is the region in the world with the lowest confidence in the safety and effectiveness of vaccines. As instructed in the Mission Letter of Commissioner Kyriakides, DG SANTE will improve communication on vaccination to explain the benefits and combat the myths, misconceptions and scepticism that surround the issue.



To do so, in 2020, work will continue to deliver on actions from the Commission Communication and Council Recommendation on strengthened cooperation against vaccine preventable diseases, in particular a feasibility study for the development of an common EU vaccination card; a study exploring the feasibility of and identifying options for physical stockpiling of vaccines; and a report on the State of Vaccine Confidence in the EU 2020.

Communication activities around vaccination will be split into two phases for the year 2020 to underline that *#VaccinesWork*. Global research for a vaccine to prevent the spread of COVID-19 is an opportunity to highlight the effectiveness of vaccination, even before a suitable vaccine is found. This will be the main angle for social media activity during the European Immunization Week. In the second half of the year, the ommission aims to support Member States to address hesitancy and safety concerns, as per the Mission letter. This will also be the opportunity to promote the European Vaccination Information Portal[5], which is coordinated by ECDC and EMA.

DG SANTE will also publish two calls in the EU Health Programme Annual Work Programme 2020, one on "increased access to vaccination for disadvantaged, isolated and difficult to reach groups of population", and one on "stakeholder activities to support strengthened cooperation against vaccine preventable diseases", targeting the Coalition for Vaccination.

In 2020, work will also continue within the European Joint Action on Vaccination, e.g. production of a report on interoperability of Immunisation Information Systems in the EU area; a proposal for a financial mechanism for centralized procurement for vaccines; and a proposal for shared funding mechanism.

[5] https://vaccination-info.eu

In response to COVID-19, DG SANTE will contribute to Commission efforts to implement the EU Vaccines Strategy to accelerate the development and availability of safe and effective vaccines in the coming 12-18 months. DG SANTE supports the Commission's committment to universal, equitable and affordable access to COVID-19 vaccines and we have taken a number of steps to promote this via the pledging campaign headed by the President, the collaborative framework for the ACT-accelerator global response and participation in the COVAX Facility. This includes securing the production of vaccines in the EU and sufficient supplies for its Member States via the use of advanced purchase agreements through the funding of the Emergency Support Instrument, as well as adapting the EU's regulatory framework and making use of existing regulatory flexibility.

Antimicrobial Resistance (AMR): AMR is a global challenge with significant consequences for the economy and human health unless tough action is taken to address it. Excessive and inappropriate use of antimicrobials in the health sector is the fundamental cause of AMR. The 'European One Health Action Plan against Antimicrobial Resistance' was adopted in June 2017. It is built on three pillars: (i) making the EU a best practice region; (ii) boosting research, development and innovation; and (iii) shaping the global agenda. As instructed in the Mission Letter of Commissioner Kyriakides, DG SANTE will work with our international partners to advocate for a global agreement on the use of and access to antimicrobials.

Data-gathering studies are ongoing to support the development of options and recommendations for an EU citizen's vaccination card, and for physical stockpiling possibilities and intra-EU exchange of supplies.

In 2020, the implementation of the European One Health Action Plan against AMR and the work in the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) will continue. One key deliverable will be the contribution to the development of the next TATFAR work plan 2021-2026. Another essential element in 2020 will be the pursuit of the preparatory work for the tertiary legislation necessary to the implementation of the wide range of concrete measures to fight AMR under the new EU Regulations on veterinary medicinal products and medicated feed, to apply from 2022 onwards. DG SANTE will also continue to undertake, together with ECDC, One Health AMR joint country visits to offer tailored support and advice to Member States in further developing and implementing their national strategies and policies against AMR. DG SANTE will promote the "One Health" approach on AMR within multilateral fora at the UN, WHO, OIE, FAO, Codex, G7 and G20 level.

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

DG SANTE will continue to support Member States in improving the effectiveness, accessibility and resilience of their health systems in 2020. DG SANTE contributes to the EU level socio-economic coordination (European Semester), provides an infrastructure for country-specific knowledge and analysis on health systems through the State of Health in the EU and promotes the use of EU funding towards investments in health. This work also supports the Member States in achieving the UN Sustainable Development Goal number 3 (Ensure healthy lives and promote well-being for all at all ages), as well as improving health systems' resilience in the wake of the COVID-19 crisis. A report on ways in which amenable mortality could be improved is currently in preparation, and should be published by the end of 2020.

DG SANTE will work to develop new ways of measuring gaps in access to healthcare and to improve existing tools in close co-operation with Member States through the Social Protection Committee and the Healthcare Systems Performance Assessment expert group. Analytical work will also include issues of health workforce planning and forecasting.

In 2020, the Steering Group on Promotion and Prevention (SGPP) will continue to enable the identification and scaling-up of best practices on health promotion and disease prevention. The Best Practice portal will continue to support the SGPP and the Member States, and will be maintained by the JRC, under supervision of DG SANTE, which will also chair evaluation committees for best practices. The SGPP will also support the governance of the health strand of the ESF+ and provide input to other DGs' initiatives in the area of health.

DG SANTE will continue to manage and use the Health Policy Platform in 2020 to consult widely with civil society stakeholders on cancer, nutrition and alcohol, research projects and other important issues.

Country knowledge: DG SANTE will continue to generate country-specific and cross-country knowledge on health systems in particular by:

- Country-specific analysis provided through the network of country desks and input into the European Semester process;
- The 3rd cycle of State of Health in the EU with the launch of the statistical compendium "Health at a Glance" in November 2020 and early work on the 2021 country profiles.
- Input to the programming of the Cohesion Policy funds (ERDF, ESF+ shared management part); the preparation of the InvestEU programme; the planning of technical support to health system reforms via the Structural Reform Support Programme; and the planning of health systems research under Horizon Europe.
- Cross-country data, analysis and concrete tools to support the transformation of health systems, in particular through the Health Systems Performance Assessment group, the SANTE Expert Panel, and specific projects on access to healthcare and medicines; integrated care; and facilitation of investments in health.
- Promoting European cooperation on health workforce planning and forecasting, as well as cross-border collaboration, exchanging national expertise and providing data, knowledge and evidence for Member States.

Substances of human origin (SoHO): SANTE will launch an impact assessment to identify best options to address the shortcomings identified in the Commission Staff Working Document on the Evaluation of the Union legislation on blood, tissues and cells published in October 2019 The overall objectives are to ensure safety, access and innovation, and specifically to ensure a high level of health protection for EU citizens and equal access of patients to high quality, effective blood tissue and cells treatments..

Several ad-hoc initiatives to address COVID-19 will already test elements for some options, e.g. the use of rapid advice issued by ECDC or the European Directorate for the Quality of Medicines (EDQM) to ensure safety, common authorisation and monitoring of novel convalescent plasma transfusion therapies, or monitoring and steering access to essential SoHO in times of crisis.

Further work in 2020 will strengthen national oversight capacities for authorisation, inspection and vigilance. Rapid Alert and Coding platforms will need to be assessed in the context of BREXIT and Northern Ireland.

Patients' right to cross-border healthcare: EU citizens have the right to access healthcare in any EU country and to be reimbursed for care abroad. Directive 2011/24/EU on cross-border healthcare (CBHC) sets out the legislative provisions in this regard. In 2019, the Court of Auditors issued an audit report on CBHC, including Commission responses to the recommendations of the report. Follow-up work by DG SANTE on the recommendations will continue in 2020. Another 2020 priority as regards cross-border healthcare will be the closure of the pilot projects on CBHC; the continuation of compliance checks and bilateral structural dialogues with Member States on remaining compliance issues; as well as the follow-up on infringement cases.

The implementation work will be strengthened by a study on CBHC with the aim to improve prior authorisation, data collection, monitoring and evaluation, capacity building and improvement of National Contact Points, related workshops with Member States. A roadmap on CBHC related activities in this Commission is also planned for 2020. The guidelines on emergency assistance in cross-border cooperation in healthcare related to the COVID-19 crisis might need a follow-up. An initiative opinion of the Committee of the Regions on CBHC is expected.

E-health: DG SANTE has a long-term goal to make the most of the potential of e-health to provide high quality healthcare and reduce inequalities in healthcare. A four strands study on cross-border digital healthcare in the EU will gather and analyse data on eHealth (including mHealth and Telehealth) services and products, artificial Intelligence in healthcare sector, use of health data. The study will also support the evaluation of Article 14 of Directive 2011/24/EU and conduct a comprehensive analysis of existing gaps and potential for EU added value in line with the Better regulation requirements.

In line with the mission letter of Commissioner Kyriakides, DG SANTE will work in 2020 on the creation of a European Health Data Space. On 19 February 2020, the Commission adopted a package of measures which include a Communication on Shaping Europe's digital future, a White Paper on Artificial Intelligence and a Communication on a European Strategy for Data to which DG SANTE substantially contributed.

Within the European Strategy for Data Communication, the Commission announced that it will create European common data spaces in several sectors, including health. The European Health Data Space is one of DG SANTE's communication priorities.

In 2020, DG SANTE will pursue the work on achieving the objectives announced in the Communication along three strands of work:

- The creation of a legal and governance framework via legislative/non-legislative measures for the European health data space; strengthening citizens' access to health data and its portability; tackling barriers to cross-border provision of digital health services and products; and support work on a Code of Conduct for processing personal health data in line with Article 40 of GDPR;

- Exploration of establishing infrastructures for exchanging/accessing data for healthcare, policy making and research and innovation;
- Contribution to health data quality and semantic interoperability for cross-border health data exchanges.

These actions will be accompanied by Better Regulation work as necessary.

In 2020, DG SANTE is also working to ensure the interoperability of tracing apps related to the COVID-19 pandemic. Work is ongoing to establish technical interoperability between tracing apps of different Member States, aimed at informing individuals who have been in contact with COVID patients within a certain distance and duration.

Furthermore, a Joint Action on the implementation of the General Data Protection Regulation in the health sector and European Health Data Space will be supported from the Health programme (2020-2023).

For use of data for healthcare, the existing eHealth Digital Service Infrastructure (MyHealth@EU) should cover cross-border electronic exchanges of Patient summaries and e-Prescriptions for 22 Member States by 2022. It will increase its geographical coverage to 25 Member States by 2025. In the future the exchanges should be gradually expanded with new services, namely cross-border electronic exchanges of laboratory reports, medical images and hospital discharge reports. The possibility of using the MyHealth@EU for secondary use of health data (policy making, regulatory and research) will also be explored, together with MS.

DG SANTE will also continue to support, coordinate and contribute to the work of the eHealth Network – a network connecting Member States' authorities responsible for eHealth - and its permanent subgroups. DG SANTE will also develop, implement and maintain appropriate technical and organisational measures related to the core services of the eHealth Digital Service Infrastructure for cross-border electronic exchanges of patient summaries and ePrescriptions (MyHealth@EU, also known as eHDSI).

DG SANTE will also undertake several eHealth audits to assess if Member States meet the relevant requirements, notably in relation to potential risks to the confidentiality and integrity of health data.

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 the diagnosis and treatment for patients in Europe. The focus in 2020 will be on achieving the ERN enlargement with 250 affiliated partners and on the evaluation of more than 700 new member applications, following the call in 2019. Another priority will be to continue the consolidation of the ERN initiative by promoting the integration of ERNs into the health systems of the Member States. Specifically, we will encourage Member States to establish clear patient pathways and referral systems and to adequately support the functioning of

the Networks. In 2020, DG SANTE will also continue the strategic reflection on the future development of the Networks, including through a study analysing their legal and financial sustainability and by developing simplified cost options. DG SANTE will also develop and implement an effective monitoring, assessment and evaluation system and encourage the Networks to prepare a research strategy.

PART 2. Modernising the administration: main outputs for the year

The internal control framework[6] supports sound management and decision-making. It notably ensures that risks to the achievement of objectives are taken into account and reduced to acceptable levels through cost-effective controls.

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

A. Human resource management

In order to ensure DG SANTE will be able to deliver on the many initiatives foreseen in the Commission's 5-year mandate in the Health and Food safety domain, DG SANTE will focus in 2020 on ensuring its organisational structure is fit for purpose. Staffing levels to the different areas will be looked and adapted when necessary. Directorates and Units will be reconfigured and their workload be rebalanced.

Moreover, during the above exercise, opportunities for the recruitment of new female middle managers will be created and will thus contribute to reaching the Commission's objective of equality between men and women at all levels of management.

DG SANTE will also put in place measures to reduce the impact of the COVID-19 crisis on Staff. Temporary redeployment to and external reinforcement of Units highly impacted by the Crisis, the creation of a SANTE@Home project aiming at easing the confinement period, Weekly Skype covid-19 meetings with all managers to inform, to take the pulse and to exchange ideas.

DG SANTE will increase staff participation and internal collaboration by consequent internal communication and the implementation of more cross-unit taskforce-based working arrangements.

[6] Communication C(2017)2373 - Revision of the Internal Control Framework

Objective: DG SANTE employs a competent and engaged workforce and contributes to gender equality at all levels of management to effectively deliver on the Commission's priorities and core business		
Main outputs in 2020:		
Output	**Indicator**	**Target**
Updated organisation chart	Validation by the College	16/05/2020
Recruitment of new female middle managers	# Appointments validated	2 by end 2020
COVID-19 crisis management accompanying measures: temporary reinforcements, creation of SANTE@Home project, weekly COVID19 management meetings	Actions implemented	During the COVID-19 period
DG SANTE staff engagement index	DG SANTE staff engagement index	>= 70%

B. Sound financial management

DG SANTE uses the organisational structure and the internal control systems suited to achieving its policy and internal control objectives in accordance with the internal control principles set by the Commission[7]. DG SANTE has established a control strategy including all control and anti-fraud measures for all types of expenditure directly managed by the DG in the two policy areas. The control measures encompass risk assessment and risk management integrated into the planning process and control activities including ex-ante and ex-post verifications. Furthermore, DG SANTE co-operates with OLAF and implements fraud prevention and detection measures. The strategy in its latest version of November 2017 is an evolving document and will be updated by the end of 2020 to reflect the organisational and procedural changes that have been or will be implemented in 2020.

On a regular basis, management receives reports on budget implementation and control results as well as communications on the progress of the implementation of action plans. In addition, DG SANTE receives feedback from external audits of the Commission's Internal Audit Service and the European Court of Auditors and compiles, implements and monitors the corresponding action plans. In its internal control system, DG SANTE embedded continuous monitoring measures to ensure that its management and internal control framework is effective. Annual management assessments of the effectiveness of key internal control systems are carried out to ascertain whether the components of internal control are present and functioning and whether deficiencies are remedied in a timely

[7] Commission Communication (2017) 2373 on the revision of the Internal Control Framework

manner. In 2020, DG SANTE followed the methodology proposed in the "implementation guide of the internal control framework of the Commission".

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

Main outputs in 2020:		
Output	**Indicator**	**Target**
Effective controls: Legal and regular transactions	Risk at payment	Remains < 2 % of relevant expenditure
	Estimated risk at closure	Remains < 2 % of relevant expenditure
Effective controls: Safeguarded assets *(stock of vaccines/antigens for animal diseases)*	Accounting closure	Remains 100% audit/review corrections considered
Efficient controls	Budget execution and Time-to-pay	Remains >95% of payment appropriations and Remains >95% of payments (in value) on time
Economical controls	Overall estimated cost of controls	Remains <2% of funds managed

C. Fraud risk management

Fraud risks are addressed by specific controls designed and implemented to mitigate the risks. To this end, DG SANTE has developed and implemented its own anti-fraud strategy and action plan since 2013 (latest update of 2017), on the basis of a specific fraud risk assessment and a methodology provided by OLAF. The controls to prevent and detect fraud are basically the same as those intended to ensure the legality and regularity of the transactions. An assessment of the risks of fraud is included in the annual risk management exercise. In addition, the five tasks listed in the table below are especially important to DG SANTE. They are identified in the action plan (2017-2020) and already well embedded in existing procedures. The internal control officer monitors the implementation of the anti-fraud action plan and reports the results to DG SANTE management twice a year, i.e. in February 2020 and again in September 2020.

Once the Multi-annual Financial Framework 2021-2027 will be adopted, DG SANTE will update its anti-fraud strategy and action plan for 2021-2024 based on a fraud risk assessment and lessons learned from the previous strategy. DG SANTE will also take the Commission Anti-Fraud Strategy and action plan of April 2019 into consideration.

Objective: The risk of fraud is minimised through the application of effective anti-fraud measures and the implementation of the Commission Anti-Fraud Strategy (CASF)[8] aimed at the prevention, detection and correction[9] of fraud

Main outputs in 2020:

Output	Indicator	Target
Continued awareness raising in DG SANTE's decentralised financial cell network and through promoting ethics training, in particular on how to deal with lobbyists	Annual implementation rate of awareness activities	>90%
Actions linked to handling "conflict of interest" in agencies, scientific committees and expert groups	Annual meeting of the SANTE inter-agencies task force on independence	1 all-agencies meeting per year, usually in September
Participation in the network "Fraud Prevention and Detection" (FPD) chaired by OLAF and dissemination of the relevant information stemming from these networks	Participation in the FPDnet meetings and feed-back given in the decentralised financial cell meetings	4 FPDnet meetings per year and 2 decentralised financial cell meetings per year
Arrangement of an appropriate level of cooperation with OLAF	Meeting OLAF-SANTE at Director level	1 meeting per year
Comprehensive update of DG SANTE's current anti-fraud strategy and action plan (2017-2020) taking into consideration the revised CAFS Communication and the accompanying action plan[10]	SANTE anti-fraud strategy (2021-2024) adopted by the Management Board	Q1 2021

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

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

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

D. Digital transformation and information management

Data[11], information and knowledge management including document management and data protection

DG SANTE is fully committed to participate in the transition to a knowledge-and data-driven Commission[12]. By mobilising indispensable support and leadership drive from senior and middle managers and working collaboratively across the DG, SANTE will develop its first **Data Strategy** accompanied by an annual **data work plan**. These will respond to updated business needs and corporate requests striving for an efficient knowledge management and explore the improvement of relevant DG's working methods, data processes and roles including streamlining the existing ones. The Data Strategy will promote and use the SANTE Collaboration platform (and its relevant features) as well as modern document management and evolving digital tools and solutions. A **transition data work plan** will address in 2020 the immediate needs of SANTE priority policy initiatives related to the COVID-19 crisis as well as the Cancer Action Plan, the Farm to Fork, and Pharmaceuticals strategy. Specific actions will focus this year on developing the SANTE local data catalogue, updating and refining the key data assets reported at corporate level, updating the data needs at DG and unit level, increasing the in-house data-searching capabilities for available information, promoting collaborative work and data sharing, raising staff's general awareness on the need to effectively manage records and data, and increasing the awareness of and ability to retrieve evidence and analyse data through dedicated trainings.

SANTE will also be involved in the Environment Knowledge Community (EKC) for the purpose of the European Green Deal and respond also to corporate requests under the Data governance and data policies,[13] as relevant to its policy priorities. Regarding document management SANTE will focus on automatizing the acquisition and preservation of relevant records in corporate document management tools.

Digital transformation

The College adopted a new digital strategy in November 2018 to steer the digital transformation of the Commission. This strategy identifies 11 core principles that should be respected by all digital solutions. These principles form the cornerstone of all new digital solutions developed in DG SANTE and many are also available in all existing solutions. For some systems, DG SANTE has reached the highest level of eGovernment maturity level, namely Transformed Government, with fully automated activities, full electronic case handling and electronic signatures for the processes implemented for user centric

[11] For the purpose of this paper data, information and knowledge is refered as data.

[12] DG SANTE Strategic Plan, Section D

[13] Data governance and data policies at the European Commission Ref. Ares(2019)7468514.

interaction with Member States, business and citizens respecting the highest level of security and privacy and making use of reusable solutions.

DG SANTE digital transformation policy aims towards the digital economy by raising the maturity level for as many digital solutions as possible, using standards and providing high value e-services towards a more transparent and open organisation. DG SANTE will establish in 2020 an IT modernisation plan and DIGITAL strategy action plan that will attempt to rationalise its information systems, foster co-creation, co-innovation and co-delivery with the SANTE policy agencies and pursue the application of the digital strategy principles across all digital solutions with gradual implementation until 2024.

Collaborative Working

DG SANTE's has been promoting collaborative working through the establishment of a collaboration policy and a digital collaboration platform and tools. This forms the standard framework for the coordination of work with operational Units and projects, follow-up of UMPs and different management committees within DG SANTE. Following the strategy towards O365 collaboration that will be launched in the Commission during 2020, DG SANTE has decided to join this corporate initiative and migrate its collaborative work and platform to O365 once the Local Data Centre Consolidation (LDC) is completed in the first semester of 2020. This will allow SANTE to be amongst the forerunners in modern electronic collaboration and further change working methods towards more efficiency, sharing and dynamics in collaboration. A network of volunteers supports this activity, pursuing and pioneering new digital forms of collaboration in different policy and administrative activities.

Data protection

SANTE successfully adapted to the regime of the new legal framework. In 2020, SANTE will focus on maintaining full compliance with data protection rules and constant implementation of therein-embodied principles. In particular, it will ensure that all actions, digital solutions and systems, including legislative, that might lead to potential processing of personal data, respect the principle of data protection by design and by default. The necessary awareness will be achieved by a variety of trainings, ranging from general to dedicated ones, developed for particular categories of SANTE staff. While fully using tools provided at a corporate level, when needed, SANTE will create its own templates, guidelines, models, etc., that will reflect its needs and provide its staff with solutions that will be at the same time easy to implement and will respect data protection rules.

Objective: DG SANTE is using innovative, trusted digital solutions for better policy-shaping, information management and administrative processes to forge a truly digitally transformed, user-focused and data-driven Commission		
Main outputs in 2020:		
Output	**Indicator**	**Target**
Information systems and processes are at the highest level of maturity (transformed government) operating as e-services for the digital single market.	Percentage of information systems and processes at the highest level of maturity (transformed government) operating as e-services for the digital single market.	65% by Q4 2020[14]
Modern collaborative tools are the standard tools to manage activities, store and share information	Percentage of units and projects using collaborative tools to manage their activities	45% by Q4 2020
The corporate data inventory includes well managed SANTE key data assets	Percentage of SANTE key data assets for which corporate principles for data governance have been implemented	30% by Q4 2020
Other available relevant data assets included in the local data inventory	The available other relevant data assets included in the local data inventory	100% of other relevant data assets included in the local data inventory;
Results of the second survey collected	Percentage of units providing additional data assets identified.	75% of the units responded to the second survey for additional other data assets.
Data strategy elaborated in response to the DG's needs and priorities	Percentage of data needs identified (classification short-, medium- and long-term)	95% of the DG SANTE needs identified
	Data strategy adopted by Management Board	Data strategy adopted in Q4 2020.
Transition data work plan 2020	Transition data work plan 2020 adopted	Transition data work plan 2020 adopted in Q3 2020; focus in COVID-19, Cancer Action Plan, Farm to Fork, Pharma Strategy.
Work plan 2021	Percentage of the short term needs included in work plan 2021	At least 50% of the short term needs included in the work plan 2021 and Work plan 2021 adopted by Management board by Q4 2020
	Work plan 2021 adopted by Management board	
Increase in awareness of staff on data protection compliance	Percentage of staff attending awareness raising activities	100% Commission newcomers and 20% rest of the staff

[14] No change since 2019, DG SANTE is preparing an IT modernisation plan and DIGITAL strategy action plan to be delivered in 2020 addressing the necessary changes and evolution of IT systems for the coming years. The target achievement will increase as of the following year, as the implementation of the these plans will be realised.

E. 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's building and site in Grange, Ireland, where DG SANTE itself manages the day to day running of the site, 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.

In 2020, DG SANTE aims to maintain the EMAS registration for Grange and continuously improve the environmental performance of the site.

In addition, DG SANTE will take measures to ensure that the targets set for the 2015-2020 period will be achieved by the end of the year, with a reduction in consumption of both utilities and resources, and a reduction in emissions and waste.

Objective: SANTE takes full account of its environmental impact in all its actions and actively promotes measures to reduce the related day-to-day impact of the administration and its work		
Main results and outputs in 2020:		
Corporate EMAS Indicator 1a, Total energy consumption of buildings (MWh/p or kW/m^2) **Corporate Target 2014-2020: -5,2%**		
Output	**Indicator**	**Target (2019 as baseline)**
Promote staff awareness actions about optimal energy use and "switching off, when not in use", in line with the EMAS corporate action on resource efficiency during March.	No. actions No. staff informed	Address all SANTE Grange staff
Raise awareness about SANTE Grange's total energy consumption; and communicate observed trends to staff (once per year), based on verified data from Commission's Environmental Statement (2018 data – per building).	No. staff informed	Address all DG/service staff Reduce energy consumption (0.85%) (compared with the previous year)
Corporate EMAS Indicator 1d, Water consumption (m3/p or L/m^2) **Corporate Target 2014-2020: -5,4% and -4,8%**		
Output	**Indicator**	**Target**
Promote staff awareness actions about optimal water use and promotion of technical services hotline in case of water leaks, in line with the EMAS corporate action on resource efficiency during March.	No. of actions No. of staff informed	Address all Grange staff Reduction of 0.85% *(compared with the previous year)*
Raise awareness about SANTE Grange's water consumption; and communicate observed trends to staff), based verified data from Commission's Environmental Statement *(2018 data – per building).*	No. staff informed	Address all Grange staff

Corporate EMAS Indicator 1e Office paper consumption (Tonnes/person or Sheets/person/day) **Corporate Target 2014-2020: -34%**		
Output	**Indicator**	**Target (2019 as baseline)**
Promote staff awareness actions about optimal office paper use in line with the EMAS corporate action on resource efficiency during March.	No. actions No. staff informed	Address all DG/service staff
Raise awareness about DG/service's office paper use and communicate observed trends to staff), based verified data from Commission's Environmental Statement.	No. staff informed	Address all DG/service staff Reduce paper consumption (0.85%%)*(compared with the previous year)*
Introduce paperless working methodologies at DG/service level: e.g. e-signatories, financial circuits, collaborative working tools.	No. new actions introduced	1 action per year
Reducing CO_2, equivalent CO_2 and other atmospheric emissions		
Corporate EMAS Indicator 2 - Reducing emissions, (actions with non-numeric indicators)		
Output	**Indicator**	**Target (2019 as baseline)**
Increase in use of VC meeting rooms in the SANTE Grange, in collaboration with DG SCIC.	No. of VC meeting rooms/sessions	Increase use by 5% *(compared with the previous year)*

F. Example(s) of initiatives to improve economy and efficiency of financial and non-financial activities

1) Public procurement procedures

Since the beginning of 2019, DG SANTE is using e-Submission as unique tool for the open calls procedure. As expected, it reduces the administrative burden, especially in the opening procedure of public procurements (no manual interventions, automatic registering and reporting, paperless filing and archiving). Moreover, DG SANTE is since August 2019 on board with the Public Procurement Management Tool programme (PPMT – corporate tool), and has been testing it during the fourth quarter of 2019 before operating this IT solution to its full capacity in 2020. This web-based application will allow operational and procurement staff to support and monitor the procurement process from early need identification to contract signature, generating pre-filled templates and liaising automatically with ARES.

2) Planning process

In January 2020, DG SANTE centralised its financial planning and monitoring tasks, i.e. the coordination of the adoption of the annual work programmes/financing decisions for the operational budget. The Unit will keep abreast of any developments towards a new corporate IT tool for the planning process. The centralisation of the process and the use of an IT support are expected to ensure a timely adoption of the decisions on annual or multi-annual EU funding programmes.

ANNEX: Performance tables

[*All outputs from the Commission Work Programme items are flagged as follows:*  .]

General objective 1: A European Green Deal		
***Specific objective 1.1**: Ensuring food and feed safety*		*Related to spending programme Single Market Programme*
Main outputs in 2020:		
External communication actions		
Output/ Result	**Indicator**	**Target**
Press and Media <u>Communicate on actions being taken by the EU especially during times of outbreaks</u>	National print media coverage of EU's actions if/when outbreaks are reported	Media coverage by at least 10 EU countries
<u>Social Media</u> Sustained tweets throughout the year on the various aspects of Food and feed safety	Increase engagement on twitter	Average a minumum of 100 engagements per tweet. (all engagements)
	Increase the number of followers on the EU Food Safety account	Increase the number of followers by another 5000 followers (shared with other specific objectives)
Website Update of related webpages	Increase in the number of visitors to the SANTE food and feed related webpages	5% increase (Baseline 2019 - 4,291,614 visits / 12,887,617 pageviews / 8,708,970 unique pageviews)
Other important outputs		
Output	**Indicator**	**Target**
Actions on animal and plant diseases under the current Common Financial Framework		
2020 Eradication, surveillance and monitoring programmes:		
Bovine brucellosis	No. of MSs with a veterinary programme approved for EU cofinancing	3
Bovine tuberculosis	No. of MSs with a veterinary programme approved for EU	6

	cofinancing	
Ovine/caprine brucellosis	No. of MSs with a veterinary programme approved for EU cofinancing	5
Bluetongue	No. of MSs with a veterinary programme approved for EU cofinancing	15
Swine diseases	No. of MSs with a veterinary programme approved for EU cofinancing	26
Avian influenza	No. of MSs with a veterinary programme approved for EU cofinancing	25
Transmissible Spongiform Encephalopathies (TSE), Bovine spongiform encephalopathy (BSE) and scrapie	No. of MSs with a veterinary programme approved for EU cofinancing	26
Rabies	No. of MSs with a veterinary programme approved for EU cofinancing	12
Salmonella in poultry	No. of MSs with a veterinary programme approved for EU cofinancing	23
Lumpy Skin Disease (LSD)	No. of MSs with a veterinary programme approved for EU cofinancing	3
Emergency measures	Adoption	In course of 2020
ASF and LSD strategies with thirds countries	No. of programmes which received co-financing	7 for ASF 4 for LSD
Actions in view of the next Multiannual Financial Framework (MFF) – Single Market Programme (SMP)		
Guidelines and standard operating procedures to manage the new SMP food and feed strand	Adoption	Q4 2020, following adoption of the SMP
Animal health and animal diseases		
Delegated Regulation supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the approval of germinal product establishments and the traceability and animal health	Adoption	Q4 2020

requirements for movements within the Union of germinal products of certain kept terrestrial animals (PLAN/2017/1290)		
Delegated Regulation supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for surveillance, eradication programmes, and disease-free status for certain listed and emerging diseases (PLAN/2018/2573)	Adoption	Q4 2020
Delegated Regulation supplementing Regulation (EU) 2016/429 of the European Parliament and the Council, as regards rules for the prevention and control of certain listed diseases (PLAN/2018/2574)	Adoption	Q4 2020
Delegated Regulation supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council, as regards animal health requirements for movements within the Union of terrestrial animals and hatching eggs (PLAN/2018/2576)	Adoption	Q4 2020
Delegated Regulation supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for entry into the Union, and the movement and handling after entry of consignments of certain animals, germinal products and products of animal (PLAN/2018/2575)	Adoption	Q4 2020
Delegated Regulation supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards animal health requirements for movements within the Union of aquatic animals and products from aquatic animals (PLAN/2018/2572)	Adoption	Q4 2020
Delegated Regulation supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for aquaculture establishments and transporters of aquatic animals (PLAN/2018/2571)	Adoption	Q4 2020
Delegated Regulation supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards animal health requirements for the production, processing and distribution within	Adoption	Q4 2020

the Union of products of animal origin (PLAN/2017/1342)		
Delegated Regulation supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards management, storage and replacement of stocks of the Union antigen, vaccine and diagnostic reagent banks and the biosecurity, biosafety and bio-containment requirements for the operation of those banks (PLAN/2019/5736)	Adoption	Q4 2020
Delegated Regulation supplementing Regulation (EU) 2016/429 of the European Parliament and of Council as regards rules for the use of veterinary medicinal products for the purpose of prevention and control of category A and B diseases in terrestrial animals (PLAN/2020/6817)	Adoption	Q4 2020
Implementing Regulation laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Identification and registration of terrestrial animals (except equidae) (SANTE/1123/2018)	Adoption	Q3 2020
Implementing Regulation laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the approval of germinal product establishments and the traceability of germinal products of bovine, porcine, ovine, caprine and equine animals (PLAN/2017/1291)	Adoption	Q3 2020
Implementing Regulation laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to Union notification, reporting, the computerised information system, eradication programmes and the disease-free status (PLAN/2018/2500)	Adoption	Q3 2020
Implementing Regulation down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regards the list of third countries for	Adoption	Q3 2020

entry into the Union of animals and products (PLAN/2018/2509)		
Implementing Regulation laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council as regard rules for EU antigen, vaccine and diagnostic banks (PLAN/2019/5737)	Adoption	Q3 2020
Commission decisions on handling evolving epidemiological situations	Adoption of emergency Decisions as necessary, according to the epidemiological situation	In course of 2020
Commission rules on safe imports, trade and related aspects	Adoption of Commission implementing rules.	In course of 2020
BTSF seminars and conferences	No. of seminars and conference held	160 (*this target was set pre-COVID-19. All BTSF activities were suspended on 6.03.20 until at least 31.08.20)
Plant health and diseases		
Rules on plant passports (PLAN/2018/2520)	Adoption	Q2 2020
Establishment of format to report on plant health surveys (PLAN/2019/5738)	Adoption	Q3 2020
Derogation ash wood US (PLAN/2020/7075)	Adoption	Q2 2020
Derogation ash wood Canada (PLAN/2020/7075)	Adoption	Q2 2020
Recognition of the US visual inspections of maize seeds in the field (PLAN/2020/7080)	Adoption	Q4 2020
Containment measures (PLAN/2020/7077)	Adoption	Q4 2020
Derogation import bonsai from Korea (prolongation) (PLAN/2020/7075)	Adoption	Q3 2020
Delegated act on PZ Plant Health Surveys	Adoption	Q4 2020
Amendment Annexes PH Regulation (PLAN 2020/7072)	Adoption	Q4 2020
Implementing act on wood packaging material (PLAN/2020/7746)	Adoption	Q4 2020
Amendment of Implementing Regulation 2019/2129 on frequency of controls at BCPs (AP fiche to be approved)	Adoption	Q4 2020
Delegated Regulation 2019/2123 on	Adoption	Q4 2020

controls at control points		
Amendment implementing Regulation 2019/66 on PH official controls. Inclusion of post-import controls for dormant plants (PLAN/2019/5745)	Adoption	Q3 2020
Adoption of decisions on high-risk plants dossiers	No. of decisions adopted	5
Commission Decisions on emergency measures against some specific pests	Adoption according to (new) outbreak situations	In course of 2020
Commission Decisions with specific import requirements for trade lines where there are too many import interceptions	Adoption according to import interception notifications from Member States	In course of 2020
Evaluation of co-financing requests of Member States eradication measures	No. of eradication measures that received co-financing	72
Review of the legislation on *Xylella Fastidiosa* (PLAN/2020/6876)	Adoption	Q3 2020
Preparatory work for IYPH events (Ministerial Conference, Global Conference):		
- IPPC Strategic Framework 2020-2030	Approved by the Council	Q1 2020
- Ministerial Declaration on International Plant Health	Approved by the Council	Q1 2020
EU financial support to the Global Conference included in 2020 budget planning		Q1 2020
Grant Agreement DG SANTE-IPPC Secretariat on EU financial support to the Global Conference signed	Signature	Q4 2020
Market access for safe substances		
Commission Implementing Regulation (EU) amending Implementing Regulation (EU) No 307/2012 establishing implementing rules for the application of Article 8 of Regulation (EC) No 1925/2006 on the addition of vitamins and minerals and of certain other substances to foods (PLAN/2020/6422)	Adoption	Q3 2020
Commission Regulation (EU) amending Commission Regulation (EC) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006 (PLAN/2020/6413)	Adoption	Q3 2020

Commission Implementing Regulation (EU) amending Commission Regulation (EU) No 234/2011 of 10 March 2011 implementing Regulation (EC) No 1331/2008 of the European Parliament and of the Council establishing a common authorisation procedure for food additives, food enzymes and food flavourings (PLAN/2020/6415)	Adoption	Q3 2020
Commission Implementing Regulation (EU) amending Commission Regulation (EU) No 257/2010 of 25 March 2010 setting up a programme for the re-evaluation of approved food additives in accordance with Regulation (EC) No 1333/2008 of the European Parliament and of the Council on food additives (PLAN/2020/6414)	Adoption	Q3 2020
Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2469 of 20 December 2017 laying down administrative and scientific requirements for applications referred to in Article 10 of Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (PLAN/2020/6416)	Adoption	Q3 2020
Commission Implementing Regulation (EU) amending Implementing Regulation (EU) 2017/2468 of 20 December 2017 laying down administrative and scientific requirements concerning traditional foods from third countries in accordance with Regulation (EU) 2015/2283 (PLAN/2020/6417)	Adoption	Q3 2020
Commission Regulation (EU) amending Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food (PLAN/2020/6419)	Adoption	Q3 2020
Commission Implementing Regulation (EU) No 844/2012 of setting out the provisions necessary for the implementation of the renewal procedure for active substances, as provided for in Regulation (EC) No 1107/2009 concerning the placing of plant	Adoption	Q3 2020

protection products on the market (PLAN/2020/6421)		
Implementing Regulation (EU) amending Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives (PLAN/2020/6420)	Adoption	Q3 2020
Regulatory measures on contaminants in feed and food following EFSA opinions	Adoption	In course of 2020
Authorisations of health and nutrition claims, generic descriptors, vitamins and mineral substances etc.	Adoption	In course of 2020
Commission Regulations prohibiting, restricting or baning the use of substances other than vitamins and minerals in food (Article 8 procedure)	Adoption	In course of 2020
Authorisations of health claims made on foods and referring to children's development	Adoption	In course of 2020
Authorisation of novel foods under the Regulation on Novel Foods	Adoption	Up to 25 in course of 2020
Authorisation of traditional foods from third countries under the Regulation on Novel Foods	Adoption	4 in course of 2020
Decisions on data protection under the Regulation on Novel Foods	Adoption	Ongoing regular activity in 2020
Authorisations for new substances and new uses of already authorised substances used as food additives or food flavourings	Adoption	Ongoing regular activity in 2020; adoption of approx. 13 acts amending the uses and use levels for food additives and flavourings.
Authorisations for new substances and new uses of already authorised substances used in food contact materials,	Adoption	Ongoing regular activity in 2020, for an estimated 15 substances.
Delegated act amending Annex II to Regulation (EU) 2019/6 (AP/2018/4493)	Adoption	Q4 2020

Implementing act on the list of variations not requiring assessment (AP/2018/3968)	Adoption	Q4 2020
Implementing act on the necessary measures and practical arrangements for the Union database on veterinary medicinal products (AP/2018/3969)	Adoption	Q4 2020
Implementing act on the good distribution practice for veterinary medicinal products (PLAN/2018/3983)	Preparation	Q4 2020
Implementing act on the good distribution practice for active substances (PLAN/2018/3965)	Preparation	Q4 2020
Implementing act on the good pharmacovigilance practice (PLAN/2018/3967)	Preparation	Q4 2020
Implementing act on the content of the pharmacovigilance system master file (PLAN/2018/3982)	Preparation	Q4 2020
Implementing act on the common logo for online sales (PLAN/2018/3981)	Preparation	Q4 2020
Delegated act on the horse passport (PLAN/2020/6502)	Preparation	Q4 2020
Authorisations of GMO for food / feed and cultivation uses	Adoption	Ongoing regular activity in 2020
Approval/ non-approval , renewal/non-renewal of active substances for plant protection products	Adoption	Ongoing regular activity in 2020
Regulations establishing maximum residues levels (MRL) for pesticides	Adoption	Ongoing regular activity in 2020
Development of cumulative risk assessment method for pesticides residues	Developed	Ongoing activity in 2020
Regulations establishing a first list of non-acceptable co-formulants in plant protection products	Adoption	Q4 2020
Implementing Regulations renewing/non-renewing the approval	Adoption	Ongoing regular activity in 2020

of biocidal active substances		
Implementing Regulations for approval/non-approval of biocidal active substances included in the review programme	Adoption	Ongoing regular activity in 2020
Implementing Regulations granting or amending Union authorisation of biocidal products	Adoption	Ongoing regular activity in 2020
Re-evaluations of authorisations, new authorisations, denial of authorisation, modifications of authorisations and renewal and non-renewal of authorisations of feed additives	Adoption	Ongoing regular activity in 2020
Authorisations of veterinary medicinal products	Adoption	Ongoing regular activity in 2020
Setting of MRLs for substances used in veterinary medicinal products	Adoption	Ongoing regular activity in 2020
Control systems, including audits, and rapid alert systems		
Exemptions from BCP checks (PLAN/2020/6654)	Adoption	Q4 2020
Derogation from accreditation requirement regarding official laboratories (PLAN/2020/6653)	Adoption	Q4 2020
Amendment to Regulation (EU) 2019/2122 on personal imports (PLAN/2020/7563)	Adoption	Q4 2020
Temporary flexibility in official controls during COVID-19 (no AP reference, review tbc) *[No DECIDE Ref – adopted as an urgency measure]*	Adoption	Q2 2020
Adoption of implementing acts on model official certificates (linked to the entry into application of the Animal Health Law):	Adoption	Q4 2020
Model official certificates for animals and goods (PLAN/2020/7566)	Adoption	Q4 2020
Model official certificates for certain categories of terrestrial animals and germinal products thereof (PLAN/2020/ 7565)	Adoption	Q4 2020

Model official certificates for certain aquatic animals and products thereof (PLAN/2020/7564)	Adoption	Q4 2020
European Reference Laboratories	Number of laboratories funded	44
European Reference Centres	Number of centres funded	3
Better Training for Safer Food	No. of trainings organised	160
Audits in the area of food safety and quality, animal health, animal welfare and plant health	Approx. 117 audits completed	In the course of 2020
Report from the Commission to the European Parliament on the overall operation of official controls performed in Member (PLAN/2020/7680)	Publication	Q3
Staff Working Document accompaning the Report on the operation of official controls performed in Member States (2017-2018) (PLAN/2020/7681)	Publication	Q3
Guidance document on multi-annual national control plans (MANCP) (PLAN/2019/5813)	Publication	Q2
Guidance document on how to conduct audits by Member States (PLAN/2019/5814)	Publication	Q2
Guidance document on how to fill in the standard model form for Member States Annual Reports (PLAN/2019/5815)	Publication	Q2
Organisation of regular meetings of networks of Member State officials responsible for the multi-annual national control plans and national audits to facilitate exchanges of experiences and the preparation of guidance to enhance official control systems	Number of meetings held	5 plenary meetings; 4 subgroup meetings
Organisation of meetings with Member State experts in a number of areas such as animal welfare or the sustainable use of pesticides to discuss common problems and	Number of meetings held	1 meeting of the working group on the Sustainable Use Directive 1-2 meetings of the National Contact Point group on animal

exchange best practices identified		welfare
Assessment of planned facilities of Border Control Posts (BCPs)	Assessments carried out	Approx.30 per year, based on demand from the Member States
Evaluation of Member States' and non-EU countries' residue monitoring plans (food of animal origin)	Number of evaluation carried out	27 Member States plans, plus the UK's; up to 50% of non-EU country plans
Management of lists of approved non-EU country establishments for the production of food of animal origin	Number of request managed	Approx. 500 requests equating to around 2000 modifications to the establishment list in TRACES
Operation and further development of the notification system EUROPHYT for plant health interceptions, outbreaks and reporting on plant pests	Publication on Europhyt monthly and annual statistics and reports	In course of 2020
Plant health surveys	Member States' survey results for harmful organisms presented to Standing Committee on PAFF	In course of 2020
Computerised systems + IT (e.g. TRACES, ADNS, EUROPHYT)		
TRACES	No of active end-users	61000
ADNS	No of active end-users	450
iRASFF	No of active user accounts	7211
EUROPHYT (Interceptions and Outbreaks)	No of active end-users	1100

General objective 1: A European Green Deal	
***Specific objective 1.2**: Ensuring sustainable food systems – the 'Farm to Fork' strategy*	*Related to spending programme Single Market Programme*
Main outputs in 2020:	
New policy initiatives	

Output	Indicator	Target
Communication on the sustainability of food systems - 'Farm to Fork' Strategy (non-legislative)	Adoption	Q2 2020
Commission Communication replying to the European Citizen initiative 'Eat original'	Adoption (if validated before July 2020)	Q4 2020
Proposal for a revision of the Sustainable Use Directive for pesticides (SUD) (PLAN/2020/6975)	Inception Impact Assessment published for feedback	29 May 2020
Evaluations and fitness checks		
Output	**Indicator**	**Target**
REFIT of Regulation (EC) No 1924/2006 on nutrition and health claims (2015/SANTE/595) Annex II of the CWP 2016	Publication of SWD	Q2 2020
Impact Assessment on food information to consumers: nutrient profiling (for Front-of-pack labelling and health claims); origin indication for certain products and date marking	Launch	Q4 2020
Evaluation of the Food Contact Material (FCM) legislation (PLAN/2016/436)	Continuation of the work	Ongoing in 2020
Impact Assessment on FCM (PLAN/2020/7637)	Launch	Q4 2020
Impact Assessment on ceramic FCM (PLAN/2018/4857)	Launch	Q4 2020
Evaluation of the feed additives legislation (PLAN/2017/988) [REFIT Scoreboard 2017]	Publication of SWD	Q4 2020
Impact Assessment on feed additives	Launch	Q4 2020
Evaluation of Regulations on plant protection products and pesticides residues (2016/SANTE/197) Annex II of the CWP 2016	Adoption/publication of Report to Parliament and Council and accompanying SWD	Q2 2020
Evaluation of the EU Animal Welfare Strategy (2012-15)	Adoption of SWD	Q4 2020
FITNESS check of the animal welfare legislation	Signature of the contract for external study	Q4 2020
External communication actions		
Output/ Result	**Indicator**	**Target**

Adoption of the Farm to Fork strategy		
Press material		
Media material produced for adoption. of Farm to Fork Strategy	Number of Online views, downloads of media material	Minimum of 200 online views, downloads
	Number of media items mentioning Commsr Kyriakides	Minimum of 10
Technical briefing organised for journalists (both in Brussels and online)	Number of journalists attending technical briefings	Minimum of 100 journalists receiving infomation
	Geographical spread of news in various EU countries	Media items in the 27 member states (as per media monitoring)
	Number of published articles on farm to Fork in non Brussels bubble media across the EU	Over 100 media articles generated, reaching 25% of EU citizens via traditional media (to be cross checked with knowledge on F2F when EB on F2F is conducted later in the year)
Social Media		
Sustained tweets during adoption and as follow up. The hashtag #EUFarm2Fork monitored continuously Paid promotion of tweets	Increase engagement on twitter per tweet	Reach average target of 100 engagements per tweet (average of 10 tweets per day)
	Increase the number of followers on the EU Food Safety account	To add 2500 followers (current level 27k)
Website	Number of visitors to the site	Resulting in increase in web traffic on the farm to Fork page. by 100% (roughly exceeding 60000 views when compared to 2019 baseline)
Update of Farm to Fork Page to include ongoing consultation as well as all F2F related documentation.	Number of visitors to the site that have a positive view on the ongoing consultation process on F2F deliverables.	80% positive satisfaction rate when asked in survey)
F2F Events and fairs		
Organisation of an event on Farm to Fork in October 2020. 650 persons invited (will be transformed into an	Usefulness of event for attendees (survey amongst	85% useful or very useful as per survey during event (online)

online event if the COVID situation does not permit mass gatherings).	attendees) Percentage of attendees having a more positive opinion of the EU's Farm to Fork Strategy as a result of the event (survey amongst attendees) Media reach of event including social and traditional	85% positive or very poisitive when asked in survey during event (online) 2500 persons across EU
Participation with a stand in international events on "farm to fork	Number of visits to Salon de l'Agriculture (SIA) and Grüne Woche (IGW) -	Retention of 2019 targets (For SIA: 140,000 visitors on the stand, 27,000 visitors engaged - For IGW: 200,000 visitors on the stand, 50,000 visitors engaged
Other important outputs		
Output	**Indicator**	**Target**
Annual conference on the Farm to Fork Strategy	Conference held	Q4 2020
Plant Protection Products and sustainable use thereof		
Report to the Council and the European Parliament on the implementation of the Sustainable Use of pesticides Directive (SUD) (PLAN/2018/4570)	Adoption	20 May 2020
Indicators for the reduction of risk and use of chemical pesticides at the EU level (Harmonised risk indicators 1 and 2 as set by Article 15 of the Sustainable Use Directive, 2009/128/EC)	Publication	Q3 2020
Adaptation of data requirements for microorganisms	Ongoing work	In course of 2020
Reduction in the use of antibiotics in animals to contribute to fight AMR		
Delegated act on the requirements for the collection of data on antimicrobial medicinal products used in animals (PLAN/2018/4495)	Preparation	Q4 2020
Implementing act on the format for the collection of data on antimicrobials (PLAN/2018/3984)	Preparation	Q4 2020
Delegated act on the detailed rules on exports from third countries to the EU (Art. 118) (PLAN/2018/4503)	Preparation	Q4 2020
Delegated act to establish the criteria for designation in the EU of those antimicrobials to be reserved for human use (PLAN/2018/4510)	Preparation	Q4 2020

Implementing act on the list of antimicrobials reserved for human use (PLAN/2018/3966)	Preparation	Q4 2020
Implementing act on the list of antimicrobials that cannot be used outside the terms of their marketing authorisations, or that can be used outside the terms of their marketing authorisations subject to certain conditions	Preparation	Q4 2020
'One Health' antimicrobial resistance (AMR) country visits	1 visit carried out	In course of 2020
Sustainable feeds		
Authorisation of feed additives contributing to more sustainable feed	Adoption of authorisations	In course of 2020
Food loss and waste		
Operational support services for the EU Platform on Food Losses and Food Waste	Operation of digital platform and user activity	Ongoing regular activity in 2020
Meetings of the EU Platform on Food Losses and Food Waste	2 meetings held	Q2/Q4 2020
Meetings of the sub-groups of the EU Platform on Food Losses and Food Waste	4 meetings held	Q2/Q4 2020
New digital resource centre, the EU Food Loss and Waste Prevention Hub	Website launched	Q4 2020
Grant (FEBA)	Launched	Q4 2020
Animal Welfare		
Pilot project on the welfare of dairy cows	Signature of contract	Q4 2020
Pilot project on the welfare of laying hens	Signature of contract	Q4 2020
Study on animal welfare labelling	Signature of contract	Q4 2020
Food Fraud		
Food fraud audits	No. of audits carried out	2 pilot fact-finding visits
Support to innovation (including novel food, plant reproductive material and innovative tecniques)		
Implementation of the plant reproductive material marketing Directives		
Revision of Regulation (EC) 637/2009 on variety denominations	Adoption	Q3 2020

(PLAN/2018/3863)/		
Updates on variety testing protocols. (no AP yet)	Adoption	Q4 2020
Temporary experiment on risk-based official field inspections for agricultural crops (PLAN/2020/7070)	Adoption	Q4 2020
Amendment of scientific names of several species in the cereals marketing Directive (PLAN/2020/7561)	Adoption	Q4 2020
Amendment of the Annexes of Directives on marketing seed of agricultural crops, including requirements on BMT	Launch	Q4 2020
Regulation of the European Parliament and of the Council on extending the duration of Community Plant Variety (AP requested)	Adoption	Q4 2020
Implementation of the Organic Regulation		
- DA on organic heterogeneous material (PLAN/2019/5552)	Adoption	Q4 2020
- Temporary experiment on organic varieties (PLAN/2020/7562)	Launch	Q4 2020
Article 241 TFEU study on NGT (PLAN/2020/6573)	Launch	Q4 2020
Food Contact Materials		
Authorisation of recycling processes for plastics used in food contact materials	Adoption	140 processes authorised in course of 2020

General objective 1: A European Green Deal		
***Specific objective 1.3**: Increased EU influence in international fora*		*Related to spending programme Single Market Programme*
Main outputs in 2020:		
External communication actions		
Output/ Result	**Indicator**	**Target**
Website Update of webpages related to the	Number of visitors to the related	5% increase in the number of

international work of DG SANTE (see also indicator under objective 1.2 Participation with a stand in international events on Farm to Fork	webpages (International Affairs web section)	visitors to the related websections (Baseline 2019: 178,235 page views)
Other important outputs		
Output	**Indicator**	**Target**
Multilateral SPS relations		
Common positions coordinated with EU Member States to promote the alignment of existing and planned EU legislation and initiatives with Codex standards	Delivered	In course of 2020
Coordinated EU position for the OIE aquatic and terrestrial Code and Manual	Delivered	In course of 2020
Coordinated EU Statements for the World Organisation for Animal Health (OIE) General Assembly	Delivered	In course of 2020
Coordinated EU positions in documents and guidelines of the International Union for the Protection of New Varieties of Plants (UPOV)	Delivered	In course of 2020
Coordinated EU positions in the resolutions of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)	Delivered	In course of 2020
Coordinated EU positions in the World Trade Organisation SPS	Delivered	In course of 2020
Coordinated EU statements and position, as well as negotiations, for the Conference of the Parties of the Cartagena Protocol on Biosafety and Coordinated EU position regarding synthetic biology and gene drives for the Conference of the Parties of the Convention on Biological Diversity	Delivered	In course of 2020
Contribution to intersessional activities under the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety – participation to SBSTTA and SBI meetings, participation in on-line	Delivered	In course of 2020

forum on risk assessment of living modified organisms		
SPS Bilateral relations		
Bilateral trade negotiations (SPS Chapter)	Negotiate comprehensive SPS Chapter that includes all the necessary tools to ensure safe and secure trade and facilitate the access of EU products to non-EU markets.	Balanced SPS Chapter within the ongoing FTA agreements
Negotiate with non-EU countries harmonised export conditions that ensure the cohesion of the EU as regards exports (EU single entity) by ensuring that the same conditions are applied to all the EU territory having the same sanitary or phytosanitary level	Negotiate harmonised export certificates for EU products	In course of 2020
Coordinate EU position in negotiations of Agreements with non-EU countries	Delivered	In course of 2020
Coordinate EU position on the management of the SPS Committees of the Agreements in force	Delivered	In course of 2020
Commission Decision amending Decision 2011/163/EU, recognising the residues monitoring plans of non-EU countries (PLAN/2020/6857)	Ongoing	Q4 2020
EU-China Memorandum of understanding on animal health (ISC/2020/01685)	Revision	Q4 2020
EU- Australia mutual equivalence recognition for beef/pork		Q4 2020
EU-US shellfish equivalence: Implementing Decisions allowing trade of bivalve molluscs between EU and US (PLAN/2018/3849)	Adoption	Q4 2020
EU-US Administrative Arrangement on Shellfish	Conclusion	Q4 2020
Meetings of the EU-US Animal Health Technical Working Group and Plant Health Technical Working Group: Facilitate trade and better	3 meetings held	Q4 2020

cooperation on animal, plant health and food safety issues with the US		
Meetings of the EU-Japan Animal Health Technical Working Group: Facilitate trade and better cooperation on animal health issues with Japan (regionalisation)	1 face-to-face meeting held	Q4 2020
Finalisation of the EU-China regionalisation project, launching and development of road map activities	Project finalised	Q3 2020

General objective 2: Promoting our European way of life		
***Specific objective 2.1**: Diminishing the impact of cancer in Europe*		*Related to spending programme European Social Fund plus*
Main outputs in 2020:		
New policy initiatives		
Output	**Indicator**	**Target**
Europe's Beating Cancer Plan (PLAN/2020/6485)	Adoption	Q4 2020
Audit guidelines for the track and trace system for tobacco products	Launched	Q2 2020
Public consultations		
Output	**Indicator**	**Target**
Roadmap consultation on Cancer Plan	Completed	Q1 2020
Public consultation on Cancer Plan	Completed	Q2 2020
Targeted consultations on Cancer Plan	Completed	Q3 2020
External communication actions		
Output/ Result	**Indicator**	**Target**
The Cancer plan is a key communication priority for 2020		
Preparation of Press material	Number of online views, downloads of media material	Minimum of 200 online views, downloads
	Number of media items mentioning Commsr Kyriakides	Minimum of 10 articles
	Geographical spread of news in various EU countries	Media items in the 27 member states (as per media monitoring)
Production of video showing the benefit of the EU Cancer Plan for citizens	Number of views, embeds and downloads	Minimum 10,000
Promotion on social media, through both owned and paid content. The hashtag #EUCancerPlan monitored continuously	Number of engagements per tweet	Average a hundred engagements per tweet
The dedicated web section on europa.eu as well as the policy page are regularly updated.	Number of page views	Increase page views by 10%Baseline 2019: 2,233 pageviews

Other important outputs		
Output	**Indicator**	**Target**
Meetings with Member States on the implementation of the Tobacco Products Directive and its implementing rules	Organised	Q4 2020
Perception study of different tobacco products (for TPD implementation report)	Completed	Q2 2020
Advertising and smoke-free monitoring study	Launched	Q2 2020
First draft of Article 28 TPD implementation report	Completed	Q4 2020
Compliance checks of TPD	On-going	Q4 2020
Eurobarometer on smoking prevalence	On-going	Q4 2020

General objective 2: Promoting our European way of life		
***Specific objective 2.2**: Patients' access to safe, innovative and affordable medicines and medical devices*		*Related to spending programme: N/A*
Main outputs in 2020:		
Public consultations		
Output	**Indicator**	**Target**
Communication on Pharmaceutical Strategy (PLAN/2020/6954)	Adopted	Q4 2020
External communication actions		
Output/ Result	**Indicator**	**Target**
Public launch of Pharmaceutical Strategy		Q2 2020
Press material		
Media material produced for adoption.	Number of Online views, downloads of media material	Minimum of 200 online views, downloads
	Geographical spread of news in	Media items in the 27 member

	various EU countries	states (as per media monitoring)
Social Media		
Sustained tweets during adoption and as follow up.	Increase engagement on twitter per tweet	Average target of 100 engagements per tweet
Paid promotion of tweets	Increase the number of followers on the EU Health twitter account	5 % increase in the number of followers
Website		
Update of Pharma-related webpages	Number of page views to the relevant section of the website (Medicinal Products)	5 % increase in the number of page views Baseline 2019: 332,357 page views

Other important outputs		
Output	**Indicator**	**Target**
Implementing acts on EU Reference Laboratories (tasks, structure, fees)	Adopted	Q4 2020
Guidance document on classification rules for medical devices	Completed	Q4 2020
Impact Assessment study on the Paediatric regulation and the regulation on Medicines for Rare Diseases (Orphan medicines)	Launched	Q4 2020
Impact Assessment study on EMA fees	Launched	Q3 2020
Audit of the clinical trials system	Launched	Q4 2020
Joint Assessments of Notified Bodies on implementation of Medical Devices Regulation	90% of the on-site assessments requested carried out	Q4 2020
Report to EP/Council on marketing authorisation procedures of medicinal products for human use	Launched	Q4 2020

General objective 2: Promoting our European way of life	
***Specific objective 2.3**: Effective response coordination of serious cross-border health threats*	*Related to spending programme European Social Fund Plus*
Main outputs in 2020:	

External communication actions		
Output/ Result	**Indicator**	**Target**
Awareness raising on tackling vaccination inequalities		
Social media campaign around #VaccinesWork	Increase twitter interactions per tweet	Averaging 100 interactions per tweet across all related tweets
Website	Number of visits to relevant SANTE web section [crisis preparedness, communicable and non-communicable diseases (excluding cancer), vaccination and AMR]	5% increase (Baseline 2019: 205,785 page views) –
Press and Media	National print media coverage	Media coverage by at least 20 EU countries

Other important outputs		
Output	**Indicator**	**Target**
Feasibility study for a common EU vaccination card	Launched	Q4 2020
Feasibility study for physical stockpiling of vaccines	Launched	Q4 2020
Report on State of Vaccine Confidence in the EU	Publication	Q4 2020
Report on interoperability of Immunization Information Systems	Publication	Q4 2020
One Health AMR country visits	country visits carried out	2 country visits

General objective 2: Promoting our European way of life	
***Specific objective 2.4**: More effective, accessible and resilient health systems*	*Related to spending programme European Social Fund Plus*

Main outputs in 2020:		
Initiatives linked to regulatory simplification and burden reduction		
Output	**Indicator**	**Target**
Evaluation of Article 14 on eHealth of Directive 2011/24/EU	Launched	Q2 2020
External communication actions		
Output/ Result	**Indicator**	**Target**
Update of relevant webpages	Number of visits to relevant SANTE web sections	5% increase (baseline 2019: 364,729)
Social media	Number of engagments per tweet	Averaging 100 interactions per tweet across all related tweets
Other important outputs		
Output	**Indicator**	**Target**
Impact Assessment on substances of human origin	Launched	Q4 2020
Report on Health Systems Resilience (by the group on Health Systems Performance Assessment)	Publication	Q2 2020
Statistical compendium “Health at a Glance”	Publication	Q4 2020
Voluntary exchanges (knowledge transfer) between Member States on health system challenges	Launched	Q4 2020
Proposals for European Semester country-specific recommendations (on health system’s resilience, accessibilitiy and effectiveness)	Adoption	Q2 2020
Projects to raise the capacity of Member States to make investments in health, address health workforce challenges and implement integrated care (financed from the Health Programme)	Signed/Launched	Q4 2020
Roadmap on cross-border healthcare	Publication	Q4 2020
Guidelines on emergencies in cross-border healthcare	Published	
Workshops on implementation of cross-border healthcare directive	Launched	Q4 2020
Finalisation of pilot projects Cross-Border Health Care	On-going	Q4 2020
Three meetings of Board of Member States of the ERNs, two meetings of ERN coordinators and the annual meeting of ERN hospital managers	Organised	Q4 2020

Assessment, Monitoring, Evaluation and Quality Improvements System (AMEQUIS) of ERNs	Launched	Q1 2020
Mobility programme of ERN professionals	Launched	Q2 2020
New Framework Contract for ERN IT Tool Clinical Patient Management System	Launched	Q4 2020
Development of ERN clinical patient guidelines	Launched	Q1 2020
Two meetings of eHealth Network together with the respective Presidencies	Organised	Q4 2020
Study (including expert workshops) on health data use in the EU	Completed	Q3 2020
Study on regulatory gaps and obstacles to cross-border digital healthcare, including AI	Launched	Q2 2020
Terms of Reference for development of a Code of Conduct on secondary use of health data in accordance with Article 40 of GDPR	Completed	Q4 2020
Joint Action supporting the development of the European Health Data Space	Signed	Q4 2020
eHealth audits in Member States	90% of the requested audits carried out	Q4 2020