European Commission

Management Plan 2018

DG Health and Food Safety (SANTE)

Contents

INTRODUCTION

DG SANTE's goal is to make Europe a safer, healthier place where citizens 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 2014-2029: (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 2018, DG SANTE will focus on the preparations of the next Multi-Financial Framework (MFF). Without prejudice to upcoming political guidance, DG SANTE will prepare options for possible successor instruments to the Health Programme and the Common Financial Framework for expenditures in the food chain area (CFF), both due to expire in 2020, to continue ensuring high level of public health and food safety. DG SANTE will focus on areas where there is strong EU added value. It is therefore crucial to keep supporting the Member States in order to ensure quick response to outbreaks of diseases and help to mitigate health and economic consequences of such outbreaks.

Recent experience has shown that infectious diseases can move quickly across borders, carried by humans, animals, food or plants. Without an effective preparedness and response in place, outbreaks of infectious diseases often have a dramatic socio-economic impact, cost lives, threaten global security and affect food safety and food security. In this context, in 2018, DG SANTE and DG RTD will prepare a joint Communication on protecting citizens against health threats from infectious diseases. Following the State of the Union speech and Letter of Intent, DG SANTE will also develop a proposal for a Council Recommendation on vaccination to combat vaccine hesitancy and promote more sustainable EU-level vaccination policies. DG SANTE will also work towards enhancing the EU's preparedness for the next epidemic waves of animal and human influenza. Our collaborative approach under a One Health umbrella will enable the exchange of scientific expertise and experience.

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 the EU can play a role in supporting Member States to promote health and invest in effective, accessible and resilient health systems. DG SANTE will do so by adopting and implementing a Communication on digital transformation of health and care, developing the legal action necessary to promote EU cooperation on Health Technology Assessments (HTA), and operationalising the European Reference Networks. On a more global scale, the SDG Health Goal is also linked with the continued global threat from antimicrobial resistance (AMR), and DG SANTE will play the lead role in implementing the EU One Health Action Plan on AMR adopted last year. DG SANTE will also continue to support other cross-cutting SDG aimed at reducing hunger, improving nutrition, environmental and climate concerns by reducing food waste, reviewing the General Food Law and actively participating in discussions on the modernisation and simplification of the Common Agriculture Policy.

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. 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 the internal market. In 2018, DG SANTE will focus on the implementation of the recently adopted Regulations on animal health, plant health and official controls and the regulatory framework for the pharmaceutical sector. Substantial work will be also carried out under SANTE's audit and analysis programme to ensure EU legislation is correctly implemented and enforced.

To promote a favourable environment for research and innovation the implementation of this legislation needs to be optimised by addressing weaknesses and streamlining processes where possible. Aiming at the simplification and modernisation of the EU legislation, DG SANTE will finalise in 2018 the evaluations on nutrition and health claims and feed additives legislations and the legislation governing the fees charged by the European Medicines Agency (EMA). DG SANTE will also work on the evaluations of legislation in the area of pesticides, food irradiation, food contact materials, orphan and paediatric medicines. Building on the findings of the Fitness Check of the General Food Law and after a public consultation, in 2018, DG SANTE plans to adopt a legislative proposal to increase the transparency, the accountability and the sustainability of the EU scientific assessment model and the risk assessment based decision-making, and other aspects such as the governance of EFSA, by amending the General Food Law Regulation and related sectorial legislation.

DG SANTE will keep contributing to the smooth functioning of the internal market also by assessing, and where relevant authorising a range of substances used in food and feed production, plant protection products, Genetically Modified Organisms and pharmaceutical products. This is crucial for giving equal access by consumers to safe and quality food and pharmaceutical products throughout the EU, and providing legal certainty to business operators.

DG SANTE will continue to work closely with its global partners in international fora by providing coordinated EU positions and promoting its policy model towards safety and quality standards. Concerning bilateral relations, the main activities planned for 2018 are to negotiate safe, secure and harmonised export conditions for EU products with non-EU countries and to manage, monitor and implement existing agreements. Notably, in 2018, DG SANTE will focus on the implementation of the agreement between the Commission and the United States Food and Drug Administration on mutual recognition of inspections of medicine manufacturers which will bring cost savings for pharmaceutical industry and regulators by avoiding multiple inspections of the same facilities, and will lead to a better use of respective inspection resources.

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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, AMR, health systems, patients' rights in cross-border healthcare, human tissues, cells, blood and organs, ERNs, medical devices and *in vitro* diagnostics medical devices, medicinal products and tobacco products.

- The work programme for 2018 will focus on a series of actions from among the 23 thematic priorities set out in Regulation (EU) No 282/2014. The priorities of the Commission as outlined by the President and Commissioner Andriukaitis' mission letter have guided the drafting of the work programme. Actions in 2018 will in particular address the three EU added value criteria identified in the 2017 mid-term evaluation of the Third Health Programme: a) addressing the cross-border dimension of health issues; b) improving economies of scale; and c) fostering the exchange and implementation of best practices. On serious **cross-border health threats** and improving health security, the focus will be on strengthening preparedness of Member States (support to implementation of relevant EU legislation and the International Health Regulations (p. 43 in Annex), a vaccination initiative (p. 43 in Annex), supporting tools for surveillance, alert notifications and identification of threats, sufficiency of stockpiles of countermeasures, training and exercises, implementation of the antimicrobial resistance (AMR) Action Plan, and an initiative on infectious diseases (p. 43 in Annex)).
- The area of **European Reference Networks** (ERNs) will receive continuous support, in particular through multiannual grants and through operational support (p. 50 in Annex).
- Reaching the **Sustainable Development Goals** will be a focus, through implementation of best practices and interventions in particular in the area of non-communicable diseases.
- Several activities are planned in cooperation with the Organisation for Economic Co-operation and Development (OECD) - on health information, AMR (p. 50 in Annex), best practices in the area of non-communicable diseases and digital health.

The two **scientific committees** – on Consumer Safety, and on Health, Environmental and Emerging Risks (funded in part by the Health Programme) will continue to make an

important contribution to risk management decisions (for instance in the fields of new cosmetic products). They are expected to publish around 25 opinions in 2018, presenting risk assessments in the areas of public health, consumer safety and the environment. These analyses 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.

An evaluation of CHAFEA's relevance, effectiveness, operational efficiency, EU added value and coherence will be launched at end of 2017. As a lead DG, SANTE will prepare a report on that evaluation, planned for the end of 2018, with input from DGs AGRI, JUST and GROW, whose spending programmes are also partly managed by the agency (p. 48 in Annex).

2018 will also see planning for the role of health within the post-2020 Multi-annual Financial Framework (MFF). DG SANTE will organise an external study aimed at filling data gaps, conduct public consultations and prepare an impact assessment on which to base a proposal for a new post-2020 funding instrument for health (p. 48 in Annex).

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 euro.

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 2018, **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 2018, 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 control measures will continue to 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). For more details please refer to point 1.6.

In 2018, DG SANTE will keep working on a Commission proposal for a post-2020 food chain funding instrument under the MFF which is expected to be adopted by September 2018. The proposal will build on the findings of a mid-term evaluation report of the CFF 2014-2020, an external study aimed at filling data gaps in the food chain policy and spending area and an impact assessment. It will aim to ensure both continuity with the successful approach implemented to date and address the emergence of new challenges affecting the safety of food, and the health of animal and plants, such as the globalisation of trade and climate change.

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 directly linked to public health: many animal diseases are transmissible to humans and good animal health is prerequisite for 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.

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 2018, 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 disease;
- Managing, isolating and preventing plant disease.

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

SANTE's work under this specific objective is supported by EFSA, EMA, ECDC and the CVPO. These agencies provide rapid scientific and technical support during crises, helping the EU to respond and manage them quickly. 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.

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 2018, DG SANTE will help Member States to reinforce preparedness and response planning to tackle serious cross-border health threats. Actions to be taken include:

- a report on the implementation of Decision 1082/2013/EU on serious cross-border threats to health;
- adaptation and re-engineering of the Early Warning and Response System;
- organisation of crisis simulations, inter-sectorial table top exercises and workshops;
- implementing the strategic Roadmap for the Health Security Committee (HSC) and developing work plans for the HSC permanent working groups on preparedness and communication;
- implementing the technical action plan to strengthen preparedness in the EU and support the implementation of the International Health Regulations (IHR) with ECDC;
- preparing a report on the 2017 Member States' reporting exercise on preparedness and response planning for the HSC;
- implementing actions on health preparedness and response to terror attacks under the Security Union.

In 2018, DG SANTE and RTD will also prepare a joint **Commission Communication on protecting citizens against health threats from infectious diseases**. The objective of the Communication is to strengthen the EU framework for more effective and comprehensive crisis preparedness and management, including research, to protect the European citizens from the threat of infectious diseases. The Commission communication will:

- Increase the level of preparedness and response to infectious diseases;
- Strengthen research for better crisis preparedness and management; and
- Reinforce the EU´s role as a global partner for health security.

The Communication will also develop synergies with the Agenda on Security, the European One Health Action Plan against AMR, the Communication on digital transformation of health and care, and other crisis preparedness and response platforms such as the Civil Protection Mechanism and the European Medical Corps.

At the same time, DG SANTE will ensure continued cooperation on health security under global initiatives, such as the Global Health Security Initiative and health initiatives of the G7 and G20, and follow activities of the Global Health Security Agenda. Working with multilateral organisations and EU agencies under a One Health approach, DG SANTE will host expert meetings to exchange views on seasonal influenza strategies with a view to preparing for potential epidemics.

Vaccination is one of the most important public health tools of the 20th 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.

To address these challenges, DG SANTE will prepare a proposal for a **Council Recommendation on strengthened cooperation against vaccine preventable diseases** in 2018, to be adopted by the Commission and subsequently agreed upon and endorsed by the Council. It will have three main pillars:

- Countering vaccine hesitancy, including by promoting vaccine acceptance in the general public and support for vaccination by health professionals and health authorities;
- Strengthening sustainable vaccine policies in the EU, through the establishment of a cooperation mechanism at EU level for vaccine policy development and ensuring that research and innovation agendas support the development of safe, innovative, better targeted and more effective vaccines;
- Ensuring EU coordination, including a common approach towards EU vaccination schedule and EU vaccination cards and registries as well as proposing EU vaccine stockpiles for emergency situations.

In parallel, SANTE will continue to strengthen EU cooperation on vaccine supply and vaccine coverage. This will help minimise cross-border health threats from vaccine preventable diseases and play a role in tackling antimicrobial resistance by reducing the overall number of infections which are treated with antimicrobials. A key instrument towards ensuring a sufficient supply of vaccines is the upcoming Framework Contract to purchase pandemic influenza vaccines, which is planned for spring 2018. Additional joint procurement procedures for vaccines, anti-toxins and personal protective equipment are planned in 2018.

Training programmes for health professionals, border officers and their trainers will also be implemented in 2018 with the view to upgrade and strengthen the skills and capabilities of first line health professionals, and promote a holistic approach to healthcare of migrants and refugees at first points of arrival in the receiving countries.

A Staff Working Document on HIV, Tuberculosis and Hepatitis is also planned in the course of 2018, which will provide a state of play and will show the mechanisms to curb these three diseases which often demonstrate the same risk factors and affect vulnerable groups.

1.1.2. Improving preparedness and management of foodborne crisis

As required by the General Food Law (Regulation (EC) No 178/2002) the Commission has drawn up a **general plan for crisis management in the field of the safety of food and feed** (Commission Decision 2004/478/EC) in close cooperation with EFSA.

In 2018, DG SANTE will follow up the recommendations made as part of the external study supporting the evaluation of the Rapid Alert System for Food and Feed (RASFF) and update the crisis management procedures in the general plan, in particular to:

- Allow a step-wise strengthening of the approach taken at EU level;
- Improve the link between the food/feed safety and public health emergency procedures at EU level in case of serious food/feed safety incidents;
- Reconsider the role of the crisis coordinators' network.

(Output on p. 43 in Annex).

Generally, DG SANTE will focus on a better prevention of outbreaks and crises and improved preparedness in order to limit the extent of outbreaks since they (e.g. E. coli in sprouts) can be very detrimental to public health and costly for the economy.

As hazards in food and feed can be of biological, chemical (including allergens) or physical nature, the scope our SANTE's preparedness and crisis management work will be wide-ranging, drawing notably on the lessons from the 2017 fipronil incident and aiming at the full operationalisation of the conclusions of the relevant Ministerial meeting of September 2017.

1.1.3. Managing and isolating outbreaks of major animal disease

DG SANTE will continue to manage the current animal health crises like African swine fever, lumpy skin disease, avian influenza and bluetongue by efficient follow up of the measures put in place both by the Commission and Member States, in particular those related to regionalisation, and by adapting our measures to the evolving disease situation.

The Commission will also approve approximately 137 annual veterinary programmes for 2018 to tackle animal diseases.

At the same time 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.

In addition, in 2018 the preparedness and early response capacity will be strengthened by further development and use of the relevant instruments, such as audits from DG SANTE, support missions by the Community Veterinary Emergency Team, training courses under the 'Better Training for Safer Food' programme, EU Reference Laboratories (EURLs) and vaccine banks for specific diseases. In addition, a proposal has been sent to the European Parliament and Council to relocate the EURL for Newcastle disease in light of Brexit.

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

An important part of DG SANTE's work in 2018 will be the development of tertiary legislation for the **Animal Health Law** (AHL - Regulation (EU) 2016/429).

DG SANTE will dedicate substantial time to review the existing rules for the prevention and control of animal diseases and for trade in animals and their products in order to set up simpler and effective rules for the control of animal diseases that contribute to safe and smooth trade in the internal market. Under the AHL, the Commission will need to adopt up to 19 delegated and implementing acts by 20 April 2019 which means that lot of time and resources will devoted into their preparation in 2018 (p. 43 in Annex 1). The AHL will be fully applicable in April 2021.

The **Animal Breeding Regulation** (2016/1012) will become fully applicable in November 2018. The majority of the tertiary legislation under this act is already adopted but in 2018 DG SANTE will prepare the remaining implementing act on the identification of equidae.

Contribution of the EU food safety programme (CFF) to animal health measures

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 productions and climate change.

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 2018 is EUR 161.5 million.

The 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 coordinated measures with the Member States.

Funds will be also available to co-fund emergency measures that allow containing animal disease outbreaks quickly (the total budget for emergency measures in case of animal and plant health outbreaks is EUR 40 million). Major sanitary and economic consequences can be avoided if the outbreak is extinguished immediately, thanks to early detection and immediate eradication.

For certain animal diseases, **vaccination** is of pivotal importance to ensure a timely reaction in the event of an outbreak. This has led to the establishment of an EU system of vaccine banks which complements the national approaches by making vaccines immediately available in case of emergency situations.

In 2018 DG SANTE will continue to support Member States and non-EU countries in their efforts to control lumpy skin disease through the EU lumpy skin disease vaccine bank. In particular, the food safety programme will fund the purchase of additional doses of lumpy skin disease vaccine for a total amount of EUR 2 million. In addition, the programme will provide financial support for the purchase of vaccines through national procurement procedures. The creation of two additional vaccine banks is in preparation, one for Peste des Petits Ruminants and one for Sheep and Goat Pox.

DG SANTE will finalise in 2018 the revision of the methodology for the calculation of unit costs. This exercise will lead to further streamlining of the reimbursement process while reducing payment times showing DG SANTE's commitment to continuing simplification in the area.

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 priority plant pests on the EU territory. There will be approximately 24 Member States participating in the annual plant health

survey with programmes to be implemented in 2018. This is enhanced by the improved reporting of outbreaks by Member States through the EUROPHYT system.

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. EFSA's activity on horizon scanning which will continue in 2018 will help risk managers to focus their preparedness efforts 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 or the European and Mediterranean Plant Protection Organisation. Interceptions and outbreaks will be discussed with Member States and followed by appropriate EU measures when necessary.

The cases of *Xylella fastidiosa*, *Bursaphelenchus xylophilus* (Pine Wood Nematode), *Epitrix* spp. and other outbreaks still limited locally, like *Anoplophora* spp, as well as the results of preventative surveys by the Member States will need attention. Existing import measures, in particular for the regulated citrus diseases, will be monitored to avoid introduction of harmful organisms into the EU. Financial requests for eradication and surveys will be examined.

Modernising and simplifying EU legislation

A new **Plant Health Law** (Regulation (EU) 2016/2031) was adopted end 2016. Some delegated and implementing acts based on this new Regulation will be adopted in early 2018, followed by other ones that need to be adopted before the legislation becomes applicable in December 2019. These acts are designed protect plant in the EU, boost long-term growth and competitiveness in the EU plant and plant products sectors and support better functioning of the EU's internal market of such products.

SANTE will prepare in 2018 acts listing high risk plants that will be prohibited from the EU until full risk assessment and plants to be exempted from phytosanitary certificates. We will also work on the listing of priority pests, as well as the updating of permanent lists of regulated (quarantine and non-quarantine) pests and measures.

Under the new Official Controls Regulation (Regulation (EU) 2017/625), a delegated act on EU Reference Laboratories for plant health will be adopted in 2018.

Contribution of the EU food safety 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. The budget in 2018 for the implementation of the 24 plant health survey programmes which allow for earlier detection and eradication of the plant pests is EUR 25 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*. Early and decisive intervention can prevent devastating costs that arise if such diseases become established.

In 2018 DG SANTE will look into ways to develop a methodology for the calculation of lump sums for funding plant health measures. It is expected that the introduction of simplified cost options will speed up the payment process and further reduce the administrative burden for both the Commission and the Member States.

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

Output table is included in Annex 1.

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 ensure safety without being overly prescriptive and stifling innovation. In order to sustain competitiveness, especially in areas of rapidly evolving technology, EU operators need a business-friendly, flexible environment in which to develop their products.

The EU has one of the highest standards of food safety and quality in the word, 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 or genetically modified organisms. This framework ensures a high level of health and environment protection across the EU and at the same time it encourages free trade, investment and 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.

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. To this end DG SANTE carries out several evaluations:

- **Fitness Check of the General Food Law** - the final report in a form of a Commission Staff Working Document (SWD) is planned for the first quarter of 2018. Building on the findings of the Fitness Check of the General Food Law and after a public consultation, in 2018, DG SANTE plans to adopt a legislative proposal to increase the transparency, the accountability and the sustainability of the EU scientific assessment model and the risk assessment based decision-making, and other aspects such as the governance of EFSA, by amending the General Food Law Regulation and related sectorial legislation (p. 44 in Annex).
- **Evaluations on plant protection products and pesticides residues** – the report of the study gathering evidence prepared by an external contractor is expected mid-2018 and a SWD will be prepared on that basis in the beginning of 2019 (p. 44 in Annex).
- **Evaluation on nutrition and health claims** – the final report in a form of a SWD is planned for mid-2018 (p. 44 in Annex).
- **Evaluation of feed additives legislation** – the final report in a form of a SWD is planned for the third quarter of 2018 (p. 44 in Annex).
- **Evaluation of food irradiation legislation** – a study will be contracted during 2018 to feed this complex and technical subject, so that a final report in a form of a SWD be produced by end 2019 (p. 44 in Annex).
- **Evaluation of food contact materials (FCM) legislation** - an evaluation study by the external contractor which will be carried out in 2018 and the outcome of a public consultation would feed into a final report in a form of a SWD which is planned for the second quarter of 2019 (p. 44 in Annex).

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 disease, and the intake of which should be reduced in the diet of EU consumers. A Commission report in 2015 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. The Impact Assessment on TFAs is underway and should be finalised in the first half of 2018 for submission to the Regulatory Scrutiny Board. If it confirms the report's findings, the Commission could take a measure aiming to restrict the use of industrially produced TFAs in foods (p. 44 in Annex).

Food labelling

DG SANTE will work on the implementation of the Regulation on food information to consumers (1169/2011) which harmonises the mandatory origin labelling of food. The Regulation also reinforces the rules on voluntary origin labelling. When the origin of a product is given and the origin of its primary ingredient is different, this difference will have to be communicated. DG SANTE is preparing an implementing act setting the modalities for applying this rule which is planned for adoption first half of 2018 (p. 45 in Annex).

DG SANTE will work on the follow up to the conclusions of the report on alcohol labelling (adopted in March 2017) which states that the sectors concerned should develop, within a year, a self-regulatory concerted proposal to provide the list of ingredients and nutrition information on all alcoholic beverages enabling consumers to make informed choices.

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, following the rejection by the European Parliament of the previous delegated act, is working on a Commission Delegated Regulation on baby foods and processed cereal-based foods which will revise the current compositional and labelling requirements applicable to such foods. For this purpose, EFSA has been mandated to update its scientific opinion and the Joint Research Centre (JRC) is carrying out a study with results expected in 2018 (p. 45 in Annex).

Novel food

Implementing the new Regulation on Novel Foods (2015/2283) which will come into application on 1 January 2018 will be a priority for DG SANTE. To facilitate and simplify the submission of applications for novel foods and traditional foods from non-EU countries an e-submission system, as part of the innovation portal, is being developed. It is expected to be delivered for novel foods by 1 January 2018 (p. 47 in Annex).

Four of the implementing acts for the new Regulation which aim to ensure swift processing of applications were adopted in 2017. The remaining implementing act which will clarify the procedures for requesting confidentiality treatment in novel food applications will be adopted by the end of 2018. DG SANTE will also work on the preparation of a delegated act adjusting the definition of "engineered nanomaterials" to technical and scientific progress after the planned revision of the definition provided in Commission Recommendation 2011/696/EU has been finalised (p. 47 in Annex).

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, established in 2016, to help accelerate the EU's progress towards the Sustainable Development Goal 12.3 target on food waste.

Measurement of food waste levels is critical to developing and monitoring food waste prevention strategies. Once adopted, the Commission's proposal to revise the Waste Framework Directive (COM(2015)595 final) will provide a legal basis for the Commission to develop a methodology to measure food waste levels consistently throughout the EU. Pending adoption, the Commission will continue to work on the key components of such a methodology. In 2018, DG SANTE will begin implementing a 3-year pilot project aiming to gather new information on food donation practices and potential barriers in the EU as well as promote dissemination and uptake of the EU guidelines on food donation. DG SANTE is also exploring actively the way to improve the use of date marking by actors in the food chain and its understanding by consumers.

The **EU Platform on Food Losses and Food Waste** will meet twice in 2018, the first meeting to be held in Kaunas on 24 May, following the invitation of the Lithuanian authorities (p. 45 in Annex). The three established sub-groups (food waste measurement, food donation and "action and implementation") will pursue their work and new digital tools, made available in 2017, will further augment sharing of learning and best practice between members and the broader stakeholder community.

As part of the Commission Action Plan to reduce food waste one of the initiatives is to valorise the nutrients of food which is no longer intended for human consumption, through its safe use in animal nutrition, without compromising animal and public health. In 2018, the Commission will publish guidelines for the use of former foodstuffs as feed (p. 45 in Annex).

Food contact materials

DG SANTE has prepared a measure on bisphenol A (BPA) in food contact materials (migration limit for plastics as well as coatings) based on the EFSA opinion to harmonise the use of this substance in the EU in these materials, where diverging national measures currently exist. Following a vote in the Standing Committee on Plants Animals Food and Feed on 25 September 2017, the measure is expected to be adopted in February 2018 (p. 46 in Annex).

In 2018, DG SANTE will also explore how to best address the limits for the release of heavy metals from ceramic food contact materials, following the finalisation of a JRC study in 2017 and its conclusions on the analytical approach.

The ongoing activities on the authorisation of plastic recycling processes will be continued in a way that minimises burden to the concerned industry and to ensure compatibility of the approach with the circular economy. The target is to resolve the matters by the end of 2018 (p. 47 in Annex).

Market access for safe substances

In 2018, 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 and supports an efficient internal market in these products.

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 per year), novel foods (over 50 authorisations and notifications yearly), and substances used in plastic food contact materials (about 20

substances added yearly to the list of permitted substances, or their permitted use being 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 (p. 47 in Annex).

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; p. 47 in Annex).

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 2018, around 9 proposals for approval/non-approval of new active substances and around 17 proposals for renewal/non-renewal of approval of active substances will be presented to the Standing Committee for Plants, Animals, Food and Feed. In the area of biocides, 50 decisions on existing active substances and 6 decisions on new active substances are expected in 2018 (p. 45 in Annex).

Maximum residues levels (MRL) for pesticides will be set by means of Commission Regulations to allow circulation of food on the internal market while at the same time guaranteeing that food is safe, wherever it is bought in the EU. MRLs are also a requirement for the import of food from non-EU countries in order to maintain the same level of safety for imported food of plant origin as for food produced within the EU. Draft proposals covering around 60 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 (p. 45 in Annex).

Maximum levels (ML) for contaminants in feed and food will be set by means of Commission Regulations on the basis of EFSA opinions to allow circulation of safe feed and food on the internal market (p. 45 in Annex).

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

DG SANTE will continue to implement the legislative framework on GMOs by processing the pending GM applications. As regards the environmental risk assessment of genetically modified plants, the adaptation of the Annexes to Directive 2001/18/EC to 2010 EFSA guidance is planned for 2018 as foreseen in the cultivation Directive (EU) 2015/412 (p. 46 in Annex).

DG SANTE will try to pursue the inter-institutional negotiations on the GM food/feed proposal which would give the possibility to Member States to take account of their national societal concerns as well as on the proposals on suspending the cloning technique on farm animals and the placing on the market of food from animal clones in the EU.

To devise appropriate policy on modern biotechnologies used in agri-food sector, DG SANTE will follow up on the conclusions of the high-level conference on "Safe Use of Modern Biotechnologies – Paving the way for responsible innovation" which took place on 28 September 2017 in Brussels. In this context, DG SANTE will take into account the ruling of the Court of Justice of the European Union on targeted mutagenesis techniques which is expected in the first half of 2018.

Sustainable use of pesticides

In 2018, DG SANTE will continue work with Member States on the implementation of the Directive on the sustainable use of pesticides (2009/128/EC) which aims at reducing the risks and impacts of pesticide use on human health and the environment and promoting the use of integrated pest management (IPM) and of alternative approaches or techniques such as non-chemical alternatives to pesticides. The follows the publication of

the Commission report on the Member States' implementation of the Directive which was published in October 2017.

In 2018, DG SANTE will perform a further four 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, and commence work with Member States to produce assessable criteria for farm level assessment of IPM, and for overarching harmonised risk indicators.

In 2018, DG SANTE will also continue to work together with Member States to implement actions identified in the implementation plan on sustainable plant protection endorsed by the Agriculture and Fisheries Council in June 2016. Following the launch of the web portal on sustainable use and the adoption of new low risk criteria in 2017, the Commission will work on technical guidance to harmonise the assessment of biopesticides – the most important candidate group for low-risk plant protection products.

Endocrine disruptors

In 2017, the Commission adopted the criteria to identify endocrine disruptors in the context of biocides (a delegated act). The Member States also voted in the Standing Committee in favour of the criteria to identify endocrine disruptors in the context pesticides (an implementing act).

In 2018, SANTE is going to work on the implementation of criteria for endocrine disruptors in the context of biocides (p. 46 in Annex).

In parallel, the development of a guidance document for the implementation of the hazard identification criteria by EFSA, ECHA and JRC continues with close involvement of DG SANTE. The guidance is expected to be finalised in the first half of 2018 to be used once the criteria will become applicable (p. 46 in Annex).

Neonicotinoids and bee guidance document

To ensure that pesticides do not harm the environment, including bees, DG SANTE, together with Member States and EFSA have worked on the Guidance Document on bees which aims to improve the current scheme to assess the risk to bees. As Member States were not able to endorse the Guidance document in a consensual procedure at the Standing Committee, the Commission is planning to adopt in 2018 the Guidance Document as a Commission Notice together with an implementation plan (p. 45 in Annex).

In 2013, the Commission significantly restricted the use of plant protection products and treated seeds containing three neonicotinoids (clothianidin, imidacloprid and thiamethoxam) to protect honeybees. Based on the evaluation by EFSA of new data related to the three neonicotinoids, the Commission proposed in 2017 to further restrict the use of these substances to permanent greenhouses only. Depending on the wider assessment of data related to neonicotinoids by EFSA, the Commission may propose in 2018, if justified, to further modify the conditions of approval of these neonicotinoids.

In 2018, DG SANTE will also manage a new EP pilot project on environmental monitoring of pesticide use through honeybees.

Plant reproductive material

In 2018, DG SANTE will authorise plant varieties and facilitate their marketing, in particular by updating requirements for registration, marketing and equivalence. The CPVO will deliver Plant Variety Rights. The Plant Variety Rights/patent relationships will be closely followed by the Commission.

A particular attention will be given in 2018 to the preparation of the modifications to 11 Directives concerning non-quarantine pests which are planned to be adopted by end 2019.

A proposal for recognition of EU equivalence for the import of seeds from Brazil and Moldova will be discussed with the European Parliament and the Council (p. 47 in Annex).

Food fraud

Following the fipronil incident (illegal use of fipronil in poultry farms resulting in contamination of eggs and poultry meat) in summer 2017, the Commission and the Member States agreed to strengthen their efforts to ensure an EU wide harmonised and co-ordinated risk management approach in case of a widespread contamination incident.

One of the priorities is to explore where communication chains and the use of the alert systems can be improved to enhance efficient detection and coordination of food fraud. In consequence, legislative adjustments will most probably be needed in 2018 as well as the development of a combined platform for the RASFF and of the Administrative Assistance and Cooperation (AAC) systems in order to bridge the gap between the two systems.

Moreover, DG SANTE will continue to coordinate its work on food fraud with other DGs, EUROJUST and INTERPOL to ensure better cooperation with police and justice authorities.

Food hygiene

In 2018, 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 and whilst maintaining a high level of food safety and remaining proportionate.

They will mainly focus on finalising delegated and implementing acts under the new 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 scientific data (p. 51 in Annex).

With regard to bovine spongiform encephalopathy (BSE), taking into account the further improvement of the BSE epidemiological situation (only one case of classical BSE was detected in the EU in 2016 and so far no case was detected in 2017), the Commission intends to continue adapting the BSE control framework while maintaining a high level of consumer protection. In this regards, DG SANTE has sent a mandate to EFSA for an update of the previously conducted quantitative risk assessment of the BSE risk of processed animal protein, which, depending on the outcome of the EFSA opinion, may offer the basis in 2018 for the Commission to start discussions with Member States and stakeholders on a possible re-authorisation of the use in poultry feed of processed protein derived from pigs.

DG SANTE measures successful intervention in the area of food hygiene by the reduction in the number of cases of diseases in humans in the EU linked to food safety or zoonoses (**result indicator 1.2.A** of SANTE's Strategic Plan 2016-2020). In 2016, there were about 94500 confirmed cases of human salmonellosis. Since a number of years no progress has been made to the substantial reduction that took place in the early years 2000 (>200000 cases per year) by controls in the poultry sector. Additional salmonella control measures (e.g. in pigs) have not been introduced since 2012, as cost/benefit analyses did not result in a clear advantage. The 2018 milestone of 67000 reported cases is likely not to be reached.

Feed hygiene

A guidance document on the interpretation of the Feed Hygiene Regulation (183/2005) will be published early 2018. The initiative aims at assisting all players in the feed chain to better understand and to apply correctly and in a uniform way the Feed Hygiene Regulation, in particular regarding the registration requirement of feed establishments (p. 47 in Annex).

Animal welfare

The Commission created (in January 2017) an EU Animal Welfare Platform, which first met in June 2017. The Platform is an expert group gathering 75 members including business organisations, civil society, independent scientific experts, Member States and international organisations involved in animal welfare. The objectives of this Platform are to improve the application of EU rules on animal welfare, through exchanges of information and best practices and the direct involvement of stakeholders, to work on voluntary initiatives and to promote EU animal welfare standards internationally and the market value of animal welfare both within and outside the EU. The Commission set up a sub-group on transport of animals at the second meeting of the Platform in November 2017. In 2018, the Commission will decide on the establishment of other sub-groups. The Platform will meet twice in 2018.

Following the adoption of the Official Controls Regulation, the Commission will also designate in 2018 the first EU reference centre for animal welfare which will provide technical and scientific support to better disseminate good practices on animal welfare in the EU with special focus on the welfare of pigs (p. 48 in Annex).

In 2018, DG SANTE will also complete the final two actions of the EU Animal Welfare Strategy 2012-2015, namely adopting the report on the application of the broiler Directive and the report on the protection of fish at the time of killing (p. 47 in Annex). DG SANTE will continue its international activities on animal welfare in particular with the World Organisation of Animal Health (OIE) as well as with its key trading partners.

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

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 excessive alcohol consumption, smoking, poor nutrition and physical inactivity. Without action, the cost of healthcare is expected to double by 2050 with crippling economic consequences.

DG SANTE's work in this field includes support for the design and implementation of targeted initiatives in EU countries to promote good health as well as to prevent and manage non-communicable disease and encourage best practice exchange. It also supports activities linked to reducing health inequalities.

In 2018, DG SANTE will invest significant efforts to follow-up on existing initiatives, including Joint Actions on dementia, non-communicable diseases, cancer, rare cancers,

mental health and frailty, as well as several EP pilot projects, to ensure that lessons learned and investments made are validated and implemented. 2018 will be the last year under the EU Compass on Mental Health and Well-being; related activities will address the topics of community care and mental health in all policies.

DG SANTE will strengthen its 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. We will also continue developing and hosting the European networks of registries on cancer, rare diseases and congenital malformations. Collaboration with stakeholders on EU health policy issues will continue in 2018 via the EU Health Policy Platform. Regular exchange will be supported through its dedicated web platform and one plenary meeting in the fourth quarter of 2018.

SANTE will streamline activities on health promotion, disease prevention and management on non-communicable diseases within the new Steering Group on Health Promotion, Prevention and Management of Non-Communicable Diseases to ensure the scaling up of implementation of best practices at national level. In this context, a resource centre for Member States to share best practices will be made operational (p. 48 in Annex). Particular efforts will be undertaken to explore funding possibilities for best practice implementation with other financial instruments. A system for submission, evaluation, and validation of best practices and support for the implementation of the first set of best practices will be provided.

In 2018, DG SANTE with the support of the Health Programme, the Structural Reform Support Service and the JRC will contribute to the implementation of the most up-to-date evidence-based recommendations on screening, diagnosis and care for breast and colorectal cancer. A platform with guidelines and accreditation schemes to label the quality of breast and colorectal cancer control in cancer centres and hospitals will cover the whole patient cycle from cancer screening until survivorship and palliative care. The new European Cancer Information System will be launched via a dedicated website.

DG SANTE will also assist in the development of links between the European Reference Networks, the Orphanet and the Rare Diseases Registration Platform (p. 50 in Annex).

There is a strong social gradient of health and a large share of the EU's disease burden is concentrated in the socioeconomically 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.

The political commitment at EU level to support Member States in their fight against HIV/AIDS, tuberculosis and hepatitis was reaffirmed with the adoption of the Commission Communication on next steps for a sustainable European future in November 2016. The Commission will work with Member States, the Think Tank and the Civil Society Forum to identify concrete measures to implement and meet the relevant target 3.3 of the UN Sustainable Development Goals. In 2018 the Commission will develop a Staff Working Document to help Member States fight against HIV/AIDS, tuberculosis and hepatitis (p. 43 in Annex). This work will be done in close cooperation with the European Centre for Disease Prevention and Control.

Reducing tobacco consumption

2018 will be a key year as the Framework Convention on Tobacco Control (FCTC) Protocol to Eliminate Illicit Trade in Tobacco Products is expected to enter into force. Following the adoption of three implementing and delegated acts on tobacco traceability

and security features, the technical roll-out can start to meet the Tobacco Products Directive (2014/40/EU) operational deadline of May 2019. Over 200 economic operators are expected to notify DG SANTE by June 2018 about the contracts for storing data. The Commission will need to approve each such contract after verifying the suitability of a data storage provider, in particular its independence and technical capacities.

Transposition checks will be concluded to ensure the TPD is effectively implemented and legal action may be launched if necessary. Other work linked to the TPD will include managing and improving the electronic reporting tool for tobacco and e-cigarettes and carrying out the practical determination whether tobacco products have a characterising flavour. This determination will be based on the work of the independent advisory panel managed by DG SANTE and the newly established technical group.

Furthermore, DG SANTE will manage the Joint Action aiming at supporting Member States on the implementation of the TPD on a wide range of issues, e.g. ingredient regulation, priority additives, and e-cigarettes. This will also include the analysis of large amounts of data generated by the reporting obligations related to tobacco product and e-cigarette ingredients and emissions, as well as comprehensive studies on priority additives carried out by manufacturers.

At international level, 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 ahead of the first Meeting of Parties expected in October 2018. Furthermore, DG SANTE will continue to contribute to the FCTC, e.g. by developing and coordinating EU positions for the eight meeting of the Conference of Parties in October 2018.

Nutrition labelling on foods

In 2018, DG SANTE will work on the report to be submitted to the Council and the Parliament on the use of Front-of-Pack labelling schemes on foods in the EU (p. 45 in Annex), on their possible impacts on the internal market and on the advisability of further harmonisation in this area. This report will be supported by a review of the scientific publications available in this area, to be performed by JRC.

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, the Commission has strengthened its country-specific and cross-country knowledge in the field of public health and health systems. In 2016, DG SANTE rolled out the "Health at a Glance: Europe" report as the first deliverable of the new two-year 'State of Health in the EU' cycle carried out in

cooperation with OECD and the European Observatory on Health Systems and Health Policies. In 2017, twenty-eight country health profiles and a Commission Companion Report were published.

In 2018, SANTE will finalise this first State of Health cycle through promotion and outreach activity on the profiles and their companion report, as well as conduct voluntary dialogues with the Member States and stakeholders involved (p. 49 in Annex). In November 2018, SANTE will launch the second State of Health in the EU with the 2018 "Health at a Glance: Europe" report. SANTE will also begin work on a second set of health profiles for the new cycle in cooperation with the OECD and Observatory on Health Systems and Health Policies.

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 selected experience measures in cooperation with Eurostat (p. 49 in Annex). Further input on country knowledge in terms of indicator availability will be provided by the Joint Action on Health Information.

In 2018, 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 (such as country profiles) 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 2018 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 is a major global challenge which has serious implications for the economy and human health. 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 jobs, growth and investments.

In 2018, work will continue on the **implementation of the new European One Health Action Plan against AMR**, which promotes swift and effective actions across the human health, animal health and environmental sectors (p. 49 in Annex). The new action plan builds on the first AMR Action Plan which ran from 2011 to 2016. The new action plan foresees 76 actions built on three main pillars:

- making the EU a best-practice region by supporting Member States to establish, implement and monitor their national One Health Action Plans against AMR;
- boosting research, development and innovation at EU and global levels to control the emergence and spread of AMR; and
- shaping the global agenda by reinforcing engagement and collaboration with multilateral organisations, and intensifying cooperation with the main EU trading partners but also the most affected developing countries.

DG SANTE will continue to engage with Member States on surveillance, risk analysis, evidence-based good practices, and awareness on the prudent use of antimicrobials. Training programmes on AMR for Member States' competent authorities will be implemented under the Better Training for Safer Food initiative. An agreement with

OECD will be sought to jointly develop the economic model of AMR and to support Member States in their economic policy development. The Joint Action on AMR and healthcare-associated infections (2017-2020) will be implemented. For actions in the global arena, please refer to point 3.1.

Given the importance of the **proposals for Regulations on veterinary medicinal products and on medicated feed** in the reduction of AMR, DG SANTE will do its utmost to reach an agreement on these files in 2018. The proposals provide a comprehensive set of requirements addressing AMR. The veterinary medicines proposal introduces, inter alia, a possibility to reserve certain antimicrobials for humans only, provides for compulsory collection of data on sales and use of antimicrobials, strengthens the prescription requirements and the rules on advertising of prescription-only medicines, includes limitations for retailing of antimicrobials by veterinarians, requires careful scientific benefit-risk assessment in the marketing authorisation procedures for antimicrobials and provides a possibility for post-authorisation requirements to marketing authorisation holders. The medicated feed proposal fights the misuse of antimicrobials by banning antimicrobials for preventive treatment or as a growth promoter, by requiring the diagnosis of a disease prior to the prescription for medicated feed and by limiting the validity of the prescription for antimicrobials and also the duration of a treatment with antimicrobials.

DG SANTE's work in this area will be supported by EFSA, ECDC and EMA to ensure that the most comprehensive 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 surveillance of antimicrobial consumption in animals, increasing the availability of new antimicrobials and alternative products for humans and animals by granting marketing authorisation for new antimicrobials, supporting the prudent use of 'old' antimicrobials and providing scientific opinions on AMR issues.

Innovative health technologies

eHealth can improve the integration of 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 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 three priorities indicated below:

- 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 2018, SANTE will focus on delivering the actions outlined in the upcoming Communication on digital transformation of health and care in the context of the DSM, which is prepared jointly with DG CNECT (p. 49 in Annex).

In 2018, DG SANTE will also work together with the Member States on the implementation of a new multi-annual Work Plan for the eHealth Network. The new Joint Action supporting the eHealth Network will take up its work on 1 June 2018 (p. 49 in Annex).

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

In 2018, DG SANTE will continue to monitor and follow up with appropriate action the transposition of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare in order to ensure its uniform implementation. In late 2018, the Commission will also report to the European Parliament and to the Council on the operation of the Directive. The report will take stock of the implementation of the Directive since the 2015 report, and highlight any good practices and shortcomings observed.

Blood, tissues and cells, organs

An evaluation of the legal framework for blood and tissues and cells is expected to be completed by end 2018 (p. 49 in Annex). This evaluation, following the Better Regulation approach, will consider whether the legislation has achieved its original objectives and remains fit for purpose. In 2018, a Joint Action will be launched on optimal collection and use of data when authorising innovative therapies. Commission-hosted platforms on rapid alerts and traceability, used by over 3000 tissues establishments, will be further strengthened. All work on blood, tissues and cells, and organs will continue in close cooperation with external expert bodies like the ECDC, Council of Europe and Member States' agencies.

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 ERN were officially launched in March 2017, each of them addressing one clinical area. In 2018, DG SANTE will focus on supporting the clinical operation of the 24 networks, the use of the networks' IT system, information exchange within the networks, and a possible extension of the existing networks with new members (p. 50 in Annex). DG SANTE will also promote communication on the ERNs addressed to relevant stakeholders and the public. The fourth ERN Conference in November 2018 will take stock of the first year of operation of the networks. DG SANTE collaborates with other key Commission departments (RTD, CNECT, JRC, EAC) on funding, IT tools and activities.

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

Output table is included in Annex 1.

DG SANTE is focusing on the optimal use of the various enforcement mechanisms available using an interactive approach to ensure effective, efficient and reliable official controls across the EU. DG SANTE's audit and analysis work is crucial to ensure the effective and correct implementation and enforcement of EU legislation on food safety, animal health, animal welfare, plant health, import controls and some areas of human health. The audits – which take place in EU countries and non-EU countries exporting to the EU – and 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. Their results and appropriate monitoring, enforcement and follow-up activities to audits contribute to evidence-based policy development, better regulation and a regulatory environment which facilitates jobs, growth and investment. 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. This dialogue is established by High Level meetings between SANTE and the Competent Authorities of the Member States and other technical meetings and BTSF trainings with the objective to bring forward important enforcement matters and find concrete solutions to problems identified.

In 2018, approximately 210 audits and fact-finding missions are planned in Member States and non-EU countries covering food safety and quality, animal health, animal welfare and plant health. In addition, DG SANTE plans to carry out approximately 40 joint assessments of notified bodies designated under the medical devices and *in vitro* diagnostic medical devices Regulations in Member States, EFTA and EEA countries, two audits in the area of active pharmaceutical ingredients for human medicines in non-EU countries, up to 12 audits of Member States' eHealth National Contact Points, and, jointly with the ECDC, four to six AMR One Health country visits in Member States.

In 2018, SANTE plans to adopt the fourth Report on official controls performed in Member States on compliance with feed and food law, animal health and welfare rules which will cover the period 2014 - 2016. This will give an overview of the delivery of official controls in these areas as required by Regulation (EC) No 882/2004. It is based on Member States' annual official control reports and on the results of controls carried out by the Commission.

Modernising and simplifying EU legislation

The revised **Official Control Regulation** (OCR) (EU) 2017/625 was adopted on 15 March 2017 and will be fully applicable 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.

The implementation of the OCR, and particularly the rules for an integrated system of official controls at EU borders, is a key challenge. These implementation activities will be developed through the empowerments derived from the OCR which have to be converted into around 35 tertiary acts over the next 2 years.

The first tertiary acts to be adopted concern the establishment and designation of animal welfare reference centres (see section 1.2) and specific EU Reference Laboratories by April 2018 (see section 1.1.3). In 2018 delegated and implementing acts will be prepared on the list of animals and goods to be checked at border control posts, re-designation of border control posts, meat inspection, import conditions and in relation to official controls on animals and goods entering the Union (p. 51 in Annex).

Use of digital technologies to strengthen official controls

The revised Official Control Regulation foresees an Integrated Management System for Official Control (IMSOC). This concept will allow current EU-managed IT systems to be

integrated. In 2018, 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 foreseen under the future IMSOC, the Trade Control and Expert System (TRACES) will also integrate certain certification procedures. 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) will also be concluded offering additional simplification for border controls authorities.

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 2018 to streamline the flow of information between the Administrative Assistance and Cooperation network, the Food Fraud network and the RASFF network.

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. A particular effort will be made in 2018 to streamline and digitalise the official control processes.

Contribution of the EU food safety programme (CFF) to official controls' related activities

All activities planned for 2018 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 programme and the EU Reference Laboratories (EURLs).

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 45 EURLs and one EU Reference Centre for Animal Welfare is planned in 2018 to maintain high level of food safety, improve the efficiency of the network and capitalise on existing knowledge. The budget for the EURLs for 2018 is EUR 17 million.

The Better Training for Safer Food programme (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. BTSF is managed administratively by CHAFEA while DG SANTE provides the policy steer and technical supervision. The BTSF programme has planned around 170 training courses on EU legislation in 2018 for Member State staff responsible for official controls along the food chain. As a complement of the traditional face to face training, it will also develop e-learning modules which will significantly increase the number of trainees. The budget for BTSF for 2018 is EUR 17.5 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 job growth and investment by providing legal certainty and ensuring the proper functioning of the internal market in the areas of food and pharmaceuticals.

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, animal health and novel foods) and EU authorisations (e.g. for food/feed additives, plant protection 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 quality food products throughout the EU.

The thriving pharmaceutical industry, which is an important source of growth and economic performance in the EU, is testament to what a mature regulatory framework can achieve in terms of internal market policy and public health protection. At the same time, we need to optimise the implementation of this legislation by addressing weaknesses and streamlining processes where possible in order to create a favourable environment for research, development and innovation.

The agri-food industry is also of key importance to the EU economy. It is the largest manufacturing sector in the EU with its output valued at EUR 410 billion in 2015. Agriculture and the food related industries and services together provide almost 44 million jobs in the EU. The food production and processing chain accounts for 7.5 % of employment and 3.7 % of total value added in the EU.[1]

The EU's decentralised agencies make an important contribution to 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.

EMA plays a key role by supporting the harmonisation of the EU pharmaceutical sector, optimising the use of the current authorisation procedures, and ensuring access to safe medicines. It also makes an important contribution to the EU network of organisations for Health Technology Assessment and facilitates patient access to innovative medicines for unmet medical needs. EMA also supports DG SANTE in its international efforts to promote EU standards globally.

As the United Kingdom has notified the European Council under Article 50 of the Treaty on European Union of its intention to leave the Union, EMA, which is currently located in the UK, will have to move to its new seat 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.

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). EFSA launched an external evaluation in 2017 to assess its working

[1] https://ec.europa.eu/agriculture/sites/agriculture/files/trade-analysis/map/2016-1_en.pdf

practices and impacts and the evaluation report by the external contractor will be published in 2018.

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, including pharmaceutical product, medical device or health intervention in a systematic and unbiased manner, and it informs decision makers on its safe and effective use. It is an important tool to achieve best outcome 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 notably, with the view to ensure the maximum benefit for individual patients and public health in general.

HTA is a priority for the Commission as mentioned in the Commission Work Programme in 2017. With the foreseen Commission's adoption of a new initiative on HTA in early 2018, the focus in the subsequent months will be on the negotiations in the Council and the European Parliament. Close contacts and interactions with Member States and MEPs are essential to build consensus and ensure a smooth process. The work will closely monitor and take account of existing cooperation mechanisms like the HTA Network and the Joint Action EUnetHTA, as well as regional groupings cooperating on HTA, such as Benelux.

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.

A vibrant EU pharmaceutical sector is essential to achieve a high level of public health protection and a competitive knowledge-based economy. In 2016, the European pharmaceutical industry was worth EUR 220 billion and employed about 750,000 people[2].

The EU legal framework for medicinal products for human use guarantees high standards of quality and safety of medicinal products and promotes the functioning of the internal market, with measures which encourage innovation and competiveness in Europe.

Marketing authorisations of medicinal products

DG SANTE will continue its work related to the authorisation of medicinal products (p. 52 in Annex). Around 80 new medicines are authorised every year and more than 200 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. The current procedures for authorisation of medicinal products, both centralised and decentralised, are also due

[2] https://www.efpia.eu/media/219735/efpia-pharmafigures2017_statisticbroch_v04-final.pdf

for a ten-year review, and DG SANTE will carry out a study on these procedures in 2018 with a view to a Commission report in 2019.

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 response to the Council conclusions' call for more insight on the impact of incentives in the pharmaceutical sector on innovation, availability and affordability of medicines, DG SANTE, with DG GROW has launched a study to this effect, to be completed in early 2018. In addition, a follow up study on medicines for rare diseases and children including incentives will also be carried out in 2018. These studies will feed into a formal evaluation of the Regulations on Orphan medicines (141/2000) and Paediatric medicines (1901/2006), which SANTE will undertake in 2018 and 2019.

DG SANTE will continue to work in close cooperation with EMA on improving the regulatory environment for advanced-therapy medicinal products (ATMPs) which comprise gene therapies, tissue-engineered products and somatic cell therapies. These medicines have the potential to offer breakthrough treatments of a wide range of conditions.

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.

In 2018, DG SANTE will also work with OECD on a project on sustainable access to innovative therapies. The Expert Panel on Health's Opinion on "Innovative models of payment of innovative pharmaceuticals" initiated in 2017, will contribute to the debate.

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, SANTE will work to strengthen synergies between EUnetHTA, STAMP and the EMA in 2018.

Legislation on fees of the European Medicines Agency

In 2018, DG SANTE will finalise an ongoing evaluation of the legislation governing the fees charged by EMA (p. 52 in Annex). The evaluation will examine the functioning of the fee system of the EMA in order to identify the strengths and weaknesses of the current system.

Implementation of the falsified medicines Directive

In 2018, the Commission will continue developing the medicine tracing and verification system, which will protect citizens from false and low-quality medicines as of 2019. The Commission will manage an expert group for the introduction of the safety features and provide guidance to Member States and stakeholders. The Commission also has a number of legal obligations stemming from the falsified medicines Directive (2011/62/EU), including producing a report to the European Parliament and the Council on penalties in cases of falsified medicines in the first quarter of 2018 (p. 53 in Annex),

and the reassessment of non-EU countries in relation to Good Manufacturing Practice rules for active pharmaceutical ingredients.

Implementation of the clinical trials Regulation

SANTE will continue the preparatory work necessary for the application of the new Regulation on clinical trials (536/2014). This includes chairing and coordinating an expert group on clinical trials and the creation/revision of several guidelines. In 2018, the Commission, in cooperation with the Member States and EMA will set up and test the clinical trial portal (p. 53 in Annex) and database and once approved by the Management Board of EMA, publish the notice (in the form of a Commission Decision).

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) which will work in 2018 on the identification of first indicators to measure resilience of health systems and in parallel, suggest options for a simplified framework for capturing, understanding and interpreting healthcare efficiency metrics.

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 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) and the International Council for Harmonisation 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 Communication on Sustainable Development Goals (SDGs) for 2030 adopted in 2016 and the new European Consensus on Development adopted in June 2017 will guide our work in internal and external policy areas in 2018. DG SANTE will ensure SDGs are mainstreamed into our activities and will seek to maximise synergies with other services and stakeholders to implement the 2030 Agenda. DG SANTE will contribute to the monitoring and reporting mechanisms set up in the Commission on implementation of SDGs and to the Reflection process towards a sustainable Europe by 2030.

Health

DG SANTE and the EU Delegation in Geneva will continue their efforts to facilitate coordinated EU positions on the agenda items in WHO Governing Bodies. These coordinated EU positions are provided at different stages, from the contribution to upstream technical consultations to the provision of EU amendments on draft decisions or resolutions under adoption. DG SANTE also cooperate with WHO in the framework of existing administrative arrangements and serves as WHO focal point for the Commission. In this light, a meeting with relevant DGs and the new WHO DG will be organised in 2018.

In 2018, DG SANTE will continue to reinforce cooperation with the 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 2018 with a likely focus on global health security issues

Key priorities for multilateral cooperation remain AMR (e.g. concerning definitions on the prudent use of antimicrobials and AMR research activities), health security, tobacco control and pharmaceuticals.

On global tobacco control, DG SANTE will continue, together with OLAF, to encourage the remaining EU Member States 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 ahead of the first Meeting of Parties expected in October 2018. Furthermore, DG SANTE will continue to contribute to the FCTC, e.g. by developing and coordinating EU positions for the eight Conference of the Parties in October 2018 and as Key Facilitator in the Working Group on regulation of tobacco products contents and disclosures).

As part of the global pillar of the new EU One Health Action Plan against AMR adopted in 2017 (see section 1.4), DG SANTE will complete in early 2018 a series of seminars focusing on different AMR issues at technical level in Argentina, Brazil, Chile, Colombia, Peru, and Uruguay supported by the Foreign Partnership Instrument (FPI). DG SANTE will intensify cooperation with the Transatlantic Taskforce on AMR (TATFAR) and with FAO to tackle the emergence and spread of AMR on farms and in food systems. SANTE will also participate in the new Codex Taskforce on Antimicrobial Resistance to work on a revision of the Codex Code of Practice to Minimise and Contain Antimicrobial Resistance and on the development of new "Guidelines on Integrates Surveillance of Antimicrobial Resistance".

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), AMR, tobacco control (including promotion of the FCTC and the Illicit Trade Protocol), and quality and safety of substances of human origin. Examples include: multi-country regional workshops on AMR in Enlargement and European Neighbourhood Policy countries with ECDC support, a communicable diseases assessment in Bosnia and Herzegovina, assessment in the field of substances of human origin in Serbia, a workshop in Moldova to support its participation in the Health Programme, targeted support to Ukraine for public health and blood system reform implementation.

DG SANTE will continue to contribute to the negotiation and implementation of association agreements with third countries and provide the health input to political bilateral dialogues as appropriate (e.g. Brazil, Mexico, Iran, Switzerland, Microstates).

Pharmaceuticals

The EU is a global leader in the pharmaceutical industry and the world's major trader in medicinal and pharmaceutical products. In 2016, the European pharmaceutical industry was worth EUR 220 billion.

In 2018, 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, the Commission is using its long standing experience to put forward the EU views. 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.

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) and Codex Alimentarius.

DG SANTE will attend three meetings of the WTO SPS Committee in 2018 to promote and defend EU interests in the field of sanitary and phytosanitary measures. SANTE will follow up the implementation by Russia of the decision of the Appellate Body in the dispute settlement case opened by the EU in 2014 against the unjustified measures of Russia on African swine fever. SANTE will also follow other dispute settlement cases, including the recent ruling on poultry in a case lodged by China against the EU.

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.

In the OIE, DG SANTE defends the EU's high animal health and welfare standards to influence the international standards. In 2018, as each year, DG SANTE will lead and coordinate the EU common position with regard to new OIE standards or revision of existing standards at the General Session on 21-25 May 2018.

In 2018, DG SANTE will continue to coordinate EU positions via electronic processes and within 14 Codex Committees and working groups to ensure there is alignment between EU legislation and Codex standards.

In IPPC, there is a strong EU input, coordinated by DG SANTE on global plant health strategy and the development of international standards for phytosanitary measures. In 2018, DG SANTE will be closely involved in the IPPC dispute settlement case on citrus black spot opened by South African against the EU on imports of citrus fruits.

The EU is one of the world's largest exporter 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. 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 2018, SANTE will continue to work towards international harmonisation in this area and in particular in relation to amendment of ITPGRFA to facilitate access to genetic resources and improve the benefit sharing mechanism.

In 2018, 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 represented at the biannual meetings of the Executive

Committee, as well as at the annual meeting of the "Tripartite" between Greece, Bulgaria and Turkey established in the framework of EuFMD.

Improving bilateral trade relations

Bilateral trade negotiations are directly linked to multiple Commission priorities, in particular general objective 1 – jobs, growth and investment. While growth is influenced by various factors, access to foreign markets is critical for the EU economy and heavily conditioned by sanitary and phytosanitary requirements which often act as barriers.

With combined imports and exports of EUR 242 billion in 2015, the EU is the world's biggest trader in agri-food products, benefiting producers and consumers within and outside the EU. 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 ban on import of a range of EU food products has raised awareness amongst industry and Member States on the important role of international trade for European agriculture, as well as the need to diversify and stabilise our export markets.

The main activities planned for 2018 are to negotiate safe, secure and harmonised export conditions for EU products with non-EU countries and to manage, monitor and implement existing agreements.

DG SANTE will lead on the negotiations on SPS chapters in the Free Trade Agreement negotiations underway, or planned, e.g. Mercosur, Indonesia, Philippines, Australia and New Zealand. 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. Moreover, DG SANTE will monitor closely imports of animal products from Brazil due to the meat fraud incident and in particular the operation of the reinforced checks at Border Inspection Posts and the position of non-compliant establishments. DG SANTE will also work towards maintaining the consensus with Member States in relation to Russia and in particular the refusal to engage with them on a bilateral basis in relation to the bans on pig meat.

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

DG SANTE will also aim for successful outcome to the extension in scope of the current EU/Swiss Agreement and of enlargement related dossiers. It 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) have successfully concluded the Mutual Recognition Agreement ('MRA') on Good Manufacturing Practices (GMP) inspections.

Work is now underway to implement the MRA in accordance with well-defined criteria and a precise legal time schedule. All 28 EU Member States will have to be assessed by the USFDA by 15 July 2019. In order to do so, the Commission will continue to monitor the progress of the Member State authorities to submit complete capability assessment

packages containing all the information specified in the agreement. The implementation of the MRA will be resource demanding for SANTE, EMA and Member States.

Animal health and food safety

Despite the suspension of free trade agreement (TTIP) negotiations with the US, DG SANTE maintains extensive contacts at technical and political level with the US, our most important global 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 will remain committed in 2018 to tackling these barriers.

DG SANTE engages at technical level specifically in two working groups on Animal Health and Plant Health. The important Animal Health Technical Working Groups had been dormant for some time and was re-instituted in 2017. A further meeting is envisaged for 2018 to follow up on the current ongoing actions.

In food safety, DG SANTE is actively engaged in a Food Safety Systems Recognition exercise with the USFDA. This project has the potential to significantly reduce the burden on food business operators in the EU when exporting to US.

PART 2. MAIN ORGANISATIONAL MANAGEMENT OUTPUTS FOR THE YEAR

A. Human resource management

Output tables are included in Annex 1.

In 2018, the major overhaul introduced in 2017 of the way Human Resource (HR) services are delivered in the DG and the Commission will be further fine-tuned and consolidated. It should allow by the middle of the year to gradually step up activity from the basic level of ensuring HR business continuity to delivering again more targeted and specific HR services to DG SANTE. The results of the Commission Staff Survey planned for the middle of 2018 will provide useful guidance. Promotion of the survey to all colleagues will be done both before the launching and during the survey, so as to ensure the highest possible response rate in view of as precise a picture of the DG as possible.

In 2018, special attention will be given to the implementation of the results of the in depth preparatory planning work done in autumn 2017 to ensure SANTE Units are adequately staffed, within the overall resources available, to cope with the many challenges and legal obligations to be delivered in 2018. It will require important investment in attracting sufficient qualified and experienced Staff during the year.

On the objective of ensuring sufficient inclusion of female managers, one of the important goals of the Commission talent management and equal opportunities initiative, DG SANTE has already met the targets of appointing three first time female managers by 2019 as specified in the 2017 Commission Communication on a better workplace for all: from equal opportunities towards diversity and inclusion. In 2018 our effort will be sustained by engaging in specific career development programmes for high potential female colleagues already in junior management positions such as deputy head of unit, head of sector and team leader.

DG SANTE will also continue with its long-term investment into more targeted action under the umbrella of the 'Culture and Engagement' pillar of its 'Towards excellent SANTE' programme with the aim to improve assertiveness and resilience of colleagues, helping them to find ways to take a more active role in improving their working conditions and environment and thus less reliant on the work of others (the organisation, management, colleagues). Managers, including Senior Managers, will be encouraged to have more regular meetings with staff, to improve communication on relevant files and to ensure more work-related visibility to individual members or groups of staff. Figures show a worrying increase of the absence rate for medical reasons of administrative support staff, the root causes of which need to be examined more closely.

The data collected with the staff survey will be used as a starting point to adapt or revise the 'Towards excellent SANTE' programme to ensure that the SANTE strategy and rolling action plan are in line with the DG's need and synchronised with initiatives at corporate level.

Finally under the umbrella 'SANTE a Healthy DG' several awareness rising actions will be organised around the 6 fit@work priorities of the Commission's Health and Wellbeing action plan. SANTE will, in partnership with other DGs, continue to host several 'Fit @ work" activities. Special focus will be given to the area of "Mental wellbeing at work" and in particular to dedicated awareness raising and trainings to help managers deal with staff facing mental health problems, and by so doing help to remove any stigma in regard to mental health.

B. Financial Management: Internal control and Risk management

Output tables are included in Annex 1.

In the 2016 Annual Activity Report (AAR), the Director-General of DG SANTE signed his 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.

The objective for 2018 is to maintain an adequate assurance building process based on solid building blocks. This will allow the Director-General to sign his declarations of assurance also for the next Annual Activity Reports.

The main expected outputs feeding into the building blocks are:

(i) a 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 implement action of audit recommendations from the Internal Audit Service (IAS) and the European Court of Auditors (ECA);

(iii) a conclusion on the cost effectiveness of controls in the 2018 Annual Activity Report.

(iv) 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 under the relevant specific objective. They are presented in the tables under the headings "All new initiatives and REFIT initiatives from the Commission Work Programme" and "other important items".

DG SANTE will continue to develop its capability to apply fully the Better Regulation principles along the policy cycle in DG SANTE, including by a focused use of scarce resources for its policy assessment work. To do so it will build on recent efforts deployed to comprehensively map its interventions and policies and ensure a regular and systematic review of its evaluation planning.

Another focus of attention will be the important work started in 2017 to prepare the adoption of tertiary legislation to implement recently adopted legislation of relevance for the Food Chain pillar (the animal health, plant health, novel foods and official controls Regulations). The Better Regulation potential of the new rules agreed upon by the co-legislator will be delivered through an important number of delegated and implementing acts, whose preparation will require careful planning and scrutiny.

D. Information management aspects

Output table is included in Annex 1.

The Commission relies on information for every aspect of its work. Therefore, DGs need to adopt specific policies and practices to ensure the effective corporate management of data, information and knowledge. These policies will allow the Commission to rely on complete and relevant information to support all its activities and make it a better performing organisation.

The Commission adopted a new corporate strategy for data, knowledge and information management in October 2016. The new strategy establishes a corporate framework while leaving room for DGs to develop and implement their own approaches tailored to their unique needs.

In particular, in DG SANTE' objective is 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 taking into account the need to protect confidential and sensitive information.

The SANTE collaboration platform policy provides the standard framework and tools for the management of key horizontal Units' activities, coordinating work with operational Units and projects within DG SANTE, other DGs and/or agencies. The goal is to use the collaboration platform for the management of all activities within and across Units for the next years. Current experience has shown that this is very effective. This allows DG SANTE to stimulate and streamline the collaborative way of work across Units, and to promote that all information produced is maintained in a single space, which is efficient and searchable.

DG SANTE's eGovernment policy is to work open and digital toward full e-government. 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 aims 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 reaches the target for filing all documents registered by the DG set by the **Indicator 1** of the DG SANTE strategic Plan 2016-2020, but the target is reached sometime after the documents have been registered and not when DIGIT makes the statistics. DG SANTE expects to reach this target also in 2018.

The 2020 target for **Indicator 2** - 75% of HAN files readable/accessible by all units in the DG and **Indicator 3** - 75% of HAN files shared with other DGs is lower than the baseline (98% in both cases). This is as expected because, as of 2016, a percentage of files will be restricted to units or persons– which make the target appear lower. Until the end of 2016 all files with normal visibility (that is DG SANTE visibility) were usually shared with one other DG. In 2017, the majority of the files which previously were created with SANTE-only visibility have been shared with the entire Commission therefore the 2020 targets were already met This will be also the case in 2018.

E. External communication activities

Output table is included in Annex 1.

Communication activities in 2018 will reflect DG SANTE's ambition to contribute to the Commission's positive agenda which helps create a Europe that protects, empowers and delivers. Communication actions are keys to explain DG SANTE's overall objectives and deliverables on the different priorities. 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.

As emphasised by President Juncker in the State of the Union speech, a particular effort will be devoted to promote the preparation of the **Council recommendation on vaccination**, complemented by the Joint Commission Communication (DG RTD – DG SANTE) on protecting citizens against **health threats from infectious diseases.** Communication actions will also focus on a legislative proposal which will look at the **transparency and sustainability of the food and feed risk assessment model**. In relation to these above mentioned new initiatives, communication will play an important role in raising awareness and mobilising stakeholders to take part in the discussions which shape the final outcome of the policy debate. The first months of 2018 will need to be used to communicate more and better on our action and demonstrate the relevance and **added value of EU health and food safety policies in view of the future Multiannual Financial Framework (MFF)**, which will mark the last Commission initiative proposed during its mandate.

DG SANTE's communication work will reinforce the Commission's messages on ongoing issues such as **antimicrobial resistance, food waste and food controls**. We will continue promoting the **State of Health** cycle supporting Member States and the **European Reference Networks** and their potential for patients and healthcare providers all over Europe and will mobilise external partners to make further progress on **digital health and care** as policy actions will be rolled out. An important part of our work will be devoted to **highly sensitive issues** such as pesticides, endocrine disruptors or GMOs, which are carefully monitored and for which the effective media actions are prepared, taking into account the political context and public opinion constraints. With these communication actions, DG SANTE will contribute to communication on the following political priorities of the Commission: Jobs, Growth and Investment, Digital Single Market and Internal Market.

In the corporate communication context, the upcoming campaign "An EU that protects" will provide an opportunity to promote relevant health and food safety policies to broader, non-specialist audiences, in addition to the ongoing "InvestEU" and "An EU that empowers" campaigns.

The activities described above do not represent an exhaustive overview of all internal and external communication of the DG which includes regular media work (media requests, lines to take, etc.), social media outreach, including Commissioner's social media accounts, and ad hoc communication support to policy units (web publishing, photo, video, graphic design, etc.).

In line with the digital transformation process, DG SANTE will restructure its information portal on health policies and will contribute to the Food, Farming and Fisheries and the Live, Work, Travel in EU content classes.

External communication overall spending

Annual communication spending:	
Baseline (2017)	Estimated commitments (2018)
EUR 1 391 902	1 225 000

This budget covers general communication activities on the above mentioned priorities but also financial contributions delegated to other DGs (COMM for corporate activities, 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.

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

1) DG SANTE expects efficiency gains in the area of contract management by rolling out the SEDIA tool (business owner is DG RTD). SEDIA provides on-line services used by economic operators for their interactions with the Commission in public procurement and grants.

   The tool helps streamlining business processes, offering both internal and external users a consistent experience and creating a truly single electronic exchange for legal entities interacting with the Commission. The electronic contract management will also cater for a better coordination with other corporate solutions used by DG SANTE such as ABAC.

2) In the 2017 Management Plan DG SANTE already announced the intention to use existing IT applications to realise efficiency gains in its procurement procedures. After having subscribed to the DG DIGIT e-submission module, DG SANTE has made the necessary preparations to be able to use the tool to full capacity in the course of 2018. 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).

3) In the framework of its stakeholder relations, DG SANTE will use the new 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. A pilot phase will start in January 2018 with the objective to reimburse already some of the experts using the AGM solution.

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 2018:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Human diseases		
Joint Action on vaccination	*Launch of the Joint Action*	*Q2 2018*
Joint action on preparedness and points of entry	*Launch of the Joint Action*	*Q2 2018*
Actions under Multiple Framework Contracts for the "Scripting, planning, conduction and evaluation of exercises, training and assessment implementing the Decision no 1082/2013/EU on serious cross-border threats to health"	*A table top exercise will focus on business continuity planning. Workshops will be organized on best practices regarding entry and exit screening, and regional workshops on the implementation of the International Health Regulations.*	*Q3 2018*
Animal and plant diseases		
Eradication/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*	*15*
Swine diseases	*No. of programmes which received co-financing*	*16*
Avian influenza	*No. of programmes which received co-financing*	*25*
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*

Lumpy Skin Disease (LSD)	*No. of programmes which received co-financing*	*3*
National survey programmes for organisms harmful to plants	*No. of Member States with programmes which received co-financing*	*24*
Emergency measures	*Adoption*	*Throughout the year*
Other important outputs		
Output	Indicator	Target
Human diseases		
Commission Communication on protecting citizens against health threats from infectious diseases (PLAN/2017/1475)	*Adoption*	*Q3 2018*
Council Recommendation on strengthened cooperation against vaccine preventable diseases (PLAN/2017/1949)	*Adoption*	*Q2 2018*
Commission Implementing Decision on the operational procedures of the epidemiological surveillance network (PLAN/2017/2137)	*Adoption*	*Q2 2018*
Staff Working Document on HIV/AIDS; tuberculosis and hepatitis (PLAN/2016/18 – SANTE)	*Publication*	*Q3 2018*
Adoption of Commission recommendation on personal data protection guidelines under Article 16(9)a of Decision 1082/2013/EU (PLAN/2017/2139)	*Adoption*	*Q2 2018*
Foodborne diseases		
Revision of Commission Decision 2004/478/EC concerning the adoption of a general plan for food/feed crisis management (PLAN/2017/1095)	*Adoption*	*Q1 2018*
Animal diseases		
Commission Implementing Regulation on categorisation of listed animal diseases and listing of animal species (AHL) (PLAN/2017/1097)	*Adoption*	*Q3 2018*
Commission Delegated Regulation concerning list of transmissible animal diseases (AHL)(PLAN/2017/1098)	*Adoption*	*Q3 2018*
Commission decisions on handling evolving epidemiological situations	*Adoption of emergency Decisions as necessary, according to the epidemiological situation*	*In course of 2018*
Commission rules on safe imports, trade and related aspects	*Adoption of Commission implementing rules.*	*In course of 2018*
Plant diseases		
Commission Delegated Act on the establishment of European Union reference laboratories for plant health (OCR) (PLAN/2017/1612)	*Adoption*	*Q1 2018*
Commission Implementing Regulation on listing high risk plants and plants to be exempted from phytosanitary certificates	*Adoption*	*Q4 2018*

(PHL) (PLAN/2017/1035)		
Commission Decisions on emergency measures against some specific pests	*Adoption of Decisions as necessary according to (new) outbreak situations*	*In course of 2018*
Commission Decisions with specific import requirements for trade lines where there are too many import interceptions	*Adoption of Decisions as necessary according to import interception notifications from Member States*	*In course of 2018*
Commission decisions on derogations for import from non-EU countries	*Adoption*	*In course of 2018*

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 2018:		
All new initiatives and REFIT initiatives from the Commission Work Programme		
Output	Indicator	Target
Fitness check of General Food Law, Regulation EC 178/2002 (2015/SANTE/427) Annex II of the CWP 2016	*Publication of the SWD*	*Q1 2018*
REFIT evaluation of Nutrition and Health Claims Regulation (2015/SANTE/595) Annex II of the CWP 2016	*Publication of the SWD*	*Q2 2018*
REFIT Evaluations on plant protection products and pesticides residues (2016/SANTE/197) Annex II of the CWP 2016	*Evaluation study by external contractor*	*Q2 2018*
Evaluation of Food Contact Materials (FCM) (PLAN/2016/436)	*Evaluation study by external contractor, public consultation*	*Q4 2018*
Evaluation of the feed additives Regulation (PLAN/2017/988)	*Publication of the SWD*	*Q3 2018*
Evaluation of the EU legal framework on food irradiation (PLAN/2016/506)	*Launch of external study*	*2018*
Commission Regulation establishing a legal limit for the industrial trans fats content in foods (2016/SANTE/143) Reference in the text of CWP 2016	*Finalisation of impact assessment*	*Q3 2018*
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Control programmes on Salmonella	*No. of programmes which received co-financing*	*25*
Study to support the preparation of delegated Regulation on processed-cereal based food and baby food	*Completion*	*Q1 2018*

Food labelling database	*operation of the database*	*Q3 2018*
Operational support services for the EU Platform on Food Losses and Food Waste	*Operation of digital platform and user activity*	*Q4 2018*
EU Platform on food waste': 2 meetings in Lithuania and Belgium	*Carried out*	*Q2 2018 and Q4 2018*
Scientific and technical support for work of the EU Platform on food waste in areas related to food waste measurement and analysis of the effectiveness of food waste prevention initiatives (JRC or external contractor)	*Support provided*	*Q4 2018*
Innovation in food processing technologies (Portal for e-authorisations)	*Start of implementation on a Portal for e-authorisations for novel foods*	*Q1 2018*
Other important outputs		
Output	Indicator	Target
Commission Proposal for a Regulation on transparency and sustainability of the EU food and feed safety risk assessment model (PLAN/2017/2216)	*Adoption*	*Q2 2018*
Implementing Regulation on voluntary food origin labelling (2015/SANTE/670)	*Adoption*	*Q2 2018*
Regulatory measures on contaminants in feed and food following EFSA opinions	*Adoption*	*In course of 2018*
Authorisations for health claims made on foods and referring to children's development	*Adoption*	*In course of 2018*
Report from the Commission on front-of-pack / simplified nutrition information (PLAN/2017/923)	*Adoption*	*Q4 2018*
Guidelines for use of former foodstuff as feed (2016/SANTE/073)	*Publication*	*Q1 2018*
Plant protection products and biocides		
Renewal/non-renewal of active substances for plant protection products	*Adoption*	*Ongoing regular activity in 2018*
Guidance Document on the risk assessment of plant protection products on bees (2016/SANTE/036)	*Adoption*	*Q1 2018*
Report to the Ombudsman on confirmatory information	*Transmission*	*February 2018*
Commission Regulation on uniform principles for evaluation and authorisation of plant protection products (2016/SANTE/039)	*Adoption*	*Q1 2018*
Establishing maximum residues levels (MRL) for pesticides	*Adoption*	*Ongoing regular activity in 2018*
Establishing list of non-acceptable co-	*Adoption*	*In course of 2018*

formulants in plant protection products		
Commission implementing Regulations renewing the approval of biocidal active substances	*Adoption*	*Ongoing regular activity in 2018*
Commission implementing Regulations for approval or non-approval of biocidal active substances included in the review programme	*Adoption*	*Ongoing regular activity in 2018*
Commission notice concerning a list of potentially low-risk active substances approved for use in plant protection products (PLAN/2017/1470)	*Adoption*	*Q1 2018*
Endocrine disruptors (ED)		
Amendment to Implementing Regulation (EU) No 844/2012 to adapt the renewal procedure in view of the new criteria for endocrine disrupting properties (PLAN/2016/483)	*Adoption*	*Q1 2018*
Adapting data requirements in the Annexes to the BPR to the ED criteria (PLAN/2017/1636)	*Adoption*	*Q3 2018*
Implementation of ED criteria – review programme biocidal active substances (PLAN/2017/1637)	*Adoption*	*Q2 2018*
Implementation of ED criteria – approved biocidal active substances (PLAN/2017/1638)	*Adoption*	*Q1 2018*
Implementation of ED criteria – renewal of biocidal active substances (PLAN/2017/1639)	*Adoption*	*Q2 2018*
Implementation of ED criteria –authorised biocidal products (PLAN/2017/1641)	*Adoption*	*Q1 2018*
Commission Notice on guidance for the implementation of ED criteria for biocidal products (PLAN/2017/1654)	*Adoption*	*Q2 2018*
GMOs		
Commission Directive aiming to update of the Environmental Risk Assessment requirements in Directive 2001/18 concerning GMO (2015/SANTE/428)	*Adoption*	*Q1 2018*
Repeal of the Guidelines on the Environmental Risk Assessment of GMOs (PLAN/2016/167)	*Adoption*	*Q1 2018*
Authorisations of GMO's food and feed uses, and for cultivation	*Adoption*	*In course of 2018*
Authorisations of substances		
Commission Regulation on Bisphenol A as	*Adoption*	*Q1 2018*

food contact material (2015/SANTE/534)		
Authorisations for new substances and new uses of already authorised substances used as food additives, food flavourings, novel foods, or substances used in plastic food contact materials	*Adoption*	*In course of 2018*
Authorisation of recycling processes for plastics used in food contact materials	*Adoption*	*Q3 2018*
Withdrawal of certain substances (flavourings)	*Adoption*	*In course of 2018*
Withdrawal of certain already authorised additives for which no applications were submitted	*Adoption*	*In course of 2018*
Feed additives/Feed hygiene		
Re-evaluations of authorisations, new authorisations , denial of authorisation, modifications of authorisations and renewal and non-renewal of authorisations of feed additives	*Adoption*	*In course of 2018*
Guidelines on the interpretation of Feed Hygiene Regulation (PLAN/2017/1270)	*Adoption*	*Q1 2018*
Implementation of the new Novel Food Regulation		
Implementing act clarify the procedures for requesting confidentiality treatment in novel food applications (PLAN/2016/267)	*Adoption*	*Q4 2018*
Delegated act on updating and adjusting the definition of "engineered nanomaterials" to technical and scientific progress (PLAN/2016/269)	*Adoption*	*after the planned revision of the definition provided in Commission Recommendation 2011/696/EU has been finalised*
Implementation of the legislation on plant reproductive material		
Implementing Decision of the European Parliament and the Council recognising EU equivalence for the certification of fodder plant seeds, oil and fibre plants and vegetable seeds in Brazil and Moldova, for the purpose of their import into the EU(PLAN/2017/917)	*Adoption*	*Q4 2018*
Animal Welfare		
Report to the European Parliament and the Council on the application of broilers Directive (2016/SANTE/114)	*Adoption*	*Q1 2018*
Report to the European Parliament and the Council on protection of fish at the time of killing (2016/SANTE/138)	*Adoption*	*Q1 2018*
Commission Implementing Regulation on designation of an EU reference centre for	*Adoption*	*Q1 2018*

animal welfare (OCR) (PLAN/2017/1609)		

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 2018:		
Important items from work programmes/financing decisions/operational programmes		
Output	**Indicator**	**Target**
Legal proposal on a possible financial instrument for EU action on health under the new MFF	*Impact assessment* *Legal proposal adopted*	*02/2018* *Mid-year 2018*
Compass conference on mental health	*Conference*	*Q1 2018*
Implementation and scaling up of best practice: resource centre on health promotion and prevention and management of non-communicable diseases	*Web based tool established*	*Q2/2018*
Support to Member States in relation to alcohol related harm	*Service contract signed*	*Q3 2018*
Framework Contract: support services to manage expert groups	*Contract signed*	*Q3/2018*
Direct Grant to the WHO/FCTC	*Contract signed*	*Q3/2018*
Direct agreement with the Joint Research Centre	*Contract signed*	*Q2/2018*
Reporting on delegated and implementing powers	*Adoption*	*Q3 2018*
JRC literature review on Front-of-Pack labelling	*Completion*	*Q3 2018*
Other important outputs		
Output	**Indicator**	**Target**
Q&A on Food Information to Consumers	*Adoption*	*Q1 2018*
Delegated act lowering the minimum protein content of follow-on formula as set out in Delegated Regulation (EU) 2016/127 (PLAN/2017/1369)	*Adoption*	*Q1 2018*
Commission's report on Front-of-Pack labelling (PLAN/2017/923)	*Adoption*	*Q4 2018*
Report on evaluation of the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) (PLAN/2016/406)	*Completed*	*Q4 2018*

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 2018:		
Important items from work programmes/financing decisions/operational programmes		
State of Health in the EU: voluntary exchanges	*Completion*	*Q4 2018*
State of Health in the EU: Launch of the second cycle.	*Health at a Glance published*	*Q4 2018*
Joint Action on Health Information	*Launch of the Joint Action*	*Q1 2018*
Direct grant agreement with OECD to support the work on AMR, implementation of best practices and patient reported measures	*Contract signed*	*Q2 2018*
Direct grant agreement with European Observatory on Health Systems and Policies	*Publication of a mapping and analysis of good practices and a book of evidence on good practices and enablers / obstacles to their transfer in the area of AMR.*	*Q4 2018*
Commission Report on the operation of the Cross-border Healthcare Directive 2011/24/EU	*Adoption*	*Q3 2018*
Study on cooperation in cross-border regions and toolbox for National Contact points	*Completion*	*Q2 2018*
Study on cross-border health services: enhancing information provision to patients	*Completion*	*Q2 2018*
Communication on Digital transformation of health and care in the context of the DSM (PLAN/2017/1353)	*Adoption*	*Q1 2018*
Joint Action supporting the eHealth network	*Launch of the Joint Action*	*Q2 2018*
eHealth Digital Service Infrastructure: building core services and national access, the eHealth Member State Expert Group	*6 national access points set up*	*Q2 2018*
Study on regulatory aspects of cross-border telemedicine	*Completion*	*Q4 2018*
Expert Panel on Health's Opinions on topical challenges in health systems	*Publication*	*Q4 2018*
Evaluation of legal framework and Union legislation on blood and tissues and cells	*Completion*	*Q4 2018*
Other important outputs		
Output	Indicator	Target
Transposition check of the cross-border healthcare Directive 2011/24/EU: identification of gaps in national laws and start relevant procedures	*Advance discussions and pilots with Member States*	*Q4 2018*

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 2018:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Support to approved ERNs	*Multi- annual grants signed and operational*	*Q4 2018*
Implementation support contract for ERNs' functioning networking, communication, developing of guidelines, capacity building	*Contract(s) signed*	*Q4 2018*
Assessment of healthcare providers wishing to join existing ERNs	*Contract signed*	*Q4 2018*
Orphanet and orphacoces	*Contracts signed*	*Q3 2018*

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 2018:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
EU Reference Laboratories	*No. of laboratories funded*	*45*
Better Training for Safer Food	*No. of trainings organised*	*170*
Computerised systems + IT (e.g. TRACES, ADIS, ADNS, EUROPHYT)	*No. of computer systems funded*	*7*
Other important outputs		
Output	Indicator	Target
Commission Report to the European Parliament and the Council on the overall operation of official controls performed in Member States to ensure the verification of compliance with feed and food law, animal health and welfare rules (2014/SANTE/011)	*Adoption*	*Q2 2018*
Commission Implementing Regulation listing the animals and goods to be subject to mandatory official controls at their entry into the Union, indicating their codes from the Combined	*Adoption*	*3Q 2018*

Nomenclature (OCR) (PLAN/2017/1611)		
Commission Implementing Decision establishing standard model forms for the submission of the annual report on the operation of their multi-annual national control plan by Member States (OCR) (PLAN/2017/1182)	*Adoption*	*Q4 2018*
210 Health and food audits and fact-finding missions	*80% of programmed audits completed* *90% of the number of programmed and new audits completed*	*end 2018*
Other DG SANTE activities to improve the performance of control systems:		
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:* *6 plenary meetings (all Member States) and 4 subgroup meetings (limited membership)*	*end 2018*
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:* *as per published SANTE audit and analysis work programme 2018*	*end 2018*
Evaluation of facilities of Border Inspection Posts	*Number of evaluations:* *on average 15*	*end 2018*
Evaluation of Member States' and non-EU countries' residue monitoring plans	*Number of evaluations: 28 Member States plans and up to 50 non-EU country plans*	*end 2018*
Management of lists of approved non-EU country establishments for the production of food of animal origin	*Approx. 500 requests from authorised countries to update individual commodity lists each year*	*end 2018*
Operation and further development of the notification system for plant health interceptions, EUROPHYT and reporting on plant pests	*Europhyt monthly and annual statistics and reports*	*end 2018*
Plant health surveys	*Four reports on harmful organisms*	*end 2018*

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 2018:	

All new initiatives and REFIT initiatives from the Commission Work Programme		
Output	Indicator	Target
Commission initiative on strengthening of EU cooperation on Health Technology Assessment (2016/SANTE/144)	*Adoption*	*Q1 2018*
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Health Technology Assessments reports under EUnetHTA Joint Action	*- Reports prepared* *-Implementation and uptake of joint work*	*- 8 (Pharma) and 8 (other technologies) in course of 2018* *- in at least 10 Member States*

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 2018:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Study to support reporting requirement on centralised and decentralised procedures for pharmaceutical products	*Start*	*2018*
Report on additional monitoring of human medicines	*Adoption*	*Q2 2018*
Report on EU pharmacovigilance activities (additional monitoring of certain medicines)	*Adoption*	*Q4 2018*
Evaluation of EMA fee system	*Completion*	*Q3 2018*
Study on legislation on medicines for rare diseases	*Launch*	*Q1 2018*
Economic study on pharmaceutical incentives and rewards – to be completed	*Completion*	*Q1 2018*
Study on medicines for rare diseases and children including incentives	*Launch*	*2018*
Marketing authorisation of medicines Authorisations of new medicines and variations to marketing authorisation of existing medicines, orphan designations for medicines for rare diseases	*Adoption*	*In course of 2018*
Other important outputs		

Output	Indicator	Target
Report to the European Parliament and the Council on the penalties in the field of falsified medicines (2015/SANTE/469)	*Adoption*	*Q1 2018*
Commission Decision acknowledging the full functionality of the clinical trials portal and database	*Adoption*	*Q4 2018*
Commission implementing Decisions establishing a list of non-EU countries with equivalent standards for active substances for medicinal products for human use pursuant to the falsified medicines Directive[3]	*Recognition of authorities of non-EU countries*	*Q4 2018*

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 2018:		
Other important outputs		
Output	Indicator	Target
Report to the Council Working Party on Public Health at Senior Level on Integrated care	*Publication*	*Q1 2018*
Report to the Council Working Party on Public Health at Senior Level on Efficiency of Health Systems	*Finalisation*	*Q4 2018 (Publication 2019)*

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

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

Relevant general objective 3: A balanced and progressive trade to harness globalisation		
Specific objective 3.1: Increased EU influence in international fora		Related to spending programme(s): NO
Main outputs in 2018:		
Other important outputs		
Output	Indicator	Target
Coordinated EU positions on WHO resolutions	*Delivered*	*20*

[3] Output refers to several separate country files; progress on individual files may vary.

EU co-sponsored WHO resolution	*Delivered*	*1*
EU statements for WHO meetings	*Delivered*	*9*
Coordination of positions in UN Meetings	*Delivered*	*2*
Common positions coordinated with EU Member States to facilitate the alignment of existing and planned EU legislation and initiatives with Codex standards	*Delivered*	*120*
Common positions coordinated with EU Member States to facilitate the alignment of the work of the Codex Task Force on antimicrobial resistance with existing and planned EU legislation and initiatives	*Development of two Codex texts:* *- Proposed Draft Revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance* *- Proposed Draft Guidelines on Integrated Surveillance of Antimicrobial Resistance*	*In the course of 2018*
Coordinated EU position for the OIE's aquatic and terrestrial Code and Manual	*Delivered*	*4*
Coordinated EU Statements for the OIE General Assembly	*Delivered*	*In course of 2018*
Coordinated EU positions in OECD meetings	*Delivered*	*In course of 2018*
Coordinated EU positions in documents and guidelines of the International Union for the Protection of New Varieties of Plants (UPOV)	*Delivered*	*In course of 2018*
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 2018*
Coordinated EU positions in the WTO SPS and TBT Committees	*Delivered*	*In course of 2018*
Bilateral trade negotiations (SPS Chapter)	*Negotiate safe, secure and harmonised export conditions for EU products with non-EU countries*	*Balanced SPS Chapter within the ongoing FTA agreements*
Coordinated EU statements and position, as well as negotiations, for the Conference of the Parties of the Cartagena Protocol on Biosafety and Coordinated EU position regarding synthetic biology and gene drives for the Conference of the Parties of the Convention on Biological Diversity	*Delivered*	*Q4 2018*

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 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 2018:		
Other important outputs		
Output	Indicator	Target
Mutual Recognition Agreement: Contribution to the recognition of Member State Good manufacturing practices inspectorates by the US through the support of audits in the framework of Joint Audit Programme; implementation of the agreement	*Recognition of around 15 EU authorities as equivalent*	*Q4 2018*
Mutual Recognition Agreement: inclusion of veterinary medicines in the operational scope; process and timelines for the capability assessment of EU Member States by FDA and equivalence assessment of FDA by the EU	*Planning of audits*	*Q1/Q2 2018*
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 2018*
Organise a meeting of the EU-US Animal Health Technical Working Group: Facilitate trade in animal products and better cooperation on animal health issues (e.g. regionalisation) with the US	*Meeting held*	*Q4 2018*

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 2018:		
Output	**Indicator**	**Target**
Towards Excellent SANTE: Training SANTE Managers on health at work	*Participation rate of SANTE managers in one or more initiatives organised in collaboration with the medical service*	*80% of managers participating to one or more activities*
Towards Excellent SANTE: Awareness rising actions around the 6 fit@work priorities of the Commission: SANTE a healthy DG programme	*Participation rate of SANTE Staff*	*70% of Staff participating to one or more activities*
Towards Excellent SANTE: Organise staff development actions to improve engagement and empowerment and to assist staff in taking a more active role in making things better.	*Carry out training activities*	*Organisation of at least 5 trainings with a participation rate of on average 15 staff*
Recruitment target of female managers: Targeted career development programme for female aspirant middle managers	*Number of female aspirant middle managers trained*	*10*

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 2018:		
Output	**Indicator**	**Target**
Legality and regularity of the underlying financial transactions in the	***Estimated residual error rate***[4] *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*

[4] 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 2015 https://myintracomm.ec.europa.eu/budgweb/EN/rep/aar/Pages/guidance.aspx

DG		*design of the programmes)*

Objective 2: Effective and reliable internal control system in line with sound financial management.		
Main outputs in 2018:		
Output	**Indicator**	**Target**
Cost effectiveness of controls in the AAR	*Conclusion reached on cost effectiveness of controls in the 2018 AAR*	*Yes*
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 from Internal Audit Service (IAS) and European Court of Auditors (ECA)	*Percentage of critical recommendations from IAS and ECA implemented within 6 months*	*100%*

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 2018:		
Output	**Indicator**	**Target**
Implementation of the anti-fraud strategy	*Percentage of implemented actions planned for 2018 deriving from the anti-fraud strategy (priority for 2018: actions related to non-spending legislative initiatives)*	*100%*

C. Better Regulation

None.

D. Information management aspects

Objective 1: Information and knowledge in your DG is shared and reusable by other DGs. Important documents are registered, filed and retrievable.		
Main outputs in 2018:		
Output	**Indicator**	**Target**
Registered documents re also filed.	*Percentage of registered documents that are not filed[1] (ratio)*	*Less than 1% by Q4 2018*
HAN files are	*Number of HAN files*	*75% by Q4 2018*

readable/accessible by all units in the DG	*readable/accessible by all units in the DG*	
HAN files are shared with other DGs	*Number of HAN files shared with other DGs*	*75% by Q4 2018*
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 2018*
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 2018*

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 2018:		
Output	**Indicator**	**Target**
Tackling vaccination inequalities – Media actions on the adoption of the Council recommendation on vaccination	- Number of visits to SANTE web section on vaccination - National print media coverage of adoption of Council Recommendation - Number of journalists attending the media briefing or roundtable with the Commissioner (tbc) + outputs - Twitter reach (including Commissioner's accounts) (regular and paid)	- 10% increase (baseline 2017[5]: 17,920 visits) - Media coverage by at least 20 EU countries - 10 including those from countries with high scepticism (e.g. France) and low vaccination rates (e.g. Romania and Bulgaria), 70% of which publish articles within 3 months - 50,000 Twitter accounts reached & 500,000 impressions
Protecting citizens against health threats from infectious diseases - emphasise the message "a Europe that protects". Media actions on the adoption of the Communication		- 10% increase (baseline 2017[1]: 5,757,520 visits) - 20,000 Twitter accounts reached & 200,000 impressions - Media coverage by at least 15 EU countries
Proposal on the transparency and	- Number of visits to SANTE web section General Food	- 10% increase (baseline 2017[1]: 41.930 page views)

[5] Disclaimer: web statistics used as 2017 benchmarks are projected figures for the entire year based on user data collected between January and September. We have calculated these figures by adding to the collected data three times the average of the first nine months.

sustainability of the food and feed risk assessment model	Law - Media coverage of adoption of legislative proposal - Twitter reach (including Commissioner's accounts) (regular and paid)	- Print (both general and specialised) media coverage by at least 15 EU countries - 30 000 accounts reached and 300 000 impressions
Participation with a stand in international events on "farm to fork" and particularly on food waste.	- Number of visits to Salon de l'Agriculture (SIA), Grüne Woche (IGW) and Salone del Gusto	-For SIA: 143.470 visitors in the stand, 27.090 visitors engaged For IGW: 214.416 visitors by the stand, 105.744 visitors engaged in the stand
Digital health and care – Media actions on the adoption of the Commission Communication	- Number of visits to SANTE web section on e-health - Twitter reach (including Commissioner's accounts) (regular and paid)	- 10% increase (baseline 2017[1]: 32,253 visits) - 30,000 Twitter accounts reached & 300,000 impressions
Implementation of the AMR Action Plan - Organization of European Antibiotic Awareness Day in cooperation with ECDC. Promotion of factsheets, Eurobarometer results, video clip, press material, social media activities.	- Number of visits to SANTE web section on AMR - Twitter reach (including Commissioner's accounts) (regular and paid) - National media coverage of final adoption of vet medicines and medicated feed legislation - National media coverage of European Antibiotic Awareness Day (EAAD)/ AMR Eurobarometer - Number of journalists attending EAAD media event including Commissioner interviews (tbc)	- 10% increase (baseline 20171: 88,026 visits) - 70,000 Twitter accounts reached & 700,000 impressions - Print media coverage by at least 15 EU countries, including both health and agriculture publications. - Media coverage by at least 20 EU countries - 10 journalists attending EAAD media event, 70% of which publish articles/interviews within 3 months
Launch of the "Health at a Glance: Europe 2018 report/State of Health in the EU" to media and stakeholders	- Number of visits to SANTE web section on State of Health - Twitter reach (including Commissioner's accounts), (regular and paid) - National media coverage of report - Number of the Commission Representations joining virtual press briefing	- 10% increase (baseline 2017[1]: 44,100 visits) - 100,000 Twitter accounts reached and 1,000,000 impressions - Print media coverage by at least 15 EU countries. - At least 8 Commission Representations joining virtual press briefing

[1] Disclaimer: web statistics used as 2017 benchmarks are projected figures for the entire year based on user data collected between January and September. We have calculated these figures by adding to the collected data three times the average of the first nine months.

Media actions around the 4th Conference of the European Reference Networks: a success story in the treatment of rare diseases	- Number of visits to SANTE web section on ERNs - Twitter reach (including Commissioner's accounts) (regular and paid) - Number of print media articles on success stories	- 10% increase (baseline 2017[1]: 85,779 visits) - 50,000 Twitter accounts reached & 500, 000 impressions - At least 10 articles published by several EU countries during the year