European Commission

Management Plan 2019

DG Health and Food Safety (SANTE)

Contents

INTRODUCTION

DG SANTE's goal is to make Europe a safer, healthier place where citizens and the environment are well protected and the EU's health and agri-food sectors can thrive. Its main aims are to:

- protect and improve public health,
- ensure Europe's food is safe and wholesome,
- protect the health and welfare of farm animals,
- protect the health of crops and forests, and
- support growth and competitiveness in the health and agri-food sectors.

DG SANTE contributes to three of the Juncker Commission's ten priorities as indicated in its Strategic Plan for 2016-2020: (1) a new boost for jobs, growth and competitiveness in the EU, (2) a deeper and fairer internal market, and (3) a balanced and progressive trade policy to harness globalisation.

In 2019, DG SANTE will focus on three tasks: facilitating the adoption of pending legislation by Parliament and Council; ensuring implementation of legislation and other actions; and setting out a strong foundation for the future and the next College of Commissioners. In addition, DG SANTE will continue the preparedness efforts for the UK's withdrawal from the EU in order to minimise disruptions for the EU27.

With regard to pending legislation, SANTE will prioritise an agreement with the Council and Parliament on the reform of the General Food Law to increase the transparency, accountability and sustainability of risk assessment in the food sector in the EU. A second key piece of pending legislation is the Commission proposal for a Regulation on Health Technology Assessment (HTA) to improve the availability of innovative health technologies for EU patients and reduce duplication for HTA bodies and industry, where DG SANTE will continue to negotiate the proposal with the Council and Parliament.

At the same time, DG SANTE is working to implement a number of key actions agreed. For example, given the importance of vaccination as a key component of prevention and preparedness, DG SANTE will take robust action in line with the 2018 Commission Communication and Council Recommendation on strengthening cooperation against vaccine-preventable diseases. This will be done, e.g., by establishing a European Vaccination Information System and vaccination portal, strengthening vaccine supply, fighting against vaccine hesitancy, and working towards an EU vaccination card.

Similarly, antimicrobial resistance (AMR) remains a major global challenge with serious implications for human health and the economy. In 2019, DG SANTE will continue to implement the 2017 European One Health Action Plan against AMR to promote swift and effective actions across the human health, animal health and environmental sectors. This will include implementation of the new veterinary medicines package, a Joint Action with Member States, two overview reports on the effectiveness of the implementation of EU legislation and guidelines as well as continued advocacy to Member States, e.g. through Ministerial letters.

In 2019, DG SANTE will also implement the new legislation on Animal Health Law and Plant Health Law, alongside with the new Official Controls Regulation by delivering a significant package of over 50 delegated and implementing acts.

We will also ensure that resources are devoted to the areas that need it most: 2019 will see discussions continue with respect to the role of health and food safety within the post-2020 Multi-annual Financial Framework (MFF). Following the Commission proposal for an "EU Budget for the Future" in May 2018, DG SANTE will participate in discussions in the Council and Parliament, in particular on the health strand of the European Social

Fund Plus and the food chain aspect of the Single Market Programme, providing input on amendments and suggesting solutions in line with DG SANTE's mandate. DG SANTE will also closely follow discussions on Horizon Europe and other relevant programmes.

Looking to the future, DG SANTE will seek to provide the next College with a strong evidence-based foundation of options for new activities. To this end, DG SANTE will work on the evaluations of legislation in the areas of nutrition and health claims, pesticides, feed additives, food irradiation, food contact materials, sustainable use of pesticides, blood, tissues and cells and orphan and paediatric medicines. DG SANTE also intends to commence an evaluation of the Animal Welfare Strategy and Impact Assessments on an initiative on ceramic and vitreous food contact materials and on options regarding the European Medicines Agency fee system.

In addition, DG SANTE will continue to fulfil its numerous mandates and responsibilities to promote good health and food safety. DG SANTE is responsible for 20% of the entire EU legislative *acquis* and is committed to its implementation for the benefit of health and food safety as well as of the internal market. Substantial work will be carried out under SANTE's audit and analysis programme to ensure EU legislation is correctly implemented and enforced. DG SANTE will also continue to assess, and where relevant authorise, pharmaceuticals and substances used in food and feed production to ensure their safety.

DG SANTE's work also contributes to the achievement of the 2030 UN Sustainable Development Goals (SDG). As the EU population ages, the strain on the health and care systems grow, and SANTE plays an important role in supporting Member States to promote health and invest in effective, accessible and resilient healthcare systems. On the food side, food waste prevention contributes to the sustainability of the food chain and brings both economic and environmental gains. DG SANTE will implement EU actions to prevent food waste as outlined in the Commission's Circular Economy Action Plan, working with the EU Platform on Food Losses and Food Waste to agree on recommendations for action and best practices at each stage of the food supply chain.

The EU's support for animal disease eradication and monitoring programmes accounts for the largest proportion of spending under the EU's food safety programme. DG SANTE will continue to manage animal health crises, such as the current outbreak of African swine fever, adapting the EU legal framework to the evolving disease situation, and financially supporting Member States' measures. Moreover, DG SANTE will continue to work towards prevention of plant disease and to tackle pest outbreaks, especially *Xylella Fastidiosa*.

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PART 1. MAIN OUTPUTS FOR THE YEAR

DG SANTE delivers its strategic vision with support from two programmes financed by the EU budget: the EU Health Programme and the Common Financial Framework 2014-2020 in the food chain area.

EU's Third Health Programme 2014-2020

The EU's Third Health Programme runs from 2014-2020 with a total budget of EUR 449.4 million. It is implemented via annual work programmes which identify priority areas in line with the priorities of the Commission and DG SANTE and the criteria for funding. The Health Programme is managed by the Commission with assistance from the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) and national contact points in EU and other participating countries. The Programme supports the achievement of the specific objectives 1.1 (Effective preparedness, prevention, reaction and eradication of human, animal and plant diseases), 1.3 (Cost effective health promotion and disease prevention), 1.4 (Effective, accessible and resilient healthcare systems in the EU), 1.5 (Increased access to medical expertise and information for specific conditions), 2.1 (Effective EU assessment of medicinal products and other treatment) and 2.2 (Stable legal environment and optimal use of current authorisation procedures for a competitive pharmaceutical sector and patients' access to safe medicines).

This includes actions on communicable diseases and other health threats, non-communicable and rare diseases, antimicrobial resistance (AMR), health systems, patients' rights in cross-border healthcare, human tissues, cells, blood and organs, European Reference Networks (ERN), medical devices and *in vitro* diagnostics medical devices, medicinal products and tobacco products.

2019 is the penultimate year of the current Health Programme; therefore, the focus will be on the best use of the remaining budget in line with the Programme objectives. The work programme for 2019 will focus on a series of actions from among the 23 thematic priorities set out in Regulation (EU) No 282/2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020). The priorities of the Commission and Commissioner Andriukaitis' mission letter have guided the drafting of the work programme.

The Annual Work Programme in 2019 will be built around the following Commission priority areas, while addressing the dimension of health inequalities as a cross-cutting issue:

1) Country specific and cross country knowledge;
2) Cross-border health threats, preparedness and response, including antimicrobial resistance and vaccination;
3) Structural support to health systems and link to digital single market;
4) Promotion of health and prevention of non-communicable diseases.

The two scientific committees – on Health, Environmental and Emerging Risks (SCHEER; funded by the Health Programme) and on Consumer Safety (SCCS; funded by the Consumers Programme) will continue to make an important contribution to risk management decisions. They are expected to publish up to 25 opinions in 2019, performing risk assessments in the areas of public health, consumer safety and the environment. A key focus in 2019 will be the area of risk assessment for endocrine disrupting substances in medical devices and cosmetics. Their opinions and scientific advice help risk managers in DG SANTE and other departments of the Commission (primarily DG GROW and DG ENV) to develop and implement EU legislation building on the best available evidence, which ensures a high level of health protection (see Article

168 TFEU) and in turn supports the Commission priorities of jobs, growth and investment, as well as the internal market.

2019 will also see planning continue for the role of health within the post-2020 Multi-annual Financial Framework (MFF). Following the Commission proposal for an "EU Budget For the Future"[1] in May 2018, DG SANTE will closely follow discussions in the Council and Parliament on the health strand of the European Social Fund Plus (ESF+), providing input on amendments and suggesting solutions in line with its mandate.

Common Financial Framework (CFF) 2014-2020 in the food chain area

EU funding for food and feed safety contributes to a high level of health and safety across the food chain from production through to point of sale. It promotes a competitive food industry, operating with high and uniform levels of safety and contributes to the stability of the EU's internal and export markets.

Activities and actions in this area are governed by Regulation (EU) No 652/2014 (CFF Regulation) and expenditure covers animal health and plant health measures, emergency measures linked to animal and plant disease outbreaks, official controls activities and relations with relevant international organisations. The total budget of the CFF 2014 – 2020 is EUR 1.892 billion.

The CFF finances actions under the specific objective 1.1 in relation to preparedness, prevention and eradication of animal, foodborne and plant diseases and the specific objective 1.6 on official controls.

In 2019, **veterinary measures** (animal health) are expected to continue representing the largest share of the food chain budget, as animal diseases remain a major priority for Member States for health, trade and political reasons. As in previous years veterinary measures will mostly cover disease prevention through veterinary programmes, emergency measures, crisis management and permanent availability of EU vaccine banks. For more details please refer to point 1.1.3.

For plants, **phytosanitary measures** are becoming increasingly important due to increased globalisation and trade, being accompanied by new threats. For 2019, the CFF will continue to cover phytosanitary programmes and phytosanitary emergency measures. For more details please refer to point 1.1.4.

DG SANTE will continue to provide support to the Member State's **official control activities** to implement measures in animal health, plant health and food safety. These cover EU databases, alert and notification tools, testing and training activities carried out by the EU Reference Laboratories (EURLs) and training activities carried out under the Better Training for Safer Food (BTSF) programme. For more details please refer to point 1.6.

With regard to the 2021-2027 Multiannual Financial Framework, DG SANTE will carry out negotiations with the co-legislators on the food chain strand of the new Single Market Programme.

[1] https://ec.europa.eu/commission/future-europe/eu-budget-future_en

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 Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Chemicals Agency (ECHA). DG SANTE is also on the Management Board of the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) and the European Foundation for the Improvement of Living and Working Conditions (Eurofound).

Collectively, these bodies represent a wealth of scientific resources, expertise and network opportunities that support SANTE's process of evidence-based policy making.

1. General objective 1: A new boost for jobs, growth and investment

1.1. Specific objective 1.1: Effective preparedness, prevention, reaction and eradication of human, animal and plant diseases

Output table is included in Annex 1.

Animal health is often directly linked to public health: Some animal diseases are transmissible to humans and good animal health is a requirement for food safety and the EU's food industry. This is why DG SANTE takes a One Health approach to preparedness and prevention, incorporating human health, animal health, food safety and environmental perspectives, wherever applicable.

The cost of dealing with emergencies and diseases, if they are not contained or well-managed, is very significant, with loss of lives, consumer confidence, internal EU and export markets, costs of disease control on the EU and Member State budgets, and costs to Member State health systems.

Crisis preparedness, prevention and response capacity in the fields of human, animal and plant health and food safety is a critical part of DG SANTE's work. While the EU has a well-developed and substantial framework for disease and crisis management, it must continually evolve to remain robust in the face of new and hybrid threats.

In 2019, actions under specific objective 1.1 will focus on the following priorities:

- Tackling serious cross-border public health threats;
- Improving preparedness and management of foodborne crisis;
- Managing, isolating and preventing outbreaks of major animal diseases;
- Managing, isolating and preventing plant diseases.

DG SANTE will also continue work on the implementation of the 2017 European One Health Action Plan against AMR.

DG SANTE's work under this specific objective is supported by the European Food Safety Authority (EFSA), the European Medicines Agency (EMA), and the European Centre for Disease Prevention and Control (ECDC). These agencies provide rapid scientific and technical support, helping the EU to prepare, respond and manage health crises. ECDC also operates dedicated surveillance networks and an early warning and response system. This plays an important part in mitigating and containing the health and economic consequences of disease outbreaks.

DG SANTE will also foster stronger proactive coordination with EU research and innovation policy makers, in particular with DG RTD and DG AGRI, within the framework of Horizon 2020 and the forthcoming Horizon Europe. This will not only support

developing robust evidence based policies, but also tackle the needs of the agencies for the provision of robust scientific advice.

1.1.1. Tackling serious cross-border health threats

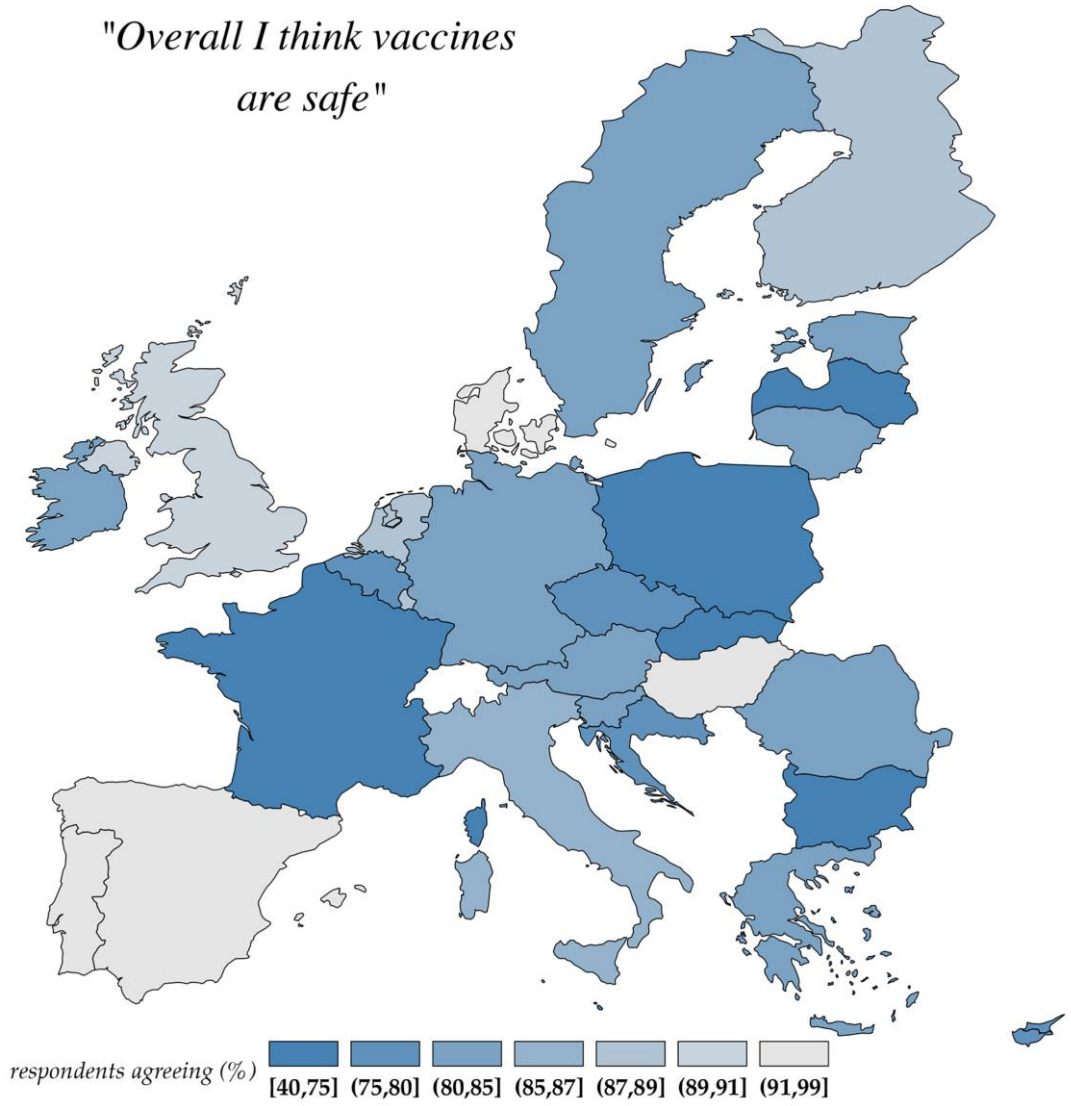
While preparedness, response planning and implementation is the responsibility of EU Member States, the EU - and DG SANTE in particular - has an important role to play in coordinating preparedness and response capacity, in the framework of Decision 1082/2013/EU on serious cross border health threats and other EU legislation (food safety, animal health and chemical, biological, radiological and nuclear threats etc.). In that context, DG SANTE will organise two plenary meetings of the Health Security Committee and help Member States implement the Health Security Committee Action Plan on preparedness and the International Health Regulations, including reviewing the reporting framework on preparedness, developing a mechanism for the exchange of medical countermeasures, and improving sharing of personal data for contact tracing purposes. To ensure that the Health Security Committee remains fit for purpose, DG SANTE will undertake a review of its rules of procedures.

DG SANTE will also launch two Joint Actions in 2019. The first Joint Action will strengthen preparedness against serious cross-border threats to health, including through laboratories in the EU (supported with EUR 7.9 million in the annual work programme 2018). The second Joint Action will focus on health preparedness for terror attacks as a means to implement actions decided by Member States in the Health Security Committee. Finally, in order to ensure Member States' compliance with their obligations under Decision 1082/2013/EU, improve the quality and usability of data and coordinate national responses to serious health threats, it is necessary to have comparable and up-to-date information on the communicable diseases and related health issues covered by epidemiological surveillance. To this end, a Commission Implementing Decision is planned on the operational procedures of the epidemiological surveillance network.

To strengthen a coordinated response to serious cross-border health threats, the Early Warning and Response System is gradually being re-engineered and interlinked with other EU early alert systems.

At the same time, DG SANTE will contribute to the work on the European Agenda on Security, the Commission work on hybrid threats and anti-terrorist preparedness and will ensure continued cooperation on health security under global initiatives, such as the Global Health Security Initiative and health initiatives of the G7, G20 and the World Health Organization.

Vaccination is one of the most important public health tools of the 21st century and a key component of prevention and preparedness. It has led to the eradication of small pox, elimination of poliomyelitis from Europe, and dramatic decrease of mortality and morbidity of communicable diseases preventable by vaccination. However, vaccination programmes are facing challenges, such as a decline in vaccination coverage in some countries, the increasing cost of new vaccines, supply shortages, and misconceptions about vaccination which have led to increased distrust and fear of possible side effects.



In 2019, DG SANTE will take robust action on vaccination in line with the Commission Communication and Council Recommendation on Strengthening Cooperation against vaccine preventable diseases, which were both adopted in 2018. DG SANTE will work with Member States to establish a European Vaccination Information System, coordinated by the ECDC; counter online vaccine misinformation and develop evidence-based information tools; and work towards strengthening vaccine supply and mitigating risks of shortages by aiming at developing a virtual European data warehouse on vaccine needs and stocks. A European Vaccination Portal will also be created, providing factual and transparent information on vaccination and vaccines and a study of the Eurobarometer will seek to measure public opinion on vaccines, possible policy actions and expectations towards the EU on this area. A follow up of the 2018 Confidence Report on vaccination will be initiated in 2019 to identify trends among the general public and healthcare professionals regarding the safety and importance of vaccines.

DG SANTE will also initiate a study to develop a proposal and template for a common physical EU vaccination card and an EU electronic vaccination card, as well as another study on the feasibility of establishing a EU stockpile for vaccines; organise a conference

on improving EU manufacturing capacity and ensuring continuity of supply; and convene a Coalition for Vaccination to bring together European associations concerned with the issue. In collaboration with DG EAC, the Schoolnet, ECDC and JRC, two additional actions will be initiated: developing training materials for teachers and secondary school students, and a behavioural study on explanations and measures to improve confidence in vaccines among the general population. Finally, a Global Vaccination Summit will be hosted under EU leadership in late 2019 to leverage genuine and strategic international efforts in this area.

Following the Joint Procurement Agreement finalised in 2018, DG SANTE will issue calls for tendering in 2019 to strengthen EU cooperation on vaccine supply and vaccine coverage. DG SANTE will also follow up on joint procurement procedures on personal protective equipment, Bacillus Calmette–Guérin vaccine, tuberculin, and diphtheria antitoxin, as well as ensure the management of the specific steering committees. DG SANTE will also organise a workshop on lessons learned from the work related to the joint procurement of the pandemic influenza vaccines.

SANTE will also reinforce its support to national vaccination efforts to increase coverage through the Joint Action on vaccination, co-funded by the Health Programme (EUR 3.55 million). The Joint Action, coordinated by France and involving 20 countries, will work towards finding agreement on list of priority vaccines for research; undertaking surveys with stakeholders on the feasibility of conducting coordinated cross-border measles vaccination campaigns; and by launching an e-learning platform for research-based knowledge, best practices and lessons learned on vaccine hesitancy. All of these actions will contribute to the achievement of specific objective 1.1 aimed at effective preparedness, prevention, reaction and eradication of diseases.

1.1.2. Improving preparedness and management of foodborne crisis

The Commission updated its general plan for crisis management in the field of the safety of food and feed (Commission Decision repealing previous Commission Decision 2004/478/EC) in close cooperation with the European Food Safety Authority and the Member States, drawing from the lessons learned from the management of various outbreaks over the last decade. In 2019, in support of specific objective 1.1 aimed at effective preparedness, prevention, reaction and eradication of diseases, SANTE will maintain its focus on better prevention of foodborne outbreaks and crises and on improved preparedness with a view to limiting the extent of outbreaks that can be detrimental to public health and costly for the economy.

This will rely on regular meetings with Member States' crisis coordinators, organisation of a crisis exercise to train them, fine tuning the Commission procedures for handling outbreaks, and dealing promptly with newly occurring incidents. On the latter, the development of new epidemiological and investigation tools will help detect more incidents and at an earlier stage.

The work will also be pursued on adapting existing legislation to draw from experience gained or from new epidemiological situations, be that zoonoses or hygiene-related questions.

1.1.3. Managing and isolating outbreaks of major animal disease

DG SANTE will continue to manage animal health crises like currently African swine fever, lumpy skin disease, avian influenza and *peste des petits ruminants* through the efficient follow-up of measures put in place both by the Commission and Member States, in particular those related to regionalisation. DG SANTE will continue adapting the EU legal framework to the evolving disease situation and financially supporting measures implemented by the Member States.

Particularly, in order to face the epidemic of African swine fever, DG SANTE will continue to prepare and adopt regionalisation measures, carry out strategic work and coordinate among Member States for disease-control purposes.

For 2019, the Commission received 146 applications for veterinary programmes to tackle animal diseases of which 144 are likely to be approved for funding. These veterinary programmes target transmissible, often epidemic, animal diseases. They have a direct impact on public health because of food safety issues and because some animal-borne diseases are transmissible to humans. Furthermore, animal disease outbreaks can trigger significant economic costs through loss of internal EU and export markets and the direct costs of disease control. Due to the highly transmissible nature of these diseases, they are best addressed at EU level through measures coordinated with the Member States.

At the same time, in support of specific objective 1.1 aimed at effective preparedness, prevention, reaction and eradication of diseases, DG SANTE will continue to assist Member States and neighbouring non-EU countries in maintaining an adequate level of disease preparedness, in particular through its continued collaboration with and support to the Food and Agriculture Organization (FAO)-based European Commission for the Control of Foot and Mouth Disease and within the framework of the Global Framework for the progressive control of Transboundary Animal Diseases, which is a joint FAO/World Organisation for Animal Health (OIE)/Commission initiative.

Preparedness and early response capacities will be further strengthened through the development and use of other relevant instruments, such as audits by DG SANTE, support missions by the Community Veterinary Emergency Team, training courses under the 'Better Training for Safer Food' programme, EU Reference Laboratories and Centres (EURLs and EURCs) expertise and the availability of vaccine banks for specific diseases.

These instruments have all proven to be effective in assisting Member States and neighbouring non-EU countries in the prevention, containment and eradication of animal disease outbreaks.

Modernising and simplifying EU legislation

The newly adopted legislation on Animal Health Law (AHL; Regulation (EU) 2016/429), alongside with the new Official Controls Regulation (OCR; Regulation (EU) 2017/625), will contribute to growth, jobs and investment by ensuring a level playing field for the agri-food sector. To ensure this, DG SANTE will deliver a significant package of delegated and implementing acts. Specifically in relation to AHL, around twenty-one delegated and implementing acts will be adopted in the course of 2019.

Contribution of the EU food and feed financing programme (CFF) to animal health measures

The EU support for animal disease eradication, control and monitoring programmes accounts for the largest proportion of spending under the EU's food safety programme.

The budget planned for the implementation of the national veterinary programmes in 2019 is EUR 163.5 million.

Due to the periodical occurrence and re-occurrence of certain animal diseases, the risk of a veterinary crisis is increasing as a result of globalisation of markets, intensification of production and climate change.

EU funds will be available during crisis times to co-fund emergency measures aiming at quickly eradicating and preventing the spread of animal disease. The total budget for such emergency measures is EUR 50 million in 2019. Major sanitary and economic consequences can be avoided when an outbreak is extinguished immediately thanks to early detection and immediate action aiming at prompt eradication.

For certain animal diseases, vaccination is of pivotal importance in the event of an outbreak. This fact has led to the establishment of an EU system of vaccine banks which complements the national approaches by making vaccines immediately available to Member States and neighbouring third countries in case of emergency situations. As of 2017 the Commission has signed contracts for a total budget of EUR 14 million for vaccine banks covering diseases like Foot and Mouth Disease, Lumpy Skin Disease and *Peste des Petits Ruminants*. One additional contract for EUR 1.7 million for the purchase of Lumpy Skin Disease vaccines was signed in 2018 and another procedure for sheep pox and goat pox should result in the signature of a contract for a total value of EUR 480,000 in the first trimester of 2019.

In 2019, DG SANTE will continue to support Member States and non-EU countries in their efforts to control and prevent exotic diseases such as lumpy skin disease, *peste des petits ruminants*, and sheep and goat pox, both through the existing EU vaccines banks and through financial support for specific protection and control measures.

1.1.4. Preventing plant disease

Globalisation of plant trade and climate change has substantially increased the risk of plant pest infestation. Early detection and control is essential to mitigate the consequences on the agricultural economy and trade, as well as on the environment.

The national survey programmes for organisms harmful to plants will facilitate the earliest possible detection and eradication of the about 50 plant pests on the EU territory. There will be 24 Member States participating in the annual plant health survey with

programmes to be implemented in 2019. This surveillance allows early findings and more effective outbreak management, which itself is enhanced by the improved EUROPHYT outbreak reporting system. In 2019, SANTE will process applications for 2020, as well as the final reports of the 2018 surveillance activity.

In 2019, DG SANTE will ensure the management of the four newly designated EU Reference Laboratories (EURL) for plant health and designate an additional one for fungi. EURLs will contribute to the improvement and harmonisation of methods of analysis, the development of validated methods and the coordinated assistance of official laboratories. This will contribute to the timely adoption of measures against plant pests in the EU.

SANTE will further increase its focus on crisis prevention, preparedness and management in the plant health area and strengthen Member States' response capacity through different instruments, including training courses under the 'Better Training for Safer Food' programme. The European Food Safety Authority (EFSA)'s activity on horizon scanning which will continue in 2019 will help risk managers to focus preparedness and controls towards new and emerging risks. The list of harmful organisms also needs to be kept up to date based on risk assessments by EFSA and by the European and Mediterranean Plant Protection Organisation. Interceptions and outbreaks will be discussed with Member States and followed up by appropriate EU measures when necessary.

The management of plant health-related interceptions at import and of outbreaks in the Member States, such as citrus Black Spot, Xylella, Pine Wood Nematode, will be pursued by adapting emergency measures to address the constantly evolving situations and through conducting targeted audits. DG SANTE will ensure a continuous update of the list of harmful organisms and related statuses within the EU, of permanent import requirements and of protected zones. Financial requests for eradication of outbreaks will be reviewed, e.g. for Xylella, Pine Wood Nematode, Anoplophora, different potato pests and for any other new outbreaks (about 30 requests are expected). Given that the EU's co-financing of such measures is subject to correct implementation of the EU plant health legislation, it provides an incentive to Member States apply such measures in a timely and effective manner. Doing so enables a better protection for the rest of the EU territory. EU financial support is also available to help operators recoup losses incurred as a result of activities aimed at eliminating pests, which in turn helps to ensure proper implementation of these measures.

Modernising and simplifying EU legislation

In 2019, DG SANTE will proceed with the adoption of six well-advanced delegated and implementing acts under the Plant Health Law (PHL; Regulation (EU) 2016/2031) and prepare seven additional ones. At the same time, in the context of the implementation of the new Official Controls Regulation, work will continue to adopt acts fully related to plant health (two acts), as well as acts where plant health aspects are relevant (eleven acts).

DG SANTE will ensure the follow-up to the entry into force – by the end of 2019 - of the implementing act provisionally prohibiting 38 high risk plants. Third-country dossiers will be assessed during 2019 and the implementing act will be updated once the full risk assessment is finalised.

In the area of seed and plant propagating material, proper and on-time implementation of the plant reproductive material legislation will be ensured in 2019 through the adoption of eleven directives on certifications and marketing requirements, whilst also starting the preparations of two implementing acts based on the Organic Regulation.

In the area of seed and other plant reproductive material, implementation, update and development of the plant reproductive material legislation will be ensured in 2019 through the adoption of five implementing acts on amending technical requirements for plant reproductive material certification, marketing or variety registration and, as a follow-up of the new Plant Health Regulation, through the modification of nine basic

Directives Annexes and five implementing Commission acts regarding quality pests. The functioning of the new voluntary Seed Fraud Network will be ensured and innovative approaches will be tested in three temporary experiments. The seed trade will be facilitated by evaluating EU equivalence of third countries and preparing proposals for granting equivalence recognition. At the same time, the preparation of delegated (heterogeneous material) and implementing (temporary experiment on organic varieties) acts for the application of the new Organic Regulation will start with the involvement and consultation of stakeholders.

In the area of Community Plant Variety Rights, the Fees Regulation will be updated in 2019 following the Community Plant Variety Office (CPVO) cost calculation exercise in 2018.

Contribution of the EU food and feed financing programme (CFF) to plant health measures

The national survey programmes for organisms harmful to plants is a new funding activity under Regulation (EU) No 652/2014 which allows for earlier detection and eradication of these plant pests. The budget in 2019 for the implementation of the plant health survey programmes is EUR 22.5 million.

Funds will be also available to tackle the outbreaks of pests. To be effective, phytosanitary eradication measures need to be implemented at the very initial stage of the outbreak, which requires a rapid response at EU level, especially for devastating bacteria, such as *Xylella Fastidiosa*. An early and decisive intervention can prevent the devastating costs that arise when such diseases become established.

Co-financing requests from Member States for the implementation of EU emergency measures may raise to EUR 13 million to be financed under the committed budget line for 2019 on emergency measures in case of animal and plant health outbreaks (EUR 20 million). By early 2019, the Commission will sign grants with Member States to combat *Xylella Fastidiosa* for a total value of EUR 3.85 million.

1.2. Specific objective 1.2: Safe and sustainable food and feed production systems

Output table is included in Annex 1.

The EU has one of the highest standards of food safety and quality in the world. These standards are ensured through a wide range of harmonised rules, as well as by EU authorisations for products and substances used in the food chain, i.e. food flavourings, food/feed additives, pesticides, biocides, plastic food contact materials and genetically modified organisms. DG SANTE verifies through its audits whether rules in force are correctly applied and enforced. This framework ensures a high level of health and environment protection across the EU and at the same time encourages free trade, investment and innovation.

It is essential that safety and competitiveness are delivered together and not in opposition to one another. Our regulatory framework on food and feed needs to be fit-for-purpose and to ensure safety without being overly prescriptive or stifling innovation.

EFSA makes an important contribution to safe and sustainable food and feed production systems through its scientific opinions on the safety of food and feed. The EU research and innovation framework programmes offer an opportunity to address scientific gaps and challenges for robust evidence based policy making, including for risk assessment.

In this context, a Eurobarometer will be launched in 2019 to better understand citizen's perceptions and expectations of an EU sustainable food system and the multiple dimensions of the food chain, from food composition to food distribution, focussing in particular on food fraud and its impact in terms of citizens' perceptions and the reputation of the food chain.

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

Modernising food policy

To promote a favourable environment for research and innovation DG SANTE aims at the simplification and modernisation of the EU legislation linked to safe and sustainable food and feed production in line with specific objective 1.2. To this end, DG SANTE is carrying out several REFITs, evaluations and reforms:

- Reform of the General Food Law and relevant sectoral legislation – In 2019 DG SANTE will negotiate with the Council and Parliament with a view to the adopting the reform of the General Food Law (Reg. 178/2002), to increase the transparency, accountability and sustainability of the EU scientific model of risk assessment based decision making and of other aspects, such as the governance of EFSA;
- Evaluation of the Nutrition and Health Claim Legislation with publication of a Staff Working Document by the first half of 2019;
- Ongoing evaluation of the Food Contact Material legislation with the publication of the Staff Working Document planned for early 2020;
- Evaluation of legislation covering both placing on the market of plant protection products and pesticides residues with the finalisation in 2019 of a Staff Working Documents;
- Evaluation of the feed additives legislation with publication of a Staff Working Document expected in late 2019;
- Evaluation of the Sustainable Use Directive (SUD), which DG SANTE will commence in 2019 by developing a roadmap and contracts with consultants, and by starting consultations with other relevant Directorates-General. Whereas the SUD was not included in the scope of the above REFIT of the pesticide legislation, any relevant findings of the latter evaluation will be incorporated in the forthcoming SUD evaluation.

Reducing intakes of trans-fatty acids in food

Different actions have been taken in Member States over the past years to address trans-fatty acids (TFAs), an important risk factor for the development of heart diseases, the intake of which should be reduced in the diet of EU consumers. A 2015 Commission report concluded that setting a legal limit for industrially produced TFAs in foods would be the most effective measure to protect consumers and public health and ensure compatibility with the internal market. An Impact Assessment on TFAs was completed in the course of 2018. In October 2018, the Commission launched the feedback mechanism on a draft Implementing Regulation on industrially produced TFAs proposing a limit of 2g per 100g in foods. Following the favourable vote of the Standing Committee on Plants, Animals, Food and Feed on 7 December 2018, the text will be examined by the European Parliament in 2019.

Food labelling

DG SANTE will work on the implementation of the Regulation on food information to consumers (Regulation 1169/2011) which – amongst other things – harmonises the

mandatory origin labelling of food and reinforces the rules on voluntary origin labelling. Following the adoption of an implementing act in 2018 laying down conditions on the provision of voluntary origin labelling, DG SANTE will prepare a guidance document in the course of 2019.

Moreover, DG SANTE will continue working towards the operationalisation of a Food Labelling Information System encompassing all EU and national mandatory labelling indications to support food business operators, in particular SMEs.

Foods for specific groups

DG SANTE 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 regulation on processed-cereal based food and baby food, which will revise the current compositional and labelling requirements applicable to such foods. Specifically, SANTE will prepare an outline of specific compositional requirements for baby foods and processed cereal-based foods for the purpose of consulting with the European Food Safety Authority.

Novel food

Implementing the Regulation on Novel Foods (2015/2283), which came into application on 1 January 2018, continues to be an important source of work for DG SANTE, especially in light of a higher than expected application volume. In 2019, DG SANTE will process authorisation applications for around 85 novel foods and 15 traditional foods. These will include the first authorisations for insects as novel foods in Europe in line with the scientific advice of the European Food Safety Authority. More than half of the authorisations will include provisions on data protection which DG SANTE will process.

Food contact materials

Linked to the Commission work on the European strategy on plastics, in 2019 DG SANTE will continue to prepare, with a view to ultimately adopt, Decisions for around 138 authorisations of plastic recycling processes. This creates a level-playing field for operators and promotes the uptake of recycled plastics by the food packaging industry, contributing to the circular economy.

In parallel, the Commission will further explore how to best address the migration into food of heavy metals, such as lead and cadmium, from ceramic and vitreous food contact materials, such as crystal glass. An Inception Impact Assessment has been prepared in 2018 and an Impact Assessment could be finalised in 2019, enabling the consideration of health-protective measures to reduce consumers' exposure to heavy metals. While the main objective is to establish a high level of health protection, the Impact Assessment will take account of the situation of small and medium artisanal and traditional producers, as well as the cultural value of some of these food contact materials.

Market access for safe substances

In 2019, DG SANTE will continue to assess, and where relevant authorise, a range of substances used in food and feed production to ensure their safety. Where their safety for health/the environment is not established, existing authorisations will be withdrawn or not renewed. This protects consumer health, supports an efficient internal market for these products, and contributes to the achievement of specific objective 1.2 aimed at safe and sustainable food and feed production systems.

These authorisations include new substances and new uses of already authorised substances used as food additives (about 20 new authorisations and about 15 amended authorisations per year), food flavourings (about 3 new authorisations and about 10 amendments to existing authorisations on flavourings per year), novel foods (over 90

authorisations and notifications expected in 2019), and substances used in plastic food contact materials (about 20 substances added yearly to the list of authorised substances, or, their use extended). DG SANTE may also propose the withdrawal of certain flavourings on the basis of relevant EFSA opinions to ensure the safety and quality of products circulating on the internal market, in the framework of the ongoing evaluation programme of existing flavourings.

New authorisations and renewals of previously authorised active substances in plant protection products and biocides will be proposed based on the outcome of the safety evaluations. In 2019, around 5 proposals for approval/non-approval of new active substances, around 35 proposals for renewal/non-renewal of approval of active substances, and around 15 proposals for approval/non-approval of basic substances will be presented to the Standing Committee for Plants, Animals, Food and Feed. In the area of biocides, around 40 decisions on existing and new active substances and around 25 decisions on authorisations for biocidal products are expected in 2019.

Maximum residues levels (MRL) for pesticides will be set by means of Commission Regulations to allow circulation of safe food on the internal market while at the same time guaranteeing that food is safe. MRLs are also a requirement for the import of food from non-EU countries in order to maintain the same level of safety for food of plant origin, be it imported or produced within the EU. Draft proposals covering around 70 routine MRL applications for specific crop-commodity combinations as well as draft proposals for the full review of around 25 active substances will be prepared and presented to the Standing Committee. In addition, DG SANTE will increase overview of Member States' activities related to emergency authorisations.

Maximum Levels (ML) for contaminants in feed and food will also be set by means of Commission Regulations on the basis of EFSA opinions. In 2019, it is foreseen to set maximum levels for acrylamide and of 3-MCPD-esters vegetable oils and fats in (certain) foods for infants and young children, and of perchlorate in certain foods.

Genetically modified organisms (GMOs), cloning and new breeding techniques

In 2019, DG SANTE will continue to implement the legislative framework on GMOs by processing GM food and feed (50 pending applications in EFSA) and cultivation applications. In case of adoption by the Commission of pending GMO authorisations for cultivation, in 2019 DG SANTE will coordinate with Member States the implementation of those authorisations.

Following the ruling of the EU Court of Justice on targeted mutagenesis techniques, DG SANTE will discuss the outcome of the ruling with Member States and stakeholders and mandate EFSA to evaluate whether the current risk assessment guidance is adequate. Moreover, DG SANTE will ensure the follow-up on the request made to the European Group on Ethics to identify ethical issues relating to gene editing, both in human health and agriculture contexts.

Finally, DG SANTE will continue to monitor the progress made in the Parliament and the Council in regard to the initiative adopted in 2015 allowing for the possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory (COM(2015)177).

DG SANTE will also continue to monitor the progress made in the Parliament and the Council in regard to the two cloning-related initiatives adopted in 2013, specifically on the cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes (COM(2013)892) and the placing on the market of food from animal clones (COM(2013) 893 final).

Sustainable use of pesticides

In 2019, DG SANTE will continue to work with Member States on the implementation of the Directive on the sustainable use of pesticides (SUD, Directive 2009/128/EC) which aims at reducing the risks and impacts of pesticide use on human health and the environment and at promoting the use of integrated pest management (IPM) as well as of alternative approaches or techniques, such as non-chemical alternatives to pesticides. In this context, in 2019 DG SANTE will prepare the second report on the Directive to Council and Parliament.

In 2019, DG SANTE will perform six additional audits to Member States and organise 'Better training, for Safer Food' training with Member States to exchange best practices specifically regarding the implementation of IPM. DG SANTE will also commence work with Member States to produce criteria for farm level assessment of IPM.

In 2019, DG SANTE will also continue to work together with Member States to implement actions identified in the implementation plan on sustainable plant protection. Following the launch of the web portal on sustainable use and the adoption of new low risk criteria in 2017, SANTE will work on technical guidance to harmonise the assessment of bio-pesticides – the most important candidate group for low-risk plant protection products.

DG SANTE will also produce a Directive establishing harmonised risk indicators to enable the effect of these actions to be measured at Union level and commence the evaluation of the SUD. Whilsts the first Commission report report on the Directive to Council and Parliament has already identified difficulties with implementation, findings and conclusions of the second report will be used to identify further objectives for the SUD evaluation. DG SANTE will continue to work with DG AGRI to ensure that the objectives of the Directive are reflected in the new Common Agricultural Policy.

Endocrine disruptors

In 2019, SANTE will implement the criteria adopted in 2017 for the identification of endocrine disruptors in the context of biocides and pesticides. DG SANTE will contribute to the implementation of the actions announced in the Commission Communication "*Towards a comprehensive European union framework on endocrine disruptors*" adopted in November 2018.

Plant reproductive material

In 2019, DG SANTE will update the Common Catalogues of plant varieties to authorise their marketing throughout the EU and facilitate marketing of plant reproductive material, in particular by updating requirements, developing innovative approaches and evaluating and preparing proposals for EU equivalence for imports. The Community Plant Variety Office (CPVO) will manage the EU's Plant Variety Rights Regime. Following the Commission notice on clarification of certain articles of the Biotech Directive, the impacts on Plant Variety Rights regime will be closely followed by DG SANTE.

Food fraud

Following the fipronil incident in summer 2017 (illegal use of fipronil in poultry farms resulting in contamination of eggs and poultry meat), the Commission and the Member States agreed to strengthen their efforts to ensure an EU wide harmonised and co-ordinated risk management in case of widespread contamination incidents. Crisis preparedness activities and training will be further developed in 2019.

The EU Food Fraud Network will continue to coordinate responses to suspicions of fraud. Security arrangements will be reinforced along the new lines defined for EU security classification. Moreover, DG SANTE will continue to coordinate its work on food fraud with

Member States, other relevant DGs, EUROPOL and INTERPOL to ensure better cooperation with police and justice authorities. DG SANTE will call for Member States experts and competent authorities to increase the collaboration/coordination of national investigative services, to ensure effective data analysis and intelligence sharing at EU level. DG SANTE will also reflect on how to strengthen activities in this field.

Food hygiene

In 2019, DG SANTE will discuss a number of policy actions with Member States linked to the EU's food hygiene legislation with a view to adapting it to biological risks and innovation, whilst at the same time maintaining a high level of food safety and ensuring proportionality.

These discussions will mainly focus on finalising delegated and implementing acts under the Official Control Regulation, as regards controls of food of animal origin (including meat inspection) and the applicable import conditions. The opportunity will be taken to modernise the existing framework, notably in light of latest available science.

With regard to bovine spongiform encephalopathy (BSE), in 2019, the focus will be on paving the way for the use of non-ruminant proteins in feed, with a view to reducing the distortion of competition between EU producers and those based in non-EU countries where requirements are less strict.

Feed hygiene and marketing

In 2019, DG SANTE will conduct preparatory work to establish the conditions for the listing of non-EU countries wishing to export feed to the EU in accordance with Commission Regulation 183/2005 on feed hygiene.

DG SANTE will also continue to ascertain a smooth functioning of the internal market for feed materials and compound feed, including pet food. Re-evaluations of authorisations, new authorisations, modifications of authorisations and renewal of authorisations of feed additives will be proposed based on the outcome of the safety evaluations (some 45 implementing regulations approving some 135 feed additives).

Preventing food waste and promoting the Circular Economy

Food waste prevention contributes to the sustainability of the food chain and brings both economic and environmental gains. DG SANTE will continue to implement EU actions to prevent food waste as outlined in the Commission's Circular Economy Action Plan. In doing so, the Commission will continue to work closely with all key players through the EU Platform on Food Losses and Food Waste to help accelerate the EU's progress towards the Sustainable Development Goal (SDG) 12.3 target on food waste.

As required by the Waste Framework Directive (COM(2015)595 final), DG SANTE will develop a methodology and indicators to measure food waste as well as the format for reporting of food waste data. These will be adopted, respectively, via a delegated and an implementing act by the end of the first quarter of 2019. Secondly, taking into account findings from a 2018 market study, DG SANTE will elaborate technical guidance to promote more consistent date marking practices. Thirdly, DG SANTE will follow-up on the 3-year EU pilot project on food donation which aims at ensuring further dissemination of the 2017 EU food donation guidelines. Moreover, DG SANTE will further encourage the safe use of food no longer intended for human consumption as animal feed by disseminating the 2018 guidelines.

The EU Platform on Food Losses and Food Waste will meet twice in 2019. The four established sub-groups (*food donation*, *food waste measurement*, *action and implementation*, and *date marking*) will pursue their work. The EU Platform will adopt recommendations for action on food waste prevention at each stage of the food supply chain and identify best practices based on a report of the Joint Research Centre. On this occasion, a public event will be organised to promote broader uptake by key players of actions needed to achieve the UN Sustainable Development Goal 12.3. By June 2019, DG SANTE will assume operations of the Horizon 2020 REFRESH Community of Experts as part of its food waste prevention digital tools.

Animal welfare

Managed by DG SANTE since its creation in 2017 and gathering 75 experts from various sectors, the EU Animal Welfare Platform aims to improve the application of EU rules on animal welfare. It also seeks to promote EU animal welfare standards and the market benefits of animal welfare both within and outside the EU. The Platform will meet twice in 2019 and DG SANTE will continue to develop the related digital tool which allows the consistent exchange of information. The Platform has two official subgroups working on welfare during transport and welfare of pigs. Each subgroup will meet twice during 2019 and will deliver their respective outputs by the end of 2019.

In light of the public and Parliament's interest for animal welfare, SANTE will pay constant attention to this area. Following recommendations of the European Court of Auditors (ECA), the evaluation of the 2012-2015 Animal Welfare Strategy will start in 2019 with a view to completing it by 2020. Moreover, the second EU Reference Centre for animal welfare will be designated by mid-2019.

A new project on animal welfare will be launched to prepare animal welfare indicators to measure the severity, extent and permanence of animal welfare problems, and how well these are accepted by both the agri-food sector and the competent authorities. This project should address one of the European Court of Auditors' recommendations. It will review the links between the cross-compliance system and official controls for animal welfare, as well as the suitability of indicators to measure the effectiveness of rural development programmes for the new Common Agricultural Policy (CAP).

DG SANTE will also start the second phase of a pilot project on the marketing of meat from uncastrated pigs which will consist in disseminating guidelines and good practices in preventing pig castration.

DG SANTE will also continue to work on better enforcement of EU legislation with priority on the welfare of pigs (especially concerning measures to reduce the systematic tail docking of piglets). It will do this through a wide range of activities, e.g. audits, data analysis, meetings with stakeholders and training courses under the 'Better training for Safer Food' programme, and through the use of a team of technical experts to support Member States.

As regards the transport of animals, DG SANTE will deliver two overview reports in 2019, following the conclusion of the main project in 2018.

1.3. Specific objective 1.3: Cost effective health promotion and disease prevention

Output table is included in Annex 1.

Up to 70% of the costs incurred by poor health are linked to preventable non-communicable diseases caused by common risk factors including harmful alcohol consumption, smoking, poor nutrition and physical inactivity. Without action, the cost of healthcare is expected to double by 2050 with crippling economic consequences.

There is strong evidence of the effectiveness of health promotion and disease prevention.[2] One euro spent on a validated public health intervention can generate savings of more than fourteen euros.[3]

DG SANTE's work in the field of health promotion and disease prevention aims at supporting the EU Member States to achieve the UN Sustainable Development Goals by 2030, in particular Goal 3: Good Health and Well-Being, ensure healthy lives and well-being for all at all ages, and to reach the targets set by the World Health Organisation. Work includes assistance for the design and deployment in EU countries of initiatives to

[2] http://www.euro.who.int/__data/assets/pdf_file/0006/283695/Promoting-Health-Preventing-Disease-Economic-Case.pdf?ua=1 (page xxii). Also "Economics of Prevention: interim report. Estimating the direct and indirect burden associated with high body mass índex and alcohol use" (page 10), reporting obligation to Chafea, still unpublished.

[3] https://ec.europa.eu/health/sites/health/files/state/docs/2017_companion_en.pdf (page 10)

promote good health and to prevent and manage non-communicable diseases in a horizontal manner rather than pursuing a multitude of disease-specific strategies. The focus lies on encouraging that validated best practices are implemented by Member States and that they tackle common challenges together.

DG SANTE will continue to provide concrete added value to the Member States and other Commission services via the recently formalised Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases. The Steering Group: i) allows for improved cooperation with Member States and other services to improve coordination of investments in health; ii) is committing to wide(r)-scale national implementation of validated best practices, and iii) is helping streamline DG SANTE's activities on public health, promotion and prevention. In 2019, DG SANTE will support the implementation of priorities and initiatives previously selected by the Steering Group, and launch the third wave of priority-setting and best practice selection. For this purpose, a Joint Action on implementation of validated best practices in the area of prevention will be launched.

Under the scope of the Steering Group process, in 2018, the Commission launched a "best practice portal" for prevention and management of non-communicable diseases. The portal brings together evaluated approaches originating from the Health Programme, from other EU funding mechanisms, or trialled in the Member States. Practices are already available in the areas of nutrition, physical activity, alcohol-related harm, health inequalities, mental health and integrated care. Those practices that are scored as "best" are submitted to the Steering Group to spark interest for transfer to other countries. In 2019, DG SANTE will further publicise the portal by organising a ceremony to highlight the good work carried out by the organisations with qualified practices.

Collaboration with stakeholders on EU health policy issues will continue in 2019 via the EU Health Policy Platform. Regular exchange will be supported through its dedicated web platform and an annual Health Policy Platform meeting. This will include the 2019 Joint Statements and the 2019 Health Award in addition to dedicated meetings with stakeholders to engage the NGOs community on DG SANTE's chosen priorities for 2019.

Recently, new arrangements related to the governance of the future Horizon Europe programme have been implemented. For the first time, DG SANTE is co-responsible for the programme development and implementation as regards pillar 2, cluster 1 ("Health"). As a consequence, an even stronger coordination mechanism on research aspects will be put in place, incorporating research aspects in the work of all units and reinforcing cooperation with DG RTD.

DG SANTE will also continue its close cooperation with the Joint Research Centre (JRC) to provide access to guidelines, recommendations and quality assurance schemes through the latest independent scientific evidence in the area of non-communicable diseases. In 2019, DG SANTE, with the support of the Health Programme and the JRC, will produce new colorectal cancer screening guidelines, as well as a breast cancer accreditation scheme to measure and accredit quality in screening measures. In addition, the 12 recommendations of the European Code against Cancer will be promoted by targeted initiatives implemented by the Joint Action on Cancer launched in 2018, through the European Cancer Leagues and through the implementation of cross-cutting best practices. We will also continue to coordinate with the JRC on the development of the European networks of registries on cancer, rare diseases and congenital malformations. A new administrative agreement with the JRC will be signed to support these tasks. Following the public procurement guidelines for healthy food in schools published in 2017, JRC in 2019 will also produce public procurement guidelines for healthy food in other settings.

To further contribute to the achievement of specific objective 1.3 aimed at cost-effective health promotion and disease prevention, DG SANTE will also support Member States' action in the area of nutrition, physical activity and alcohol related harm through: the launch of a call for tender on alcohol related harm in 2019; the implementation of several other studies/activities launched in 2018[4]; the implementation of the Tartu Call for Healthy Lifestyles signed by Commissioner Andriukaitis, Hogan and Navracsics; and the publication of the OECD report on the societal costs of unhealthy diets, physical inactivity and alcohol consumption.

There is a strong social gradient of health and a large share of the EU's disease burden is concentrated in the socio-economically disadvantaged parts of the population. DG SANTE continues to foster actions which tackle inequalities in health and address people at risk of poverty or social exclusion, including the implementation of the Joint Action on health inequalities. The aspect of inequalities will form an integral part of all DG SANTE activities in the public health area.

To support Member States that have to cope with extraordinary needs in the area of health linked to arrivals of migrants, a direct grant providing such support is planned in 2019.

Reducing tobacco consumption

The revised Tobacco Products Directive (TPD) entered into force on 19 May 2014 and became applicable in EU countries on 20 May 2016. The Directive lays down rules governing the manufacture, presentation and sale of tobacco and related product, whilst assuring a high level of public health. The proper implementation of the new TPD rules is expected to decrease smoking prevalence by 2% by 2021, which means 2.4 million fewer smokers in the EU.

While the Member States needed to transpose the Directive in their national legislations, the Commission developed a number of tertiary acts necessary to give effect to the rules laid down in the Directive and facilitate the uniform application of the new TPD provisions across all Member States. This included adopting legislation necessary to make an EU-wide traceability system for tobacco products, in order to address the issue of illicit trade, fully operational. The EU's traceability system will be the world's first regional system of its kind for tobacco products, and is set to be operational as of 20 May 2019.

In 2019, SANTE will start substantial work on the compliance checks of the Directive by Member States. SANTE will also organise Expert Group meetings and provide assistance to Member States to ensure effective and uniform application of the Directive, including on the implementation of acts on tracking and tracing and security features adopted in 2018. In respect of tobacco product ingredients, DG SANTE will manage the Joint Action on tobacco control. Finally, SANTE will launch a study and do preparatory work ahead of the formal review required by 2021 under the TPD.

In the context of track and trace, SANTE will focus on ensuring that the IT system is operational by 20 May 2019 for cigarettes and roll-your-own. To this end, DG SANTE will undertake the required verification of storage operators and approval of data storage

[4] Two studies on alcohol related harm, a joint TAXUD/SANTE study on distance selling of alcohol and on guide limits for individual personal cross-border purchase of alcohol/tobacco, a joint CNECT/SANTE study on children's exposure to marketing of unhealthy food, a study on monitoring of food reformulation, an international conference on health promotion and disease prevention.

contracts, approve auditors, and authorize ID issuers in case Member States fail to do so for track and tracing purposes.

The year 2018 saw the entry into force of the Framework Convention on Tobacco Control (FCTC) Protocol to Eliminate Illicit Trade in Tobacco Products. In 2019, DG SANTE will continue, together with OLAF, to encourage ratification of the FCTC Illicit Trade Protocol and promote the EU system as a blue-print of the traceability system. Furthermore, DG SANTE will continue to contribute to the FCTC, in particular to participate in the working groups set up by the Eighth Conference of the Parties (COP8) and the First Meeting of the Parties (MOP1).

Nutrition labelling on foods

Besides the continuous implementation of the Nutrition and Health Claims Regulation (approximately 40 decisions on the authorisation of health claims, generic descriptors, nutrition claims), in 2019, DG SANTE will work on the evaluation of said Regulation, in particular in relation to nutrient profiles and health claims of the so-called "botanicals". The publication of a Staff Working Document is expected in the first half of 2019.

1.4. Specific objective 1.4: Effective, accessible and resilient healthcare systems in the EU

Output table is included in Annex 1.

Healthcare systems need to become more cost-effective, accessible and robust to remain sustainable. This requires them to adapt to specific challenges and embrace and make full use of innovative new technologies that support more cost-effective and flexible healthcare solutions.

This approach was underlined in the 2014 Commission communication on effective, accessible and resilient health systems and in President Juncker's mission letter to Commissioner Andriukaitis which called for "*expertise on performance assessments of health systems […] to build up country-specific and cross-country knowledge [and] inform policies at national and European level*".

In response to the challenges ahead, and to achieve specific objective 1.4 aimed at effective, accessible and resilient healthcare systems in the EU, the Commission has strengthened its country-specific and cross-country knowledge in the field of public health and health systems. In 2018, SANTE launched the Second State of Health in the EU cycle by publishing jointly with OECD the 2018 "Health at a Glance: Europe" report, to be followed in 2019 by a new set of Country Health Profiles and a Companion Report. SANTE will also revamp the "voluntary dialogues" with Member States.

SANTE will continue to provide support to OECD work on patient-reported experience and outcome measures (PREMs and PROMs) through the OECD PaRIS initiative, as well as for the piloting of a limited number of questions on patient experience measures in cooperation with Eurostat for potential inclusion in wave 3 of the European Health Interview Survey. Further input on country knowledge in terms of indicator development and availability will be provided by the Joint Action on Health Information.

In 2019, DG SANTE will continue to contribute to the European Semester Country Reports aimed at identifying challenges in the health systems of Member States, based on the results of the State of Health deliverables and on the intelligence gathered through our interaction with national authorities and stakeholders. SANTE will continue to

ensure that we have the analytical capacities and expertise to input in the Semester process through the network of country desks.

The Expert Panel on Health, which provides expertise on health systems and public health, will continue in 2019 to provide the Commission with independent and multi-sectoral advice on effective ways of investing in health and on which to base the Commission's health system agenda.

Antimicrobial resistance (AMR)

AMR remains a major global challenge with serious implications for human health and the economy. Each year, drug resistant infections result in at least 25,000 deaths in the EU and cause EUR 1.5 billion worth of healthcare and productivity losses in the EU. Unless tough action is taken to combat AMR it will continue to have a significant negative impact on health and growth.

In 2019, work will continue on the implementation of the 2017 European One Health Action Plan against AMR[5] to promote swift and effective actions across the human health, animal health and environmental sectors, in order to (i) make the EU a best-practice region; (ii) boost research, development and innovation; and (iii) shape the global agenda. This implementation will continue to be closely monitored by DG SANTE[6].

In 2019, important milestones will include the publication of two overview reports to follow up respectively (i) on a series of audits to assess the effectiveness of the

[5] https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf

[6] http://ec.europa.eu/health/amr/sites/amr/files/amr_2018-2022_actionplan_progressreport_en.pdf

implementation of EU legislation on AMR monitoring in food-producing animal populations and food in Member States; and (ii) on the fact-finding missions conducted in the Member States to assess the implementation of the EU guidelines for the prudent use of antimicrobials in veterinary medicine.

DG SANTE will continue to strongly engage with Member States and stakeholders. Examples will include (i) the biannual meetings of the AMR One Health Network to foster the exchange of best practices and mutual learning between EU Member States, (ii) One Health visits to the Member States to provide assistance in the further development and implementation of national policies and strategies for tackling AMR, (iii) the support to the upcoming Romanian Presidency priority on AMR, and (iv) the implementation of projects *e.g.* the Joint Actions on antimicrobial resistance and healthcare associated infections and on vaccination. DG SANTE will launch a call for projects to professional organisations and stakeholders to contribute to the implementation of the EU Action Plan on AMR by implementing the EU guidelines on prudent use of antimicrobials in human health. SANTE will also launch a call for tender for support for EU networking of reference laboratory functions to improve responses to antimicrobial resistance in human health.

Training will continue to be a key component in the prevention and control of AMR across the human, veterinary and food sectors. The Better Training for Safer Food initiative will therefore continue for Member States and will be extended to third countries to promote internationally EU policies and international recommendations on AMR.

On international aspects, the bilateral activities and the collaboration with multilateral organisations, such as the World Health Organisation, the World Organisation for Animal Health, the Food and Agriculture Organisation, and the Organisation for Economic Cooperation and Development will remain of utmost importance in order to contribute to ambitious regional and global action against AMR. In addition, AMR will also take a prominent role in our bilateral relations with non-EU countries and in particular during the negotiations of bilateral Free Trade Agreements. Further detail on this international cooperation is outlined below under specific objective 3.1 (Increased EU influence in international fora).

The new Regulations on veterinary medicinal products and on medicated feed, which entered into force in late 2018, constitute a major achievement in the fight against AMR. The Regulations will apply three years after their entry into force, i.e. by the end of 2021. They lay down a wide range of measures to fight antimicrobial resistance following the One Health Approach. These measures include a ban on preventive use of antibiotics in groups of animals; restrictions on metaphylactic use; the possibility to reserve certain antimicrobials for humans only; a ban on the use of all antimicrobials in animals for promoting growth in addition to the prohibition of antibiotics as feed additives in 2006; compulsory data collection on sales and use of antimicrobials; and restriction on the import of animals and animal products from non-EU countries which use antimicrobial veterinary products as growth promoters or antimicrobials designated in the EU as reserved for human use. The provisions of the legislation also include incentives for development of new antimicrobials through a period of protection of technical documentation, which can now be extended up to 18 years. Meanwhile, a number of delegated and implementing acts will have to be prepared in time for the entry into application.

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

DG SANTE's work to fight against AMR will continue to be supported by the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) to ensure that the most comprehensive scientific advice is available to support regulatory and policy activities.

EFSA is responsible for collecting, analysing and reporting the incidence of AMR in bacteria from food and food-producing animals, and for providing scientific opinions on AMR issues. ECDC plays an important role in surveillance and reporting on key indicators for antimicrobial consumption and resistant infections in humans. EMA plays a key role in monitoring veterinary antimicrobial sales and in their use. They also play a central role in increasing the availability of new antimicrobials and alternative products for humans and animals by advising developers on specific development plans and drafting guidelines on the requirements, supporting the prudent use of antimicrobials, working on the modernisation of 'old' antimicrobials and providing scientific opinions on AMR issues. Finally, EMA fosters international dialogue with regulators from other regions outside EU.

Innovative health technologies

eHealth can improve the integration of health and care and help deliver targeted, personalised and efficient healthcare, reducing errors and hospitalisation times. Member State cooperation in eHealth can bring significant added value to national health systems.

In the 2017 mid-term review of the Digital Single Market (DSM) Strategy, the Commission proposed to increase coordination efforts on the digital transformation of health and care in Europe focusing on the following three priorities:

- Citizens' secure access to electronic health records, including the possibility to share them across borders and the use of e-prescriptions;
- Supporting data infrastructure to advance research, disease prevention and personalised health and care in key areas, including rare, infectious and complex diseases;
- Facilitating feedback and interaction between patients and healthcare providers to support prevention and citizen empowerment as well as quality and patient-centred care, focussing on non-communicable diseases and on a better understanding of the outcomes of healthcare systems.

In 2019, DG SANTE will work with DG CNECT to deliver the actions outlined in the Communication on Digital Transformation of Health and Care in the context of the DSM, which was adopted in 2018. This includes the adoption of the Commission Implementing Decision on the eHealth Network and contributing to the work by DG CNECT on the European exchange format for electronic health records, with a view to further expanding the scope of the cross-border exchange of health data.[7] DG SANTE will also support the expansion of the eHealth Digital Service Infrastructure from cross-border exchange of ePrescriptions and patient summaries to cover electronic health records and include more Member States. In parallel, it will undertake the challenging work of addressing the legal, data protection and financing needs of these digital infrastructures. Particular attention will be paid to ensuring patients' access to their data and the possibility to share it with healthcare providers across borders, as well as to improving the diagnosis and treatment of patients through the sharing of health and genomic data at EU level (in cooperation with DG CNECT and RTD).

DG SANTE will also organise and provide secretariat for the two meetings of the eHealth Network in June and November, organise the meetings and ensure the secretariat of the eHealth Digital Service Infrastructure and will follow the work of the Joint Action supporting the eHealth Network.

[7] This work will be linked to the Commission Recommendation to establish a format for European Health Record Exchange, which is undertaken by DG CNECT.

Finally, in 2019, DG SANTE will continue to test and audit the readiness of Member States for the exchange of e-prescriptions and e-patient summaries before such an exchange is launched. The aim is to build trust between Member States in that their data confidentiality, integrity and availability are adequately assured.

Implementation of the Directive on patients' rights in cross-border healthcare

With the EU's legal framework for cross-border cooperation in healthcare, EU citizens now have the possibility to access high quality and safe treatment and care across Member States, whilst benefitting from their statutory reimbursement scheme.

The 2019 priority as regards cross-border healthcare will be to follow-up to the 2018 implementation report of the Directive as well as the monitoring and support of the transposition of the Directive. DG SANTE will also carry out the annual data collection exercise and provide timely input to Court of Auditors report on the implementation of the Directive. DG SANTE will follow the network on Cross-Border Healthcare in the Health Policy Platform and promote cooperation and improvement of the work of the National Contact Points.

Blood, tissues and cells, organs

EU legislation on blood, tissues and cells was adopted in 2002-2004. Recent years have seen major developments in the field of substances of human origin, including technical progress and innovation (e.g. transplants of tissues without cells, new virus inactivation tools), increased movements of substances across the EU and the need to shield donations from increasingly frequent disease outbreaks (e.g. West-Nile virus, Zika).

The Commission is currently evaluating whether the legislation on blood, tissues and cells is still adapted to these changes. The findings will be presented in a Commission Staff Working Document planned for early 2019. The evaluation will be followed by dissemination and other adequate follow-up measures.

Commission-hosted platforms on rapid alerts and traceability, used by over 3,000 tissues establishments, will be further strengthened. Collaboration with data-registries run by professionals will be further improved in the context of the Digital Healthcare agenda. All work on blood, tissues, cells and organs will continue in close cooperation with external expert bodies like the European Centre for Disease Prevention and Control, the Council of Europe and Member States' agencies, including international cooperation with the US Food and Drug Administration and other relevant non-EU countries.

1.5. Specific objective 1.5: Increased access to medical expertise and information for specific conditions

Output table is included in Annex 1.

European Reference Networks (ERNs) promote greater access to medical expertise and information for rare, low prevalence and complex medical conditions, bringing together highly specialised healthcare providers from different EU Member States in areas where expertise is scarce. They represent one of the most important and innovative cross-European cooperation initiatives in healthcare. They are also expected to provide important economies of scale and allow a more efficient use of increasingly stretched EU healthcare resources, although the exact gains in this regard will need to be assessed via an evaluation. 24 ERNs were officially launched in 2017, each of them addressing one clinical area, and bringing together more than 900 healthcare providers across Europe. By October 2018, more than 250 patients had already been treated by the ERNs.

In 2019, DG SANTE will focus on supporting the clinical operation of the 24 Networks, the use of the networks' IT system, and information exchange within the networks to allow more patients to be treated. DG SANTE will encourage Member States to establish clear patient pathways and referral systems and to adequately support the functioning of the Networks. SANTE will organise three meetings each of the Board of Member States and of the Coordinators Group. These actions will further support specific objective 1.5 aimed at increased access to medical expertise and information for specific conditions.

DG SANTE will also start the process of opening the Networks to new members, as well as ensure the smooth joining of Affiliated Partners and will also handle the changes in the Networks related to the UK's withdrawal from the EU. DG SANTE will develop and implement an effective monitoring and evaluation system and encourage the Networks to prepare a research strategy. DG SANTE will also finalise the amendment of the Implementing Decision 2014/287/EU on ERNs, with the aim of (i) clarifying the role of the ERN Board of Member States in steering the ERN initiative, (ii) modifying the procedure concerning the application for membership in existing Networks and (iii) introducing new rules on the establishment of the Clinical Patient Management System and on the protection of personal data that this system processes. Finally, a call will be launched for rare diseases registries for ERNs.

1.6. Specific objective 1.6: Effective, efficient and reliable official controls

Output table is included in Annex 1.

DG SANTE promotes the optimal use of the available mechanisms for the enforcement of legislation on food safety, animal health, animal welfare, plant health, import controls and some areas of human health. This is done using an interactive approach that ensures effective, efficient and reliable official controls across the EU.

DG SANTE's audit and analysis work is crucial in this respect. Taking place in EU countries and in non-EU ones exporting to the EU alike, audits as well as complementary desk-based control activities are essential to ensure our high standards and safety levels are not compromised and that the industry can operate on a level playing field. Audit results and appropriate monitoring, enforcement and follow-up activities contribute to evidence-based policy development, better regulation and a regulatory environment which facilitates jobs, growth and investment.

DG SANTE is engaged in various forms of informed dialogue with the Member States to ensure coordination and consistency in the application of the official controls rules and to bring forward enforcement matters and find concrete solutions to identified problems. This dialogue is established through High Level meetings between SANTE and the Member States Competent Authorities, through other technical meetings as well as through "Better Training for Safer Food" trainings.

In 2019, in support of specific objective 1.6, DG SANTE plans to perform up to 225 audits and other on-the-spot visits. This will include:

- 165 in the area of food safety and quality, animal health, animal welfare and plant health in Member States and non-EU countries (including 10 general follow-up audits in Member States and one fact-finding mission); and

- up to 60 in the health protection area (around 40 joint assessments of notified bodies for medical devices and *in vitro* diagnostic medical devices in Member States, EFTA and EEA countries, up to four audits in non-EU countries on good

manufacturing practices for production of medicinal products, up to 12 audits of Member States' eHealth National Contact Points jointly with the ECDC, and four AMR One Health country visits in Member States).

Unexpected events may require changes to the programme in the course of the year.

In the context of Brexit, DG SANTE will provide expert input in relation to import requirements post-Brexit, including on the land border between the UK and Ireland.

Modernising and simplifying EU legislation

The revised Official Control Regulation (OCR) (EU) 2017/625 was adopted on 15 March 2017 and the majority of provisions will apply from December 2019. The OCR creates a single framework for all official controls along the entire agri-food chain, including plant health and animal by-products. It applies a risk-based approach to official controls and allows more harmonised, coherent and efficient controls and resulting enforcement actions.

In relation to Official Controls, the overall objective for 2019 is to bring to completion at least 20 acts implementing Regulation 2017/625. Their adoption is crucial to ensure smooth food safety controls by the date of entry into force of the new OCR.

As such, in 2019, delegated and implementing acts will be prepared *inter alia* on import controls; residues of veterinary medicine products and contaminants; food and feed hygiene; official controls for plant health and animal health/welfare related aspects, and on a standard model form for Member States' annual report on the operation of their multi-annual national control plans.

Use of digital technologies to strengthen official controls

The revised Official Control Regulation foresees the establishment of an Integrated Management System for Official Control (IMSOC). This concept will allow the current EU-managed IT systems to be integrated. In 2019, DG SANTE will continue working on standards to align all electronic transactions from farm to fork, including digitalisation of animal and plant health certificates, laboratory tests, animal identifications, tracking and tracing and alert management.

In keeping with the integration principle inspiring IMSOC, the Trade Control and Expert System (TRACES) will also integrate certain certification procedures managed by other Commission services. These will include organic certificates under the responsibility of DG AGRI, catch certificates under DG MARE and the Forest Law Enforcement, Governance and Trade certificates under DG ENV. Work to integrate TRACES and the EU's alert systems (RASFF and EUROPHYT) using the IMSOC concept will also be concluded. This will ultimately bring about additional simplification for border controls authorities and full paperless procedures.

IMSOC aims also at streamlining the flow of alerts. In line with the conclusions of the Ministerial Conference on the follow up of the fipronil incident (Brussels, 26 September 2017), specific measures and a single IT platform are planned in 2019 to streamline the flow of information between the Administrative Assistance and Cooperation network, the Food Fraud network and the RASFF network.

Moreover, in 2019 DG SANTE, jointly with the Romanian Presidency of the EU, will host a conference in Brussels to celebrate the 40th anniversary of the creation of the RASFF network.

Finally, eCommerce for food products is rapidly increasing in most Member States. DG SANTE will contribute to the Digital Single Market Strategy and the eGovernment action plan through actions which promote digitalised and integrated food chain and boost consumer's confidence in eCommerce via more efficient controls.

Contribution of the EU food and feed financing programme (CFF) to official controls' related activities

All activities planned for 2019 aim to enhance the capability of the EU system as a whole to detect violations of the food chain requirements and strengthen Member States' capacity to ensure cross-border enforcement. These activities include the Better Training for Safer Food (BTSF) programme and the EU Reference Laboratories (EURLs).

The BTSF will continue to play a key role in improving the efficiency and reliability of official controls by promoting their uniform implementation throughout the EU. The BTSF is administrated by CHAFEA, while DG SANTE provides the policy steer and technical supervision. For 2019, around 170 training courses on EU legislation are planned for Member State staff responsible for official controls along the food chain. As a complement to the traditional face to face training, e-learning modules will also be developed which will significantly increase the number of officials that can benefit from BTSF trainings. In 2019, DG SANTE plans to launch the BTSF Academy, including through close monitoring of relevant IT-developments. The budget for the BTSF for 2019 is EUR 18 million.

The EURLs will continue to 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 in their efforts to provide state of the art analytical and diagnostic services to national authorities and enforcers. Funding for 44 EURLs and two EU Reference Centres for Animal Welfare is planned in 2019 to maintain high level of food safety, improve the efficiency of the network and capitalise on existing knowledge. The budget for the EURLs for 2019 is EUR 20.1 million.

2. General objective 2: A deeper and fairer internal market with a strengthened industrial base

DG SANTE's work makes an important contribution to the EU internal market by ensuring that trade can take place freely – in particular in food and pharmaceutical products – and that innovation is encouraged. This work also contributes to General Objective 1 in terms of boosting jobs, growth and investment by providing legal certainty and ensuring the proper functioning of the internal market.

The safety of food and feed in the EU is ensured by the implementation of a wide range of harmonised EU rules (e.g. Regulations on official controls, plant health and animal health) and EU authorisations (e.g. for food/feed additives, novel foods, plant protection and biocidal products). This framework contributes to the smooth functioning of the internal market by facilitating the free circulation of food/feed products, providing legal certainty to business operators, and giving equal access by consumers to safe and high-quality food products throughout the EU.

The agri-food industry is of key importance to the EU economy. Food products are for decades amongst the top 5 intra-EU exported goods in terms of their value. The value of the food intra-EU exports has risen from around 107 billion in 2004 to 226 billion in 2016 (i.e. growth by 211%). Intra-EU exports of food and drink products accounted for more than 25% of the annual turnover in 2016. Moreover, the food and drink industry is the leading employer in the manufacturing industry across the EU, providing 15 % (2014) of total employment in the EU with 4.24 million people directly employed in the industry and 24 million people employed in the food supply chain. Moreover, with combined imports and exports of EUR 259 billion in 2017, the EU is the world's biggest trader in agri-food products, benefiting EU producers and consumers. Finally, the food and drink industry is also the biggest employer in manufacturing in half of the EU Member States (2015)[8].

The pharmaceutical industry is a strong driver of economic growth, jobs and trade for the EU. In 2017, the EU pharmaceutical industry generated around EUR 258 billion. R&D expenditure is estimated at EUR 35.2 billion. The sector offers a positive trade balance for Europe (estimated EUR 98 billion in 2017). In 2017, the pharmaceutical industry directly employed an estimated 750,000 people and generated three to four times more employment indirectly[9]. In 2017, the European animal medicines industry had a turnover of about EUR 6 billion, providing for nearly 50,000 jobs in the animal medicines industry itself.

The EU's robust legal framework for medicinal products guarantees high standards of quality and safety for patients in the EU, and promotes innovation and competitiveness of this sector in Europe. A large body of legislation has developed to govern the development, manufacturing and authorisation of medicines. Medicinal products may be placed on the market only following a marketing authorisation granted at EU level by the Commission or at national level by the competent authorities. Once on the market, the safety of a product is continually monitored throughout its entire lifespan through the EU system of pharmacovigilance.

[8] http://ec.europa.eu/eurostat/statistics-explained/index.php/Intra-EU_trade_of_the_most_traded_goods.

[9] EFPIA, The Pharmaceutical Industry in Figures. Key Data. 2018, 28 June 2018, www.efpia.eu.

The EU's decentralised agencies make an important contribution to DG SANTE's internal market priorities, feeding into its policy making process, encouraging innovation, and ensuring that trade in food and pharmaceutical products can proceed unhindered.

The European Medicines Agency (EMA) plays a key role by evaluating medicines along their lifecycle from early stages of development, through marketing authorisation to safety monitoring once they are on the market, by supporting the implementation of the EU pharmaceutical legislation, optimising the use of current regulatory tools provided by the pharmaceutical legislation to support development of medicines for unmet medical needs, and facilitating timely patient access to innovative and safe medicines. EMA also supports DG SANTE in its international efforts to promote EU standards globally.

As the United Kingdom notified the European Council of its intention to leave the Union, EMA, which is currently located in the UK, will move to its new seat in Amsterdam by 1 April 2019. DG SANTE, as the 'mother DG' of EMA, will carefully follow the process and support the agency in ensuring business continuity.

The European Food Safety Authority (EFSA) also contributes to the EU's internal market priorities through its assessments and advice on regulated products in food and feed production (e.g. plant protection products and food additives).

2.1. Specific objective 2.1: Effective EU assessment of medicinal products and other treatment

Output table is included in Annex 1.

Health Technology Assessment (HTA) presents information on a health technology, pharmaceutical product, medical device or health intervention in a systematic and unbiased manner, and informs decision makers on its safe and effective use. It is an important tool to achieve best outcomes for patients, health professionals and health systems. HTA supports innovative technologies which bring added value, and provides stimulus for innovation and growth in the pharmaceutical and medical devices sectors, with a view to ensuring maximum benefit for individual patients and public health. The European Medicines Agency works together with the Joint Action EunetHTA and the HTA Network to foster synergies between the HTA and regulatory process, aiming to improve the evidence available for both processes, e.g. through Parallel Consultations on evidence generation plans of the manufacturer.

In 2018, the Commission adopted a proposal for a Regulation on HTA. This initiative seeks to: improve the availability of truly innovative health technologies for EU patients; ensure efficient use of resources and improve business predictability; promote convergence in HTA tools, procedures and methodologies; reduce duplication of efforts for HTA bodies and industry; and ensure the use of joint outputs in Member States.

In 2019, in support of specific objective 2.1, DG SANTE will continue to negotiate the proposal with the Council and Parliament, while undertaking dialogues with stakeholders and experts to ensure that the proposal is well-understood and is supported by its proposed beneficiaries. In addition to this work, DG SANTE continues to support cooperation on HTA by chairing and organising the HTA Network and its working groups, involving Member States, Iceland and Norway, as well as the Joint Action on HTA. DG SANTE is also planning to facilitate cooperation between regional initiatives active in the area of HTA.

2.2. Specific objective 2.2: Stable legal environment and optimal use of current authorisation procedures for a competitive pharmaceutical sector and patients' access to safe medicines

Output table is included in Annex 1.

Marketing authorisations of medicinal products

DG SANTE will continue its work related to the authorisation of medicinal products for human and veterinary use. Around 90 new medicines for human use are authorised every year and around 150 orphan designations are granted for medicines for rare diseases. DG SANTE adopts more than 1,000 decisions to manage and amend marketing authorisations of existing medicines. This continuous work will contribute to safe and timely access of patients to innovative medicines and to a competitive pharmaceutical sector. It also ensures that immediate action is taken when new unexpected safety issues are detected with an authorised medicinal product. Where appropriate, the marketing authorisation is suspended and the product is recalled ensuring that all EU citizens enjoy the same level of protection. Brexit-related changes (e.g. transfer of marketing authorisations) have led to a temporary increase in the volume of decisions in 2018, which will continue in 2019.

DG SANTE will also continue to work on the report to the European Parliament and the Council on the experience acquired as a result of the operations of the centralised and decentralised marketing authorisation procedures that, according to the requirements of Regulation (EC) No 726/2004 and Directive 2001/83/EC, should to be published every ten years. As a first step, an external study assessing the current procedural system should be finalised in 2019. Results of this study will provide the evidence base for the Commission report that should be adopted and submitted to the European Parliament and the Council in early 2020.

Separately from the above-mentioned report on the marketing authorisation procedures, another report will be prepared on the experience of EMA and the Member States on the implementation of additional monitoring of certain medicines following the strengthening of the pharmacovigilance legislation.

Veterinary medicinal products

The EU's legal framework for veterinary medicinal products will be improved and strengthened following the formal adoption of the new veterinary medicines package by the European Parliament and the Council in late 2018. Date of application will be three years later (towards the end of 2021). The package consists of three Regulations: on veterinary medicinal products (VMP), on medicated feed, and on the European Medicines Agency (EMA).

The main achievement of the new Regulations is to address the public health risk of antimicrobial resistance (AMR). They lay down a wide range of concrete and effective measures to fight AMR following the "One Health" approach. These measures are described in detail under specific objective 1.4 above related to antimicrobial resistance.

A second important achievement is the promoting of availability of veterinary medicines stimulating competitiveness and innovation by a simplified assessment procedure for authorisation and an extended data protection period.

With regard to medicated feed, the new legal framework will ensure an economically-viable production of safe medicated feed throughout the EU. Moreover, the medicated feed rules foster innovation in medicated pet food as they create provisions concerning production, prescription and distribution of medicated pet food which allows that pet

owners can treat their chronically diseased animals with their regular feed whereas currently these pets need to be treated with pills or pastes.

For the VMP Regulation, 25 tertiary legal acts are scheduled (eight delegated and 17 implementing acts). The main topics are: AMR (data gathering, list of critically important substances for human use; import conditions), application process and databases, good distribution practice of active substances and veterinary medicines, special provisions for horses and aquatic species, maximum residue levels and cascade use of veterinary medicinal products. In 2019, 12 of these legal acts are to be launched (four delegated acts and eight implementing acts).

Improving access to medicines

Patient access to affordable medicines and the balance between pharmaceutical innovation and sustainability of health systems in the EU is a priority for DG SANTE and the EU as a whole. This was highlighted by Council conclusions on strengthening the balance in the pharmaceutical systems in the EU and its Member States (June 2016) and the European Parliament's own initiative report on "EU options for improving access to medicines" (February 2017).

In 2019, DG SANTE will undertake an extensive evaluation of the Regulations on orphan medicines (141/2000) and paediatric medicines (1901/2006), including a study, a staff working document, and outreach to stakeholders. The purpose of this evaluation is two-fold: first, to assess whether the Orphan Regulation has catered for innovative medicines for real unmet medical needs, and whether it can accommodate scientific progress and changing business models; and second, to gain insight into how the various legislative incentives have been used in practice and the financial consequences for companies and society. This evaluation will also consider how such incentives could be used to promote wider aims related to antimicrobial resistance, specifically whether they can be used for novel antimicrobials and innovative alternative medicinal products that currently do no generate sufficient returns on investment. The overall evaluation is expected to be completed by the third quarter of 2019.

DG SANTE will continue to work on initiatives to improve the regulatory environment for advanced-therapy medicinal products (ATMPs) which comprise gene therapies, tissue-engineered products and somatic cell therapies. In particular, DG SANTE will continue working with the national competent authorities to optimise the interplay of the pharmaceutical framework with the GMO framework (relevant for gene therapy medicinal products) and dialogue will continue on the implementation on the hospital exemption. In addition, the development of Guidelines on Good Clinical Practice Specific to Advanced Therapy Medicinal Products will be finalised.

In parallel, the Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) will continue to work towards optimising the use of existing regulatory tools for increasing patient access to innovative medicines and improve the aspects of the regulatory framework, including possibilities for repurposing of well-established (off-patent) medicines in areas of unmet medical need.

To further underpin specific objective 2.2, DG SANTE will also work closely with the EMA to improve the development and assessment of medicines that fulfil unmet medical needs, in particular mechanisms to enhance the development of new antimicrobials and alternative products, as well as therapeutic approaches against infectious diseases caused by microbes resistant to existing antimicrobials.

As patient access to medicines depends on links between regulatory frameworks, health technology assessment and pricing and reimbursement aspects, DG SANTE will work to strengthen synergies between EUnetHTA, STAMP and the EMA in 2019, while safeguarding the different remits of different players and processes.

Legislation on fees of the European Medicines Agency

In 2018, the EMA fee system was the subject of a formal evaluation. Following a recent amendment of Regulation 726/2004 (the Founding Regulation of the EMA), the Commission is obliged to review the legal framework for fees by 2019 and to put forward, as appropriate, legislative proposals with a view to update that legal framework. Consequently, in 2019, DG SANTE intends to carry out an impact assessment to assess options.

Moreover, the review will address the proper financing of new procedures following the changes to the veterinary medicines legislation.

Implementation of the Falsified Medicines Directive

In 2019, DG SANTE will continue overseeing the development of the medicines authentication system under the Falsified Medicines Directive (2011/62/EU), which protects citizens from fake and low-quality medicines. The system is stakeholder-led and the pharmaceutical industry is responsible for setting it up by 9 February 2019.

The new system will require industry to place safety features (a unique identifier and anti-tampering device) on prescription medicines and upload information on each product into an EU-wide repository system. At the end of the supply chain, all pharmacies and hospitals in Europe will need to verify the authenticity of each medicinal product against the EU repository and decommission the product at dispense. Wholesalers are also required to verify products they receive from an uncertain source.

DG SANTE will continue to facilitate the implementation of the safety features before and after 9 February 2019. This includes providing advice to Member States in the Expert Group on safety features, agreeing a Q&A document for stakeholders with Member States and addressing challenges in implementation such as hospital preparedness. DG SANTE also holds regular meetings with European stakeholder associations to monitor implementation by end-users.

DG SANTE will continue to work with Member States and stakeholders towards full and timely implementation of the new rules.

Implementation of the Clinical Trials Regulation 536/2014

In 2019, DG SANTE will continue to cooperate with the European Medicines Agency (EMA) for the setting up of an EU portal and database on clinical trials, and on chairing the EU Clinical Trials Regulation coordination group to take strategic decisions on the portal and database as well as on other aspects related to the implementation of the Clinical Trials Regulation. DG SANTE will support EMA on specifications, provide guidance to ensure alignment of the portal and database with the Regulation, attend meetings of the various EMA groups and undertake testing of the system.

DG SANTE will also manage an expert group on clinical trials to provide expertise in regard to the implementation of the Clinical Trials Regulation and to provide a forum for discussion and coordination of regulatory issues on clinical trials in the EU (e.g. academic clinical research, interplay with the General Data Protection Regulation).

The application of the Clinical Trials Regulation is conditional on the conduct of an independent audit to verify that the portal and database has achieved full functionality and the systems meet the functional specifications. Once the EMA Management Board informs the Commission that the audit is successful, the Commission will publish a notice in the Official Journal, six months from which the Clinical Trials Regulation will become applicable, estimated to occur in early 2020.

2.3. Specific objective 2.3: Common Member States' tools and methodologies used for EU health systems performance assessments

Output table is included in Annex 1.

DG SANTE is building expertise on the performance of health systems in EU Member States to identify tools and methodologies that will contribute to better and more accessible healthcare and more efficient and resilient healthcare systems.

To achieve this, DG SANTE set up and co-chairs a Commission expert group on health systems performance assessment (HSPA). In 2019, reports will be prepared on the measurement of efficiency of health systems, and on the measurement of resilience of health systems. SANTE will also start reflecting on future topics for 2020.

The expert group on HSPA will also carry out tailored seminars and workshops in Member States to respond to specific requests for technical assistance in designing and building national health performance assessment systems.

3. General objective 3: A balanced and progressive trade policy to harness globalisation

DG SANTE works closely with other Commission departments, Member States and export industries to tackle sanitary and phytosanitary barriers to trade and to improve market access to non-EU countries.

DG SANTE also defends and promotes the EU interest in international fora. This in turn, contributes to high levels of health protection and boosts growth and employment opportunities in the EU's food and pharmaceutical sectors.

3.1. Specific objective 3.1: Increased EU influence in international fora

Output table is included in Annex 1.

DG SANTE works closely with its global partners in the World Trade Organisation (WTO), the World Health Organisation (WHO), the Organisation for Economic Cooperation and Development (OECD), the Codex Alimentarius Commission, World Organisation for Animal Health (OIE), Food and Agricultural Organisation (FAO), the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT), the International Plant Protection Convention (IPPC), the International Council for Harmonisation (ICH) and Convention on Biological Diversity (CBD) and its protocols on GMOs to ensure its food- and health-related standards are recognised and promoted at bilateral and multilateral level.

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 2016 Commission Communication on "Next steps for a sustainable European future" and the 2017 European Consensus on Development will guide DG SANTE's work in internal and external policy areas throughout 2019. DG SANTE will ensure the UN Sustainable Development Goals are mainstreamed into its activities and will seek to maximise synergies with other services and stakeholders to implement the 2030 Agenda. In light of the Reflection Paper "Towards a Sustainable Europe by 2030" addressing the EU's contribution to the achievement of the SDGs, DG SANTE will contribute to the monitoring and reporting mechanisms set up in the Commission on the implementation of the SDGs and will reflect on future initiatives to facilitate the achievement of specific targets, especially in relation to SDG 2 – *Zero hunger*; SDG 3 - *Good health and well-being*; SDG 12 - *Responsible consumption and production*.

Health

In support of specific objective 3.1 and ensuring increased EU influence, DG SANTE and the EU Delegation in Geneva will strengthen their efforts to facilitate coordinated EU positions on the agenda items in the WHO Governing Bodies, including at the Executive Body (meets twice), World Health Assembly (meets once), and the Europe Regional Office (meets twice). DG SANTE also cooperates with WHO in the framework of existing administrative arrangements and serves as WHO focal point for the Commission. A Senior Officials Meeting between WHO (Headquarters and Regional Office) and the Commission will be held in 2019. An assessment of DG SANTE's collaboration with the WHO Europe Regional Office since 2015 will also be carried out in 2019.

In 2019, DG SANTE will continue the successful cooperation with the Organisation for Economic Co-operation and Development (OECD) in the framework of the new cooperation arrangement from 2016. In recent years, the G7 and G20 have also taken up

global health challenges and this is expected to continue in 2019 under the Presidencies of France for G7 and Japan for G20.

On global tobacco control, DG SANTE will continue, together with OLAF, to encourage non-EU countries to ratify the WHO Framework Convention on Tobacco Control (FCTC) Illicit Trade Protocol and promote the EU system as a blue-print of the traceability system. DG SANTE will follow-up on the outcomes of the Eighth Conference of the Parties (COP8), such as COP decisions on Article 9 and 10, and on novel and emerging tobacco products. This will include providing input on Terms of Reference for the expert groups; supporting the contribution of the Joint Research Centre to requested laboratory work; and participation in meetings. DG SANTE will also follow up on the first Meeting of the Parties (MOP1), which decided to establish a working group on tracking and tracing. Given the EU leadership in implementing and promoting the traceability systems, SANTE is naturally expected to take the role of a key facilitator in this working group. The group is likely to start its work in the first half of 2019.

As part of the global pillar of the 2017 EU One Health Action Plan against AMR (see section 1.4), DG SANTE will continue cooperation with the Transatlantic Taskforce on AMR (TATFAR); with the Food and Agriculture Organisation (FAO) to tackle the emergence and spread of AMR on farms and in food systems; and with the World Health Organisation on AMR-related human health activities.

In 2019, DG SANTE will cooperate with OECD on AMR to take forward the results of the first phase of the development of a model of the economic impact of AMR by OECD, which was completed in November 2018 and carried out with the support of the EU Health Programme. This will include an extension of the AMR model to incorporate additional policy interventions and assessments of wider societal impacts and dissemination activities for EU Member States.

AMR has been a priority under both G7 and G20 in 2018. If AMR is ultimately prioritised under the upcoming French G7 Presidency and the upcoming Japanese G20 Presidency in 2019, DG SANTE will continue to express support for a "One Health" approach and a prudent and responsible use of all antimicrobials; focus on the link between AMR and the environment; further support the AMR Research & Development Hub; advocate for the development of new antimicrobial products; and, in the G20 context, reiterate the need to phase out antimicrobials for growth promotion in food animals.

A new training project organised within the "Better Training for Safer Food" initiative has been launched in September 2018 for non-EU countries. This project aims to strengthen cooperation activities on AMR at international level with a view to further raise awareness about the AMR threat and ways to best address it, to promote international recommendations and contribute to the adoption and implementation of measures to tackle AMR nationally and regionally. It also aims to internationally promote EU policies on AMR, and particularly the One Health approach. In 2019, six workshops will be offered in: Eastern Europe (1), the Mediterranean basin (1), Latin America (1), Africa (2) and China (1).

Enlargement and neighbourhood countries and health

In the framework of the EU's enlargement and neighbourhood policies, DG SANTE carries out health policy dialogue and works at bilateral and regional level with partner countries to support capacity building and their implementation of EU health acquis and practices.

Key thematic priorities for cooperation and country support cover health security (including implementation of the International Health Regulations), communicable diseases (including AMR and vaccination), non-communicable diseases and tobacco control (including promotion of the FCTC and the Illicit Trade Protocol), and quality and

safety of substances of human origin. Examples of activities planned for 2019 include: multi-country regional workshops on AMR in enlargement and European neighbourhood policy countries with ECDC and EFSA support; a communicable diseases assessment in Bosnia and Herzegovina; and targeted support to Moldova, Georgia and Ukraine for public health and blood system reform implementation.

Non-EU countries and health

DG SANTE will continue to contribute to the negotiation and implementation of association agreements with non-EU countries and provide the health input to political bilateral dialogues as appropriate (Brazil, Mexico, Iran, Switzerland, microstates, Central Asia).

Pharmaceuticals

The EU is a global leader in the pharmaceutical industry and the world's major trader in medicinal and pharmaceutical products.

In 2019, DG SANTE will continue to represent the Commission in ongoing work linked to the selection of topics for harmonisation at the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and ICH reform. As one of the founding regulatory members of the ICH, DG SANTE will continue work to ensure implementation of the ICH reform to increase membership and uptake of global harmonised guidelines and reinforce relations with international partners.

DG SANTE will continue to work on the implementation of the mutual recognition agreements on good manufacturing practices with various non-EU countries (e.g. Japan, Canada in the context of the CETA). In addition, DG SANTE will continue to hold regular regulatory dialogues as foreseen in the various bilateral cooperation arrangements/ agreements with our key strategic partners such as the US, India and China in order to further strengthen the collaboration and mutual understanding. Furthermore, DG SANTE will work to ensure a smooth cooperation for the quality of medicines with the European Directorate for the quality of medicines (EDQM).

Animal health, plant health and food safety

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. Harmonisation is an important priority in the food sector. The EU will continue to promote its policy model towards safety and quality standards.

DG SANTE will continue to strive for alignment between international and EU standards through our representative work in international fora to reduce our exposure to dispute settlements. This particularly concerns the positions taken by the EU in the WTO's sanitary and phytosanitary committee (SPS Committee) and the other international standard setting bodies, the World Animal Health Organisation (OIE), International Plant Protection Committee (IPPC), Codex Alimentarius and Convention on Biological Diversity (CBD) and its protocols (e.g. Cartagena Protocol on Biosafety).

DG SANTE will attend three meetings of the WTO SPS Committee in 2019 to 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, e.g. legislation on pesticides and the EU approach to endocrine disruptors; new requirements on imports following the adoption of the Regulation on veterinary medicinal products linked to AMR, and new requirements on imports of high risk plants following the adoption of the new plant health law. DG SANTE will continue to monitor the implementation by Russia of the WTO Appellate Body decision on the EU-launched 2014 dispute on the Russian restrictive measures on African swine fever.

DG SANTE also contributes to the work 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 OIE, DG SANTE defends the EU's high animal health and welfare standards with a view to influencing international standards. In 2019, DG SANTE will continue to coordinate the EU common position with regard to new OIE standards or revision of existing standards at the General Session in May 2019.

In 2019, DG SANTE will continue to coordinate EU positions within the Codex Alimentarius via electronic processes as well as in the context of 13 Codex Committees, of the Codex intergovernmental Task Force on Antimicrobial Resistance and of various working groups to ensure as far as possible that there is a good alignment between EU legislation and Codex standards. SANTE will continue to chair electronic Working Groups, for example in the field of contaminants and food additives on matters of interest to the EU.

As concerns the International Plant Protection Convention (IPPC), DG SANTE will also continue to coordinate a strong EU input on global plant health strategy, including the new IPPC Strategic Framework for 2020-2030, the development of international standards and guidelines for phytosanitary measures and the preparations of the International Year of Plant Health in 2020. In 2019, DG SANTE will be closely involved in the preparation of the plenary meeting of the Commission on Phytosanitary Measures (CPM, in April 2019) as well as of the meetings of the CPM subsidiary bodies (Standards Committee, Implementation and Capacity Development Committee), of the Strategic Planning Group and of various other technical and expert groups**.**

At European level, DG SANTE is intensively involved in the scientific work that is performed by the European and Mediterranean Plant Protection Organisation (EPPO) in the framework of pest risk assessment and pest risk management. Participation in several Panels (for phytosanitary measures, for common positions for the IPPC CPM, for diagnostic protocols and for phytosanitary inspectors), in technical workshops, in the Working Party for Phytosanitary Regulations and in the annual Council meeting assure a streamlined EU phytosanitary approach for the European Region.

The EU also is one of the world's largest exporters of seeds. International policies on seeds play an important role for securing jobs in the EU, but also for food security, climate change adaptation and sustainability of agricultural production. DG SANTE takes part in discussions with the OECD Seed and Forest Schemes, the United Nations Economic Commission for Europe (UNECE), the International Union for the Protection of New Varieties of Plants (UPOV) and the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) to shape the international governance of seed trade, related intellectual property rights and the access to plant genetic resources. In 2019, DG SANTE will continue to work towards international harmonisation and governance in this area and in particular towards implementing the new OECD Seed Schemes strategy, working on International System of Cooperation within UPOV, and improving access to plant genetic resources and the sharing of benefits arising from this access in the context of ITPGFRFA.

Concerning the fruit trade, DG SANTE will continue to monitor imports into the EU to verify the absence of quarantine pests, especially for citrus originating from Brazil, Argentina, Uruguay and South Africa that are subject to the specific phytosanitary import requirements established in the emergency measure dealing with the citrus black spot disease. Also, the recent EU measures against the introduction of the false coddling moth via fruits (like peppers and citrus) from African countries will need further follow-up.

In the animal health area, in 2019 DG SANTE will continue to support through a specific Grant Agreement the activities of European Commission for the Control of Foot and Mouth Disease (EuFMD), a statutory body of FAO, and will be present at the biannual meetings of its Executive Committee, as well as at the annual meeting of the "Tripartite" between Greece, Bulgaria and Turkey established in the framework of EuFMD.

<u>Improving bilateral trade relations</u>

Bilateral trade negotiations are also directly linked to the priorities of the Juncker Commission, in particular the one relating to jobs, growth and investments. Access to foreign markets is critical for the EU economy and heavily conditioned by sanitary and phytosanitary requirements which often act as non-technical barriers.

The EU is the world's largest importer and exporter of agri-food products. With combined imports and exports of EUR 259 billion in 2017, the EU is the world's biggest trader in agri-food products, benefiting producers and consumers within and outside the EU. For the 12-months period between August 2017 and July 2018, EU agri-food *exports* reached

a value of EUR 136.8 billion, corresponding to an increase of 0.9% in value terms compared to the same period the previous year. Agri-food *imports* from third countries in the 12-months period between May 2017 and April 2018 accounted for EUR 114.5 billion, i.e. a decrease of -2.5% compared to the same period the previous year. Driven by the stronger export performance over the 12-months period, the export surplus remains at EUR 22.2 billion (+EUR 4.1 billion; +23%).

The EU's external trade has to take place under safe conditions, both to protect health and to avoid trade disruption. This requires direct engagement with trade partners to ensure that the relevant safety requirements are met. Many of these requirements are of such a nature that they can only be overseen and verified by public authorities.

The main activities planned for 2019 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 aiming to demonstrate the EU solid, transparent and reputable food, animal and plant health systems.

DG SANTE takes a leading role in negotiations at both bilateral and multilateral level to ensure that EU priorities are met. These priorities are primarily related to health and food safety but also have a very important economic and political dimension. Owing to the importance of agri-food products in international trade, SPS measures cannot be divorced from wider trade negotiations and DG SANTE has been required to take a prominent role in both the sectoral and overall negotiations.

Agreements are a powerful tool to promote the EU SPS system, as noted in the State of the Union Address of President Juncker on 12 September 2018. The main objectives of the SPS chapter within a Free Trade Agreement (FTA) negotiation is to protect human, animal or plant life and health in the territory of the Parties while facilitating trade between the Parties. DG SANTE ensures that the SPS provisions are in line with EU requirements to avoid that the obligations contracted in the Agreements require modifications to our food safety acquis. In case of scientific uncertainties, DG SANTE does so by applying the so-called precautionary principle, which is a key element of the EU SPS system that is at times criticised by non-EU countries. In order to be cleared for importing, third countries' products have to meet the EU's product specific requirements, such as microbiological food safety criteria, residues (hormones, growth promoters), contaminants, GMO, etc. All such provisions in and requirements for an FTA SPS chapter are considered by the Commission to be in line with the obligations of the EU in the WTO and in the international standard setting bodies.

DG SANTE will lead on the negotiations on SPS chapters in the Free Trade Agreement negotiations underway, or planned, e.g. Australia (first round July 2018), New Zealand (first round July 2018), Indonesia, Philippines, Malaysia, Chile, Tunisia and Morocco.

It will also identify the SPS issues which need to be resolved to best exploit the export opportunities once the new EU-Japan FTA becomes operational, after its adoption by the Japanese Parliament and the EU. In particular, SANTE will work on the animal health mutual recognition project with the aim to see Japan enforcing the regionalisation principles.

It will also cooperate with Australia and closely monitor imports of animal products from Brazil due to the meat fraud incident and the operation of the reinforced checks at Border Inspection Posts. DG SANTE will address the risks to EU exports of new import measures

being introduced in China (Food Safety Law). An enhanced cooperation on animal health (in particular on regionalisation principles), e-certification and e-commerce would help confidence building with China whilst ensuring safe imports in EU from the second biggest export country.

Started in 2018, the implementation of the ambitious EU-Canada Comprehensive Economic and Trade Agreement (CETA) in the sanitary and phytosanitary area will continue in 2019 with the purpose to open the Canadian markets to more SPS commodities from all EU Member States.

Regarding the 2018 FTA agreed between the EU and Vietnam, progress is sought in 2019 to ensure that applicable SPS provisions can be implemented right from the moment of the entry into force of the agreement. Technical assistance will be offered to Vietnam in order support the country's competent authorities in increasing preparedness for the implementation of the SPS chapter, with priority to plant health and aquaculture products safety.

DG SANTE will also aim for successful outcome to the extension in scope of the current EU-Swiss Agreement and of enlargement related dossiers. Following the political decision, the screening exercise and the setting of benchmarks for candidate countries (FYROM and Albania) will be launched.

DG SANTE will continue to work on the implementation of the SPS chapters of the agreements the EU has established with its neighbouring countries in the east. These range from the creation of *Deep and Comprehensive Free Trade Areas* with Ukraine, Georgia and Moldova, whereby these countries are working to align their SPS legislation to the EU *acquis communautaire,* to *Partnership agreements* with other countries in the region, including Central Asia.

Although the EU is a net exporter of agri-food products, the export of European agriculture products is still impeded by a significant number of unjustified SPS obstacles in non-EU countries. The 2014 Russian political ban on import of a range of EU food products – which remains in place to date - has raised awareness amongst industry and Member States of the important role of international trade for European agriculture, as well as of the need to diversify and stabilise our export markets. In this regard, DG SANTE will work towards maintaining the consensus with Member States in relation to Russia and in particular the refusal to engage on a bilateral basis in relation to the bans on pig meat.

Another priority for DG SANTE is the preparation of negotiations on the post-Brexit SPS requirements for trade in agri-food products with the UK.

DG SANTE will address the priority list of non-EU countries and issues in the field of SPS agreed with TRADE and AGRI in pursuit of improved market access for EU agri-food exporters.

3.2. Specific objective 3.2: A balanced agreement with the US on pharmaceutical products and in SPS area

Output table is included in Annex 1.

Health

In 2017, the Commission and the United States Food and Drug Administration (USFDA) successfully concluded the Mutual Recognition Agreement (MRA) on pharmaceutical Good Manufacturing Practices (GMP) inspections.

Work is underway to implement the MRA. All 28 EU Member States will have to be assessed by the US Food and Drug Administration by 15 July 2019. As of September 2018, 15 Member States had been recognised.

In line with the MRA, joint preparations started for the first of 12 veterinary medicines audits in EU Member States, starting in November 2018. In turn, EU Member States and the Commission will conduct an audit of US veterinary medicine facilities in early 2019.

By mid-July 2019 the Joint Sectoral Committee composed of representatives from SANTE, the European Medicines Agency, and the US Food and Drug Administration, will consider whether to include veterinary products in the scope of the MRA. This decision will be guided by the outcome of the audits.

Moreover, SANTE will also facilitate extension of the MRA to vaccines in the coming years. Specifically, SANTE will encourage joint inspections between EU and US inspectors to gain experience and ultimately extend the scope.

Animal health and food safety

Despite the suspension of negotiations for the Transatlantic Trade and Investment Partnership (TTIP) with the US, DG SANTE maintains extensive contacts at technical and political level with the US, our most important agri-food trading partner.

This collaboration remains focussed on attaining a fair and balanced trading relationship based on reciprocity. DG SANTE conducts these negotiations on the basis of the pragmatic 'EU as Single Entity' concept. Currently, the EU is excluded either wholly or partially from many important US agri-food markets due to sanitary and phytosanitary barriers. A number of key EU agricultural products are affected including beef, sheep and goat meat, pasteurised dairy products, egg products, apples and pears. DG SANTE remains committed to tackling these barriers in 2019.

To underpin the achievement of specific objective 3.2, DG SANTE engages with the US at technical level in the context of two working groups on – respectively - Animal Health and Plant Health. The Animal Health Working Group had been dormant for some time and was re-instituted in 2017. Further meetings are expected in 2019 to follow up on the Juncker-Trump joint statement of 26 July 2018.

In food safety, DG SANTE is working closely with the US competent authorities with the objective of finding common ground, avoiding trade disruptions and creating new market opportunities. The ongoing projects on "Systems recognition" and "Shellfish equivalence" represent the best examples of this close collaboration with the US Food and Drug Administration and are expected to produce concrete results as of 2019. More concretely, the project on "Systems Recognition" will reduce the burden on EU food business operators exporting to US, while the "Shellfish equivalence" project will allow the re-opening of bilateral trade of bivalve molluscs.

PART 2. MAIN ORGANISATIONAL MANAGEMENT OUTPUTS FOR THE YEAR

A. Human resource management

Output tables are included in Annex 1.

2019 will be a transition year, as it will be the last year of this College and the UK will exit the EU. A new European Parliament will be elected and a new President and Commissioners will be appointed. By the end of the year, the revised Commission and its guidance related to DG SANTE's priorities and organisational structure should be known and be implemented.

To be ready for these changes, DG SANTE will encourage and engage all staff in the preparatory work through an inclusive process, which will also provide input into the overall DG SANTE HR strategic plan covering the first two to three years of the new College.

DG SANTE has already exceeded its quantitative target of first time appointment of women to middle management positions as set out in the Commission Decision of 19th July 2017.

The results of the 2018 staff survey will be available in spring 2019 and will be analysed in detail. The data will be compared against the results of the 2016 and 2014 surveys and complement the input described above in the SANTE HR strategy.

DG SANTE will place a greater emphasis on internal communication in 2019 with a view to ensuring that all staff is well informed, engaged and motivated. New internal communication initiatives to be launched throughout the year include further development of the MySANTE intranet as a hub for all information needed by staff; videos to share knowledge about the work of different units and the people behind the files; and an online interactive tool. The proposals above will be assessed in late 2019 to verify whether they are useful, appreciated and, above all, if they offer a real added value for colleagues.

Continuous efforts will also be made to ensure that DG SANTE's vacancy rate remains low. Filling vacancies quickly is important in order to alleviate the high workload stemming from the increasingly sensitive, complex and high-profile health and food safety files. As such, follow-up of recruitment processes will be stepped up. Ensuring that a fresh competition list of specialists is available early in the new year will help to fill posts falling vacant.

With regard to learning and development, more focus will be given to organising training to assist colleagues in keeping up with developments in their fields of specialisation. The implementation of DG SANTE's pre-management policy, which started in 2018, will continue, including by helping officials with leadership potential to develop their skills and competencies. Special priority will be given to female colleagues in order to contribute to the Commission's target of increasing the number of female managers, a target which DG SANTE has already reached.

B. Financial Management: Internal control and Risk management

Output tables are included in Annex 1.

In the 2017 Annual Activity Report (AAR), the Director-General of DG SANTE signed the declaration of assurance stating that he had reasonable assurance that resources were used in accordance with the principles of sound financial management, and that the

control procedures put in place gave the necessary guarantees concerning the legality and regularity of the underlying transactions including prevention, detection, correction and follow-up of fraud and irregularities.

In accordance with the Strategic Plan, the objective for 2019 is to maintain an adequate assurance-building process based on solid building blocks. This will allow the Director-General to confidently sign the declarations of assurance for the next Annual Activity Reports.

The main expected outputs feeding into these building blocks are:

(i) Reliable estimate of the residual error rate in payments made in the public health and food and feed safety policy areas to measure the legality and regularity of the underlying financial transactions in the DG;

(ii) Timely implemented actions related to audit recommendations from the Internal Audit Service (IAS) and the European Court of Auditors (ECA);

(iii) Conclusion on the cost effectiveness of controls in the 2018 Annual Activity Report;

(iv) Finalisation of the overall assessment of the "presence and functioning" of all internal control components according to the Commission's new internal control framework in the context of the 2018 Annual Activity Report.

C. Better Regulation

The main planned outputs linked to the Better Regulation objective in the Strategic Plan are listed in Part 1 and Annex 1 under the relevant specific objective in the tables. The full list of ongoing projects (evaluations and studies, including those supporting impact assessment work) is recorded in the dedicated Inter-institutional Studies Database, (updated regularly and, for the purposes of the multi-annual planning, in October 2018).

DG SANTE will continue to regularly assess the fitness for purpose and the simplification potential of its vast regulatory acquis. The introduction of the KOEL system, which is fully deployed and expected to be used by all SANTE services in 2019, will allow a more efficient and systematic monitoring of the acquis for which SANTE is responsible.

The results of several ongoing evaluations will become available in 2019, and feed into reflections on possible policy adjustments (health claims, orphan and paediatric medicines, pesticides, EMA fees, blood, tissues and cells). Ex-post evaluation work will continue in a number of other areas (including food contact materials, feed additives, food irradiation), and new evaluations will start on animal welfare and sustainable use of pesticides.

Impact assessment work will be carried out in relation to possible changes to the rules on lead and cadmium in ceramic and vitreous materials that come in contact with food, on the rules which govern European Medicines Agency fees (following up on the ongoing evaluation), and possibly in other areas should the results of the ex-post analyses, once available, so warrant.

D. Information management aspects

Output table is included in Annex 1.

In line with the Commission’s corporate strategy for data, knowledge and information (DKI) management and the DG SANTE Strategic Plan, DG SANTE is planning to develop

its approach to DKI management so as to contribute to the corporate objectives. This will include, as first steps, initiatives aimed at better appreciating the range of data sets and resources already available and at increasing their accessibility, and continued efforts to map and understand data needs for policy making purposes. Strengthened support for data collection in relation to better regulation projects will be continued and stepped up.

DG SANTE's document management policies also contribute to DKI management corporate objectives. In particular, DG SANTE's practices aim to ensure that information and knowledge is shared and reusable by other DGs, and that important documents are registered, filed and retrievable. Any new DG SANTE Ares file is created by default with Commission visibility, unless specific reasons are given by the owner department to restrict access. Document management correspondents across the DG are trained on how best to implement the new policy while taking into account the need to protect confidential and sensitive information.

The DG SANTE collaboration platform policy provides the standard framework and tools for the management of horizontal Units' key activities, coordinating work with operational Units and projects within DG SANTE, other DGs and/or agencies. Recent developments address the goal of using the collaboration platform for the management of all activities within and across Units in the coming years. Current experience with a selected number of projects and activities has shown that this is very effective. This experience will be used to further stimulate and streamline the collaborative work process across Units, and to promote the maintaining of information produced in a single space, that can be searched and retrieved in an efficient way.

DG SANTE's eGovernment policy is to work towards full eGovernment. For some systems, DG SANTE has already 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 interaction with Member States, business and citizens. The policy is fully in line with the Commission's IT Board policies and contributes towards the digital economy by raising the maturity level for as many applications as possible, using standards and providing high value e-services, and reducing bureaucracy where possible. DG SANTE actively promotes and publishes all available information in the European Union Open Data Portal (ODP) in human and machine readable formats.

DG SANTE meets the target for filing all documents registered by the DG set by **Indicator 1** of the DG SANTE Strategic Plan 2016-2020 (although the target is reached sometime after the documents have been registered, i.e. after DIGIT makes the statistics available). DG SANTE expects to meet this target in 2019 as well.

The 2020 target for **Indicator 2** - 75% of HAN files readable/accessible by all units in the DG and for **Indicator 3** - 75% of HAN files shared with other DGs is lower than the baseline (98% in both cases). This is to be expected, because, up until late 2016, files with normal visibility (i.e. DG SANTE visibility) were usually only shared with one other DG. In 2017, however, the majority of the files which were previously created with SANTE-only visibility have been shared with the entire Commission and therefore a percentage of files with confidential information needed to be restricted to SANTE units or persons. This was the case in 2018 and will be the case in 2019 as well.

E. External communication activities

Output table is included in Annex 1.

Communication activities in 2019 will reflect DG SANTE's ambition to contribute to the Commission's positive agenda on creating a Europe that protects, empowers and defends. Communication actions are aimed at explaining the Commissioner's mission

letter and DG SANTE's overall objective, i.e. promoting good health. The activities will support policy implementation by highlighting the added value of the Commission's work on health and food safety, explaining the Commission's position on sensitive issues and ensuring its credibility and reputation.

There will be a very particular communication context in 2019. It is the last year of the current College's mandate, and resources will be devoted to explaining the achievements of the last five years at corporate level and as achieved by individual policies, all while continuing to shape the future. Particular efforts will be devoted to priority areas within the Commissioner's mission letter, specifically health and food safety crisis prevention and management, as well as health systems performance assessment.

DG SANTE's communication work will continue to reinforce Commission messages on key issues such as vaccination, food waste, crisis preparedness and the legislative proposals regarding the General Food Law and Health Technology Assessment. We will continue to promote EU initiatives on Antimicrobial Resistance, the State of Health in the EU cycle, and the European Reference Networks by highlighting their potential for patients and healthcare providers across Europe. Communication on these priorities will highlight that they are linked to three of the Juncker Commission's ten priorities (new boost for jobs, growth and competitiveness in the EU; a deeper and fairer internal market; and a balanced and progressive trade policy to harness globalisation) and will contribute to the Commission's positive agenda and corporate communication campaigns (in particular "EU Protects", which includes specific deliverables such as the recently lanched video on rare diseases, a visual story on crisis preparedness and a new product in preparation on food safety, as well as "InvestEU", which includes the promotion of several Health-related projects).

The European Parliament electoral campaign will provide a particularly complex context for some of DG SANTE's most sensitive files (e.g. pesticides, endocrine disruptors, GMO, food contact materials, food additives, animal health – in particular African swine fever – and welfare). Additional efforts will be required on media analysis (traditional and social) in order to explain the Commission's position on these files and ensure its credibility and reputation.

These efforts are in addition to the regular media work (media requests, lines to take), social media outreach and *ad hoc* communication support to policy units (web publishing, photo, video, graphic design).

DG SANTE will also continue the work on digital transformation within both the "*Food, Farming and Fisheries*" and "*Live, Work, Travel in the EU*" areas of the Commission's new web presence.

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

1) Further to the pilot use of e-submission in its public procurement procedures in the fourth quarter of 2018, DG SANTE will use this IT solution to its full capacity in 2019. It is expected to reduce the administrative burden, especially in the opening procedure of public procurements (no manual interventions, automatic registering and reporting, paperless filing and archiving). To complement e-submission, DG SANTE also plans to roll out GEKKO (local development) or eOrdering (standard solution) for the automatic generation of the procurement contract. Moreover, this tool will reduce the workload for the processing and control of timesheets and for the payment of invoices for external IT contractors. The final decisions on the use of either GEKKO and/or eOrdering for such contracts will be made in early 2019.

2) In the framework of its stakeholder relations, DG SANTE finalised the pilot phase to use the IT solution AGM, a standard solution in the Commission with PMO as system owner and DIGIT as system provider. The objective is to manage the entire process from planning a meeting to inviting and reimbursing experts using one single electronic tool. To that end, the link with/inclusion of WEBDOR into AGM will become operational in 2019.

DG SANTE is also broadening the use of AGM to include all scientific committees and all expert panels to increase not only the efficiency of organising the meetings but also to reduce the financial risks and delays linked to the (currently paper-based) process for reimbursement of experts and paying the fees, notably to the members of the scientific committees. DG SANTE will also look at the possibility to use AGM for other types of meetings organised outside the premises of the Commission.

3) In April 2018, DG SANTE started to implement an IT tool called KOEL (Knowledge Online on European Legislation) to manage and share information about EU legislation. The primary objective is to better manage the administrative aspects of DG SANTE's vast acquis to ensure sound planning for the follow-up of existing and future obligations, valuable to both the Management and the Units to keep track of the evolution of the Commission’s obligations and powers in SANTE’s areas of competence. The KOEL system has been fully deployed and is expected to be used by all SANTE services in 2019, and DG SANTE intends to ensure that recurrent legal obligations are effectively reflected in the KOEL system.

4) Under the third Health Programme (2014-2020), the Commission contributes to the costs of European Reference Networks (ERN) on the basis of one-year specific grant agreements (SGAs) under the five-year framework partnership agreements (FPA). In 2018, DG SANTE took the first steps to move from one-year to three-year specific grant agreements covering the remaining period of the FPA's. This multi-annual co-financing significantly reduces the administrative burden for both the Member States and the Commission as only one – instead of three – award procedures per ERN has to be managed. It also gives planning security to the ERNs to guarantee the sustainability of their actions.

Annex 1. Tables

PART 1. MAIN OUTPUTS FOR THE YEAR

1. GENERAL OBJECTIVE 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT

1.1. Specific objective 1.1: Effective preparedness, prevention, reaction and eradication of human, animal and plant diseases

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT		
Specific objective 1.1: Effective preparedness, prevention, reaction and eradication of human, animal and plant diseases		**Related to spending programmes: - 3rd EU Health Programme - CFF for the Food Chain 2014-2020**
Main outputs in 2019:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Human diseases		
Agreement with Member States on list of priority vaccines for research	*Agreement*	*Q3 2019*
Launch of an e-learning platform as regards research-based knowledge, best practices and lessons learned on vaccine hesitancy	*Launch*	*Q1 2019*
Survey/interviews with relevant stakeholders on coordinated cross-border measles vaccination campaigns	*Start*	*Q3 2019*
Creation of a European Vaccination Portal	*Operational*	*Q4 2019*
Animal and plant diseases		
2019 Eradication, surveillance and monitoring programmes:		
Bovine brucellosis	*No. of programmes which received co-financing*	*3*
Bovine tuberculosis	*No. of programmes which received co-financing*	*6*
Ovine/caprine brucellosis	*No. of programmes which received co-financing*	*5*
Bluetongue	*No. of programmes which received co-financing*	*16*
Swine diseases	*No. of programmes which received co-financing*	*20*
Avian influenza	*No. of programmes which received co-financing*	*26*
Transmissible Spongiform Encephalopathies (TSE), Bovine spongiform encephalopathy (BSE) and scrapie	*No. of programmes which received co-financing*	*27*

Rabies	*No. of programmes which received co-financing*	*12*
Salmonella in poultry	*No. of programmes which received co-financing*	*25*
Lumpy Skin Disease (LSD)	*No. of programmes which received co-financing*	*4*
Emergency measures	*Adoption*	*Throughout the year*
Other important outputs		
Output	Indicator	Target
Human diseases		
Template proposal for a common physical EU vaccination card and an EU electronic vaccination card	*Completed*	*Q3 2019*
Launching Conference of the Coalition for Vaccination	*Organisation of the meeting*	*Q1 2019*
Conference on improving EU vaccine manufacturing capacity and ensuring continuity of supply	*Organisation of the meeting*	*Q3 2019*
Workshop on lessons learnt on joint procurement of vaccines	*Workshop organised*	*Q3 2019*
Global Vaccination Summit	*Organisation of the meeting*	*Q3 2019*
Implementing acts under Decision 1082/2013/EU on the operational procedures of the epidemiological surveillance network (PLAN/2017/2137)	*Adopted*	*Q1 2019*
Launch of Joint Action to strengthen preparedness against serious cross-border threats to health	*Launched*	*Q1 2019*
Launch of Joint Action on health preparedness for terror attacks	*Launched*	*Q3 2019*
Animal diseases		
Commission decisions on handling evolving epidemiological situations	*Adoption of emergency Decisions as necessary, according to the epidemiological situation*	*In course of 2019*
Commission rules on safe imports, trade and related aspects	*Adoption of Commission implementing rules.*	*In course of 2019*
Delegated Act on movement of terrestrial animals and products of animal origin (PLAN/2018/2576)	*Adoption*	*Q3 2019*
Delegated Act on Movement of aquatic animals and products of animal origin from aquatic animals (PLAN/2018/2572)	*Adoption*	*Q3 2019*
Delegated Act on Entry into the EU of animals, general products and products of animal origin (PLAN/2018/2575)	*Adoption*	*Q3 2019*
Delegated Act on Notification, reporting, surveillance, eradication programmes, disease freedom (PLAN/2018/2573)	*Adoption*	*Q3 2019*
Delegated Act on Disease control measures	*Adoption*	*Q3 2019*

– List A, B, C diseases (PLAN/2018/2574)		
Delegated Act on animals (terrestrial): Registration and approval of establishments, identification and registration of animals (PLAN/2018/2577)	*Adoption*	*Q3 2019*
Delegated Act on approval of germinal product establishments, traceability and animal health requirements for the movements within the Union and entry into the Union of germinal products of certain kept terrestrial animals (PLAN/2017/1290)	*Adoption*	*Q1 2019*
Delegated Act on animal health requirements for the production, processing and distribution within the Union and entry into the Union of products of animal origin (PLAN/2017/1341)	*Adoption*	*Q3 2019*
Delegated Act on aquatic animals - registration and approval, types of establishments, transporters exempted, exemptions from record keeping (PLAN/2018/2571)	*Adoption*	*Q3 2019*
Implementing Act on categorising transmissible animal diseases and setting up a list of species to which the measures for specific listed diseases are to apply at Union level ('listed species') (PLAN/2017/1097)	*Adoption*	*Q1 2019*
Plant diseases		
Implementing Act listing regulated pests, plants, plant products and other objects (PLAN/2017/1442)	*Adoption*	*Q4 2019*
Delegated Act on rules on plant passports and criteria for professional operators issuing plant passports (article 81(2) PHL) (PLAN/2018/2570)	*Adoption*	*Q1 2019*
Delegated Act on establishment of conditions concerning the authorisation for movement of quarantine pests and certain plants and plant products (PLAN/2017/1443)	*Adoption*	*Q4 2019*
Delegated Act on establishment of a list of priority pests (PLAN/2017/1440)	*Adoption*	*Q4 2019*
Commission Decisions on emergency measures against some specific pests	*Adoption according to (new) outbreak situations*	*In course of 2019*
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 2019*

1.2. *Specific objective 1.2: Safe and sustainable food and feed production systems*

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT		
Specific objective 1.2: Safe and sustainable food and feed production systems		**Related to spending programme CFF for the Food Chain 2014-2020**
Main outputs in 2019:		
Delivery on legislative proposals pending with the legislator		
Output	Indicator	Target
Negotiation with Council and Parliament of a proposal for a Regulation on the transparency and sustainability of the EU risk assessment in the food chain (2018/088 (COD))	*Political agreement*	*Q2 2019*
Initiative on possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory (2015/0093 (COD))	*Continue to monitor progress in the Parliament and the Council*	*Q2 2019*
Initiative on cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes (2013/SANCO/007)	*Continue to monitor progress in the Parliament and the Council*	*Q2 2019*
Initiative on placing on the market of food from animal clones (2013/SANCO/007)	*Continue to monitor progress in the Parliament and the Council*	*Q2 2019*
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Food Labelling Information System	*Operation of the database*	*Q4 2019*
Evaluation of Nutrition and Health Claims Regulation (2015/SANTE/595) Annex II of the CWP 2016	*Publication of the SWD*	*Q2 2019*
Evaluation of Regulations on plant protection products and pesticides residues legislation (2016/SANTE/197) Annex II of the CWP 2016	*Publication of SWD and of Reports to Parliament and Council*	*Q2 2019*
Evaluation of the feed additives legislation (PLAN/2017/988) [REFIT Scoreboard 2017]	*Adoption of SWD*	*Q4 2019*
Operational support services for the EU Platform on Food Losses and Food Waste	*Operation of digital platform and user activity*	*Ongoing regular activity in 2019*
Operations of Horizon 2020 REFRESH as part of SANTE food waste prevention digital tools	*Operation of website*	*Q2 2019*
Report analysing the effectiveness of food waste prevention initiatives (implemented by JRC)	*Publication*	*Q4 2019*
Meetings of the EU Platform on food waste:	*2 meetings and 1 event to*	*Q2, Q4 2019*

	disseminate Platform recommendations for action in food waste prevention held	
Delegated Act on measurement methodology (PLAN/2018/2496)	*Adoption*	*Q1 2019*
Implementing act on format for reporting data on food waste (PLAN/2018/3473)	*Adoption*	*Q1 2019*
EP Pilot project on food redistribution: reports on Tasks 1 and 2 – mapping and analysis of policy, regulatory and operational frameworks	*Publication*	*Q1 2019*
Action grant to support European Federation of Food Banks (strengthening and expansion of network in the EU)	*Adoption of grant agreement*	*Q3 2019*
Implementation of grants programme to support action of Member States and actors in the food value chain to prevent food waste and strengthen sustainability	*Completed*	*Q4 2019*
Innovation in food processing technologies (Portal for e-authorisations of food improvement agents and novel foods)	*Operation of the portal*	*Q4 2019*
Other important outputs		
Output	Indicator	Target
Implementation of Regulation on the transparency and sustainability of the EU risk assessment in the food chain, if adopted by co-legislators	*Adoption*	*Q4 2019*
Implementing act establishing a legal limit for the industrial trans fats content in foods (2016/SANTE/143) *Reference in the text of CWP 2016*	*Adopted*	*Q1 2019*
Commission guidance document on origin indication of the primary ingredients of food	*Adoption*	*Q4 2019*
Report from the Commission on front-of-pack / simplified nutrition information (PLAN/2017/923)	*Adoption*	*Q1 2019*
Regulatory measures on contaminants in feed and food following EFSA opinions	*Adoption*	*In course of 2019*
Authorisations for health claims made on foods and referring to children's development	*Adoption*	*In course of 2019*
Authorisations of health and nutrition claims, generic descriptors, vitamins and mineral substances etc.	*Adoption*	*In course of 2019*
Outline of specific compositional requirements for baby foods and processed cereal-based foods for the purpose of consultation with the European Food Safety Authority	*Completion*	*Q4 2019*

Delegated act amending the maximum vitamin D and erucic acid content permitted in infant formulae (PLAN/2018/3475)	*Adoption*	*Q1 2019*
Measure on ceramic food contact material (PLAN/2017/2348)	*Publication of IA*	*Q3 2019*
Plant protection products and biocides		
Renewal/non-renewal of active substances for plant protection products	*Adoption*	*Ongoing regular activity in 2019*
Decisions establishing maximum residues levels (MRL) for pesticides	*Adoption*	*Ongoing regular activity in 2019*
Decisions establishing list of non-acceptable co-formulants in plant protection products	*Adoption*	*In the course of 2019*
Implementing Regulations renewing the approval of biocidal active substances	*Adoption*	*Ongoing regular activity in 2019*
Implementing Regulations for approval or non-approval of biocidal active substances included in the review programme	*Adoption*	*Ongoing regular activity in 2019*
Sustainable use of pesticides		
Report to the Council and the European Parliament on the implementation of the Sustainable Use of pesticides Directive (SUD)	*Adoption*	*Q4 2019*
Commission Directive on Harmonised Risk Indicators in the context of the Sustainable Use of Pesticides Directive (PLAN/2018/2731)	*Adoption*	*Q1 2019*
Endocrine disruptors (ED)		
Implementation of the new ED criteria in the approval/renewal of active substances	*Implemented*	*Ongoing regular activity in 2019*
GMOs		
Authorisations of GMO for food / feed and cultivation uses	*Adoption*	*Ongoing regular activity in 2019*
Authorisations of substances		
Authorisations for new substances and new uses of already authorised substances used as food additives, food flavourings, or substances used in plastic food contact materials	*Adoption*	*Ongoing regular activity in 2019*
Authorisation of 138 recycling processes for plastics used in food contact materials	*Adoption*	*In course of 2019*
Feed additives/Feed hygiene/Feed marketing		
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 2019*
Establishment of requirements for the feed business operators importing feed from non-EU countries	*Preparation*	*Q4 2019*

Revision of existing dietetic feed authorisation and authorisation of new dietetic feeds (2015/SANTE/111)	*Adoption*	*Q2 2019*
Implementation of the Novel Food Regulation		
Authorisation of novel foods under the Regulation on Novel Foods	*Adoption*	*85 in course of 2019*
Authorisation of traditional foods from third countries under the Regulation on Novel Foods	*Adoption*	*15 in course of 2019*
Decisions on data protection under the Regulation on Novel Foods	*Adoption*	*Ongoing regular activity in 2019*
Implementation of the legislation on plant reproductive material		
Amendment to delete references to regulated non-quarantine pests from the marketing Directives for seeds and propagating material and several implementing measures (PLAN/2018/4394)	*Adoption*	*Q4 2019*
Amendment of the list of vegetable genera and species covered by the marketing Directives (PLAN/2018/2643)	*Adoption*	*Q1 2019*
Bio-chemical and bio-molecular techniques in seed certification (PLAN/2018/3686)	*Adoption*	*Q4 2019*
Update of the requirements for soy bean seed. (PLAN/2018/3687)	*Adoption*	*Q2 2019*
Guidelines for variety reference sample and maintenance of varieties (PLAN/2018/3864)	*Adoption*	*Q4 2019*
Quantitative restrictions for not-yet-listed varieties of maize (PLAN/2018/3865)	*Adoption*	*Q4 2019*
Extension of the validity of decisions concerning equivalence of seed potatoes from third countries (PLAN/2018/3704)	*Adoption*	*Q1 2019*
Amendment of the fees payable to the Community Plant Variety Office (PLAN/2018/3685)	*Adoption*	*Q4 2019*
Update of variety testing protocols (PLAN/2018/3708)	*Adoption*	*Q4 2019*
Denomination rules for variety registration	*Adoption*	*Q3 2019*

(PLAN/2018/3863)		
Animal Welfare		
Meetings of the Platform on Animal Welfare	*2 meetings held*	*Q4 2019*
Meetings of the subgroups of the Platform on Animal Welfare	*4 meetings held*	*Q4 2019*
Evaluation of Animal Welfare Strategy	*Launched*	*Q4 2019*
Commission Implementing Regulation on the designation of an EU reference centre for animal welfare (PLAN/2018/3717)	*Adoption*	*Q2 2019*
Audit reports in the context of the indicators project	*4 audit reports published*	*Q4 2019*
Stakeholder meeting in the context of the indicators project	*1 meeting held*	*Q4 2019*
Audit reports and final report in the context of the pig tail docking project	*4 audit reports and project final report published*	*Q4 2019*
TAILs reports in the context of the pig tail docking project	*2 reports launched*	*Q2 2019*
Overview reports in 2019 in the context of the project on animal welfare during transport	*2 overview reports published*	*Q3 2019*

1.3. Specific objective 1.3: Cost effective health promotion and disease prevention

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT		
Specific objective 1.3: Cost effective health promotion and disease prevention	**Related to 3rd EU Health Programme**	
Main outputs in 2019:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Joint Action on implementation of validated best practices	*Launch*	*Q4 2019*
Administrative Agreement with Joint Research Centre	*Signature*	*Q2 2019*
Call for tender to support Member States in reducing alcohol related harm	*Launch*	*Q4 2019*
Direct Grant to be decided	*Launch*	*Q4 2019*
Colorectal cancer screening guidelines (implemented by JRC)	*Completed*	*Q4 2019*
Breast cancer accreditation scheme (implemented by JRC)	*Completed*	*Q4 2019*
Public procurement guidelines for healthy food in public settings (implemented by JRC)	*Completed*	*Q4 2019*

Other important outputs		
Output	Indicator	Target
Manage the Joint Action on tobacco control based on the JRC administrative agreement	*Delivered*	*Q4 2019*
Start of the track and trace system to control illicit tobacco trade	*Launch*	*Q2 2019*
Launch of the second stage of the compliance checks for the Tobacco Products Directive	*Delivered*	*Q4 2019*
3rd wave of priority setting and best practices selection by the Steering Group	*Completed*	*Q4 2019*
Recognition ceremony for institutions contributing to the Best Practices Portal	*Ceremony organised*	*Q2 2019*
OECD report on the societal costs of unhealthy diet, physical inactivity and alcohol consumption	*Completed*	*Q2 2019*

1.4. Specific objective 1.4: Effective, accessible and resilient healthcare systems in the EU

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT		
Specific objective 1.4: Effective, accessible and resilient healthcare systems in the EU		Related to 3rd EU Health Programme
Main outputs in 2019:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Finalising the adoption of the revised Commission Implementing Decision on eHealth Network (PLAN/2018/2808)	*Adopted*	*Q2 2019*
State of Health in the EU: 28 country health profiles and Commission Companion Report	*Published*	*Q4 2019*
Staff Working Document to finalise the evaluation of the Directives on blood (2002/98/EC) and tissues and cells (2004/23/EC) (PLAN/2016/154)	*Published*	*Q1 2019*
Service Contract EU Networking and support for reference laboratory functions for antimicrobial resistance	*Launch*	*Q4 2019*
Other important outputs		
Output	Indicator	Target
Delegated act on the requirements and methods for gathering data on antimicrobial resistance (sale and use of antimicrobials) (PLAN/2018/4495)	*Launched*	*Q4 2019*
Delegated act on the criteria for designation of antimicrobials reserved for human use (PLAN/2018/4510)	*Launched*	*Q4 2019*

Implementing act on the complete format for the collection of data on antimicrobials (PLAN/2018/3984)	*Launched*	*Q4 2019*
Implementing act on the list of antimicrobials reserved for human use (PLAN/2018/3966)	*Launched*	*Q4 2019*
Overview report on a series of audits to assess the effectiveness of the implementation of EU legislation on AMR monitoring in food-producing animal populations and food in Member States	*Completion*	*Q2 2019*
Overview report concerning Member States' implementation of EU guidelines for the prudent use of antimicrobials in veterinary medicine	*Completion*	*Q2 2019*
AMR One Health country visits (with the ECDC)	*4 visits completed*	*Q4 2019*
Ministerial Conference on AMR under Romanian Presidency	*Meeting organised*	*Q2 2019*
Launch of a call for projects to contribute to implementation of the EU Action Plan on AMR by implementing the EU guidelines on prudent use of antimicrobials in human health	*Call launched*	*Q3 2019*
Conformity checks for the Cross-border Healthcare Directive (final stage): country analyses, bilateral structural dialogues on major issues, infringement cases	*Delivered*	*Q4 2019*
Provision of administrative support, documentation, testing and auditing services, legal and data protection advice and funding for the cross-border exchange of ePrescriptions and patient summaries	*Delivered*	*Q4 2019*
Two meetings of the eHealth Network and four meetings of the eHealth Member State Expert Group	*Meetings organised*	*Q4 2019*
eHealth audits of National Contact Points	*Approx. 12 audits completed*	*Q4 2019*
Feasibility study of an active substance based review system ('monographs') and other potential alternatives for the environmental risk assessment of veterinary medicinal products	*Launched*	*Q4 2019*

1.5. Specific objective 1.5: Increased access to medical expertise and information for specific conditions

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT		
Specific objective 1.5: Increased access to medical expertise and information for specific conditions		Related to 3rd EU Health Programme
Main outputs in 2019:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Rare diseases registries for European Reference Networks	*Call launched*	*Q2 2019*
Other important outputs		
Output	Indicator	Target
Three meetings each of the Board of Member States and Coordinators Group	*Meetings organised*	*Q4 2019*
Finalise the amendment of Commission Implementing Directive on European Reference Networks (2014) (PLAN/2018/2544)	*Finalised*	*Q1 2019*

1.6. Specific objective 1.6: Effective, efficient and reliable official controls

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT		
Specific objective 1.6: Effective, efficient and reliable official controls		Related to spending programme CFF for the Food Chain 2014-2020
Main outputs in 2019:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
EU Reference Laboratories	*No. of laboratories funded*	*46 (45 EURL + 1 EURC)*
Better Training for Safer Food	*No. of trainings organised*	*170*
Computerised systems + IT (e.g. TRACES, ADIS, ADNS, EUROPHYT)	*No. of active end-users*	*40.000*
European Reference Laboratories	*Number of laboratories funded*	*44*
European Reference Centres	*Number of centres funders*	*2*
Other important outputs		
Output	Indicator	Target
Launch of the BTSF Academy	*Launched*	*Q4 2019*
Commission Implementing Regulation on a standard model form for Member States annual report on the operation of their multi-annual national control plans	*Adoption*	*Q1 2019*

(PLAN/2017/1182)		
Delegated act on additional categories subject to border controls (composite products, Hay and Straw) (PLAN/2017/1682)	*Adoption*	*Q2 2019*
Delegated act on animals and goods exempt from official controls at border control posts (PLAN/2018/2666)	*Adoption*	*Q2 2019*
Delegated act on border Control Staff Training (ISC/2018/05883)	*Adoption*	*Q1 2019*
Delegated act on CHED as an accompanying document (PLAN/2018/3725)	*Adoption*	*Q2 2019*
Delegated act on border control posts: rules on transhipment, transit and onward transportation of animals and goods (PLAN/2018/2661)	*Adoption*	*Q2 2019*
Delegated act on documentary checks during transhipment, transit of plants, plant products and other products (PLAN/2018/2662)	*Adoption*	*Q2 2019*
Delegated act on rules on official controls that may be performed at places other than the border control post of first arrival (PLAN/2018/2664)	*Adoption*	*Q2 2019*
Delegated act on derogations from certain border control post requirements (PLAN/2017/1681)	*Adoption*	*Q2 2019*
Delegated act on rules on the performance of specific official controls and on measures for cases of non-compliance given the specificities of certain categories of animals and goods coming from third countries (PLAN/2018/2667)	*Adoption*	*Q2 2019*
Implementing act on border controls - Lists of animals and good with Common Nomenclature (PLAN/2017/1611)	*Adoption*	*Q2 2019*
Implementing act on operations to be carried out during and after the documentary, identity and physical checks at the Border Control Posts (PLAN/2018/2669)	*Adoption*	*Q2 2019*
Implementing act on frequency of identity and physical checks at Border Control Posts (PLAN/2018/2663)	*Adoption*	*Q2 2019*
Implementing act on prior notification of certain consignments of animals and goods entering the Union through a Border Control Post (PLAN/2018/2658)	*Adoption*	*Q2 2019*
Implementing act on border control post listing (PLAN/2018/2659)	*Adoption*	*Q2 2019*
Implementing act on border control post facilities (PLAN/2018/2660)	*Adoption*	*Q2 2019*
Implementing act on intensified controls (PLAN/2017/1696)	*Launched*	*Q4 2019*
Implementing act on certification for ship suppliers and rules on channelling and transit / follow up of consignments accompanying	*Adoption*	*Q2 2019*

documents (PLAN/2018/3167)		
Implementing Act on the designation of the European Union reference laboratories for pests of plants (PLAN/2018/2674)	*Adoption*	*Q1 2019*
Delegated Regulation establishing specific rules for official controls on meat & live bivalve mollusc production and relaying area (PLAN/2017/1547)	*Adoption*	*Q2 2019*
Implementing Regulation on practical arrangements for official controls of food of animal origin (PLAN/2017/1786)	*Adoption*	*Q2 2019*
Delegated Regulation laying down import conditions for food (PLAN/2017/1684)	*Adoption*	*Q2 2019*
Implementing Regulation listing third countries for import of products of animal origin (PLAN/2017/1930)	*Adoption*	*Q2 2019*
Implementing Regulation on health certificates for products exported to the EU (PLAN/2017/1926)	*Adoption*	*Q2 2019*
Other DG SANTE activities to improve the performance of control systems:		
Audits in the area of food safety and quality, animal health, animal welfare and plant health	*Approx. 165 audits completed*	*Q4 2019*
Medical Devices joint assessments of Notified Bodies with Member States, EEA and EFTA countries	*Approx. 40 assessments completed*	*Q4 2019*
Good Manufacturing Practices (GMP) for medicinal products for human use from non-EU countries	*Up to 4 audits completed*	*Q4 2019*
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	*Number of meetings held*	*4 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 exchange best practices identified	*Number of meetings held*	*As per published SANTE audit and analysis work programme 2018*
Evaluation of facilities of Border Inspection Posts (BIPs)	*Number of evaluations carried out*	*Ca. 15. Due to Brexit, more BIPs may require approval (expanded facilities or new facilities).*
Evaluation of Member States' and non-EU countries' residue monitoring plans	*Number of evaluation carried out*	*27 Member States plans;*

		up to 50 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 (subject to Brexit)*
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 2019*
Plant health surveys	*Number of Member States' survey results to for harmful organisms presented to Standing Committee on PAFF*	*13*
Biannual reviews of temporary harmonised import controls on certain food and feed of non-animal origin	*Completed*	*Q3 2019*

2. GENERAL OBJECTIVE 2: A DEEPER AND FAIRER INTERNAL MARKET WITH A STRENGTHENED INDUSTRIAL BASE

2.1. Specific objective 2.1: Effective EU assessment of medicinal products and other treatment

Relevant general objective 2: A DEEPER AND FAIRER INTERNAL MARKET WITH A STRENGTHENED INDUSTRIAL BASE		
Specific objective 2.1: Effective EU assessment of medicinal products and other treatment	Related to 3rd EU Health Programme	
Main outputs in 2019:		
Delivery on legislative proposals pending with the legislator		
Output	Indicator	Target
Negotiation with Council and Parliament on Proposal for a Regulation on Health Technology Assessment (HTA) (2016/SANTE/144)	*Political agreement*	*Q4 2019*

2.2. Specific objective 2.2: Stable legal environment and optimal use of current authorisation procedures for a competitive pharmaceutical sector and patients' access to safe medicines

Relevant general objective 2: A DEEPER AND FAIRER INTERNAL MARKET WITH A STRENGTHENED INDUSTRIAL BASE	
Specific objective 2.2: Stable legal environment and optimal use of current authorisation procedures for a competitive pharmaceutical sector and patients' access to safe medicines	Related to 3rd EU Health Programme
Main outputs in 2019:	

Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Evaluation of the Regulations on orphan medicines (141/2000) and paediatric medicines (1901/2006) (including study, stakeholder outreach, and Staff Working Document) (PLAN/2017/2099)	*Completed*	*Q3 2019*
Impact Assessment for the EMA Fees legislation (PLAN/2018/4193)	*Completed*	*Q4 2019*
Report on the experience acquired as a result of the procedures for authorisation and monitoring of medicinal products for human use	*Completed*	*Q2 2019*
Report on the experience of the use of the list of human medicinal products subject to additional monitoring	*Completed*	*Q1 2019*
Other important outputs		
Output	Indicator	Target
Guidelines on Good Clinical Practice Specific to Advanced Therapy Medicinal Products (PLAN/2018/3056)	*In Progress*	*Q3 2019*
Authorisation of new medicinal products, variations to existing marketing authorisations, including Brexit related modifications, decisions following referral procedures, Periodic Safety Update Reports, orphan designations etc.	*Adoption of more than 1000 decisions*	*In course of 2019*
Veterinary Medicines		
Delegated act on restructuring Annex II to the basic act (technical documentation necessary for an application for a marketing authorisation) (PLAN/2018/4493)	*Launched*	*Q4 2019*
Implementing act on the list of variations without assessment(PLAN/2018/3968)	*Launched*	*Q4 2019*
Implementing act on the veterinary medicinal product database (PLAN/2018/3969)	*Launched*	*Q4 2019*
Delegated act on the detailed rules on exports from third countries (PLAN/2018/4503)	*Launched*	*Q4 2019*
Implementing act on the good distribution practice for veterinary medicinal products (PLAN/2018/3983)	*Launched*	*Q4 2019*
Implementing act on the good distribution practice for active substances (PLAN/2018/3965)	*Launched*	*Q4 2019*
Implementing act on the good pharmacovigilance practice (PLAN/2018/3967)	*Launched*	*Q4 2019*
Implementing act on the content of the pharmacovigilance system master file (PLAN/2018/3982)	*Launched*	*Q4 2019*

Implementing act on the common logo for online sales (PLAN/2018/3981)	*Launched*	*Q4 2019*

2.3. Specific objective 2.3: Common Member States' tools and methodologies used for EU health systems performance assessments

Relevant general objective 2: A DEEPER AND FAIRER INTERNAL MARKET WITH A STRENGTHENED INDUSTRIAL BASE		
Specific objective 2.3: Common Member States' tools and methodologies used for EU health systems performance assessments	Related to 3rd EU Health Programme	
Main outputs in 2019:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Report on measurement of efficiency of health systems	*Completed*	*Q1 2019*
Launch and progress on the report on measurement of resilience of health systems	*Draft report completed*	*Q4 2019*
Initial work on new report to be developed in 2020	*Background paper completed*	*Q4 2019*
Carry out tailored seminars and workshops in Member States on the national health performance assessment systems.	*Meetings organised*	*In course of 2019*

3. GENERAL OBJECTIVE 3: A BALANCED AND PROGRESSIVE TRADE POLICY TO HARNESS GLOBALISATION

3.1. Specific objective 3.1: Increased EU influence in international fora

Relevant general objective 3: A balanced and progressive trade policy to harness globalisation		
Specific objective 3.1: Increased EU influence in international fora	Related to spending programme(s): NO	
Main outputs in 2019:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Present EU positions (ensuring alignment with EU legislation and policy on pharmaceuticals) in International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) meetings, particularly as regards ICH guidelines (with the scientific support of the European Medicines Agency), defend and advance EU interests and the EU regulatory model for pharmaceuticals.	*Delivered*	*In course of 2019*

Present EU positions in IPRP meetings (International Pharmaceutical Regulators Programme); promote the EU regulatory system for pharmaceuticals	*Delivered*	*In course of 2019*
World Health Organisation (WHO) Senior Official meeting	*Meeting organised*	*Q3 2019*
Internal assessment of cooperation to implement Vilnius Declaration	*Prepared*	*Q3 2019*
Other important outputs		
Output	Indicator	Target
Coordinated EU positions on WHO resolutions	*Delivered*	*20*
EU co-sponsored WHO resolution	*Delivered*	*1*
EU statements for WHO meetings	*Delivered*	*9*
Coordination of positions in UN meetings	*Delivered*	*2*
Coordinated EU positions in OECD meetings	*Delivered*	*In course of 2019*
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 2019*
Coordinated EU position for the OIE aquatic and terrestrial Code and Manual	*Delivered*	*In course of 2019*
Coordinated EU Statements for the World Organisation for Animal Health (OIE) General Assembly	*Delivered*	*In course of 2019*
Coordinated EU positions in documents and guidelines of the International Union for the Protection of New Varieties of Plants (UPOV)	*Delivered*	*In course of 2019*
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 2019*
Coordinated EU positions in the World Trade Organisation SPS	*Delivered*	*In course of 2019*
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 2019*
Coordinate EU position in negotiations of Agreements with non-EU countries	*Delivered*	*In course of 2019*
Coordinate EU position on the management of the SPS Committees of the Agreements in force	*Delivered*	*In course of 2019*
Coordinated EU statements and position, as	*Delivered*	*In course of 2019*

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		
Contribution to intersessional activities under the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety – participation in on-line forum and Ad hoc technical expert groups on synthetic biology and gene drives and on risk assessment of living modified organisms	*Delivered*	*In course of 2019*
Contribution to the CBD's Fourth National Report on the implementation of the Cartagena Protocol on Biosafety	*Delivered*	*In course of 2019*

3.2. Specific objective 3.2: A balanced agreement with the US on pharmaceutical products and in SPS area

Relevant general objective 3: A balanced and progressive trade policy to harness globalisation		
Specific objective 3.2: A balanced agreement with the US on pharmaceutical products and in SPS area	Related to 3rd EU Health Programme	
Main outputs in 2019:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
EU-US mutual recognition agreement on good manufacturing practices on pharmaceuticals	*For human medicines: 8 authorities to be recognised by the US Food and Drug Administration* *For veterinary medicines: conduct of audits in the veterinary agencies: around 6 audits in 2019 (12 in 2018-2019)*	*Q4 2019*
Food Safety Systems Recognition exercise: Reduction in burden on EU Food Business Operators and Competent Authorities	*US to have completed assessment of seven pilot Member States with consequent decision taken on the need or otherwise for further assessments.* *EU to have completed assessment of the US food safety system*	*Q4 2019*
Organise meetings of the EU-US Animal Health Technical Working Group and Plant Health Technical Working Group: Facilitate trade and better cooperation on animal and plant health issues with the US	*Meetings held*	*Q4 2019*

Shellfish equivalence: Implementing Decisions allowing trade of bivalve molluscs between EU and US (ref PLAN/2017/1799 and PLAN/2018/3849)	*Publication of the Implementing Decisions*	*Q1 2019*

PART 2. MAIN ORGANISATIONAL MANAGEMENT OUTPUTS FOR THE YEAR

A. Human resource management

Objective: The DG deploys effectively its resources in support of the delivery of the Commission priorities and core business, has a competent and engaged workforce, which is driven by an effective and gender-balanced management and which can deploy its full potential within supportive and healthy working conditions.		
Main outputs in 2019:		
Output	**Indicator**	**Target**
Increase Staff engagement: Implement an inclusive approach towards preparing DG SANTE for the next College.	*Organisation of a SANTE management study day and a SANTE staff engagement day*	*By end of spring management day with participation of all SANTE managers and Deputy HoUs. By end of summer staff day with all DG SANTE staff*
Staff wellbeing: Contribute to reducing excessive workload by ensuring optimal use of available resources.	*Vacancy rate*	*At least 25% lower than Commission average*
Talent management: Organise staff development actions to allow staff to keep up with the developments in SANTE's fields of expertise and competence.	*Establish and implement specific training activities (job shadowing, conferences, expert classes, etc.)*	*Organisation of expert trainings benefitting at least 30 staff.*
Talent management – Equal opportunities: Continue to implement SANTE's 2018 policy on pre-management functions with special focus on female staff members	*Establish and develop preparatory management career development programmes*	*Plans for 10 Staff members of which at least 6 are female*
Action plan as follow-up of staff opinion survey 2018	*Approval of action plan by Director-General*	*By end of Q2 2019*

B. Financial Management: Internal control and Risk management

Objective 1: Effective and reliable internal control system giving the necessary guarantees concerning the legality and the regularity of the underlying transactions.		
Main outputs in 2019:		
Output	Indicator	Target

Legality and regularity of the underlying transactions in the DG	*Estimated residual error rate[10] of on-the spot controls (ex-post) for each policy area*	*Residual error rate not exceeding 2% in value of the relevant payment budget per policy area (annually or multi-annual depending on the design of the programmes)*
	Execution of the ex-post control plan	*Execution rate: 100%; i.e. all audit visits planned in 2019 should take place in 2019*

Objective 2: Effective and reliable internal control system in line with sound financial management.		
Main outputs in 2019:		
Output	Indicator	Target
Cost effectiveness of controls in the Annual Activity Report	*Conclusion reached on control costs over funds managed in the 2018 AAR*	*Maintain at least the average levels of the past three years*
Timely execution of payments	*Percentage of payments (both in number and in amounts) made within the time limits set in the Financial Regulation*	*>95%*
Timely implementation of audit recommendations	*Percentage of critical recommendations from the Internal Audit Service (IAS) and the European Court of Auditors (ECA) implemented within 6 months*	*100%*
Increased level of awareness of new Internal Control Framework	*% of staff participate in the survey on DG SANTE's Internal Control Framework*	*>70%*

Objective 3: Minimisation of the risk of fraud through application of effective anti-fraud measures, integrated in all activities of the DG, based on the DG's anti-fraud strategy (AFS) aimed at the prevention, detection and reparation of fraud.		
Main outputs in 2019:		
Output	Indicator	Target

[10] For the definition of error rates, see the Commission's guidance on the calculation of error rates, the financial exposure as amount at risk, the materiality for a potential reservation and the impact on the AOD's declaration of November 2017 https://myintracomm.ec.europa.eu/budgweb/EN/rep/aar/Documents/AAR2017-2.1.5-Materiality-Guidelines.pdf

Implementation of the anti-fraud strategy as planned for 2019	*% of implementation of actions planned for 2019 in the anti-fraud strategy*	*100%*
Increased level of anti-fraud awareness focussing on conflicts of interest in EU decentralised agencies	*EU decentralised agencies task force meeting on independence once per year with participants and contributions from all EU agencies for which DG SANTE is parent*	*All 5 EU decentralised agencies represented in the annual meeting*

C. Better Regulation

The main planned outputs linked to the Better Regulation objective in the Strategic Plan are listed in Part 1 and Annex 1 under the relevant specific objective in the tables.

D. Information management aspects

Objective: Information and knowledge in your DG is shared and reusable by other DGs. Important documents are registered, filed and retrievable.		
Main outputs in 2019:		
Output	Indicator	Target
Development of the role of a central contact point for data information and knowledge management in the DG.	*Central Data Knowledge Information (DKI) contact point appointed*	*Q4 2019*
Better use of electronic workflows, to reduce errors caused by the double circulation and to reduce paper storage in eligible cases.	*Number of registered documents with a fully approved e-signatory (no paper circulation in parallel if ink signature not required).*	*70% of registered documents approved in full electronic mode (without paper signatories circulation).* *Q4 2019*
Identification of the needs of the Directorate-General in terms of data information and knowledge	*Questionnaire sent to all Directorates for mapping their needs.*	*40% of Directorates' needs mapped.* *Q4 2019*
HERMES Integration of newly developed IT systems	*Assessment of the fulfilment of the requirements for integration of newly developed IT systems*	*5% of the IT systems being developed assessed against the integration requirements.* *Q4 2019.*
Registered documents are also filed.	*Percentage of registered documents that are not*	*Less than 1% by Q4 2019*

	filed[1] (ratio)	
Hermes Ares NomCom (HAN) files are readable/accessible by all units in the DG	*Number of Hermes Ares NomCom (HAN) files readable/accessible by all units in the DG*	*75% by Q4 2019*
HAN files are shared with other DGs	*Number of HAN files shared with other DGs*	*75% by Q4 2019*
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.*	*45% by Q4 2019*
Better use of standard electronic tools to manage Units activities and store information	*Percentage of units using collaborative tools to manage their activities*	*45% by Q4 2019*

E. External communication activities

Objective: Citizens perceive that the EU is working to improve their lives and engage with the EU. They feel that their concerns are taken into consideration in European decision making and they know about their rights in the EU.		
Main outputs in 2019:		
Output	Indicator	Target
Tackling vaccination inequalities – awareness raising following the adoption of the Council recommendation on vaccination, European Immunisation Week, Release Eurobarometer	- Number of visits to SANTE web section on vaccination - National print media coverage - Twitter reach (including Commissioner's accounts) (regular and paid)	- 10% increase (baseline 2017: 17,858 page views) - Media coverage by at least 20 EU countries - 500,000 impressions and 500 interactions (shares and likes)
Digital health and care – Media actions on the exchange of patient records and e-prescriptions	- Number of visits to SANTE web section on e-health - Twitter reach (including Commissioner's accounts) (regular and paid)	- 10% increase (baseline 2017: 34,930 page views) - 300,000 impressions and 300 interactions (shares and likes)
Publication of the Country Health profiles and companion Report on the "State of Health in the EU" to media and stakeholders	- Number of visits to SANTE web section on State of Health - Twitter reach and engagement (including Commissioner's accounts), (regular and paid) - National media coverage of report	- 10% increase (baseline 2017: 77,606 page views) - 1,000,000 impressions and 1,000 interactions (shares and likes) - Print / audio-visual media coverage by at least 15 EU countries.
The European Reference Networks: a success story in the	- Number of visits to SANTE web section on ERNs - Twitter reach (including	- 10% increase (baseline 2018: 25,4361 page views) - 500, 000 impressions and 500

treatment of rare diseases	Commissioner's accounts) (regular and paid) - Number of print media articles on success stories	interactions (shares and likes) - At least 10 articles published by several EU countries during the year
General Food Law: explaining the concrete functioning of the new legislation after its adoption.	- Number of visits to SANTE web section - National print media coverage of adoption - Number of journalists attending the media briefing or roundtable with the Commissioner (tbc) - Twitter reach (including Commissioner's accounts) (regular and paid)	- 10% increase (baseline 2017: 44,109 page views) - Media coverage by at least 15 EU countries - At least 10 articles published by several EU countries during the year - 300,000 impressions and 300 interactions (shares and likes)
Animal Health, and in particular presence of African swine fever (ASF) in the Member States	- Number of visits to SANTE web section - National print media coverage of EU's actions if/when outbreaks are reported - Number of journalists attending media briefing or roundtable with the Commissioner (tbc) - Twitter reach (including Commissioner's accounts) (regular and paid)	- 10% increase (baseline 2017: 8,110 page views; 2018: 23,469[11]) - Media coverage by at least 10 EU countries - At least 10 articles published by several EU countries during the year - 200,000 impressions and 500 interactions (shares and likes)
Participation with a stand in international events on "farm to fork", AMR and on food waste.	- Number of visits to Salon de l'Agriculture (SIA) and Grüne Woche (IGW)	- For SIA: 140,000 visitors on the stand, 27,000 visitors engaged - For IGW: 200,000 visitors on the stand, 50,000 visitors engaged

Annual communication spending[12]:	
Baseline (2018)	Estimated commitments (2019)
1 225 000	1 465 000

[11] Disclaimer: Web statistics used as 2018 benchmarks are data collected between January and September.

[12] This budget covers horizontal communication activities but also financial contributions delegated to other DGs (COMM for corporate actions, OP for publications, DIGIT for websites annual fee and AGRI for the participation on international events) and the Health Award on Vaccination. The latter, together with the participation with a stand in international events, are specific requests by Commissioner Andriukaitis.