European Commission

Management Plan 2017

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 agrifood sectors can thrive. Our 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.

The food production and processing chain accounts for 7.5 % of employment and 3.7 % of total value added in the EU.[1] In 2015, health spending reached 9.9% of GDP[2] and health sector accounted for 11% employment[3] in the EU.

DG SANTE contributes to three of the Juncker Commission's ten priorities as indicated in its Strategic Plan for 2014-2020[4]: (1) a new boost for jobs, growth and competitiveness in the EU, (2) a deeper and fairer internal market, and (3) a reasonable and balanced free trade agreement with the US.

Promoting sustainable growth and competitiveness in the EU's health sector

EU action in the field of health policy complements national policies and encourages cooperation between Member States. It is shaped under Article 168 of the Treaty on the Functioning of the EU which specifies that Member States are responsible for the design and management of their national health policies. Good health and well-functioning health systems have a vital role to play in social cohesion, economic growth and investment and the EU plays an important supporting and coordinating role.

The EU Health Programme promotes actions in areas where there is a clear added value to EU intervention. This includes supporting best practice exchange and networks for knowledge sharing, tackling serious cross-border health threats, unlocking the potential for innovation in health, improving economies of scale and addressing certain issues linked to the internal market where the EU has substantial legitimacy to ensure high-quality solutions across Member States.

Key areas of activity in 2017 include strengthening our preparedness and response capacities to tackle serious cross-border health threats and promoting innovative health technologies.

Specific outputs which will contribute to a new boost for jobs, growth and investment in the EU (general objective 1) will include the publication of the first series of country health profiles as part of the two year analysis into the "State of Health in the EU". This work, carried out in partnership with the OECD and European Observatory on Health Systems and Policies will make an important contribution to more effective, accessible and resilient health systems. The first

[1] Agri-food trade in 2015: China boosts EU exports, Monitoring Agri-trade Policy, MAP 2016– 1, Eurostat, p. 3.

[2] Health at a Glance: Europe 2016, State of health in the EU cycle, p. 12

[3] This includes employment in following activities: human health, residential care and social work without accommodation, source: Eurostat.

[4] http://ec.europa.eu/atwork/synthesis/amp/doc/sante_sp_2016-2020_en.pdf

European Reference Networks will be launched in 2017, bringing together around 1000 healthcare providers and researchers from across the EU to provide better and more innovative treatment, particularly for patients with rare forms of disease.

Antimicrobial resistance (AMR) is a high priority under general objective 1. A new EU Action Plan is due to be proposed in 2017 to tackle this growing global threat across the human, animal and environmental health sectors.

Contributing to a deeper and fairer internal market (general objective 2), a major new initiative to strengthen EU cooperation on health technology assessments (HTA) will be launched. It forms part of the Commission's Work Programme 2017 and will support continued cooperation on innovative health technologies. Access to affordable medicines and health systems performance assessment are other important priorities under this objective.

Promoting relations with non-EU countries

A balanced free trade agreement with the US is SANTE's third general objective, with the specific aim to secure better access to the US market and greater trade possibilities for food and pharmaceutical products without compromising EU standards. Work will continue on implementing the EU/US mutual recognition agreement on pharmaceuticals and to reduce trade barriers not in line with international standards in the food sector. DG SANTE will also continue to collaborate closely with other trade and global partners.

Contributing to jobs, growth and investment in the EU's food and feed sectors

The EU's food and feed policies are supported by a comprehensive legal framework that promotes a well-functioning and safe food chain. The aim is to create the right environment for growth and investment in this important sector – the largest manufacturing sector in the EU - whilst ensuring a high level of human, animal and plant health and a high level of food safety.

The implementation of EU programmes in this area plays a crucial role in disease surveillance and eradication and in maintaining a high level of food safety. This is a key public health and economic priority and there is a proven added value to coordinating and defining activities in this area at EU level. Serious animal and plant disease outbreaks have serious, cross-cutting consequences and require a coordinated response to minimise the impact on human, animal and plant health, industry and markets. Substantial work is carried out under SANTE's audit and analysis programme to ensure EU legislation is correctly implemented and enforced.

An important part of SANTE's work in 2017 will be the finalisation and follow-up to EU legislation designed to modernise and simplify the legal framework governing the food and feed sector. A new Official Control Regulation is expected to be adopted in early 2017. There is also a range of implementing legislation linked to the Animal Breeding Regulation and Novel Foods Regulation which are going to be prepared by the end of 2017. SANTE will also start work on the implementing measures under the Animal Health, Plant Health and Officail Controls Regulations.

Evaluations linked to the EU's General Food Law, plant protection products and pesticide residues and nutrition and health claims will be ongoing in 2017 as part of the Commission's Regulatory Fitness assessment.

Other important work in 2017 includes the implementation of the Directive on the sustainable use of pesticides and a possible restriction of the use of industrially produced transfatty acids in food. SANTE will also continue its work linked to

market access for safe substances handling, amongst others, authorisations for substances used as food additives and plant protection products. Activities in 2017 also include follow-up to the Circular Economy package in the area of food waste and the launch of the new EU animal welfare platform which aims to improve enforcement and best practice exchange.

Using digital technologies to boost jobs, growth and investment in the EU

SANTE will continue to integrate the use of digital technologies to aid and improve delivery of its objectives in both its policy areas, making an important contribution the Commission's Digital Market Strategy. In food and feed safety, SANTE will use digital technologies to strengthen its system of official controls while in health the focus will be on increasing the EU's eHealth capacity.

Key organisational and management outputs in 2017

SANTE will participate in the Commission's pilot project to centralise Human Resources functions and as such will see its local HR capacity significantly reduced over the course of 2017. Despite this, it will continue its "Towards Excellent SANTE" initiative to cultivate a positive work environment. The 2016 Staff Survey showed reductions for a number of categories – notably as regards involvement in decision-making and the role of senior management – and these factors will feed into this ongoing initiative.

SANTE's communication priorities for 2017 are closely aligned with the DG and Commission's key priorities and include the new action plan for AMR, the publication of the first series of country health profiles, the launch of the European Reference Networks (ERNs), food waste and the proposed initiative on HTA, where the Commissioner will have an active role.

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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 plans which identify priority areas in line with the Political Guidelines 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 work programme for 2017 will focus on a series of actions from among the 23 thematic priorities set out in annex I of Regulation (EU) N° 282/2014. It includes:

- support for country-specific and cross-country knowledge;
- grants to European Reference Networks;
- an innovative partnership on Action against Cancer;
- Joint Actions on health information, vaccination; preparedness and actions at points of entry;
- actions for the prevention and the management of chronic diseases;
- support for eHealth and fight against health inequalities; and
- action to integrate refugees, in line with the EU's agenda on migration.

A mid-term evaluation of the Third Health Programme is due to be completed by mid-2017 and will determine if there is a need to modify the thematic priorities of the Programme or to review its objectives for the remainder of its lifespan. An open public consultation on the first two years of the Third Health Programme will form part of this evaluation.

A specific study will also be commissioned to analyse the long term impact and sustainability of the Health Programmes. It will be used to develop the proposal for a new financial framework for health post 2020.

The two **scientific committees** (funded by the Health Programme) will continue to make an important contribution to policy decisions 2017. They are expected to publish around 25 opinions in 2017 including risk assessments of cosmetic ingredients and endocrine disruptors in medical devices.

The EU's 2014-2020 Public Health Programme is managed by the **CHAFEA** and supports actions on communicable diseases and other health threats, chronic and rare diseases, antimicrobial resistance (AMR), health systems, patients' rights in cross-border healthcare, human tissues, cells, blood and organs, European Reference Networks (ERNs), medical devices, medicinal products, tobacco products and advertising.

An evaluation of CHAFEA will be launched in 2017 and will cover the period of 1 January 2014 to 31 December 2016. Pursuant to Council Regulation 58/2003, the Commission is required to carry out an evaluation of the operation of each executive Agency every three years. A previous evaluation was carried out in 2012 for all executive Agencies together. As a lead DG, SANTE will prepare a report on the evaluation with input from the assosiated DGs, i.e. AGRI, JUST and GROW which is planned for the end of 2018.

The objective of this evaluation is to assess the relevance, effectiveness, operational efficiency, EU added value and coherence of CHAFEA's implementation of the delegated parts of the financial programmes it manages. The results will be used in any reflection on eventual future changes.

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 and expenditure covers animal health measures, plant health measures, emergency measures linked to animal and plant disease outbreaks, official controls activities and relations with relevant international organisations.

A mid-term evaluation of the CFF 2014-2020 is ongoing and due to be completed in early 2017. Its purpose is to assess the results and impacts of the veterinary and phytosanitary programmes and emergency measures, EU reference laboratories and training activities in the food chain area. It will provide considerable input for the proposal for follow-up activities under the next financing period.

A study is planned for 2017 to develop a methodological approach to implement an analysis of cost-effectiveness in the areas of food safety spending. This methodology will be used in the ex-post evaluation of the CFF (due mid-2022) and is expected to become a key evaluation tool for spending under the CFF.

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 Protection and Control (ECDC), the European Food Safety Authority (EFSA), the European Medicines Agency's (EMA) and the European Chemicals Agency (ECHA).

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. The cost of dealing with emergencies and diseases, if existing measures do not function correctly, is very significant, with loss of internal EU and export markets, costs of disease control on the EU and Member State budgets, and costs to Member State health systems for treating zoonotic diseases (animal diseases transmissible to humans). The Commission will approve approximately 120 annual veterinary programmes for 2017 to tackle animal diseases.

Epidemics and infections represent a serious security risk and a direct economic cost for growth, consumer confidence and international market access if they are not contained or well-managed. 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 challenges.

EU contribution to emergency measures will further target in 2017 the proper and rapid management of potential future outbreaks.

In 2017, actions under specific objective 1.1 will focus on the following priorities:

- Tackling serious cross-border health threats;
- Managing, isolating and preventing outbreaks of major animal disease;
- Managing, isolating and preventing plant disease.

SANTE's work under this specific objective is supported by EFSA, ECDC and the CVPO. The 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 countries, the EU - in particular, DG SANTE - has an important role to play in coordinating preparation and response capacity.

In 2017, DG SANTE will help Member States to reinforce preparedness and response planning to tackle serious cross-border health threats. The rules and procedures for Member States cooperation on preparedness, surveillance and medical countermeasures will be strengthened via the adoption of the three implementing decisions on EU early warning and response system, listing of communicable diseases and case definitions for diseases. In addition, several actions under the Joint Procurement Agreement of medical countermeasures will be launched, including the procurement of pandemic vaccines.

SANTE will also strengthen EU cooperation on vaccine supply and vaccine coverage. This will help prevent 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. These activities are also linked to the implementation of core capacities under the International Health Regulations and will help SANTE to reach its 2017 interim target of 14 Member States with improved preparedness and response planning strategies (SANTE Strategic Plan 2016-2020, **result indicator** 1.1A).

<u>Financial contribution to tackling serious cross-border health threats</u>

To reinforce preparedness and implementation of the Decision on serious cross-border threats to health, SANTE is proposing a Joint Action on preparedness and action at points of entry (air, maritime and ground crossing). It also follows-up on the Ebola report on lessons learned on health preparedness in the transport sector.

In addition, meetings and workshops will be organised to test Member States' preparedness and provide information on the gaps between the knowledge and skills required to comply with the requirements of the International Health Regulations. They will contribute to preparedness and response planning, cross-sectoral capacity and improve information sharing within EU regions and with

neighbouring countries. A dedicated workshop on best practices for entry and exit screening will also be financed.

In 2017, SANTE will begin a Joint Action on vaccination. The Action aims to develop a strategy on vaccines comprising a coherent series of actions that will support Member States to improve vaccine coverage.

Training programmes for health professionals, border officers and their trainers working at local level will be implemented in 2017 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.

1.1.2. Managing and isolating outbreaks of major animal disease

Modernising and simplifying EU legislation

In an ever evolving context when new diseases can present and spread quickly, it is essential to ensure that the legislative framework remains fit for purpose. An important part of DG SANTE's work in 2017 will be the preparation of implementing legislation linked to significant Regulations adopted in 2016: Regulation on transmissible animal diseases ("Animal Health Law") and the Animal Breeding Regulation.

DG SANTE will, under the **Animal Health Law**, dedicate substantial time to systematically look into 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, effective, preventive and strategic driven future rules for the control of animal diseases and contributing to smooth and safe trade in the internal market. The adoption of the first delegated and implementing acts is foreseen for 2018 and 2019. To meet these deadlines an important part of the work to develop these acts will need to be completed in 2017.

Under the **Animal Breeding Regulation** four delegated and implementing acts are foreseen for 2017, for instance laying down model forms for the zootechnical certificates and for the presentation of information on the recognised breed societies and breeding operations. Most importantly, an EU reference centre for zootechnics in relation to purebred breeding animals of the bovine species will be appointed.

Financial contribution to sanitary (animal health) measures

EU support for animal disease eradication, control and monitoring programmes accounts for the largest proportion of spending under the EU's food safety budget. The budget planned for the implementation of the **national veterinary programmes** in 2017 is EUR 165 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 cost of disease control on the EU and Member State budgets. 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** related to animal health (the total budget for emergency measures in case of animal and plant health is EUR 20 million) in order to contain animal disease outbreaks quickly. If not treated immediately, outbreaks can come at a huge cost for the EU.

In 2017, SANTE will continue to manage current animal health crises – including African swine fever, lumpy skin disease, avian influenza and bluetongue – and help Member States and neighbouring non-EU countries to maintain an adequate level of preparedness.

For the purpose of prevention and control of foot-and-mouth disease in Member States and in non-EU countries, DG SANTE is to launch a public procurement procedure in 2017 in order to update and purchase additional quantities of vaccines for foot-and-mouth disease for the Union vaccine bank. DG SANTE will also continue to support Member States and non-EU countries with the initial response to the lumpy skin disease outbreak from the vaccine bank.

1.1.3. 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 economy and trade.

The **national survey programmes** for organisms harmful to plants will facilitate further in 2017 the earliest possible detection and eradication of priority plant pests on the EU territory. There will be approximately 24 annual survey programmes to be implemented in 2017.

Percentage of the EU territory covered by surveys for pests will reach 90%, exceeding the 2017 milestone of 70% set in **result indicator 1.1.E** of SANTE's Strategic Plan 2016-2020. The surveys for pests considered to be most dangerous will cover the whole EU territory as per the milestone for 2017 (SANTE Strategic Plan 2016-2020, **result indicator 1.1 F**).

Emergency measures to control outbreaks of harmful organisms within the EU will be issued or updated as appropriate. In particular, outbreaks of Xylella (in Italy with a second outbreak in France), Pine Wood Nematode (in Portugal) and Epitrix (Spain and Portugal) will be monitored closely, as will the results of preventative surveys carried out by Member States. Existing import measures, in particular for citrus blackspot (measures cover Brazil, South Africa, Uruguay), will be closely monitored to avoid harmful organisms entering the EU.

The 2017 target for the "success rate of eradication of pests not known to occur in the Union" (**result indicator 1.1 H** from SANTE's Strategic Plan 2016-2020) is 60%. Achieving this target depends on the different types of pest and the number of outbreaks identified. DG SANTE will monitor this closely via its evaluations of Member States' co-financed eradication plans and the notifications and the information they submit following outbreaks. This information will be discussed with Member States to improve overall knowledge and best practice.

In addition to the already existing EUROPHYT system for the notification of interception of plant pests, a new module for the reporting of pests outbreaks will be available to Member States to streamline the transmission of the necessary information. This will help to progressively reduce the time of notification by the Member States of the outbreaks of pests (**result indicator 1.1 G** from the SANTE's Strategic Plan 2016-2020) and to reach the milestone for 2017 of 20 days.

Modernising and simplifying EU legislation

A new **Plant Health Law** was adopted in 2016. The first delegated and implementing acts will need to be adopted already in early 2018, followed by the most important ones to be adopted within three years following the coming into force of the Regulation. To achieve these deadlines, an important part of the work to develop these acts will need to be completed in 2017.

These acts include for instance the designation of an EU reference laboratory for plant health and the listing of regulated and non-regulated pests and other products and priority pests. Collectively these acts are designed to boost long-term growth and competitiveness in the EU livestock, plant and plant products sectors and support better functioning of the EU's internal market of such products.

Financial contribution for plant health measures

The **national survey programmes** for organisms harmful to plants ensure early detection and eradication of pest outbreaks. This is a new funding activity in the food and feed area introduced by Regulation (EU) No 652/2014. The budget planned for the implementation of the plant health survey programmes is EUR 15 million.

Funds will be also available to tackle the **outbreaks** of pests (the planned budget available for emergency measures in case of animal and plant health is EUR 20 million).

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

Output table is included in Annex 1.

The EU's food safety policy ensures the internal market in this sector runs smoothly and that citizens are well-protected and feel confident within it. Food and animal feed is subject throughout the EU to a well-developed legal framework that protects a high level of safety and quality at the same time as it encourages free trade, investment and innovation. EFSA makes an important contribution to this specific objective through its scientific opinions on the safety of food and feed.

Modernising and simplifying EU legislation

REFIT and better regulation play an important part DG SANTE's work and several REFIT exercises linked to safe and sustainable food production included in the 2016 Commission Work Programme are ongoing:

- **Fitness Check of the General Food Law** - needs to be finalised (in a form of a Staff Working Document) and go through Regulatory Scrutiny Board review process in 2017. Based on the results, the Commission will assess what (if any) follow up is needed in 2017.
- **Evaluations on plant protection products and pesticides residues** – a roadmap has been published and a call for tender is planned to be launched at the end of 2016. The study supporting the evaluation will start in the first half of 2017 and the evaluation results can be expected in mid-2018. The study will be the basis for a report to the Council and the European Parliament at the end of 2018/beginning 2019.
- **Evaluation on nutrition and health claims** – the roadmap has been published in March 2016. The study is expected to be completed in mid-2017 and the Commission's conclusions to be finalised by the beginning of 2018.

Moreover, evaluations of the legislations on **feed additives, on food contact materials (FCMs) and on food irradiation** will be launched in 2017.

Concerning FCMs, the Regulation (EC) No 1935/2004 provides the legal EU framework setting out general requirements and empowering the Commission to adopt specific measures on FCMs. However, there is currently no specific EU measure addressing printed FCMs. Certain constituents of printing inks used in or on printed FCMs may endanger human health if they transfer into food. This was highlighted by Germany in its notification on national rules for printing inks. In response to this notification, the Commission has confirmed that it is starting work on a specific initiative on printed FCMs to address this issue at EU level.

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. However, trans-fatty acids are still present at levels of concern in certain foods and intakes are excessive for certain population groups. 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. An inception impact assessment has been published on TFAs and a supporting study is under preparation to complement the data for the impact assessment analysis. If the impact assessment confirms the report's findings, the Commission will launch an initiative in 2017 aiming to restrict the use of industrially produced TFAs in foods.

Food labelling

The Regulation on food information to consumers (1169/2011) 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 in 2017.

DG SANTE is working on a report on **alcohol labelling** concerning the application of the mandatory indication of the list of ingredients and of the nutrition declaration, from which alcohol is currently exempted, foreseen for publication in 2017.

Novel food

Implementing the new Regulation on Novel Foods (2015/2283) in the course of 2017 is a priority for DG SANTE. The new Regulation will improve the efficiency and transparency of the safety evaluation and authorisation procedure, and provide for faster and more proportionate safety assessment for traditional foods from non-EU countries which have a history of safe food use and promote innovation. Its success is monitored by **Result indicator 1.2.C** which measures DG SANTE's compliance rate with its legal obligation to complete delegated and implementing acts identified as a priority under the new Regulation on novel foods.

The new Regulation will be supported by seven implementing acts (four of them will be adopted by the end of 2017) describing the type of information that will be needed in the applications. This will ensure the swift processing of applications. The Regulation will also be supported by a delegated act updating and adjusting the definition of "engineered nanomaterials" to technical and scientific progress. These acts will be prepared in course of 2017 in order to ensure the full implementation of the new Regulation which will come into application on 1 January 2018.

Food and feed in the circular economy

DG SANTE will continue to implement **prevention of food waste** provisions of the the Action Plan on the Circular Economy package. Support to actions which aim to prevent food waste contributes to the sustainability of the food chain and brings both economic and environmental gains. In 2017, the EU Platform on Food Losses and Food Waste, which started its discussions in 2016, will focus on the preparation of methodology to measure food waste consistently across the EU and on the development of EU guidelines to facilitate the donation of safe, edible food.

DG SANTE is exploring actively the way to improve the use of date marking by actors in the food chain and its understanding by consumers. For this purpose, it has launched a study for which results will become available at the end of 2017. The publication of guidelines for the feed use of former foodstuff in 2017 will facilitate the use of food as feed instead of wasting it. Furthermore, the launch of a risk assessment concerning new materials from the agri-food sector to be used as feed will be a step to contribute to the circular economy while simultaneously guaranteeing animal and public health.

Market access for safe substances

DG SANTE will put forward a number of draft **authorisations** in 2017 for substances used in the production and processing of food and feed, based on requests from food business operators and on the scientific safety evaluations carried out by the European Food Safety Authority (EFSA) and the European Chemicals Agency (ECHA).

These 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 (20 substances added yearly to the list of permitted substances). In addition, over 100 authorisations for recycling processes of plastics used in food contact materials will be prepared with a view to be authorised in 2017.

New authorisations and the renewal of previously authorised active substances in plant protection products and biocides will be proposed based on the outcome of the safety evaluations (about 60 regulations per year approving about 50 new substances).

It is foreseen to modernise the authorisation IT systems that would allow applicants to save time, make more efficient use of Commission and Member States resources and provide the necessary transparency. It will also allow a better exchange of information with EFSA. Although it is unlikely that SANTE will reach the 2017 milestone of 80% rate of authorisations approved by the legal deadline for pesticides and food additives (**result indicator 1.2 B** of the SANTE's Strategic Plan 2016-2019), the current work on modernisation of authorisations IT system in collaboration with EFSA will contribute in the long term to improvements in this result indicator.

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. There are around 50 MRLs decided for different substances yearly.

DG SANTE will also propose the **withdrawal of certain substances** (flavourings, pesticides) to ensure the safety and quality of products circulating on the internal

market. In addition, 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. The measure is planned to be adopted in 2017.

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 food and feed and cultivation 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 2017 as foreseen in the cultivation Directive (EU) 2015/412.

DG SANTE will 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 emerging biotechnologies used in agri-food sector, DG SANTE will organise a conference in the course 2017 to promote public debate on the safe innovation in modern biotechnologies. This debate will be supported by the work of the Commission's Scientific Advice Mechanism (SAM).

Sustainable use of pesticides

In 2017, 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 and of alternative approaches or techniques such as non-chemical alternatives to pesticides.

A Commission report on the Member States implementation of the provisions of the Directive will be produced in September 2017, based on Member State feedback, a desk study and a number of fact finding visits to Member States.

In 2017, DG SANTE will also continue working together with the Member States on the execution of the implementation plan prepared by the Expert Group on Sustainable Plant Protection which was endorsed by the Agriculture and Fisheries Council in June 2016. The Plan identifies actions for increasing the availability of low-risk plant protection products and speeding up the application of integrated pest management in Member States.

Endocrine disruptors

On 15 June 2016 the Commission presented two draft legal acts, one on pesticides and one on biocides, establishing criteria for the hazard identification of endocrine disruptors. The decision-making process started and will continue in 2017 with meetings of the relevant regulatory committee and expert groups and subsequently the scrutiny period for the European Parliament and Council.

In parallel, the development of a guidance document for the implementation of the hazard identification criteria has been launched so that the criteria can be applied immediately when they enter into force. This work will be carried out by EFSA, ECHA and JRC. DG SANTE will closely monitor the process and ensure through an administrative arrangement that JRC has the adequate resources to contribute to this work.

Food hygiene

In 2017, 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 innovation and biological risks whilst remaining proportionate and maintaining a high level of food safety.This will include more flexible temperature conditions for the transport of meat, tests for certain marine toxins in shellfish, hygiene criterion for Campylobacter in slaughterhouses, authorisation to use insects as protein for fish and adaptations to the rules on specified risk material and export of processed ruminant proteins in light of new information on the epidemiological situation of BSE in Europe.

Animal welfare

Following repeated calls from several Member States, the European Parliament and stakeholders, the Commission began work in 2016 on an **EU Platform on animal welfare**. The Platform aims to increase stakeholder dialogue on animal welfare and improve the implementation and enforcement of existing legislation and exchange of information and best practices. In 2017 the Platform will be launched with the first meeting planned for the end of the Maltese Presidency (first half 2017).

DG SANTE must also designate an EU reference centres for animal welfare within one year of the entry into force of the new EU Regulation on official controls (foreseen in early 2017 - see section 1.6 below).

DG SANTE will also complete all remaining actions of the EU Animal Welfare Strategy 2012-2015 by the end of 2017, namely: best practices in protection of animals during transport, application of broilers Directive, impact of animal welfare international activities, EU guidelines on the protection of animals at the time of killing, transport and killing of farmed fish (study) and protection of fish at the time of killing (report).

Moreover DG SANTE will continue its international activities on animal welfare in particular with the World Organisation of Animal Health 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 on tail docking) and the transport of animals through audits, meetings and trainings.

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 chronic 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. Chronic disease prevention has been identified as a priority by both the EU and the World Health Organisation.

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 chronic disease and encourage best practice exchange. It also supports activities linked to reducing health inequalities.

In 2017, SANTE will focus on multiple priorities under this objective – the majority of which are funded under the Health Programme – including:

- **Chronic diseases**: supporting Member States to develop an integrated approach to chronic diseases focussing on implementation and scaling up of best practice in health promotion, prevention and management of chronic diseases. New Joint Actions with Member States on chronic diseases and frailty will begin and an EU best practice resource centre on chronic diseases will be set up.
- **Cancer**: preparatory work on updated guidelines for colorectal cancer screening will begin, a new Joint Action with Member States on cancer will be launched to strengthen population based national screening plans and work linked to Joint Action on rare cancers as well as a pilot initiative on breast cancer accreditation and updated guidelines for breast cancer screening will continue;
- **Rare diseases**: developing links between the new European Reference Networks (see section 1.5) and ongoing rare diseases activities like Orphanet and Rare Diseases Registration Platform, RD-ACTION;
- **Food reformulation and food marketing:** including setting food category benchmarks and supporting the definition and piloting of adequate national food composition systems, voluntary guidelines for the public procurement of food and initial work on a report assessing children's exposure to the marketing of foods high in fat, sugar or salt;
- **Transfats:** carrying out an impact assessment, followed by an initiative in 2017 (see section 1.2);
- Guidance on **mental health** in the workplace will be developed and a conference on mental health will be organised under the Compass Consortium; and
- Continued support to Member States to tackle harmful **alcohol consumption** and to promote **physical activity**.

By the end of 2017, the aim is to have integrated National Plans in place to address major chronic diseases in 19 Member States (SANTE Strategic Plan 2016-2020, **result indicator 1.3A**) and national initiatives on the reduction of saturated fat, salt, sugar and alcohol related harm in place in 26 EU countries (SANTE Strategic Plan, **result indicator 1.3.B**). These efforts will contribute to this objective.

At the same time, SANTE will strengthen its cooperation with the JRC to facilitate access to the latest independent scientific evidence on chronic conditions and further develop the registries on rare diseases. Our work will also be supported by expert groups on cancer control, rare diseases, mental health and dementia. Collaboration with stakeholders on EU health policy issues will continue in 2017 via the **EU Health Policy Forum.** Regular exchange will be supported through its dedicated web platform and the forum will meet at least once in 2017. It will also organise the 2017 EU health award.

DG SANTE continues to foster actions which tackle inequalities in health and address people at risk of poverty or social exclusion. Actions related to the health challenges of the current **migrants' influx will continue**, notably supported by Health Programme Projects and the new Joint Action on Health Inequalities which will be launched in 2017**.**

A Joint Action on the quality of prevention and linkage to care of **HIV/AIDS/sexually transmitted infections, viral hepatitis and tuberculosis** was formally launched in 2016 under the Health Programme. It will take up its work in 2017 to support the implementation of the Commission Communication on HIV/AIDS, as well as the recently adopted Communication for a sustainable European future. This reaffirms the Commission's support to help Member States to fight against HIV/AIDS, tuberculosis and hepatitis.

Reducing tobacco consumption

In this area, the main priority in 2017 is to ensure the adoption of three implementing acts on tracking and tracing under the EU's Tobacco Products Directive (2014/40/EU) can be adopted. Transposition checks will also be carried out in EU countries to ensure the Directive is effectively implemented and legal action launched where necessary. Other work linked to the Tobacco Products Directive will include managing and improving the electronic reporting tool for tobacco and e-cigarettes and establishing the procedure for determining whether tobacco products have a characterising flavour.

At international level, DG SANTE will work with OLAF, the EU's anti-fraud department, to encourage ratification of the World Health Organisation's (WHO) Framework Convention on Tobacco Control (FCTC) Illicit Trade Protocol.

A Joint Action on tobacco control financed by the Health Programme which was launched in 2016 will take up its work in 2017 to ensure effective implementation and application of the existing tobacco legislation. In particular, it will focus on the reporting of ingredients and the notification of e-cigarettes, including laboratory capacity, analysis and assessment.

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 first deliverables of the new two-year **'State of Health in the EU**' cycle.

The first cycle (2016-17) comprises a 'Health at a Glance: Europe report' (launched on 23 November 2016) and work will continue in 2017 with the launch of twenty-eight country health profiles and an accompanying Commission Staff Working Document (to be published in November 2017) and voluntary ex-post policy dialogues with the Member States (end of 2017).

In 2017 DG SANTE will continue to contribute to the European Semester Country Reports aiming at identifying challenges in the health systems of Member States, based on the processing of health indicators from our assessment tool and on the intelligence gathered through interaction with national authorities and stakeholders.

As part of the above, the Expert Panel on Health, bringing together expertise on health systems and public health, will continue in 2017 to provide the Commission with independent and multi-sectoral advice on effective ways of investing in health and contribute to the basic set of policy tools on which to base our input to the Commission's agenda on health systems.

The importance of strategic, growth-friendly investment in healthcare, as a way to implement necessary reforms in health systems and to improve outcomes and thus enhance competitiveness of the economy will be taken forward with the organisation of a workshop on "New forms of investment for new forms of care" in 2017, contributing directly to the implementation of the President Juncker's Investment Plan.

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.

Better control of AMR would contribute to a healthier population, sustainable health systems, healthier animals and sustainable agricultural systems and generate substantial efficiency gains for national economies and the EU as a whole. It has been estimated that, if not addressed, AMR could reduce global GDP by 0.5% by 2020 and by up to 3.5% by 2050.[5] The impact on growth is therefore highly significant.

The Council conclusions of June 2016 called for reinforced EU measures to combat AMR and called upon the Commission to develop a new and comprehensive EU Action Plan on AMR based on the One-Health approach. AMR issue is also high on the political agenda within G7, G20 and United Nations. On 21 September 2016, a political declaration was signed at the UN General Assembly, making a commitment to take a coordinated approach to address AMR across multiple sectors, especially human health, animal health and agriculture.

Building on the evaluation of the current Action Plan that expires in 2017, the recent Council conclusions and the UN General Assembly declaration, the Commission is going to propose in 2017 a **new Action Plan against AMR** which will promote swift and effective actions across the human, animal and environmental health sectors. The Action Plan will focus on three key areas where there is clear EU added value:

- to reinforce the one-health approach in Member States and make the EU a best practice region on AMR;
- to further develop research and innovation for new antimicrobials, alternative treatments (including vaccines) rapid diagnostic tests and new business models, as well as increase knowledge on the transmission mechanisms of AMR; and
- to further contribute to global efforts to tackle the threat of AMR in collaboration with international partners.

Given the importance of the **proposals on veterinary medicinal products** and on **medicated feed** in the fight against AMR, the Commission will do its utmost to reach an agreement on these files in 2017. A Joint Action on Antimicrobial Resistance and Healthcare-Associated Infection (2017-2020) – financed under the Health Programme – is expected to take up its work in spring 2017.

This work should contribute to an overall decline in EU consumption of antibiotics in humans which is an important interim milestone for 2017 from the SANTE Strategic Plan 2016-2020 (**result indicator 1.4.B**).

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[5] Review on Antimicrobial Resistance. Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations. December 2014, https://amr-review.org/Publications

SANTE's work in this area is supported by EFSA, ECDC and EMA to ensure the most comprehensive advice is available to support our regulatory and policy activities. EFSA is responsible for collecting, analysing and reporting data on AMR in bacteria from food and food-producing animals. ECDC plays an important role in surveillance and reporting on key indicators for antimicrobial consumption and resistant infections in humans.

EMA increases availability of new antimicrobials and alternatives by granting marketing authorisation for new antimicrobials, supporting the prudent use of 'old' antimicrobials and by providing scientific opinions on AMR issues. SANTE follow-up to EMA opinions can include further discussions with Member States and/or stakeholders, provision of informed inputs to various regulatory developments, and adoption of legal acts.

Innovative health technologies

eHealth can improve integration of care and help deliver targeted, personalised and efficient healthcare, reducing errors and length of hospitalisation. Member State cooperation in eHealth can bring significant added value to national health systems. DG SANTE's contribution to the Digital Single Market Strategy aims to foster the standardisation and interoperability of eHealth solutions through three actions targeting:

1) portability of electronic health data from one EU Member State to another

2) deployment of telemedicine within the European Reference Networks (ERNs – see section 1.5);

3) Patients' electronic access to their health data.

On (1), the eHealth Digital Service Infrastructure (DSI), a network of national contact points for eHealth for the exchange of patient summaries and e-prescriptions will start in 2017 with a view to being expanded over the next four years. The planned number of countries with the capacity for health data exchange and participating in cross-border eHealth information services (eight) will be met in 2017 (**result indicator 1.4.A** in SANTE's Strategic Plan 2016-2020). On (2) SANTE will complete a study on regulatory aspects of cross-border telemedicine in 2017 and on (3) it will support Member States' work to develop a report and recommendations on patient access to their digital health data, which should be adopted by the eHealth Network in May 2018.

The preparations for the third Joint Action to support the eHealth network, funded by the Health Programme, will start in 2017.

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

The transposition of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare continues to be monitored and followed up with appropriate action to ensure its uniform implementation. In 2017, studies on cooperation in regional cross-border care and better information to patients and healthcare providers will support the work of National Contact Points and improved cooperation.

Blood, tissues and cells

An evaluation of the legal framework for tissues & cells and blood will be launched in 2017 and is expected to be finalised in 2018.

From April 2017, over 2000 tissue establishments will implement a new common traceability system for tissues and cells, financed by the Health Programme and supported by a dedicated Commission platform.

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 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 provide important economies of scale and allow a more efficient use of increasingly stretched EU healthcare resources.

2017 is a crucial year for the ERN process. The first designated networks will start their clinical and other work supported by an annual grant from the Health Programme and their operation will be launched at the Kick-Off Workshop and Conference, 9-10 March 2017 in Vilnius. A virtual patient management IT platform will also be put in place to enable networks to exchange clinical data safely and effectively. Over the course of 2017, the Board of Member States and the Networks will create efficient administrative and clinical cooperation practices.

The success of ERNs depends on strong coordination and support from DG SANTE. DG SANTE will provide the Networks an IT platform for clinical care (telemedicine), organise technical workshops, arrange training and capacity building, and support their networking. 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'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 and some areas of human health. These audits – which take place in EU countries and non-EU countries exporting to the EU - are essential to ensure our high standards and safety levels are not compromised and that the industry can operate on a level playing field.

These results contribute to evidence-based policy development, better regulation and a regulatory environment which facilitates jobs, growth and investment.

In 2017, **205 audits** are planned in Member States, EU candidate countries and non-EU countries covering food safety, animal health, animal welfare and plant health. 25 joint assessments are planned with designating authorities from Member States, EFTA and EEA countries to assess the performance and designation of Notified Bodies in the medical devices sector.

DG SANTE aims to have 70% of its audit recommendations (from the reporting cycle 2012-2014) satisfactorily addressed by Member States with corrective action in 2017 (**result indicator 1.6.A,** SANTE's Strategic Plan 2016-2020). This depends heavily on the willingness and vigour of Member States authorities.

In 2017, SANTE plans to adopt the Report on the operation of official controls in EU Member States on food safety, animal health and animal welfare, and plant health. 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 controls carried out by the Commission.

Modernising and simplifying EU legislation

Following political agreement in 2016, the revision of the **Official Control Regulation** is expected to be adopted in early 2017. The new Regulation creates a single framework for all official controls along the entire agri-food chain, including plant health and animal by-products. It aims to modernise, harmonise, simplify and clarify the system of official controls, strengthen enforcement tools, improve efficiency of controls, tackle food fraud and improve transparency on official controls and their financing. It applies the risk based approach to all areas of the food chain and allows a more harmonised and coherent approach to official controls and resulting enforcement action.

Preparatory work will start in 2017 to draft the delegated and implementing acts under the new Official Control Regulation. The first acts to be prepared concern the establishment and designation of animal welfare reference centres (see section 1.2) and specific EU reference laboratories in view of their entry into force in 2018.

Use of digital technologies to strengthen official controls

eCommerce for food products is rapidly increasing in most Member States. The food and feed chain should make a better use of digital means to re-inforce food safety and develop its economic efficiency. Therefore DG SANTE plans to contribute to the **Digital Single Market Strategy** and the eGovernment action plan through actions which aim to achieve digitalised and integrated food chain and boost consumer's confidence in eCommerce by better controls. A particular effort will occur in 2017 to streamline and digitalise the official control processes.

The revision of the Official Control Regulation foresees an **Integrated Management System for Official Control (IMSOC)**. This concept will allow current EU-managed IT systems to be integrated. The preparatory work will start in 2017.

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.

Financial contribution to official controls' related activities

All activities planned for 2017 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 (see below) and the European Reference Laboratories which coordinate the work of the national laboratories.

The **European Reference Laboratories** will continue to contribute to better implementation of EU legislation in the agri-food chain by supporting the Commission and national reference laboratories in their efforts to provide state of the art analytical and diagnostic services to national competent authorities and

enforcers. Funding for 43 EU reference laboratories is planned in 2017 to maintain the efficiency of the network, capitalise on existing knowledge, and maintain the same high level of food safety in the EU. The budget for the EURLs for 2017 is EUR 16.5 million.

The **Better Training for Safer Food programme (BTSF)** will play a key role in improving the efficiency and reliability of official controls in 2017. It is managed by CHAFEA. 170 training courses on EU legislation are planned in 2017 for Member State staff responsible for official controls along the food chain. It will also focus on developing e-learning modules which will significantly increase the number of trainees. The audits and related control activities of the Commission in both Member States and non-EU countries exporting to the EU, aim to verify that national controls are carried out in accordance with EU legislation and that they are effective (reimbursement for 125 national experts to go on audits is planned for 2017). The budget for BTSF for 2017 is EUR 16.5 million.

1.7. Specific objective 1.7: 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, the World Organisation for Animal Health (OIE), the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT), and the International Plant Protection Convention (IPPC) to ensure its standards are recognised, accepted and promoted at bilateral and multilateral level. This contributes to high levels of health protection and boosts growth and employment opportunities in the EU's food and pharmaceutical sectors.

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.

DG SANTE will contribute to the relevant goals and targets of the Sustainable Development Goals as part of the Commission wide exercise.

Health

DG SANTE and the EU Delegation in Geneva will continue their efforts to facilitate coordinated EU inputs and positions on topics discussed in WHO Governing Bodies as set by the 2017 milestones of the **result indicator 1.7A** from the SANTE Strategic Plan 2016-2020 (coordinated EU inputs reflected in: 90% of WHO Executive Board's resolutions negotiated, 75% World Health Assembly's resolutions negotiated and 70% WHO Regional Committee for Europe's resolutions negotiated). These coordinated EU inputs 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 will also cooperate with WHO in the framework of existing administrative arrangements. Moreover, DG SANTE will work with OLAF to encourage ratification of the WHO's Framework Convention on Tobacco Control (FCTC) Illicit Trade Protocol.

DG SANTE will also reinforce its cooperation with the Organisation for Economic Co-operation and Development (OECD) in the framework of the new cooperation arrangement from 2016. In recent years the G7 and G20 have also taken up global health challenges and this is expected to continue in 2017. Key priorities for multilateral work remain AMR, health security, tobacco control and

pharmaceuticals. SANTE will continue to work with enlargement and neighbourhood countries on health 'acquis' and policy.

In February 2017, the Commission will host the Ministerial Meeting of the Global Health Security Initiative (GHSI) organised by DG SANTE. This will provide an opportunity to emphasise the role the EU plays in global health security and public health crisis management and to influence future priorities for the initiative.

In order to contribute towards global efforts to tackle the threat of AMR in collaboration with international partners (see section 1.4) and help achieve objectives of the WHO Global Action Plan on AMR, DG SANTE will organise, under a 'One-Health' approach, a conference on this topic partnering with countries of the South American region (Argentina, Brazil, Chile, Colombia, Paraguay, Peru and Uruguay). The event is organised in collaboration with the EU Delegation in Brasilia and is planned for spring 2017.

Pharmaceuticals

The EU is a global leader in the pharmaceutical industry and the world's major trader in medicinal and pharmaceutical products - amounting to over EUR 170 billion in 2013.

In 2017, 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. The ICH reform will facilitate an increased membership and introduction of membership fees for all members and ensure the necessary transfer of all ICH activities to the new legal entity. **Result indicator 1.7.B** of SANTE's Strategic Plan 2016-2020 monitors the recognition of ICH guidelines at global level and global harmonisation, including with the US.

Animal health, plant health and food safety

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) and the other international standard seting bodies World Animal Health (OIE), International Plant Protection Committee (IPPC) and Codex Alimentarius. The 2017 milestone of "no more than seven WTO cases brought against the EU" (SANTE Strategic Plan 2016-2020, **result indicator 1.7.C)** also depends on the number of WTO members bringing cases against the EU.

SANTE will attend three meetings of the WTO SPS Committee in 2017 to promote and defend EU interests in the field of sanitary and phytosanitary measures. SANTE will follow up the appeal lodged by Russia in the dispute settlement case opened by the EU against the unjustified measures of Russia on African swine fever with a view to having the conclusions of the WTO in August 2016 reinforced in the EU's favour. SANTE will also follow other dispute settlement cases, including the recent ruling on poultry in a case lodged by China against the EU.

In the OIE, DG SANTE defends the EU's high animal health and welfare standards to influence the international standards. In 2017, 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 in May.

In 2017, we will continue to coordinate EU positions in 13 Codex committees and working groups to ensure there is alignment between EU legislation and Codex standards. A new taskforce on Antimicrobial resistance will convene in late 2017 to revise AMR guidelines.

In 2017, we 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. A new Taskforce on Antimicrobial Resistance will convene in late 2017 to revise the Codex Code of Practice to Minimise and Contain Antimicrobial Resistance and to develop new "Guidelines on Integrates Surveillance of Antimicrobial Resistance".

In IPPC, there is a strong EU input, coordinated by SANTE on global plant health strategy and the development of international standards for phytosanitary measures. In 2017, 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 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 Organisation for Economic Co-operation and Development (OECD), 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 2017, SANTE will continue to work towards international harmonisation in this area.

Improving bilateral trade relations

Bilateral trade negotiations are directly linked to multiple Commission priorities, in particular priority 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 2017 are to negotiate safe, secure and harmonised export conditions for EU products with non-EU countries and to manage, monitor and implement existing agreements.

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

DG SANTE's work makes an important contribution to EU internal market priorities by ensuring trade can take place freely – in particular in food and pharmaceutical products –and that innovation is encouraged.

Food and feed safety is ensured in the EU by adoption and implementation of a wide range of harmonised rules (e.g. the recently adopted Regulations on official controls, plant health, animal health and novel foods), as well as by EU authorisations for e.g. food/feed additives, plant protection products or GMOs. 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 EU's decentralised agencies make an important contribution to SANTE's internal market priorities, feeding into its policy making process, ensuring that trade in food and pharmaceutical products can take place freely and that innovation is encouraged.

EMA plays a key role – it supports 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.

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). An external evaluation of EFSA will be launched in 2017 to assess its working practices and impacts. The evaluation report by the external contractor is expected to 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, pharmaceutical product, medical device or health intervention in a systematic and unbiased manner to inform decision makers on its safe and effective use. It is an important tool to achieve best outcome and value for money 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.

In 2017, the Commission will put forward a new initiative on HTA targeting better and more structured cooperation between Member States and a more coherent approach. It should help ensure that EU cooperation on HTA built over the last 20 years is sustained and transformed into a permanent mechanism. It responds to calls in the EU's Single Market Strategy and the 2016 Commission Work Programme to improve the internal market for health products, as well as requests from Member States and the European Parliament.

In parallel, DG SANTE will continue to support, via the Health Programme, the work of the HTA Network and activities foreseen in the HTA Network Multiannual Work Programme 2016-2020. It will also monitor, in collaboration with CHAFEA, the

activities of EUnetHTA Joint Action 3. This will ensure synergy and complementarity between the work of the HTA Network and EUnetHTA. During the course of 2017 the EUnetHTA Joint Action is expected to perform joint assessments whilst also starting to ensure the implementation and uptake of joint work.

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 2014, the EU sector was worth EUR 220 billion and employed about 885,000 people.

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

In 2017, as part of its reporting obligation under Regulation 726/2004 and Directive 2001/83, the Commission will procure a study of centralised and decentralised procedures for pharmaceutical products. The study will provide important evidence and potential recommendations for improving and amending centralised and decentralised procedures for authorisation of medicinal products in the EU with a view to a Commission report in 2019.

At the same time, DG SANTE will continue its work related to the authorisation of medicinal products, improvement of the regulatory environment for advanced therapy medicinal products in close associatiation with EMA, including guidance on good manufacturing practice, and particular aspects of the regulatory framework for orphan medicines. This continuous work will contribute to achieving stable legal environment and optimal use of current authorisation procedures for a competitive pharmaceutical sector and patients' access to safe medicines.

In 2017, DG SANTE will continue to work with EMA to meet 90% target for the authorisation of new medicines within the legal deadlines (**result indicator 2.2** from the SANTE Strategic Plan 2016-2002).

Improving access to medicines

Patient access to affordable medicines and the balance between pharmaceutical innovation and sustainability of health systems in the EU is one of the DG SANTE's priorities, especially in the light of the June 2016 Council conclusions on the pharmaceutical system and the European Parliament's own initiative report on "EU options for improving access to medicines".

DG SANTE is working on several deliverables in 2017 to address the issues raised in the Council conclusions: study and report on the Paediatric Regulation; and together with GROW, study analysing the impact of Supplementary Protection Certificates and pharmaceutical incentives and rewards – such as data and market protection, market exclusivity for orphan medicinal products, and paediatric rewards – on innovation, accessibility and availability of medicinal products.

In parallel the Expert Group on Safe and Timely Access to Medicines for Patients (STAMP) will continue to work towards optimal use of existing regulatory tools to give earlier access to innovative medicines (e.g. conditional marketing

authorisation) and improve the application of other aspects of the regulatory framework.

In 2017, improvement and coordination will be further explored in repurposing (development of new indications) of off-patent medicines, compassionate use programmes and off-label use of medicines and better links and synergies will be built between expert groups.

DG SANTE will also continue to work with RTD and GROW on research and EMA on schemes intended to optimise the development and assessment of medicines that fulfil unmet medical needs (e.g. PRIME – PRIority MEdicines and the adaptive pathways concept).

Legislation on fees of the European Medicines Agency

DG SANTE will carry out a study to support the evaluation of the legislation governing the fees charged by EMA. The evaluation is expected to be finalised in 2018.

Implementation of the pharmaceutical legislation on clinical trials and falsified medicine

In 2017 DG SANTE will work on implementing the falsified medicines Directive, including assessing the equivalence of the good manufacturing practice rules of non-EU countries for active pharmaceutical ingredients (within the Health Programme 2017), setting up the medicines authentication system which will become operational in 2019, preparing the Commission implementing Directive on good manufacturing practices for medicinal products for human use and drafting a report on penalties.

SANTE will also continue the necessary preparatory work for applying the new Regulation on clinical trials, in particular establishing the clinical trial portal and the creation/revision of several guidelines. It is envisaged that EMA will carry out a first verification/testing of the new IT portal in summer 2017.

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 is expected to finalise a report on integrated care in February 2017 and work on primary care in the course of 2017. It is expected that Member States will refer to the recommendations provided by the expert group to the extent they represent added value in national policy-making (the 2017 milestone set by the **result indicator 2.3A** from the SANTE Strategic Plan 2016-2020 is five Member States referring in the national policy documents to recommendations/findings of expert group on HSPA).

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 assessment systems.

3. General objective 3: A reasonable and balanced Free Trade Agreement with the U.S.

A balanced free trade agreement with the United States (US) should result in better access to the US market and more trade possibilities for food and pharmaceutical products without compromising the EU's high safety standards.

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.

3.1. Specific objective 3.1: A balanced agreement with the US on pharmaceutical products and in SPS area

Output table is included in Annex 1.

Health

A free trade agreement with the US and the **mutual recognition of good manufacturing practices** (GMP) inspections for pharmaceuticals would allow the EU and the US to rely on each other's GMP inspections and exchange confidential information on inspection reports. This would entail significant cost savings for industry and avoid the current overlap in inspections between EU, US and non-EU countries. It would also promote more efficient use of inspection resources and global adoption of high quality medicinal products as well as reduce risk.

In 2017, DG SANTE will work towards implementing the EU/US mutual recognition agreement by following up the recognition of EU authorities considered equivalent by the US.

Animal health and food safety

A decrease in the number of trade "irritants" on the US side is one of the EU's main aims under the Transatlantic Trade and Investment Partnership (TTIP) negotiations. 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 goatmeat, pasteurised dairy products, egg products, apples and pears. DG SANTE will remain committed in 2017 to tackling these barriers.

A strong, ambitious Sanitary and Phytosanitary (SPS) Chapter within the TTIP negotiations is very much in the EU interests. Progress in 2017 is uncertain, primarily due to the change in US administration in January.

To reduce the number of trade barriers that are not in line with international standards (SANTE Strategic Plan 2016-2020, **result indicator 3.1.B**), the Commission is negotiating with the US administration to achieve SPS import conditions compatible with international standards that will allow EU products to have access to the US market. This negotiation runs in parallel to the negotiation of the TTIP SPS Chapter and is carried out in two working groups EU-US working groups: one on animal health and other on plant health. This requires intensive work with Member States.

The significant work done on plant health has allowed an action plan to be concluded for apples and pears. It raised reasonable expectations that the 2017 milestone set by **result indicator 3.1.A** in SANTE's Strategic Plan 2016-2020 could be achieved (the "Number of Member States which are authorised for export of beef, sheep/goatmeat, Grade A (pasteurised) dairy products, eggs, apples and pears"). However, the reluctance of US administration to meet the animal health

working group has limited our expectations for animal products. The change in the US administration could limit this further.

PART 2. MAIN ORGANISATIONAL MANAGEMENT OUTPUTS FOR THE YEAR

A. Human resource management

The local HR function will undergo an in-depth overhaul in 2017 as part of the Commission Communication on Synergies and Efficiencies of April 2016. HR services will be delivered by an Account Management Centre (AMC) inside DG HR. Each DG will have an HR Business Correspondent (BC), responsible for defining HR strategy and taking HR decisions, in consultation with the management of the DG, as well as ensuring that the DG gets the HR service it needs, in cooperation with the AMC. DG SANTE's BC team will have a staffing of maximum four. DG SANTE will be supported by AMC2 which will serve the following group of DGs: AGRI, EAC, ENER, MARE, MOVE and RTD. This change will need important initial investment to ensure basic HR functions and services can continue to be delivered.

DG SANTE will participate from January 2017 in the pilot project. This implies an important initial investment to ensure basic HR functions and services can continue to be delivered. It is expected that at least during the first six months of the year there will be little room for HR activities other than those which are critical such as appraisal, promotion, staff selection. The aim will be to minimise negative impacts on the HR services delivered to DG SANTE staff.

Despite the above challenges SANTE's major organisational development initiative 'Towards Excellent SANTE' launched in 2016 will be continued. In particular the 360° senior management feedback exercise launched towards the end of 2016 will deliver its results in 2017 and will provide a better basis for senior management to assess and address the issues identified in past staff surveys, and especially the 2016 survey, related to their management skills and behaviours. The experience of running this project will also feed later in 2017 into a similar exercise for middle management which should help them to develop into better, more effective leaders. SANTE currently scores above the Commission average on staff engagement.

As regards the issue of ensuring sufficient inclusion of female managers which is one of the important goals of the Commission talent management and equal opportunities initiative, DG SANTE will continue in 2017 to make further progress towards reaching the targets set for the DG. Female middle management representation has not changed since November 2014 in spite of a reduction of 7 units. The important efforts made in 2016 (80% of middle-manager appointees since November 2014 are female) have brought the DG closer to these targets.

DG SANTE will also engage into more targeted action under the umbrella of the 'Culture and Engagement' pillar of its 'Towards excellent SANTE' programme. The aim is to work on improving assertiveness of colleagues, helping them to find ways to take a more active role in improving their working conditions and environment and thus less reliyiantg on the work of others (the organisation, management, colleagues). In addition, the programme on prioritisation and simplification will continue with the optimisation of a number of heavy and complicated workflows. In line with this "Focus on staff members" approach work is engaged with the European School of Administration to roll out a series of 'Pillars of Mental Wellbeing' events.

Finally the creation of a dedicated wellbeing room by the end of 2016 in SANTE's Brussels buildings will be an important asset for above initiatives but will also allow the setting up of dedicated SANTE Fit@work activities in Brussels. In addition, series of awareness raising events will take place in DG SANTE to ensure that SANTE staff avails of the in-house expertise on health determinants.

B. Financial Management: Internal control and risk management

Output tables are included in Annex 1.

In the 2015 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 2017 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) to obtain 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) to timely implement audit recommendations from Internal Audit Service (IAS) and European Court of Auditors (ECA);

(iii) to reach a conclusion on the cost effectiveness of controls in the 2017 AAR.

(iv) to update the risk based control strategy and the anti-fraud strategy of the DG in 2017.

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 strengthen 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 expected to start in 2017 to prepare the adoption of tertiary legislation to implement recently negotiated Regulation 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 to enable a change of culture ensuring 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, our objective is that information and knowledge in DG SANTE is shared and reusable by other DGs and that important documents are registered, filed and retrievable.

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. As current experience has shown 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 eGovernment policy has been to work open and digital toward full e-government. For some systems, DG SANTE has reached the highest level of eGovernment maturity level, namely Transformed Government, with fully automated activities, full electronic case handling and electronic signatures for the processes implemented for interaction with Member States, business and citizens. The policy 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 us, but the target is reached sometime after the documents have been registered and not when DIGIT makes the statistics.

The target (2020) for indicator 2 and 3 is lower than the baseline. This is expected because, as of 2016, a percentage of files will not be publicly accessible – it is this percentage that makes the target to appear lower.

E. External communication activities

Output tables are included in Annex 1.

DG SANTE communication activities for 2017 will contribute to the Commission political priorities, the general and specific objectives of DG SANTE in the Strategic Plan and the Commission work programme for next year. Communication will focus on the main key policy deliverables and will have a direct impact on the Institution's credibility, in particular in areas such as antimicrobial resistance (AMR), with a clear economic impact; the country-specific and cross-country knowledge that the *State of Health in the EU* cycle will bring and as requested in the mission letter and as a support for national policies; or the European Reference Networks, a collaboration model between healthcare providers across the EU that will have a direct impact on the life of citizens with rare diseases (30 000 million in Europe). Our communication will also stress the importance and economic relevance of a strong and efficient EU preparedness, prevention and response to crises in the health and food sector. It will also contribute to corporate

communication, notably by underlining the importance of health investments for Growth and Jobs or the contribution to refugees' and migrants' health.

DG SANTE communication will also contribute to manage the Commission's reputational risks by monitoring traditional and social media and preparing solid press material in sensitive areas which are of direct concern for public opinion in the health and food safety areas. To integrate upstream the policy making process and communication priorities following closely the political agenda, a separate detailed communication work plan for 2017 is prepared. For each priority, communication plans are developed, implemented, monitored and evaluated in close coordination with policy units.

In 2017, communication activities will focus on the following areas:

a) The new EU Action Plan to combat Antimicrobial Resistance and the subsequent discussions in Council and the Parliament as well as with stakeholders. Communication will include a media seminar, one animated clip as well as press material, social media, web and graphic material around the main AMR events such as the European Antibiotic Awareness Day.

b) Publication of the first series of Health Country profiles within the first complete "*State of Health in the EU*" cycle, which will deliver 28 country health profiles and a Commission Staff Working Document. The initiative, carried out in close partnership with the OECD and the European Observatory on Health Systems, will provide country-specific and cross-country knowledge which supports effective, accessible and resilient health system policies at national and European level. Communication will give visibility to and promote the use of the deliverables of the cycle among Member State authorities and other stakeholders.

c) Launch of the European Reference Networks (ERN): Around 1,000 health care providers and researchers will join forces in the first 24 ERN for rare diseases to deliver faster, better and more innovative treatment. The initiative is a successful example of how EU legislation (the 2011 Directive on cross-border healthcare) responds to the needs of patients and stakeholders and leads to concrete added value, especially in areas with scarce and scattered knowledge and expertise such as rare diseases. Communication in 2017 will focus on informing and involving the medical community and on raising media attention.

d) Food Waste: a key contribution to the Circular Economy Package in an area of big public concern. Communication activities will give visibility to the Food Waste Platform, the study on date marketing, the adoption of food donation guidelines and our input to the Waste Framework Directive.

e) Strengthening of the EU cooperation on Health Technology Assessment (HTA), foreseen in the Commission's Work Programme for 2017, is a topic which raises a lot of attention (and often expectations) among stakeholders and partners from public authorities, NGOs and industry. In 2017 the focus will be on analysing the policy options (following the public consultation which will run until mid-January 2017) and developing an initiative (to be ready by the end of the year).

An important part of DG SANTE communication activities seek strengthening the Commission's capacity to react in crisis, both in the health and food safety areas. This involves a careful monitoring and excellent planning in cooperation with agencies such as the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC) or the European Medicines Agency (EMA).

In 2017, a number of SANTE files (in particular those related to pesticides, endocrine disruptors or GMO) will require specific proactive and/or reactive monitoring and actions, given their newsworthiness and media coverage, as well as their constant follow-up by stakeholders and NGOs, including in social media. These

activities are not described below as they cover subjects that go beyond the political priorities and are often led by other actors including media.

DG SANTE will also contribute to several Commissions' corporate communication campaigns in 2017-2018 as on the central theme of the "Investment Plan for Europe: health sector delivering pioneering projects" by contributing to the ambition of making the Plan and the (extended) European Fund for Strategic Investment (EFSI) better known among stakeholders and the wider public. The communication on EU actions related to refugees' and migrants' health linked with the refugee crisis will also be a priority. Following the State of the Union speech by the President in October 2016, new Commission-wide actions may be developed. Communication strategies for these actions will be developed by DG COMM and, where relevant and appropriate, DG SANTE will take up an active role in the thematic communication teams

In addition to the communication actions referred to above, and regarding the communication infrastructure, the rationalisation of the SANTE website in the framework of the Digital Transformation programme will continue. SANTE web content will be further optimised according to the user test data and gradually integrated within a common Commission structure. DG SANTE will continue to use our social media accounts (@EU_Health and @Food_EU) strategically to give visibility to the political priorities and to the Commissioner's role, including through cooperation with strategic partners and stakeholders and, where appropriate, with social media buying.

Tables (3A – 3G) with the presentation of main outputs are included in Annex 1.

External communication overall spending

Annual communication spending:	
Baseline (2016)	Estimated commitments (2017)
EUR 2 543 000	EUR 2 402 092

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

1) In the framework of its stakeholder relations, DG SANTE is planning to use IT solutions for better organising meetings. The aim is to manage the entire process from planning a meeting to inviting and reimbursing experts in one single electronic tool. The IT tool AGM is currently developed by DG EMPL, with a number of pilot DGs, and preparations to integrate DG SANTE are envisaged to start early next year. As soon as DG DIGIT has taken over as System Supplier, the IT tool will be become fully operational. This is expected to reduce DG SANTE's administrative burden considerably especially by significantly reducing the number of manual interventions and avoiding double encodings.

   DG SANTE foresees to use existing IT applications to realise efficiency gains in its procurement procedures. As a first step, DG SANTE subscribed to the e-submission module of DG DIGIT which reduces the administrative burden especially in the opening procedure (no manual interventions, automatic registering and reporting, paperless filing and archiving). In order to be in line with the e-submission requirements, DG SANTE is putting in place the required security aspects, is adapting its procurement documents, and is following dedicated training courses to become fully operational in early 2017.

ANNEXES TO THE MANAGEMENT PLAN

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 programme(s) - 3rd EU Health Programme - CFF for the Food Chain 2014-2020	
Main outputs in 2017:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Human diseases		
Long term impact and sustainability of the Health Programmes	*Impact study launched*	*Q3/2017*
Two studies related to vaccination (on the added-value of the strategic and life-course approach to vaccination & a study on shortcomings related to low vaccination coverage in health care workers)	*Final reports with recommendations*	*December 2017*
Joint Action on vaccination	*Launch of the Joint Action*	*Q2 2017*
Joint Action on preparedness and action at points of entry (air, maritime and ground crossing	*Launch of the Joint Action*	*Q2 2017*
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*	*14*
Swine diseases	*No. of programmes which received co-financing*	*13*
Avian influenza	*No. of programmes which received co-financing*	*25*
Transmissible Spongiform Encephalopathies (TSE), Bovine spongiform encephalopathy (BSE) and	*No. of programmes which received co-financing*	*27*

scrapie		
Rabies	*No. of programmes which received co-financing*	*13*
National survey programmes for organisms harmful to plants	*No. of programmes which received co-financing*	*24*
Emergency measures	*Adoption*	*Throughout the year*
Other		
Commission Report to the European Parliament and the Council on mid-term evaluation of the Common Financial Framework (CFF) 2014-2020 (2015/SANTE/462)(CFF also contributes to objectives 1.2 and 1.6)	*Adoption*	*Q2 2017*
Commission Report to the European Parliament and the Councilon mid-term evaluation of the Health Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020 (2015/SANTE/680) (Health Programme also contributes to specific objectives: 1.3, 1.4, 1.5, 1.6, 2.1, 2.2, 2.3)	*Adoption*	*Q2 2017*
Public procurement on purchase and supply of foot-and-mouth disease (FMD) antigens and lumpy skin disease (LSD) vaccine to the Union bank	*FMD antigens and LSD vaccine doses purchased and supplied to the Union bank*	*2017*
Other important outputs		
Output	Indicator	Target
Human diseases		
Commission implementing Decision with regard to procedures for the functioning of the early warning and response system for notifying alerts, and for the information exchange, consultation and coordination of response under Decision 1082/2013/EU on serious cross-border health threats (2015/SANTE/172)	*Adoption*	*Q1 2017*
Commission implementing Decision to adapt the list of communicable diseases under surveillance and to amend case definitions for diseases under Decision 1082/2013/EU (2015/SANTE/021)	*Adoption*	*Q4 2017*
Animal diseases		
Commission decisions on handling evolving epidemiological situations	*Adoption of emergency Decisions as necessary, according to the epidemiological situation*	*In course of 2017*
Commission rules on safe imports, trade and related aspects	*Adoption of Commission implementing rules.*	*In course of 2017*
Commission implementing Decision for updating the current Decision 2014/709/EU that relates to the regionalisation for African swine fever (PLAN/2016/68)	*Adoption*	*Q1 2017*

Safeguard measure on Chronic Wasting Disease in Norway (2016/SANTE/163)	*Adoption*	*Q3 2017*
***Implementation of the Animal Breeding Regulation**:* *1) implementing Regulation laying down model forms for the zootechnical certificates (2016/SANTE/205)* *2) implementing Regulation laying down the model forms for the presentation by Member States to the public of the information to be included in the list of recognised breed societies and breeding operations (2016/SANTE/206)* *3) implementing Regulation on the designation of the EU reference centre contributing to the harmonisation or improvement of the methods of performance testing and genetic evaluation of purebred breeding animals of the bovine species (2016/SANTE/207)* *4) delegated Regulation as regards the content and format of zootechnical certificates issued for purebred breeding animals of the equine species contained in a single lifetime identification document for equidae (2016/SANTE/250)*	*Adoption*	*1) Q2 2017* *2) Q2 2017* *3) Q2 2017* *4) Q2 2017*
Plant diseases		
Commission Decisions on emergency measures against some specific pests	*Adoption of Decisions as necessary according to (new) outbreak situations*	*In course of 2017*
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 2017*
Commission decisions on derogations for import from non-EU countries	*Adoption*	*In the course of 2017*
Commission implementing Directive updating the Annexes of the Council Directive 2000/29/EC on protective measures against harmful organisms (2015/SANTE/153)	*Adoption*	*Q2 2017*

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(s) CFF for the Food Chain 2014-2020
Main outputs in 2017:	
All new initiatives and REFIT initiatives from the Commission Work Programme	

Output	Indicator	Target
Commission Regulation on plant protection products to specify criteria to identify endocrine disruptors (2015/SANTE/001) Reference in the text of CWP 2016	*Adoption*	*Q1 2017*
Commission delegated Regulation on endocrine disruptors (biocides) (2016/SANTE/045) Reference in the text of CWP 2016	*Adoption*	*Q1 2017*
Commission Regulation establishing a legal limit for the industrial trans fats content in foods (2016/SANTE/143) Reference in the text of CWP 2016	*Adoption*	*Q3 2017*
Fitness check of General Food Law, Regulation EC 178/2002 (2015/SANTE/427) Annex II of the CWP 2016	*Publication of the SWD*	*Q2 2017*
Study supporting REFIT evaluation of Nutrition Health Claims Regulation (2015/SANTE/595) Annex II of the CWP 2016	*Study to be completed*	*Q2 2017*
Study supporting REFIT evaluation of plant protection products and maximum residue levels legislation (2016/SANTE/197) Annex II of the CWP 2016	*Start of the study*	*Q2 2017*
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Control programmes on Salmonella	*No. of programmes which received co-financing*	*24*
Study to support the preparation of delegated Regulation on processed-cereal based food and baby food	*Completion*	*Q4 2017*
EU Platform on Animal Welfare (PLAN/2016/12)	*Adoption of the Commission Decision*	*Q1 2017*
Food labelling database	*Completion of the database*	*Q4 2017*
Operational support services for the EU Platform on Food Losses and Food Waste	*Establishment of digital platform and user activity*	*Q4 2017*
Innovation in food processing technologies	*Start of the work on a Portal for e-authorisations*	*Q4 2017*
Conference on Modern Biotechnologies and Innovation in Sustainable Agriculture	*Completion*	*Q3 2017*
Study on date marking	*Completion*	*Q4 2017*
Other important outputs		
Output	Indicator	Target
Plant protection products and biocides		
Renewal/non-renewal of active substances for plant protection products	*Adoption*	*Ongoing regular activity in 2017*
Commission Report to Parliament and	*Adoption*	*Q3 2017*

Council on the Directive on sustainable use of pesticides (2015/SANTE/024)		
Guidance Document on the risk assessment of plant protection products on bees (2016/SANTE/036)	*Adoption*	*Q2 2017*
Commission Regulation on uniform principles for evaluation and authorisation of plant protection products (2016/SANTE/039)	*Adoption*	*Q2 2017*
Commission Implementing Regulation renewing approval of active substance glyphosate for use in plant protection products (2016/SANTE/007)	*Adoption*	*Q4 2017*
Establishing maximum residues levels (MRL) for pesticides	*Adoption*	*Ongoing regular activity in 2017*
Establishing list of non-acceptable co-formulants in plant protection products	*Adoption*	*In course of 2017*
Commission implementing Regulations renewing the approval of biocidal active substances	*Adoption*	*Ongoing regular activity in 2017*
Commission implementing Regulations for approval or non-approval of biocidal active substances included in the review programme	*Adoption*	*Ongoing regular activity in 2017*
GMOs		
Commission Directive aiming to update of the Environmental Risk Assessment requirements in Directive 2001/18 concerning GMO (2015/SANTE/428)	*Adoption*	*Q3 2017*
Authorisations of GMO's food and feed uses, and for cultivation	*Adoption*	*In course of 2017*
Authorisations of substances		
Commission Regulation on Bisphenol A as food contact material (2015/SANTE/534)	*Adoption*	*Q1 2017*
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 2017*
Authorisations of recycling processes for plastics used in food contact materials	*Adoption*	*In course of 2017*
Regulatory measures on contaminants in feed and food following EFSA opinions	*Adoption*	*In course of 2017*
Withdrawal of certain substances (flavourings)	*Adoption*	*In course of 2017*
Authorisations and re-authorisations of feed additives and new uses of feed additives.	*Adoption*	*In course of 2017*
Withdrawal of certain already authorised	*Adoption*	*In course of*

additives for which no applications were submitted		*2017*
Implementation of the new Novel Food Regulation		
Implementing act on procedural steps of the consultation process regarding determination of novel food status (PLAN/2016/265)	*Adoption*	*Q4 2017*
Implementing act on initial establishment of the Union list (transfer of existing authorisations to the Union list) (PLAN/2016/266)	*Adoption*	*Q4 2017*
Implementing act on administrative and scientific requirements for traditional foods from a Third Country in relation to transitional measures (PLAN/2016/264)	*Adoption*	*Q3 2017*
Implementing act on administrative and scientific requirements for novel food applications (PLAN/2016/263)	*Adoption*	*Q3 2017*
Delegated act on updating and adjusting the definition of "engineered nanomaterials" to technical and scientific progress (PLAN/2016/269)	*Adoption*	*Q4 2017*
Implementation of the legislation on plant reproductive material		
Implementing acts amending the annexes as regards the certification marketing requirements of the 12 basic Directives	*Adoption*	*2017*
Decision(s) on EU equivalence for seed certification and field inspection	*Adoption*	*2017*
Implementation of the legislation on Community Plant Variety Rights		
To support new innovative plant varieties by updating the rules on variety denominations	*Adoption*	*2017*
Food hygiene		
Adapt rules for Specified Risk Materials in small ruminants (2016/SANTE/241)	*Adoption*	*Q2 2017*
Review export rules for the export of Processed Animal Proteins (2016/SANTE/240)	*Adoption*	*Q3 2017*
Commission Regulation on processed animal protein derived from insects (2016/SANTE/095)	*Adoption*	*Q1 2017*
Process hygiene criterion for Campylobacter at slaughterhouse (2016/SANTE/035)	*Adoption*	*Q2 2017*
Creation of a new EU Reference Laboratory on viruses (PLAN/2016/228)	*Adoption*	*Q3 2017*
Implementation of Animal Welfare Strategy 2012-2015		
Report to the European Parliament and the Council on the application of broilers	*Adoption*	*Q4 2017*

Directive (2016/SANTE/114)		
Report to the European Parliament and the Council on protection of fish at the time of killing (2016/SANTE/138)	*Adoption*	*Q4 2017*
Report to the European Parliament and the Council on impact of animal welfare international activities (PLAN/2016/499)	*Adoption*	*Q4 2017*
Pilot project on best practices in protection of animals during transport	*Publication*	*Q3 2017*
Study on best practices on the protection of animals at the time of killing	*Publication*	*Q4 2017*
Study on transport and killing of farmed fish	*Publication*	*Q4 2017*
Others		
Implementing Regulation on voluntary food origin labelling (2015/SANTE/670)	*Adoption*	*Q2 2017*
EU guidelines on food donation (2016/SANTE/072)	*Adoption*	*Q4 2017*
Report to the European Parliament and the Council on labelling of alcoholic beverages (2015/SANTE/681)	*Adoption*	*Q1 2017*
Guidelines for use of former foodstuff as feed (2016/SANTE/073)	*Adoption*	*Q2 2017*

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 spending programme(s) 3rd EU Health Programme	
Main outputs in 2017:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Report from the project on the implementation of the Action Plan on Childhood Obesity	*Completion*	*Q4 2017*
Support to the preparation of voluntary guidelines for public procurement of food	*Launch tender*	*Q4 2017*
Support and piloting of adequate monitoring systems for reformulation initiatives	*Launch tender*	*Q4 2017*
Preparatory work for a collection of best practice on physical inactivity	*Launch tender*	*Q4 2017*
Report from the project on exposure of children to marketing of foods high in fat, sugar or salt	*Launch tender*	*Q4 2017*

Compass conference on mental health	*Conference*	*Q3 2017*
Guidance on mental health at the workplace	*Guidance documents available*	*Q4 2017*
Organise meetings of the EU Health Policy Forum	*1-2*	*Q4 2017*
Completion of the First Joint Action on chronic diseases	*Final conference in January*	*Q1 2017*
Dissemination of project results in the area of chronic diseases	*Cluster meeting with European journalist*	*Q2 2017*
Collection of best practices in health promotion and prevention	*Call for proposal launched*	*Q3 2017*
Strengthen evidence base for chronic diseases	*Administrative agreement with JRC signed*	*Q4 2017*
Develop support for rare diseases registries interoperability	*Administrative agreement with JRC signed*	*Q2 2017*
Launch of Joint Actions with Member States	*- on chronic diseases* *- on rare cancers* *- on frailty* *- on innovative partnership on action against cancer* *- on health inequalities launched*	*Q2 2017* *Q1 2017* *Q1 2017* *Q1 2017* *Q4 2017*
Cancer control	*- Implementation report on EU cancer screening published* *- pilot action on the initiative on breast cancer launched* *- updated guidelines on screening of breast cancer published*	*Q1 2017* *Q2 2017* *Q1 2017*
Characterising flavours in tobacco products	*-establishment of an advisory panel to assist Member States and the Commission in determining tobacco products with characterising flavour* *-establishment of a technical group to assist the advisory panel with sensory and chemical analysis*	*Q1 2017* *Q4 2017*
Reporting on tobacco and electronic cigarettes	*-ensure a well-functioning electronic reporting tool (EU Common Entry Gate) for reporting in accordance with TPD from industry to national regulators*	*Q2 2017*
Supporting the transition towards a sustainable EU Health Information System	*Completion of BRIDGE-Health project*	*Q4 2017*

Other important outputs		
Output	Indicator	Target
Guidelines on allergen labelling, on Quantitative Ingredients Declaration (QUID) and Q&A on Food Information to Consumers (2015/SANTE/647)	*Adoption*	*Q1 2017*
Commission delegated Regulation on total diet replacement for weight control (2015/SANTE/146)	*Adoption*	*Q2 2017*
Delegated act authorising new sources of iron and calcium for process cereal-based food, baby food and food for special (2016/SANTE/239)	*Adoption*	*Q1 2017*
Commission Decisions on tracking and tracing under the Tobacco Products Directive (201440/EC): *1) tracking and tracing system for tobacco products (2015/SANTE/694)* *2) data storage contracts between manufacturers and importers of tobacco products and an independent third party (2015/SANTE/695)* *3) technical specifications for the security feature for tobacco products (2015/SANTE/696)*	*Adoption*	*Q4 2017*

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 spending programme(s) 3rd EU Health Programme	
Main outputs in 2017:		
Important items from work programmes/financing decisions/operational programmes		
State of Health in the EU: 28 Country health profiles and accompanying Commission Staff Working Document	*Health profiles and Staff Working Document published*	*Q4 2017*
Study on antimicrobial resistance and causes of non-prudent use of antibiotics in human medicine.	*Completion*	*Q2 2017*
Joint Action (JA) between EU and EU Member States on AMR (2017-2020)	*Launch of the Joint Action*	*Q1 2017*
Direct grant agreement with WHO EURO for cooperation on AMR	*Establishment of the grant*	*Q3 2017*
Direct grant agreement with OECD	*Publication of a model assessing the health and economic burden caused by AMR and estimating*	*Q4 2017*

	the cost-effectiveness of policies aimed at tackling AMR	
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 2017*
Study on cooperation in cross-border regions and toolbox for National Contact points	*Completion*	*Q4 2017*
Study on cross-border health services: enhancing information provision to patients	*Completion*	*Q4 2017*
eHealth Digital Service Infrastructure: building core services and national access, the eHealth Member State Expert Group	*8 national access points set up*	*Q4 2017*
Study on regulatory aspects of cross-border telemedicine	*Completion*	*Q4 2017*
Direct grant to OECD and European Observatory on Health Systems and Policies	*Contract*	*Q4 2017*
Workshop on "New forms of investment for new forms of care"	*Organisation of event*	*Q1 2017*
Other important outputs		
Output	Indicator	Target
New Commission's Communication on Action Plan against antimicrobial resistance (2016/SANTE/176)	*Adoption*	*Q2 2017*
Guidelines on prudent use of antimicrobials in human medicines	*Publication*	*Q2 2017*
Commission Report to the European Parliament and the Council on the implementation of the organ legislation (2015/SANTE/504)	*Publication*	*Q1 2017*
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 2017*

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 spending programme(s) 3rd EU Health Programme
Main outputs in 2017:		
All new initiatives and REFIT initiatives from the Commission Work Programme		
Output	Indicator	Target
None		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
Kick-off conference for the European Reference Networks (ERNs)	*Organisation of the conference*	*March 2017*
Virtual patient handling IT system for ERNs	*Operational*	*Q2 2017*
Establishment and effective coordination of approved ERNs	*All annual grants signed and operational*	*Q2 2017*
Coordination support contract for ERNs' functioning (training, communication, standard templates)	*Contract(s) signed*	*Q2 2017*
Other important outputs		
Output	Indicator	Target
Revision of Commission Regulation 847/2000 on orphan medicinal products (2016/SANTE/043)	*Adoption*	*Q2 2017*
Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products ("ATMPs") (2015/SANTE/573)	*Adoption*	*Q2 2017*
Link between ERNs and the Rare Disease Registration Platform	*Cooperation established*	*Q3 2017*

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(s) CFF for the Food Chain 2014-2020
Main outputs in 2017:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
EU Reference Laboratories	*No. of laboratories funded*	*43*

Better Training for Safer Food	*No. of trainings organised*	*175*
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 operation of official controls in the Member States on food safety, animal health and animal welfare, and plant health (2014/SANTE/011)	*Adoption*	*Q2 2017*
Health and Food Safety audits	*80% of programmed audits completed* *90% of the number of programmed and new audits completed*	*end 2017*
Other SANTE activities to improve the performance of control systems:		
Organisation of regular meetings of networks of Member State officials 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 2017*
Organisation of meetings with Member State experts in a number of areas such as animal welfare, slaughter hygiene or live bivalve molluscs to discuss common problems and exchange best practices identified	*Number of meetings:* *as per published SANTE audit and analysis work programme 2017*	*end 2017*
Evaluation of facilities of Border Inspection Posts	*Number of evaluations:* *on average 50*	*end 2017*
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 2017*
Management of lists of approved non-EU country establishments for the production of food of animal origin	*127 lists by country (27 lists by sector)*	*end 2017*
Operation of the notification system for plant health interceptions, EUROPHYT and reporting on plant pests	*Europhyt annual report*	*end 2017*

1.7. Specific objective 1.7: Increased EU influence in international fora

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT		
Specific objective 1.7: Increased EU influence in international fora		Related to spending programme(s): NO
Main outputs in 2017:		
Other important outputs		
Output	Indicator	Target
Coordinated EU positions on WHO resolutions	*Delivered*	*20*
EU co-sponsored WHO resolution	*Delivered*	*1*
EU statements for WHO meetings	*Delivered*	*9*
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	*Delivered*	*In the course of 2017*
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 2017*
Coordinated EU positions in Organisation for Economic Co-operation and Development (OECD) meetings	*Delivered*	*In course of 2017*
Coordinated EU positions in documents and guidelines of the International Union for the Protection of New Varieties of Plants (UPOV)	*Delivered*	*In course of 2017*
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 2017*
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*

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 spending programme: 3rd EU Health Programme	
Main outputs in 2017:		
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*	*Q4 2017*
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*	*In course of 2017*

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 spending programme(s) 3rd EU Health Programme	
Main outputs in 2017:		
Important items from work programmes/financing decisions/operational programmes		
Output	Indicator	Target
On-site audit/assessment by DG SANTE for listing of non-EU countries	*Assessment finalised*	*1*
Study to support reporting requitement on centralised and decentralised procedures for pharmaceutical products	*Launch*	*2017*
Other important outputs		
Output	Indicator	Target
Report to the European Parliament and the Council on the performance of the EU's paediatric Regulation(2015/SANTE/530)	*Adoption*	*Q4 2017*
Commission implementing Directive laying	*Adoption*	*Q1 2017*

down the principles and guidelines of good manufacturing practices for medicinal products for human use (2015/SANTE/141)		
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	*Recognition of authorities of non-EU countries*	*In course of 2017*

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 spending programme(s) …
Main outputs in 2017:		
Other important outputs		
Output	Indicator	Target
Report to the Council Working Party on Public Health at Senior Level on Integrated Care	*Publication*	*Q1 2017*
Report to the Council Working Party on Public Health at Senior Level on Primary Care	*Publication*	*Q4 2017*

3. General objective 3: A reasonable and balanced Free Trade Agreement with the U.S.

3.1. Specific objective 3.1: A balanced agreement with the US on pharmaceutical products and in SPS area

Relevant general objective 3: A REASONABLE AND BALANCED FREE TRADE AGREEMENT WITH THE U.S		
Specific objective 3.1: A balanced agreement with the US on pharmaceutical products and in SPS area		Related to spending programme(s) 3rd EU Health Programme
Main outputs in 2017:		
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	*Submission of 12 audit reports to US; Recognition of around 10 EU authorities as equivalent*	*Q4 2017*

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 2017:		
Output	Indicator	Target
Towards Excellent SANTE: 360° feedback exercise for senior and middle managers.	*All managers have received an individual report on personal strengths and weaknesses.*	*100%*
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.	*Roll out a series of training activities*	*Organisation of at least 5 trainings with a participation rate of on average 15 staff*
Towards Excellent SANTE: Organisation of dedicated SANTE Fit@work activities in Brussels premises.	*Number of sessions and participation rate*	*Between 5 and 10 sessions with a participation rate of on average 6 -10 staff*
Recruitment of female managers: fill vacant management posts.	*+2 female middle managers*	*>35%*

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 2017:		
Output	Indicator	Target
Legality and regularity of the underlying financial transactions in the DG	***Estimated residual error rate***[6] *of on-the spot controls (ex-post) for each policy area*	*Residual error rate not exceeding 2% in value of the relevant payment budget per policy area (annually or multi-annual depending on the design*

[6] 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

		of the programmes)

Objective 2: Effective and reliable internal control system in line with sound financial management.		
Main outputs in 2017:		
Output	Indicator	Target
Cost effectiveness of controls in the AAR	*Conclusion reached on cost effectiveness of controls in the 2017 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 2017:		
Output	Indicator	Target
Implementation of the anti-fraud strategy	*Percentage of implemented actions planned for 2017 deriving from the anti-fraud strategy (priority for 2017: actions related to non-spending legislative initiatives)*	*100%*
Update of the anti-fraud strategy of 2014	*First comprehensive update to be finalised in 2017 taking into consideration the revised OLAF Methodology and guidance for DGs' anti-fraud strategies as issued in February 2016.*	*Update at least every 3 years*

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 2017:		
Output	Indicator	Target
Registered documents re also filed.	*Percentage of registered documents that are not filed[1] (ratio)*	*Less than 1% by Q4 2017*
HAN files are readable/accessible by all units in the DG	*Number of HAN files readable/accessible by all units in the DG*	*75% by Q4 2017*
HAN files are shared with other DGs	*Number of HAN files shared with other DGs*	*75% by Q4 2017*
Better use of standard electronic tools to manage Units activities and store information	*Percentage of units using collaborative tools to manage their activities*	*40% by Q4 2017*
Briefings are managed in accordance with a uniform business process and using a common tool	*Percentage of briefings managed in accordance with a uniform business process and using a common tool*	*100%*
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.*	*40% by Q4 2017*

E. External communication activities

Table 3.A

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 2017: Specific communication actions in the four main areas: Antimicrobial Resistance (AMR), Country knowledge in Health care systems, European Reference Networks (ERN), Food Waste and crisis preparedness/management, notably in Plant Health and the EU as a global health and food safety player.		
Output	Indicator	Target 2020
Direct reach of the DG communication actions via SANTE Web, press material, media seminars, media info session, social media, audiovisual material,	*Number of DG SANTE unique visitors, social media impressions, participants at events, reach of media seminars and info session, page views of press material, subscribers to e-news, print*	*20 000 million contacts*

events, publications, e-news and graphic material	*runs, online views of graphic material*	
Debate with Commissioner on the occasion of 7 Citizens' Dialogues organised	*Number of participants*	*1260 participants in all the events.*

Table 3.B

Objective: The role of the EU as a global best practice region in the 'One Health' EU Action Plan to combat AMR **This objective contributes to specific objective 1.4. Effective, accessible and resilient healthcare systems in the EU** **Main outputs in 2017: Media Seminar on AMR, Animated clip and promotion plan, web updates, social media promotion**		
Description	**Indicator**	**Target**
Media seminar	- *Number of journalists attending media seminar* - *Percentage of journalists who write a follow-up article* - *Number of follow up articles*	- *Up to 30 journalists attending media seminar* - *70% journalists write a follow up article or publish a news item in the next 3 months* - *24 articles published*
Animated clip and promotion plan	- *Number of views* - *Number of stakeholders contacted and engaged* - *Number of journalists contacted*	- *20.000 views in 6 months* - *500 stakeholders contacted with an engagement rate of 10%* - *150 journalists specialised in AMR*
Web	- *number of visits to DG SANTE Website section on AMR*	- *10% increase of visits to DG SANTE Website section on AMR (baseline 2016: 35.400 visits)*
Social media	- *number of social media posts* - *social media reach (regular and paid)*	- *At least 30 dedicated social media posts (at least 5 paid)* - *35.000 Twitter accounts reached* - *500 000 impressions (baseline 208k mid-review 2016)*

Table 3.C

Objective: Increased awareness and stakeholder engagement on the "State of the Health in the EU" cycle **This objective contributes to 1.4. Effective, accessible and resilient healthcare systems in the EU** **Main outputs in 2017: delivery of 28 country health profiles and a Commission Staff Working Document, on the basis of the joint Commission-OECD report Health at a Glance: Europe**		
Description	**Indicator**	**Target**
Communication on the publication of the first series of Health	– *number of journalists attending the press conference and media*	– *15 journalists attending* – *70% journalists write an*

Country Profiles – Media Seminar	*Seminar (November 2017)* – *number of articles covering the event*	*article on the report or publish a news item in the next 3 months*
Web	– *number of views of the report/summary on SANTE website*	– *5 000 web visits in the 6 months after the publication*
Social media	- *number of social media posts* - *social media reach (regular and paid)*	- *20 tweets (at least 4 paid)* - *35 000 Twitter accounts reached* - *300 000 impressions*
Animated video-clip	- *Number of views*	- *5 000 views in 6 months*

Table 3.D

Objective: Increased awareness and stakeholder engagement on the European Reference Networks (ERNs) **This objective contributes to specific objective 1.5. Increased access to medical expertise and information for specific conditions** **Main outputs in 2017: ERN 3rd conference, promotion (web, social media, media) and organisation 4th conference**		
Description	Indicator	Target
3rd ERN conference in Vilnius on March 2017 and organisation of the 4th conference in 2018	– *number of journalists attending the conference* – *number of articles covering the topic of ERNs following the conference*	– *5 journalists attending ERN conference* – *5 articles on ERN topic following the conference*
Web	– *number of views on ERN web page on SANTE website*	– *5% increase in ERN page views*
Social media	- *number of social media posts* - *social media reach (regular and paid)*	- *10 regular & 2 sponsored tweets* - *30 000 accounts reached* - *200 000 impressions (baseline 70k at mid review 2016)*
Media Info session	- *Number of journalists attending media info session* - *Percentage of journalists who write a follow-up article* - *Number of follow up articles*	- *Up to 15 journalists attending media info session* - *70% journalists write a follow up article or publish a news item in the next 3 months* - *10 articles published*

Table 3.E

Objective: Increased interaction with Food Waste stakeholders and relevant national authorities in the area of Food Waste and the Circular Economy Package. **This objective contributes to specific objective 1.2. Safe and sustainable food and feed production systems** **Main outputs in 2017: Social media action on Food Waste**		
Description	Indicator	Target
Social media	– *number of social media posts*	- *15 tweets (at least 4 paid)* – *20000 accounts reached*

	– *social media reach (regular and paid)*	– *200 000 impressions*

Table 3.F

Objective: Increased confidence in the EU control systems and recognition of the added value of action at EU level, thus contributing to facilitate trade. This objective contributes to specific objective 1.6. Effective, efficient and reliable official controls Main outputs in 2017: multimedia material to be promoted on web, stakeholder events and social media		
Description	Indicator	Target
Series of videos explaining the role of the DG SANTE's Directorate on Health and Food Audits and Analysis in the EU control systems and the identification and dissemination of best practices.	– *Number of views in DG SANTE Website* – *Number of videos distributed in stakeholders meetings*	– *400 video files distributed* – *2.000 views (videos to be released mid-2017)*
Social media	– *number of social media posts* – *social media reach (regular and paid)*	– *At least 4 regular tweets* – *15 000 accounts reached* – *100 000 impressions*

Table 3.G

Objective: Trade partners' understanding of Sanitary and Phytosanitary (SPS) requirements is facilitated in the fields of Plant Health, Animal Health and Food Safety This objective contributes to specific objectives 1.6. Effective, efficient and reliable official controls, 1.4. Effective, accessible and resilient EU healthcare systems, 1.7. Increased EU influence in international fora and 3.1. A balanced agreement with the US on pharmaceutical products and in SPS area. Main outputs in 2017: Three animated clips and factsheets on Food Safety, Plant Health and Animal Health		
Description	**Indicator**	**Target**
3 animated clips on Food Safety, Plant Health and Animal Health	- *Number of views online*	- *2000 views in 6 months*
3 Factsheets on Food Safety, Plant Health and Animal Health	- *Number of clicks online* - *Number of factsheets printed and distributed*	- *2000 clicks* - *1500 factsheets distributed*
Social media	- *number of social media posts* - *social media reach (regular and paid)*	- *At least 10 dedicated social media posts (3 paid)* - *30 000 Twitter accounts reached* - *200 000 impressions*