Ref. Ares(2016)2075174 - 02/05/2016

European Commission

Strategic Plan 2016-2020*

DG Health & Food Safety

*The current Commission's term of office runs until 31 October 2019. New political orientations provided by the incoming Commission for the subsequent period will be appropriately reflected in the strategic planning process.

Contents

PART 1. Strategic vision for 2016-2020

A. Mission statement

"Promoting health and food safety – supporting growth and competitiveness"

The mission of DG Health and Food Safety (DG SANTE) is to:

- Improve and protect human health, and support the modernisation of Europe's health systems;
- Ensure that all food, feed and medicinal products marketed in the EU are safe and that EU standards are promoted globally;
- Protect animal health and welfare and plant health;
- Contribute to a well-functioning and fair internal market in food, feed, agricultural and medical products.

By fulfilling our mission, we support the Commission's priorities for jobs, growth, investment and competitiveness in two of the EU's most important economic sectors – health and food.

We encourage innovation while safety and quality remain paramount. We play a leading role in the prevention of, and the EU's response to, crisis situations linked to food safety and threats to human, animal and plant health.

As regards human health, we contribute to EU Member States' efforts for better public health and better access, effectiveness and resilience within their health systems, in accordance with the rules of the Treaty of the European Union on proportionality and subsidiarity. In order to improve the quality and effectiveness of public expenditure and contribute to prosperity and social cohesion, we develop expertise on health systems and support actions that help prevent and reduce the impact of ill-health on individuals and economies. We encourage and support innovation and the uptake of modern technologies for better care delivery and cost-effectiveness.

In food and feed safety, we work to modernise and simplify the well-developed EU regulatory framework in line with Better Regulation principles and to verify its correct application. We strive to guarantee world-class standards of animal and plant health, safe and trustworthy products, and an efficient internal market, with confident consumers and business operators. By working with international institutions and other stakeholders, we aim to help Europe maintain a competitive position on the world market and uphold its internationally recognised safety brand.

B. Operating context

DG SANTE is responsible for health and food safety, two sectors which have a direct and significant impact on the economy and daily individual lives. Our ultimate goal is to create and sustain a solid framework "based on scientific facts" and "a high level of protection"[1] that supports growth, investment and competitiveness within these sectors and ensures their long-term sustainability.

DG SANTE's activities are principally linked to Articles 114 (Internal market) of the Treaty on the Functioning of the European Union (TFEU), 168 (Public Health) and 13 (Animal Welfare).

The context in which the European Commission will need to operate and deliver on its political priorities throughout the period 2016 – 2020 will remain increasingly complex.

The consequences of the economic crisis and the austerity measures dictate a different prioritisation of Commission's spending plans to that which has been set out at the beginning of the current financial framework. They require not only an adaptation of policy deliverables at DG level, but also mean that DGs are asked to deliver more and better with less financial and human resources. Such efficiency gains can be achieved, but not without identifying negative priorities. Similarly, as pressure on public spending in Member States continues to grow, their delivery on the common priorities becomes increasingly difficult.

This situation, coupled with the migration and refugee crisis, has brought to light warning signals of a diminishing sense of solidarity among Member States put into question the very essence of the European project. In such a context, the essential role of the Commission and every one of its DGs is to show very clearly that there is added value for the Member States and their citizens in joint EU action. In contribution to this, DG SANTE will focus its efforts on the range of issues outlined below, in order to successfully tackle the key challenges of better cost effectiveness and efficiency, of delivering both safety to citizens and competitiveness to the economy, and of tackling global threats, all of this based on sound evidence, and taking place in a sensitive environment with numerous sector interests.

Key challenges for 2016-2020

Achieving greater cost-effectiveness

Given the multiple pressures on public spending and the current financial context, all public policies need to be streamlined in coming years to improve their performance and cost-effectiveness. This challenge is particularly pertinent in health and food safety where the cost of non-action is significantly greater than that of action.

An important part of DG SANTE's work in this respect will be making the necessary and relevant improvements to the legal framework for food safety in line with the EU's principles for Better Regulation. In public health, DG SANTE's work will focus on active support for health system reforms in Member States, chronic disease prevention and promotion of good health. It will also continue to build on the various networks already established under the EU's public Health Programme that link health specialists, national and regional health authorities and other stakeholders. These are well recognised to make an important contribution to better information exchange and greater health capacity in the EU with a positive knock-on effect for cooperation and research. In many cases, outcomes and actions funded by the Health Programme represent the most effective, if not the only way to build the evidence base for

[1] Article 114 of the Treaty on the Functioning of the European Union

defining much broader regulatory policies e.g. on cancer, dementia, Alzheimer, rare diseases and health inequalities.

We can also strengthen our partnership with EU agencies to ensure the strongest possible link between their work and the Commission's objectives. By delegating more and providing better strategic orientation and articulation between the different programmes and priorities, the Commission can make better use of these valuable resources without compromising their independence.

Safety versus competitiveness

Given that high standards of safety and quality are integral to the EU "brand," it is essential that safety and competitiveness are delivered together and not in opposition to one another. Our regulatory framework needs to be fit-for-purpose without being overly prescriptive and stifling innovation. The rapid authorisation of pharmaceutical products, for example, needs to achieve the right balance between rapid market – and patient - access and safety, quality and efficiency guarantees. In order to sustain competitiveness, especially in areas of rapidly evolving technology, EU operators need a business-friendly, flexible environment in which to develop their products.

Tackling emerging global threats

Other factors beyond the EU's control which challenge – and often subsequently shape – our policies include climate change, globalisation and human, animal and plant disease. The increasing fluidity of trade and travel means that disease can spread rapidly with catastrophic consequences for the economy and for health. This risk in particular is compounded by the rising and increasingly urgent challenge posed by antimicrobial resistance. In all of these areas, the EU must make a leading contribution.

Evidence-based policy making

Policy making in the field of health and food safety is built on a scientific evidence base and DG SANTE will continue to ensure it remains so. However, this sometimes proves difficult in some sensitive areas where the evidence is hard to produce e.g. because of the highly innovative nature of the subject considered, or controversy in the scientific results which means they are not sufficiently conclusive when it comes to regulating.

Addressing sector interests

Health and food safety policies touch the daily lives of Europeans and concern huge sectors of industry as well as attracting the interests of a large part of civil society. The responses to the public consultations DG SANTE has launched on some planned initiatives demonstrate the wide range of people and sectors affected and how different the interests are. DG SANTE will continue working in a manner that enables health and food safety policies to be developed in a way which guarantees the appropriate level of safety to citizens while maintaining a well-functioning industrial sector.

Supporting Member States to deliver EU priorities

The EU's degree of influence in health and food safety is directly shaped by the Treaty. Health policy in particular is explicitly limited by Article 168 which stipulates that "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care".

As a consequence, EU action in this policy area is mainly linked to incentive measures e.g. raising awareness to prevent chronic disease and promote good health, and cooperation measures to

create stronger links between health systems in the different EU Member States. Both are highly dependent on the will and commitment of Member States to drive their success. However, by encouraging and supporting health systems to have a strong focus on key health determinants and chronic disease prevention, DG SANTE's initiatives make an important mark further downstream, with the aim of reducing absenteeism and the cost of health and social care linked to ill-health and by consequence, increasing productivity and making an important contribution to the broader economy. Closer cooperation with Member States is envisaged with a view to making national strategies on chronic diseases operational.

In food safety, while the EU is directly responsible for designing and implementing a common policy framework, its success depends on Member States enforcing the EU's rules correctly, and Food Business Operators (FBO) complying at all stages of the production and trading process. Any weaknesses in the chain compromise our ability to achieve our policy objectives.

In both policy areas, the EU has an important supporting role to play, providing guidance and tools to promote cooperation and help national systems operate more effectively. This is particularly important for risk management and crisis preparedness and to protect the EU's citizens, animals and plants from serious cross-border health threats.

DG SANTE will focus on a number of specific examples where collaborative actions help to deliver our priorities. In health policy, they include the Health Security Committee (HSC), the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) and the EU's Joint Procurement Agreement (JPA) for medicines.

In food safety, they include the Rapid Alert System for Food and Feed (RASFF) the Animal Disease Notification System (ADNS) and EUROPHYT, the system used to identify plant health risks on imported products. All these systems enable a coordinated response to risks that can seriously undermine the food safety, animal and plant health and cause significant disruption to the internal market and the economy.

Strengthening cooperation with EU Agencies and Scientific Advisory Committees

DG SANTE will work closely with five EU Agencies to achieve its objectives: European Centre for Disease Protection and Control (ECDC), the European Chemicals Agency (ECHA), the European Food Safety Authority (EFSA), the European medicines Agency (EMA) and the Community Plant Variety Office (CVPO). Collectively, these agencies represent a wealth of resources, expertise and networks that provide vital support to EU policy.

DG SANTE will continue to rely on the advice and expertise of three independent Scientific Committees: the Scientific Committee on Consumer Safety (SCCS), the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), and the Scientific Committee on Health and Environmental Risks. The two will be merged into one Committee as of April 2016.

Both the committees and agencies make an essential contribution to the process of evidence-based policy making: they feed into policy design, underpin the Commission's position in international fora, improve resource efficiency, and help to protect a high level of consumer health and safety.

Collaborating with stakeholders

To achieve our objectives DG SANTE will rely on a high degree of stakeholder consultation, as per the Commission's Better Regulation guidelines. Many measures will be taken through procedures that involve Member States in the process. DG SANTE has established a permanent advisory group to support dialogue with stakeholders, the Advisory Group on the Food Chain and Animal and Plant Health (AGFC).

To support dialogue with health stakeholders, DG SANTE has also set up the EU Health Policy Platform, a concept which consists of regular meetings with health stakeholders , an IT tool and a health award for best practices of NGOs .

Promoting EU values and standards globally

DG SANTE will work closely with international partners to promote the European policy model and its agenda for EU safety and quality standards, to ensure our standards are respected and trade can take place freely.

DG SANTE represents the EU in a variety of international organisations including the World Health Organisation (WHO), the World Trade Organisation (WTO) and the Organisation for Economic Cooperation and Development (OECD). We will focus on ensuring that our obligations are fulfilled and EU interests promoted, in particular when trade disputes arise.

We will actively participate in multilateral fora. In health, the key task will be to harmonise standards in the field of medicinal products, including the International Conferences on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and Veterinary Medical Products (VICH). In food safety, the objective is to influence the work of standard-setting bodies and include the Codex Alimentarius, the World Organisation for Animal Health (OIE) and the International Plant Protection Convention (IPPC).

DG SANTE will continue to coordinate input into the enlargement and neighbourhood processes including support for capacity building, training and other initiatives linked to the implementation of our standards and rules. Ukraine will continue to merit a particular focus in this work, in particular to follow up work on the implementation of the Association Agreement. The reunification of Cyprus will constitute another major challenge involving a need for an assessment of the actual situation and capacity building.

Promoting trade relations

Talks with the US in the context of the Transatlantic Trade and Investment Partnership (TTIP) are a top priority; we will aim to remove trade barriers in a wide range of economic sectors - including pharmaceuticals and intellectual protection – to help trade in goods and services between the EU and US.

The EU has a number of Free Trade Agreements (FTA) with countries outside of the EU which DG SANTE will continue to ensure are properly implemented. These include South Korea, Mexico, Chile, Switzerland, the Veterinary Agreement with New Zealand and the European Economic Area Agreement (EEA).

In addition, there are ongoing FTA negotiations with Japan, Malaysia, Vietnam and Thailand, India, the Mercosur group and Morocco. They include chapters on medicinal products and sanitary and phytosanitary standards.

We also have a number of bilateral agreements in place with countries outside of the EU to foster effective cooperation and trade in safe products. They include Brazil, Canada, China, Russia, and the United States (US).

Monitoring the application of EU law

DG SANTE will work closely with Member States and the relevant authorities responsible for controls in countries outside of the EU to ensure our standards for food safety are met and

adhered to. Our controls are essential to reassure consumers, producers, processors and traders that the measures we have in place are properly implemented.

The Directorate on Health and Food Audits and Analysis (formerly the Food and Veterinary Office – FVO) will play an important role in enforcing EU rules, carrying out over 200 audits every year and further strengthening the link between the evidence gathered through audits and the policy making in this area. The "Better Training for Safer Food Scheme" complements this work by training control staff to recognise fraud and non-compliance.

Funding for DG SANTE's activities

Funding for DG SANTE's activities is fixed within the EU's 2014-2020 Multiannual Financial Framework. The total allocation for the period is € 2 340 million: €1 891 million for activities linked to "Food and Feed" and €449 million for "Public Health".

The priority for DG SANTE is to provide the contribution for the mid-term review of the 2014-2020 multiannual financial framework in order to ensure that the DG has sufficient financial resources to support the policy activities.

Management modes linked to the spending programme

Expenditure is directly managed by DG SANTE and, to a lesser extent (about 22%), the Consumer, Health and Food Executive Agency (CHAF-EA). CHAF-EA implements large parts of the EU's 3rd Health Programme in particular. EU financing is available through grants, procurement and voluntary payments to international organisations active in its policy areas. It can also be used to co-finance emergency measures in case of a sudden outbreak of certain animal and human diseases.

All DG SANTE's expenditure falls under Heading 3 of the EU budget: Security and Citizenship (except financing of the ECHA biocide activities which fall under Heading 2).

C. Strategy

Europe's health and food sectors make an important contribution to the EU economy and have great potential for growth, investment and innovation despite being – by necessity - highly regulated. DG SANTE's overarching objective is to ensure the most appropriate framework exists to encourage citizens to actively engage in the internal market and growth and productivity to thrive.

DG SANTE's strategy for 2016-2020 is built around three priorities:

1. A new boost for jobs, growth and investment in the EU
2. A deeper and fairer internal market with a strengthened industrial base
3. A reasonable and balanced free trade agreement with the U.S.

The EU health sector accounts for 10% of GDP, 15% of public expenditure and 8% of the EU's workforce and has a high potential for innovation and growth. However, it also faces important challenges with huge economic consequences if they are not adequately addressed: the EU will need, for example, 1 million new health professionals by 2020. The cost of healthcare is expected to double by 2050 if nothing is done to tackle key challenges, notably preventable chronic diseases. Work hours lost to ill-health currently cost 2.5% of GDP every year and impact all levels of the economy. In short, reforms are needed to help health systems survive.

The EU must play a critical role in this process. Even with the limited scope it has for health policy, it can – and must – play an important supporting role, helping Member States to reform their health systems while at the same time respecting the rules on subsidiarity and proportionality. Better coordination and cooperation between EU countries, better use of cost-effective and efficient technologies and EU-wide health promotion initiatives are all examples of ways in which the EU can channel a more efficient use of resources and reduce pressures on public finances. Such actions will make an important contribution to economic stability as well as productivity, mobility and adaptability within the workforce.

"Health" policy is not simply a case of keeping people healthy. It is keeping them living, working and ageing in good health, actively engaged in society and actively contributing to the economy. As a consequence, health is now an integral part of most major EU initiatives and the TFEU requires the EU to follow a "Health in all Policies" approach: most Commission initiatives are obliged to examine potential impacts on health and health systems in the policy design process.

Similarly, safe food is essential for public health and long-term economic development, competitiveness and growth. The food industry – with a turnover of €1.2 trillion - is the largest manufacturing sector in the EU and a leading employer that accounts for about 2% of the EU's workforce (4.2 million employees). The agri-food sector as a whole - "from farm to fork" - represents 25 million jobs, the majority of which are Small and Medium Sized Enterprises.

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 complex yet 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.

Our food safety standards are amongst the highest in the world. They constitute an internationally recognised and respected "trademark" representing safety and quality. This allows European producers and processors to occupy a strong, competitive position on the global market and reduces the economic and social costs associated with inappropriate standards causing diseases.

Full performance tables are found in annex 1.

General objective 1: A new boost for jobs, growth and investment in the EU

Given the economic importance and potential of the health and food sectors, DG SANTE's primary objective is to contribute to jobs, growth and investment in the EU. It aims to do this by supporting health system reforms to make them more efficient, resilient and accessible, and by creating the right environment for growth and investment in the food and feed sector.

EU public health policy: supporting growth, employment and social inclusion

Health is frequently described as "a value in itself"[2] with important implications for the economy. The link between effective public health policies and positive economic outcomes has been well documented by numerous international institutions including the World Bank and the Commission on Macroeconomics in Health.

EU public health activities – which focus principally on facilitating and supporting effective public health policy by Member States – are explicitly oriented to delivering EU policy objectives that not only improve health in its own right but also contribute to policy objectives in employment and social exclusion.

Impact indicator 1.1 monitors the employment rate of the population aged 20-64. Public health policies play an important role in this respect, impacting directly on premature mortality and morbidity as well as indirectly on labour force participation and productivity. The percentage of long term unemployed with a significant disability is up to 50% in the 40-64 year old age group in some EU Member States. The principal cause of this is chronic disease – including a high proportion of preventable diseases e.g. cardiovascular disease, chronic respiratory disease, some mental disorders and chronic infectious disease including HIV and hepatitis.

Health policies at both national and EU level are critical to reduce this burden. Coordinated policies and initiatives targeting key health determinants will contribute to fewer annual workdays lost as well as fewer long lasting work disabilities linked to chronic conditions. EU action to help Member States prevent and control chronic disease can also help reintegrate people with chronic disease into the labour market and reduce disease-related early retirement.

DG SANTE policies also help to address people at risk of poverty or social exclusion (impact indicator 1.2). In part, this is via employability - the single most important cause of poverty is inability to work. In part, it is by encouraging and supporting effective public health policies that reduce premature mortality and morbidity and exclude fewer people from the labour market for long-term health conditions.

Secondly, health policies aim to reduce stigma and discrimination, for example in relation to people with HIV or mental illness. Fighting stigma and discrimination against people living with HIV is one of the priorities under the existing EU HIV/AIDS Action Plan 2014-2016. To this end, projects under the Health Programme[3] contribute with concrete activities on the ground, such as training of healthcare workers to improve access to prevention, testing and care for vulnerable groups. Similarly, a report of the European Framework of Action for Mental Health and Well-being[4] includes recommendations to avoid stigma in patients with mental health problems. Coordinated policies and initiatives at EU level that target less health inequality contribute to a lower rate of work disability in vulnerable populations. People with low socio-economic status and other vulnerable groups have a higher tendency to engage in unhealthy lifestyle behaviours and have worse overall health. Reducing health inequalities can mitigate the vicious cycle of ill health and poverty.

[2] European Commission Staff Working Document (2013) 43 – Investing in Health
[3] For example, Chafea/2015/Health/38
[4] http://www.mentalhealthandwellbeing.eu/

An important priority for DG SANTE is to support the modernisation of health systems in Member States, in particular to reduce levels of "amenable" and "preventable" mortality[5] without increasing the level of public spending on healthcare i.e. those deaths influenced by public health interventions and prevention strategies and those influenced by health care. Doing so would make an important contribution to the economic structure of Member States as well as rates of labour force participation.

Similarly, DG SANTE targets an increase in the number of jobs in health activities and residential care, again, not through higher spending, but greater efficiency and productivity i.e. maintaining a constant level of spending per capita. The Commission will help Member States to tap into the job-creation potential of the healthcare sector by supporting skills analysis and improved labour market intelligence. This will help the EU to better anticipate skills needs and inform education and training in the health sector (including new professional roles).

A focus on antimicrobial resistance

AMR is a global challenge with significant consequences for the economy and human health unless tough action is taken to address it. 700 000 deaths in the world each year are currently linked to antimicrobial resistance; the associated economic cost is estimated to be €1.5 billion in loss of productivity and healthcare costs. By 2050, recent projections suggest that lives lost to AMR will rise to 10 million and the cumulative economic cost will be around 1.5 times the world's GDP today.

The EU is a global leader in the fight against AMR. Its 2011 Action Plan is viewed as a precursor to a number of global initiatives including the WHO's Global Action Plan on AMR, launched in May 2015. Building on the work carried out so far, the Commission can create the momentum for a coordinated response and focus its efforts on three key areas where there is clear European added value:

- Make the EU a global best practice region on AMR and create a strong EU "One-health" AMR network bringing together with Member States and relevant experts from both veterinary and human health fields.
- Promote research and innovation and boost the development of antimicrobials, rapid diagnostics tests, vaccines and alternative treatments.
- Strengthen the role of the EU in the global agenda, notably through the WHO Global Action Plan on AMR and enhanced strategic cooperation with key international organisations and partners.

A decrease in antimicrobial resistance would contribute to a healthier population, more sustainable health systems and generate substantial efficiency gains for national economies and the EU as a whole. In order to make the EU a global best practice region on AMR, DG SANTE will , among other actions, explore defining EU AMR targets for the reduction in antimicrobial consumption across the EU within 5 years in humans and animals as well as voluntary targets for reducing key resistant infections; draft harmonised guidelines on prudent use of antimicrobials in the human health sector based on good practices and lay down, in cooperation with the Member States and relying on their experience, recommendations for harmonised monitoring of AMR in the human health sector.

[5] Amenable mortality" is influenced by health care, whereas "preventable mortality" is influenced by public health interventions and prevention strategies focussing on wider health determinants e.g. behaviour and lifestyle factors, socioeconomic status and environmental factors

Specific objective 1.1: Better preparedness, prevention and response to human, animal and plant health threats

Tackling cross-border health threats

In both the health and food sectors, epidemics and infections represent a serious security risk and a direct economic cost. They have a devastating impact on growth, consumer confidence and international market access if they are not contained or well-managed. On the basis that "prevention is better than cure" and more cost-effective, crisis preparedness, prevention and response capacity in the field of human, animal and plant health and food safety will remain a top priority.

While the EU already has a well-developed and substantial framework for managing crises and disease outbreaks, it must continually evolve to remain robust in the face of new challenges linked, for example, to AMR. Member States increasingly turn to DG SANTE for leadership in crisis management situations, even when the legal framework – e.g. for public health – provides limited scope for intervention. It is well recognised that the EU has an important role to play in helping Member States coordinate their preparation and response capacity.

This objective is essential to ensure full implementation of the EU's legislation on serious cross-border health threats (Decision 1082/2013/EU) and to help Member States strengthen their International Health Regulation (IHR) core capacities, improve inter-sectoral collaboration and business continuity planning, outreach to other zones including accession countries and neighbourhood countries, and to align strategies on communicable disease and other health threats with the "all hazards" approach of WHO.

Progress under this objective will be measured against the number of Member States which have improved preparedness and response planning[6] and the number of Member States with improved preparedness and response planning addressing arrangements aimed at ensuring interoperability between the health sector and other critical sectors (result indicators 1.1A and 1.1B).

In order to provide support to Member States in improving vaccine coverage with a view to reinforcing prevention and preparedness in respect of communicable diseases, DG SANTE will develop a series of actions on vaccines between 2016-2019.

Under the framework of Decision 1082/2013/EU, the Commission will continue to facilitate coherent monitoring of communicable diseases across the EU by adopting case definitions and putting communicable diseases under surveillance. The framework also ensures that the European Centre for Disease Prevention and Control rapidly provides risk assessments which are shared among Member States within the Health Security Committee and the Early Warning and Response System.

As with all areas of health policy, preparedness, response planning and implementation is the responsibility of Member States and the degree to which EU intervention can be successful is largely dependent on Member States providing adequate resources for the relevant activities.

Managing and isolating outbreaks of major animal disease

Similarly, one of the EU's most important tasks in animal health policy is to ensure we can rapidly react to, isolate and eradicate outbreaks of major animal disease, the most important of

[6] in accordance with Article 4 of Decision 1082/2013/EU on serious cross border health threats, in particular with regards to the implementation of the core capacity standards under the International Health Regulations (IHR)

which are foot-and-mouth disease, classical and African swine fever, highly pathogenic avian influenza and the emerging lumpy skin disease.

When such outbreaks do occur, they impact across the industry from primary producers to trade and export restrictions. An effective crisis management policy allows us to mitigate potential damages and ensure the internal market for live animals and animal products continues to function smoothly and safely and international trade continues unrestricted. This requires the continuous fine-tuning of numerous animal health rules and the management of actual, evolving situations.

Our success in doing so will be measured against 1) the reduction of restrictions in the EU caused by outbreaks of major epidemic animal diseases (foot and mouth disease, classical swine fever, African swine fever, avian influenza and lumpy skin disease) and 2) containment of spread of these diseases in the EU after the initial outbreak (result indicators 1.1C and 1.1D). The latter in particular shows the effectiveness of Member States - with help and coordination from the Commission – to halt the spread of these diseases where they occur. Its success is therefore dependent on Member States implementing EU rules properly and stakeholders complying with them.

Preventing plant disease

Globalisation of plant trade has substantially increased the risk of plant pest infestation - EU Member States currently notify over 200 plant health outbreaks every year. Whilst the current plant health crisis management system is effective, there is a recognised need to improve it at both national and EU level. In the coming years, DG SANTE plans to reinforce it with a harmonised surveillance and detection system for new pests and early intervention which will form part of a new EU Plant Health Regulation due to be adopted in 2016. This will help mitigate the very high costs linked to phytosanitary risks.

In particular, there is a need for a transparent, permanent EU surveillance structure for new pests. It is essential for early detection and control actions and to limit the economic/trade impact of plant disease and infestations. Under the new plant health proposal, annual survey programmes will become compulsory. However, success will depend on the Member States' financial and administrative capacity to introduce relevant survey programmes.

Four result indicators will be used to monitor EU action on plant health. 1.1E measures the percentage of the EU territory covered by surveys for pests, in particular for pests not known to occur in the Union territory[7]. The target is 100% by 2020 – up from 50% in 2015.

Result indicator 1.1F measures the percentage of the EU territory covered by surveys for pests considered to be most dangerous[8] i.e. the main regulated quarantine pests known to be present within the EU for which early detection is essential. Obligatory monitoring allows us to follow the evolution of these pests in EU: coverage is currently 100% which should be maintained.

Result indicators 1.1G and 1.1H focus on our response to plant disease, in particular the time between finding and notifying plant pests not known to occur in the EU (1.1G) and the success rate in eradicating such pests (1.1H). The current legal framework sets an 8 day compulsory notification deadline. In 2015, on average it took 42 days for Member States to notify a pest from its finding. Member States must improve significantly their performance in order to comply with the deadline. The Commission will monitor closely and support Member States in enhancing their administrative efficiency to meet the deadline. A short timeframe between the introduction and notification would force eradication measures to be introduced more quickly,

[7] as defined in Directive 2000/29/EC (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme)

[8] as defined in Directive 2000/29/EC

be more cost-efficient and likely more effective, protecting both the environment and the economy from significant damage.

Maintaining well-developed rapid alert systems

Crisis management in each of SANTE's sectors is supported by a series of well-established mechanisms, notably the EU's rapid alert systems, which aim to identify problems early and allow rapid information sharing, response and effective cooperation. They are – and will remain - subject to regular simulation exercises to identify gaps and strengthen the system outside of crisis situations.

Recent statistics highlight the important role these rapid alert systems play: in 2014, 3 157 notifications were sent via RASFF alone, the EU's Rapid Alert System for Food and Feed, 751 of which required immediate action. Similarly, 13 435 animal disease alerts were notified through the Animal Disease Notification System (ADNS). SANTE aims to respond to 100% of its RASFF alerts within 24 hours. This will continue to be the case over the course of the strategy.

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

A high number of human diseases linked with the food/feed chain can seriously affect consumers' health and jeopardise confidence in food safety across the EU single market. Past crises such as E. coli in 2011 had serious economic consequences for the agricultural and food production sectors due to the sudden loss of confidence as well as major difficulties in maintaining the EU's trade relations with its international partners.

There is a specific need for an EU coordinated response to challenges posed by outbreaks of foodborne pathogens, continual fine-tuning of the EU's rules and close, effective management of evolving situations. Day-to-day management will focus on prevention, reducing the incidence of animal diseases and plant pests and minimising the impact of any outbreaks to health and the economy.

Success in this respect is measured by the reduction in the number of cases of diseases in humans in the EU linked to food safety or zoonoses (result indicator 1.2.A). The indicator targets a sustained negative trend in the incidence of human salmonellosis which will depend on maintaining effective control measures, based on sound scientific evidence. While it is up to Member States to take such control measures, the EU plays a key coordinating role in cases of high-profile, multinational outbreaks of foodborne pathogens. At the same time, audits performed by DG SANTE (see specific objective 1.6) assess contingency planning in Member States for food-borne emergencies and promote constant improvement of control systems.

Encouraging innovation in the food sector

DG SANTE manages a substantial number of approval processes for substances used in the production and processing of food including additives, flavourings, enzymes and food contact material, GM food & feed, novel foods, and products used at farm level e.g. pesticides and feed. All these approvals contribute to innovation and are needed to help the food industry and agricultural sector remain competitive. The legal framework provides, in most cases, clear deadlines for the approval processes (food additives/pesticides). It is DG SANTE's responsibility to respect these deadlines to ensure predictable market access and guarantee that any product entering the market can remain there as long as it meets safety requirements.

SANTE also manages the establishment of enforcement levels, such as maximum residue levels. This contributes to the free movement of products within the single market as well as imports,

and provides the relevant information to enforcement authorities to detect non-compliant products so that appropriate measures can be taken to protect the EU consumer.

Progress will be measured by the compliance rate with legal deadlines for authorisations and re-approvals of substances used in food (food additives and pesticides) – result indicator 1.2.B. The target is to increase this rate from 76% to 85% by 2020. Even though approval processes are largely dependent on DG SANTE, enforcement is down to Member States and Food Business Operators are ultimately responsible for applying the rules at source.

Ensuring effective implementation of EU food legislation

On implementation, the EU has a unique and critical role to play, responsible on one hand for applying and harmonising food and feed safety standards at EU level while on the other ensuring that Member States and stakeholders enforce and fulfil its rules "at source". It also has an important duty to keep legislation up-to-date and fit-for-purpose to ensure citizens feel well-protected and the internal market for food products continues to function uninterrupted.

As production and innovation increase so too do requests for legislative authorisations within the food sector. Each year, DG SANTE sends around 200 requests for scientific opinions and 500 questions to the European Food Safety Agency (EFSA). In 2014, there were 50 authorisations and notifications for novel foods alone, 3000 seed registrations and 50 decisions on pesticide residues.

Result indicator 1.2.C focuses on DG SANTE's compliance rate with its legal obligations to complete delegated and implementing acts identified as a priority under new EU legislation on novel foods (Regulation (EU) 2015/2283). This allows us measure whether the EU, within the limits of its competences, has fully satisfied its legal obligations to regulate priority areas.

Better Regulation: streamlining the EU's framework for animal health

The EU's new Animal Health Law, due to be adopted in 2016, will make an important contribution to the competitiveness and sustainability of EU agriculture and aquaculture, refining and improving the existing framework to provide more flexibility and clarity within these sectors.

Over the course its strategy, DG SANTE will consolidate a series of supporting measures – tertiary legislation – to help deliver key objectives including the prevention and eradication of disease and the use of modern technologies to support surveillance and detection. At the same time, work to conclude discussions on new proposals to improve the system for official controls will continue.

Such simplification efforts play an important economic role. In particular, SANTE's contribution to effective animal disease control has helped to reduce public expenditure in this area over the last 25 years. It has also played an important part in increasing EU exports in food from animals over the same period.

Ensuring a sustainable food production that improves the welfare of animals

Good treatment of animals is an integral part of a sustainable food production. Consumers and citizens are increasingly concerned by the conditions in which animals are treated. In the animal welfare area the Commission will first complete the EU animal welfare strategy adopted in 2012, ensure a follow-up of the Eurobarometer survey as well as establish regular stakeholders' dialogues. Activities will largely focus on enforcement of existing rules in Member States, the development of joint actions with stakeholders as well as on exploring the potential market value of EU animal welfare standards at global level. All these objectives will be increasing

integrated with other policy objectives for a sustainable production and trade in order to ensure a coherent approach for developing innovation and competitiveness in a global perspective.

The outcomes of these works will be used as input for evaluating the possible actions beyond the completion of the strategy foreseen by the end of 2017.

Improving food information to consumers

DG SANTE is carrying out the follow up actions set out in Regulation (EU) No 1169/2011 on the provision of food information to consumers. It is working on the report concerning the application to alcoholic beverages of the mandatory indication of the list of ingredients and of the nutrition declaration, from which they are currently exempted. The report is expected in 2016.

Helping to reduce food waste

Efforts will be made over the course of the strategy to contribute to initiatives that reduce food waste at each stage of the food supply chain. This links to work in the context of the Circular Economy Package and the Sustainable Development Goal (SDG) on food waste adopted by all Member States in 2015. It aims to halve per capita food waste at retail and consumer level by 2030.

DG SANTE will play an instrumental role in the EU's Action Plan, due to start in 2016. It will develop a common EU methodology to measure food waste and define relevant indicators and create a new platform bringing together Member States and all actors of the food chain to examine how to achieve the SDG, share best practices and evaluate progress. DG SANTE will also examine ways to improve EU legislation on food waste including on the use of former foodstuffs for animal feed and on date marking (e.g. "best before").

Fighting against food fraud

Efficiently combating food fraud will remain a priority, because the integrity of food is essential to ensure a high level of safety and quality of EU food products, and for the protection of consumers. The Commission continues the work initiated in this area with the Member States, giving full consideration to the European Parliament's recommendations. The Commission has built a team dedicated to the fight against food fraud in order to better coordinate the actions between the Member States authorities and the European and international bodies acting in the field of police (EUROPOL, INTERPOL) and justice (EUROJUST).

The creation of an EU Food Fraud Network (28 Member States and the Commission) ensures cross-border cooperation in case of suspicion of frauds. Since July 2013 the network has exchanged information on more than 200 cases. Its members are communicating through a dedicated IT system while making largely use of existing means as notifications coming from the RASFF network and traceability data coming from the border inspection operators in the TRACES system. Building effective synergies between these three networks is a major action for 2016. The Commission will also keep on proposing specialised training to food inspectors and law enforcement agents on new investigation/control techniques related to food fraud.

After having strengthened the collaboration between Member States, the Commission will engage on specific cooperation with non-EU counties on these issues.

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

Specific objectives 1.3 and 1.4 target more cost-effective and sustainable healthcare systems. A significant part of the cost of health to society – up to 70% - is linked to chronic disease, the majority of which can be prevented if certain key risk factors are addressed - alcohol, smoking, poor nutrition and physical inactivity. If nothing is done to manage current trends, the cost of health care is expected to double by 2050 with crippling consequences for the economy. Preventing chronic disease would generate substantial cost-savings in related care, prolong healthy work life and reduce the impact of ill health on the labour market and economy. It is an EU priority as well as a global one identified by the World Health Organisation (WHO).

Though health policy is a national responsibility, experience shows that an effective way to promote health and prevent disease is to share best practice and support Member States in the design and implementation of targeted initiatives, involving stakeholders where relevant and appropriate. The Joint Action on chronic diseases produced a systematic review of good practice for prevention of chronic diseases, as well as recommendations on how to structure and implement national diabetes plans. Moreover, in implementing the Strategy on Nutrition, Overweight and Obesity-related Health Issues 2007, Member States have made great strides in the context of the EU Framework for National Initiatives on Selected Nutrients. The High Level Group on Nutrition and Physical Activity agreed in December 2015 to an Added Sugars Annex promoting a voluntary reduction of 10% in added sugars in processed food by 2020. This document was validated by all EU Member States, Norway and Switzerland.

Reformulation has clear cross-border implications both for companies and authorities wishing to achieve public health objectives. EU-level coordination is crucial for Member States to be effective in controlling excessive intake of nutrients of concern and to ensure consistency across the EU market.

DG SANTE is also working on an impact assessment on trans fats, following a report which suggested a legal limit for industrially produced trans fats as the most effective measure in terms of public health, consumer protection and compatibility with the internal market. Based on the impact assessment the Commission may propose an initiative aiming to restrict the use of industrially produced trans fatty acids in foods.

Three result indicators will measure progress under this objective. Result indicator 1.3A measures the number of Member States with an integrated national plan to address chronic disease in place which implements the WHO non-communicable diseases (NCD) targets. The target is that all Member States will have national plans by 2019 which reflects EU priorities as well as the WHO global action plan and the UN process on non-communicable disease.

Similarly, result indicator 1.3B will monitor the number of EU countries with national initiatives on 1) reduction of saturated fat, 2) reduction of salt, 3) reduction of sugar and 4) reduction of alcohol-related harm, with coverage in all Member States the target by 2020.

Result indicator 1.3C will track the number of EU countries in which a European accreditation scheme for breast cancer services is implemented, currently none, but targeting 24 by 2019.

Screening programmes are an important part of preventive medicine, reducing mortality levels as well the need, in some cases, of more advanced and complex treatments – early detection of cancer significantly increases the chance of survival and can save billions of euros in subsequent care.

Cancer screening guidelines were developed through EU level cooperation between highly qualified experts across the EU. They represent the official health care quality standard at EU

level and have been implemented in Member States to mandate population-based screening programmes to improve the diagnosis and management of cancer.

Such guidelines could not have been achieved by Member States operating separately and individually. The cost of developing EU guidelines on breast and cervical cancer screening was €21 million. It would have cost significantly more to develop guidelines at Member State level and would have resulted in less coherency across the EU. For less than €0.05 per EU citizen, anyone participating in an EU screening programme for breast or cervical cancer has the assurance that there are common EU standards.

Implementing a European accreditation scheme for breast cancer will reduce inequalities between Member States, facilitate the implementation of evidence-based recommendations provided by guidelines and improve cancer prevention.

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

To face the dual challenge of rising healthcare costs and public spending constraints, healthcare systems need to become more cost-effective, accessible and robust to remain sustainable. In part, this requires adapting to and facing specific challenges, in particular preventable chronic disease and the rise of AMR. In part, it means embracing and making full use of innovative new technologies that can support more cost-effective and flexible healthcare solutions.

Directive on patients' rights in cross-border healthcare supports Member States in promoting access to care, regional collaboration, data exchange and achieving efficient healthcare systems. The Directive contains provisions for patient mobility and for innovative cooperation among health systems, such as eHealth and European Reference Networks. The proper transposition and implementation ensures that the Directive will be a strategic healthcare tool in the EU.

Promoting innovation in healthcare

eHealth – including telemedicine and mHealth - will play an essential role in this: it offers important opportunities both in respect of treatment and care and the economy and growth. Indeed, the market for telemedicine alone is expected to reach €45 billion by 2020. It is a key element of the Digital Market Strategy and has the potential to bring about significant cost reductions and better patient outcomes within a modern, open care framework.

DG SANTE will actively support and encourage increased interoperability of digital health solutions between Member States, notably via the EU's eHealth network and through its eHealth Action Plan 2012-2020. The Action Plan is now in an important phase in which activities are focussed on the deployment of a European infrastructure, and specifically on the cross-border exchange of ePrescriptions and Patient Summaries. eHealth has an important role to play in delivering the objectives of the EU's Directive on cross-border healthcare: greater patient mobility, cross-border data exchange on patients, and the possibility for patients to access safe and high-quality care, treatment and medication outside of their own Member State. By connecting health systems within the Digital Single Market, it gives both patients and the healthcare industry greater access to innovative and cost-effective products in their home country and adds treatment options cross-border. This is particularly relevant, for example, in the treatment of rare diseases.

The deployment of eHealth solutions across Member States' health systems can play an important role in increasing more efficient use of scarce resources and providing possibilities for an integrated approach through better flow of information in healthcare. Furthermore, eHealth could increase the quality of healthcare by preventing duplication and mistakes. Telemedicine

improves access to healthcare for people living in remote areas or those who are less mobile. As an example, the EU funded project United4Health evaluated the impact of real life deployment of telemedicine services for chronically ill patients in fourteen regions of eleven countries. The MAST method evaluation demonstrated the benefits of telehealth and unlocking the market for these services.

Result indicator 1.4A will measure the number of countries that have the capacity to health data exchange and join the Cross-Border eHealth Information Services, with a target of 18 by 2020. In an ideal world, all 28 Member States will have connected to the infrastructure by 2020. However, the reality is that a number are not yet sufficiently advanced in their application of ePrescriptions and patient summaries.

Reducing antimicrobial use in humans

Given the enormity of the challenge presented by antimicrobial resistance (AMR) and its potential to impact catastrophically on human and the economy and healthcare systems, urgent and far-reaching action is needed. OECD estimates value the cumulative impact of current levels of AMR at €2.9 trillion, mainly due to increased healthcare costs and lost productivity. Another UK government forecast estimates that if AMR levels continue to rise, the economic impact could be 100 times this figure. In 2013, the British Medical Journal described AMR as "an "apocalyptic" threat similar to that of climate change".

Tackling AMR requires action at all levels. Excessive and inappropriate use of antimicrobials in the health sector is the fundamental cause of AMR and the health sector needs to adopt a new and up-to-date approach that limit abuse of antimicrobials and increases awareness of the need to use them correctly. Result indicator 1.4B focusses on this precise challenge: a reduced level of average EU consumption of antibiotics in humans. Though ambitious, the target of a 30% reduction in EU consumption of antibiotics in humans by 2021 is achievable if current best practice consumption patterns are adopted for the majority of the EU population.

Action on AMR will also have direct consequences for competitiveness and efficiency e.g. in social welfare and labour market participation. The EU must continue to play a leading role in the fight against AMR, promoting cooperation across Member States and actively engaging at international level.

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

DG SANTE's fifth specific objective is to promote greater access to medical expertise and information for medical conditions, notably via European Reference Networks (ERN). ERNs are expected to become operational in 2016, with the first call for proposals planned for February 2016. They will bring together highly specialised healthcare providers from different EU Member States in areas where expertise is rare, giving patients with specific conditions better access to high quality, affordable healthcare and providing a focal point for medical training and research, information exchange and healthcare evaluation. In doing so, they will provide important economies of scale and allow a more efficient use of increasingly stretched EU healthcare resources. Their implementation is currently one of the most important and innovative pan-European cooperation initiatives in health care and the only one at EU level with a legal base.

The objective will be measured against the number of established European Reference Networks (result indicator 1.5A) with a target of 30 set for 2020. This depends however on the number of proposals received and the number of approvals granted by the ERN board of the Member State. There is also an important challenge vis-à-vis funding since the legal base does

not provide a mandate to the Commission to provide administrative budget to the approved Networks. Financial support to some key activities related with to networking and core coordination activities is needed. Currently the Health Programme is the only tangible tool to finance Network but is limited to short actions both in terms of time and available budget.

In order to provide information on rare diseases, including existing guidance on diagnosis and care, the Commission, will continue to support the development and maintenance of the Orphanet database (the world reference database on rare diseases). The database describes approximately 6000 rare diseases and is the major repository of information for health professionals and patients. The support for the development and maintenance of the Orphanet database will be measured by number of data requests from the database (result indicator 1.5B).

In the area of rare disease registries, the Commission will maintain its efforts to ensure a transparent and coordinated approach between several actors in the field. The European Platform on Rare Diseases Registration plays a key role addressing the fragmentation and sustainability of data on rare diseases. It works on interoperability of data and supports a coherent way of data collection from existing rare diseases registries. The development of the European Platform on Rare Diseases Registration will be measured by the number of supported rare diseases and by the size of the EU population covered by surveillance networks (result indicator 1.5C).

The Commission will continue to cooperate with national and regional authorities through the European Network of Cancer Registries (ENCR), which is the only European repository for epidemiological data for a chronic disease. Nothing similar exists for any other chronic diseases. Up to date, more than 200 cancer registries are connected under the Network in Europe. Data collection systems in different countries reflect the specific organisation of national health systems. Barriers persist in data access and not all national indicators are comparable across the EU. In order to improve quality and harmonisation of data, the ENCR and the Joint Research Centre are organising a call for data intended for all the European Cancer Registries in order to build a unique anonymised database of cancer data. This will permit to have much more accurate calculations for cancer survival rates.

Specific objective 1.6: Effective, efficient and reliable controls

Strict enforcement of the EU's rules on food safety, animal health, plant health and animal welfare are essential to ensure that our high standards are not compromised and that industry can operate on a level playing-field. I it is essential that the legislative framework for official controls across the food chain functions well to ensure businesses and consumers benefit and profit from it to growth and competitiveness within this important sector.

DG SANTE verifies that EU rules for food safety are complied with and that official controls respect EU law. Following an audit, DG SANTE makes recommendations to EU or non-EU countries to address any shortcomings via an action plan which it then evaluates and monitors. Its analysis and verification of control systems also feeds into policy development and best practice initiatives.

Result indicator 1.6.A measures the percentage of DG SANTE's recommendations following its audits that Member States have satisfactorily addressed with corrective action. It indicates the effect that the recommendations have in promoting compliance with the relevant single market rules. However, the desired effects and expected outcomes depend heavily on the willingness and vigour of Member States and non-EU country authorities to act.

Specific objective 1.7: Increased EU influence in international fora

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) and the International Plant Protection Convention (IPPC) to ensure that EU standards are recognised and accepted and that the EU is well represented with "one voice" in international fora. 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.

Contributing to global health resolutions

As part of its global health policy the Commission collaborates with the WHO and contributes actively to many international activities relating to health security, medicinal products, products of human origin, public health etc. In this context, we are working towards a comprehensive and sustainable framework for public health information with the WHO and the OECD.

Historically, EU Member States have negotiated texts individually at WHO governing bodies but in recent years there has been a move towards more coordinated EU action. This is associated with greater uptake of EU input into the texts of agreed resolutions, a trend which will be monitored by result indicator 1.7.A – percentage of the total number of WHO Governing Body Resolutions adopted annually which contain EU input. It shows the way in which the EU promotes its standards and regulatory models at global level and feeds in to shape global norms and policies.

Contributing to harmonisation in the pharmaceutical sector

The EU pharmaceutical industry is a global leader in a highly innovative sector. It generates more than €200 billion annually, is the EU's top sector in R&D intensity (14.4%) and one of Europe's major high-technology employers accounting for around 885 000 direct and 3.5 million indirect jobs. The EU is by far the major world trader in medicinal and pharmaceutical products, with trade amounting to over €170 billion in 2013.

DG SANTE's priorities for pharmaceutical regulation and innovation for 2016-2020 include promoting a stable and efficient regulatory framework and promoting EU health and safety standards for pharmaceuticals globally. An important part of this is harmonising standards internationally through the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

DG SANTE, supported by EMA, is heavily involved in ICH and its activities. Harmonisation through the adoption of ICH guidelines will facilitate access to multiple markets, including those of US, Switzerland and Japan, the three most important export markets for the EU. It has an important role to play in maintaining and boosting EU competitiveness.

DG SANTE is also promoting the expansion of ICH to regulators from other important or emerging markets, such as Russia, China, Australia and Brazil, establishing conditions and incentives for the relevant regulators to join ICH and implement its harmonised guidelines.

Result indicator 1.7.B will monitor the increased recognition of ICH guidelines at global level and increased global harmonisation, including with the US.

Aligning EU food safety legislation with international standards

Harmonisation is also an important priority in the food sector. As the largest exporter and importer of food in the world with a well-recognised and respected framework of food safety legislation, the EU must ensure that its food safety standards are aligned with the relevant international standards e.g. notably those set in the WTO, Codex Alimentarius, OIE and IPPC to ensure its competitive position is not compromised.

Sometimes the EU approach is challenged within the WTO when measures taken by the EU are thought to limit trade from other countries. Equally the EU may take a case to the WTO when non-EU countries impose unsubstantiated import bans on EU products.

In mid-2014, the EU launched such a WTO dispute settlement procedure against the Russian Federation due to their ban on live pigs and pig products from the EU. This EU-wide ban was imposed despite an outbreak of African Swine Fever in a rather small corner of the EU covering parts of Lithuania, Poland, Latvia and Estonia and significant control measures being introduced. The EU considers the ban to be disproportionate and in breach of the regionalisation principle which is specifically designed to allow trade to flow from disease-free areas of a country. The final report of the WTO panel is foreseen in April 2016.

Ideally, disputes are resolved through negotiations (the EU only initiates a WTO dispute settlement case when alternative solutions have been unsuccessful). Result indicator 1.7.C will monitor the number of WTO cases brought against the EU, targeting a maximum of 5 cases by 2020 based on the assumption that as EU legislation is increasingly aligned with international standards, fewer cases will be brought against it by other WTO members.

At the same time, SANTE aims to put in place an ambitious export promotion strategy, in cooperation with Member States, stakeholders and other Commission departments to identify where we can work better together to increase exports and reduce Sanitary and Phytosanitary (SPS) barriers.

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 – in particular in food and pharmaceutical products – can take place freely and that innovation is encouraged. Overall progress under this objective will be measured via impact indicators 2.1-2.4.

SANTE will monitor the contribution of the health sector to the Commission's impact indicator on the Gross Value Added (GVA) of EU industry in GDP (2.1). This will be supported by the sector specific data (Table 1 in Annex 1), GVA of the EU health sector (human health activities) in GDP remained stable between 2008 and 2013 and amounted to 4,6%.

SANTE will also monitor its contribution to the Commission's impact indicator measuring the intra-EU trade in goods as a percentage of GDP which aim to increase by 2020. The data for Intra-EU trade in food (and live animals) as a % of GDP show a steady increase since 2008 reaching 1,9% in 2013 and remaining at the same level in 2014 (Table 2 in Annex 1). This demonstrates a well-functioning internal market due to clear and harmonised rules being applied and adhered to across the EU by operators and authorities and being recognised as both proportionate and efficient.

The steady increase in intra-EU export/import in live animals and food products is expected to continue, in 2014 reaching respectively 263.7 billion euro and 258.6 billion euro (Table 4 in Annex 1). This trend will be further supported by ongoing efforts to reduce administrative burden in the sector.

The trust created by the body of harmonised legislation regulating food safety in the EU goes beyond EU borders as figures show. While intra-EU exports/imports in food are growing, it is at a slower pace than the growth of extra EU export/import in food (Tables 3 and 4 in Annex 1). The increase in extra-EU trade in food is the result of the recognition of the EU's high standards. The EU brand is known for its quality, especially on foods which thus win markets despite higher production costs in Europe.

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

Health Technology Assessment (HTA) is a multidisciplinary process that presents information about the medical, social, economic and ethical issues related to the use of a new health technology (pharmaceutical product, medical device or health intervention) in a systematic, transparent, unbiased and robust manner.

It informs decision makers on the formulation of safe, effective health policies that achieve best outcome and value for money for patients, health professionals and health systems. It answers questions like: Is the technology effective? For whom does it work? What costs are entailed? How well does it work compared to alternative technologies? HTA offers great opportunities to promote efficiency and effectiveness of healthcare. It allows promoting sustainability in the healthcare system but also the use of innovative products directly benefiting patients.

It offers clear opportunities to further President Juncker's priorities: "A new boost for jobs, growth and investment"; "A deeper and fairer internal market with a strengthened industrial base", and the greater reliance on evidence based policy making.

Over the last decade the EU has sought to develop coordination and support mechanisms together with Member States. One of the key results has been the design and establishment, in 2006, of the EUnetHTA, a widely recognised network and community developing common assessment methodologies, information tools and starting to produce joint reports. By 2019, the last possible year to offer financial support, the Health Programme managed by DG SANTE will have invested around EUR 23 million on the EUnetHTA through three consecutive Joint Actions.

In the Single Market Strategy (COM(2015) 550 final) the Commission committed itself to improve the functioning of the internal market for health products and to introduce an initiative of health technology assessments to increase coordination in order to avoid multiple assessments of a product in different Member States. This will build on the EUnetHTA and ensure a sustainable, permanent cooperation mechanism after 2019.

One key output indicator of EUnetHTA is the production of joint HTA reports. Assessments can be of various nature, such as joint EU rapid assessments of pharma products and medical devices at the time of licensing, joint reassessments of the same technologies after some years, early dialogues and scientific advices.

The key external element is the Member States' willingness and resources to engage in joint work and to produce national reports taking the advantage of the EU reports. A second external factor is the willingness of individual companies to engage in the assessments.

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

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 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. It is based on the principle that medicinal products may be placed on the market only following a marketing authorisation granted either at EU level by the European Commission or at national level by Member States' competent authorities.

Innovation in healthcare gives citizens and patients access to novel products, services and treatments. The European Commission bases authorisations for centrally authorised medicinal products on the opinion of the European Medicines Agency (EMA). By ensuring new medicinal products are authorised within the legal deadlines, particularly innovative medicines of major interest to public health, DG SANTE supports competitiveness in the pharmaceutical industry, ensuring earlier market access for products and improving patients' access to safe medicinal products (result indicator 2.2). A target of 95% by 2017 allows for delays in certain procedural steps in the approval process that are outside of the Commission's control.

As a means to support companies and academia, in particular SMEs, with the development of promising new medicines to address unmet medical needs, EMA plans to introduce a new scheme, PRIME (PRIority Medicines) in 2016. This will give those developing eligible products access to an early dialogue and scientific advice to ensure that the data generated during development meets the standards required for regulatory approval. The scheme is expected to support prompt evaluation and authorisation and give patients access to new medicines that address unmet medical needs.

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

In response to President Juncker's mission letter to Commissioner Andriukaitis, SANTE is strengthening its country-specific and cross-country knowledge. In 2016-17, SANTE intends to roll out the deliverables of this expertise in the first two-year *State of Health in the EU* cycle, together with the OECD and the European Observatory on Health Systems and Policies.

In even years, the joint EU-OECD report *Health at a Glance: Europe* will be published, readjusted to the Commission's priorities of effective, accessible and resilient health systems.

In every odd year, twenty-eight individual country health profiles for will be published, along with a Commission Staff Working Document that distils a cross-country, EU level narrative, focussing on best practices, concrete tools and processes and further EU added value. The country health profiles will be prepared in a tripartite collaboration with the OECD and the European Observatory on Health Systems and Policies.

These deliverables will support Member States' capacity to improve the effectiveness, accessibility and resilience of their health systems and will help identify potential areas of EU added value in which the Commission could support Member States through EU action.

DG SANTE is also building expertise on the performance of health systems in EU Member States, as requested by President Juncker in his mission letter to Commissioner Andriukaitis. This country expertise is ultimately intended to identify tools and methodologies that will contribute to better and more accessible healthcare and more efficient and more resilient healthcare systems. It also contributes to more cost-effective health promotion and disease prevention by providing the necessary evidence base for such policies. Moreover, the country knowledge on the performance of health systems goes beyond the work of the European Semester to inform policies at national and European level.

To achieve this, DG SANTE has set up and co-chairs a Commission expert group on health systems performance assessment (HSPA) which establishes a policy priority for each calendar year. SANTE supports the works of the expert group and encourages Member States to exchange best practices and to adopt findings and recommendations endorsed by the expert group. Result indicator 2.3.A measures the number of Member States that refer in national policy documents to the recommendations and findings of the expert group on HSPA, with a target of 15 by 2020.

General objective 3: A reasonable and balanced free trade agreement with the US

A free trade agreement with the 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 will measure its contribution to the Commission's impact indicator 3.1 - 'Share US in total EU FDI stocks' (in Annex 1) by comparison of data for sectors which are under SANTE policy, namely pharmaceuticals and food. Unfortunately, the data for the food sector is combined with tobacco and beverages and cannot be separated due to confidentiality reasons. Table 5 (in Annex I) illustrates that in 2013, as much as 60% of the total FDIs (Foreign Direct Investments) in food, beverages and tobacco in the EU were from the US and as much as 78% in pharmaceutical sector. On the other hand, 18% of the EU FDI in food, beverages and tobacco sector were invested in the US and 62% in the pharmaceutical sector.[9] These ratios are expected to increase as a result of the TTIP negotiations.

DG SANTE will also measure its contribution to the free trade agreement with the US by looking at the trend in the share of US trade in food and live animals of the total EU-extra trade in food and live animals. This share has been steadily increasing since 2011 (see Table 6 in Annex 1). In 2014 it reached 7.7%. Concluding negotiations on TTIP and making exchange easier between the two sides of the Atlantic would likely contribute to further increases.

Similarly, DG SANTE would measure its contribution to the free trade agreement with the US by looking at the number of inspections on Good Manufacturing Practices for pharmaceutical products. DG SANTE would aim at a decrease in the number of inspections due to mutual recognition of these inspections. A free trade agreement with the US and the mutual recognition of Good Manufacturing Practices inspections would allow the EU (with all Member States inspectorates recognised as a single entity) 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 would lead to a better use of respective inspection resources by avoiding the current overlap of inspections carried out by the different EU, US and authorities of non-EU countries.

Resources freed could be redeployed to other inspection priority areas in non-EU countries. This strengthened bilateral collaboration would provide greater capacity to control the safety of products irrespective of origin. This should lead to reduced risk and promote the global adoption of high level quality standards for the production of medicinal products.

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

Achieving a balanced SPS Chapter that addresses US market access barriers is one of the EU's main aims in the Transatlantic Trade and Investment Partnership (TTIP) negotiations. In particular, this should provide for proportionate, transparent and predictable procedures for EU exporters when wishing to access the US market. Our ultimate goal is to achieve better conditions for trade: greater market access for EU exports at the same time as ensuring our food safety standards are not compromised on imports. DG SANTE also wants to agree with the US that the privileged relationship and increased mutual understanding engendered by TTIP should

[9] The sectoral data include "Special Purpose Entities" FDI

be leveraged to allow an increased reliance on the audits and regionalisation decisions made by each side, thus reducing workload on competent authorities and burden on producers.

The Commission also aims at the EU to be treated as a Single Entity for export, which guides all our international negotiations rather than a collection of 28 individual Member States assessed independently. This would mean that the US would have to accept EU-wide applications for export and carry out systems audits based on visits to a representative sample of Member States, which is currently not the case.

Sanitary and Phytosanitary (SPS) products

Currently, the EU is excluded either wholly or partially from many important US agri-food markets due to SPS barriers. The process of addressing these issues has been formalised in TTIP "Action Plans", which are being negotiated by the EU and US in parallel to the TTIP SPS Chapter.

A second Action Plan was agreed in 2015 which aims to address a number of SPS barriers in the short-medium term (18-24 months). These include those impeding EU Member States from exporting beef, sheep and goat meat, pasteurised dairy products, egg products, apples/pears and other fruit and vegetables. If the barriers are resolved, all interested EU Member States will have the opportunity to export these products to the US.

Progress will be measured by result indicators 3.1.A and 3.1.B, the number of EU Member States authorised to export relevant products to the US, expected to eventually increase to almost all interested Member States on the basis of ongoing authorisations, and the number of barriers not in line with international standards, linked to Sanitary and Phytosanitary (SPS) measures, which is expected to decrease following a successful outcome of the negotiations. A limiting factor here will be the capacity/willingness of the US authorities to address EU Member State applications.

Pharmaceutical products

Increased regulatory cooperation and further harmonisation of requirements for the authorisation of medicinal products will help common development of products and thereby their access on both markets. The EU and the US will work together in the framework of the International Council for Harmonisation (ICH) to further harmonise requirements regarding quality, safety and efficacy of medicinal products. In addition, specific efforts will be made to foster further improvements of the US authorisation system and marketing requirements of biosimilars to improve market access for this type of medicinal products. This is an area where the EU has paved the way for the establishment of a dedicated regulatory framework and where the EU pharmaceutical industry is a world leader. Similarly, the EU will seek to engage more intensively with the US to facilitate market access of generics and in particular generics requiring development programs that include extensive clinical studies.

D. Key performance indicators (KPIs)

KPI 1: Containment of spread of major epidemic animal diseases in the EU after initial outbreak (foot and mouth disease, classical swine fever, African swine fever, avian influenza and lumpy skin disease)

Please see the details in the Annex 1, a table for specific objective 1.1, result indicator 1.1D.

KPI 2: Number of established European Reference Networks

Please see the details in the Annex 1, a table for specific objective 1.5, result indicator 1.5.A.

KPI 3: Estimated residual error rate of on-the spot controls (ex-post) for each policy area

Please see the details for the objective 1, Indicator 1 (Part 2 Organisational management under the section B Financial Management)

PART 2. Organisational management

A. Human Resource Management

DG SANTE HR activities are fully integrated into SANTE's overall management plan. Effective HRM is crucial for the DG's capacity to deliver on its mission. It impacts directly on the main asset of the DG - its staff members - through actions targeting the physical and organisational work environment and individual staff members' professional aspirations, competences, skills and performance.

However action needs to be targeted to the real needs and respect the subsidiarity principle to avoid duplication and inefficient use of resources. Hence, and in accordance with DG SANTE's long expertise of evidence (science) based policy making, a significant effort has been invested in examining the results of the latest Commission Staff Survey involving an in-depth internal DG SANTE scrutiny comprising several steps:

- Trends analysis based on the comparison of SANTE 2014 Staff Survey results against previous Staff Survey exercises (2010, 2013) and to Commission averages (2013, 2014);

- Presentation of the general findings and discussion with SANTE management and staff within dedicated HR Management Committee and knowledge hour. Discussions in each Directorate on their specific survey results aimed at identifying the specific needs for targeted local and DG wide action.

While we learned that DG SANTE's staff satisfaction level declined compared to the 2013 Staff Survey the decline was less marked than the general Commission trend. Moreover, the DG continued to perform much better than the general Commission average. As a result DG SANTE climbed significantly up the rankings of the 54 Commission DGs and agencies based on the different Staff survey key performance indicators (Staff engagement, job and workplace satisfaction).

Despite this, our objective for future performance is broader, especially in areas where staff appreciation was too low. In areas such as 'Senior management', 'Learning and Development (L&D) assistance', 'Talent and Performance management', 'Work life balance', and '2-way communication and feedback' DG SANTE's goal is to reach a more satisfactory performance level.

The feedback received highlighted that the recent and ongoing changes (i.e. Staff Regulations reforms, staff cuts, reorganisations and uncertainty linked to the new Commission) have had an important negative effect on the Staff Survey results. These issues are not directly part of the remits of DG SANTE. Initiatives are being developed and launched at corporate/central level to tackle some of the difficulties highlighted by the results (e.g. the Commission Talent Management Strategy; the fit@work programme; the ongoing examination of the Commission's administrative delivery methods to identify efficiency gains, the ongoing revision of the Commission Decisions on Middle Management, part-time and tele-work, etc.).

Therefore, initiatives at DG SANTE level will complement the central approach in the most effective way and focus on enhancing good communication, inspiring leadership, effective resource planning etc. At the same time, DG SANTE will actively collaborate with central services to suggest possible improvements and to voice the specific needs of colleagues located outside Brussels.

Finally, the result of this "examination" process was presented to DG SANTE's management board at the end of 2015 providing a strategic framework for DG SANTE action towards

achieving organisational excellence. It was agreed that in coming years DG SANTE's HR work would focus on and be structured around the following 4 domains:

- develop the DG's organisation culture and its management (including strong leadership and ownership by its management and balanced gender representation);

- top class organisation and planning (ensuring the adequacy of resource allocation in accordance with DG's priorities and streamlining processes and procedures);

- engage, empower and develop staff (increasing appreciation and recognition of the value of individual contributions, managing talent, supporting well-being on the workplace and better professional v. private life balance);

- better working together (ensuring a working place fostering collaboration, communication and knowledge sharing).

In each domain a number of work packages have been identified and concrete actions are being developed. The list of needs for action cannot all be taken forward at the same time and will be spread over several years and be detailed on an annual basis in DG SANTE's AMP. Prioritisation over time and synchronisation with initiatives and reforms at the corporate level will be essential.

As regards the achievement of the key indicator on female representation in middle management, SANTE needs only recruit 4 additional female middle managers (of a total of 37 middle managers in DG SANTE). The analysis of the potential vacant posts (4 in beginning 2016), the expected turnover (+/- 4) and the number of qualified and experienced female administrators present (e.g. 13 female Deputy Heads of Unit and 10 female Heads of Sector) indicate it should not cause major problems.

Additional benefits for staff engagement will come from pursuing specific activities aimed at encouraging staff to improve areas such as personal assertiveness, pro-activity, self-improvement, independent of the organisation/management. It is envisaged to focus on self-awareness raising activities linked to various soft/interpersonal skills (e.g. assertiveness, and encouraging staff to be pro-active in improving individual skills and taking learning into their own hands).

Efforts to improve Staff well-being action will include further improvements to DG SANTE's approach to flexible working conditions including training on how to manage staff in a flexible working environment. More emphasis will be placed on establishing a 'results based' culture instead of rewarding hours spent in the office. Also special focus will be given to improve awareness – both of managers and staff members - of the impact of effective stress management on the working environment and staff relations. Last but not least DG SANTE's offer of 'fit at work' activities will be increased.

Objective 1: The DG deploys effectively its resources in support of the delivery of the Commission's 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.	
Indicator 1: Percentage of female representation in middle management **Source of data:** Sysper	
Baseline: 27% at end 2015	Target: 35% by 2019 in accordance with the specific targets in SEC(2015)336, "Targets for female representations in management functions in the European Commission for the years 2015-2019". Milestone 1: 30% by 2017
Indicator 2: Percentage of staff who feel that the Commission cares about their well-being[10] **Source of data: Commission staff survey**	
Baseline: 42% in 2014 Staff survey	Target: gradual increase every year reaching above 50% by 2019
Indicator 3: Staff engagement index **Source of data: Commission staff survey**	
Baseline 69% in 2014 Staff survey and place 17 out of 54 DGs and services	Target: keep DG SANTE within top 30% of best performing Commission services

B. Financial Management: Internal control and Risk management

Overarching objective: The Authorising Officer by Delegation should have reasonable assurance that resources have been used in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions including prevention, detection, correction and follow-up of fraud and irregularities.

To achieve the objective, DG SANTE has established a control strategy including all control and anti-fraud measures for all types of expenditure directly managed by the DG in the two policy areas. The control measures encompass risk assessment and risk management integrated into the planning process and control activities including ex-ante and ex-post verifications. Furthermore, DG SANTE co-operates with OLAF and implements fraud prevention and detection measures.

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

Objective 1: Effective and reliable internal control system giving the necessary guarantees concerning the legality and the regularity of the underlying transactions	
Indicator 1: Estimated residual error rate[11] of on-the spot controls (ex-post) for each policy area **Source of data:** Internal follow-up sheet, reported in AAR	
Baseline	Target (according to the control strategy approved by the DG)
2014: 1% (policy area Feed and Food) 2014: 0% (policy area Public Health)	Less than 2% in value of the relevant payment budget (annually or multi-annual depending on

[10] This indicator may be replaced by a fit@work index on which DG HR is currently working.
[11] For the definition, see the first annex to the AAR instructions 2014 "Key definitions for determining amounts at risk" at https://myintracomm.ec.europa.eu/budgweb/EN/rep/aar/Documents/aar-standing-instructions.pdf.

	the design of the programmes)
Indicator 2: Estimated overall amount at risk for the year for the entire budget under the DGs responsibility **Source of data:** Internal follow-up sheet, reported in AAR	
Baseline	Target *(none in EUR amount)*
2014: best estimate of the amount at risk: between EUR 1,6 and 2,8 million	Maximum of 2% of the annual payments made.
Indicator 3: Estimated future corrections **Source of data:** Internal follow-up sheet, reported in AAR	
Baseline	Target *(none in EUR amount)*
2009-2014: average recovery orders and financial corrections further to ex-post controls since 2009: annual average amount of EUR 2,3 million	100% of actual corrections to be made

Objective 2: Effective and reliable internal control system in line with sound financial management.	
Indicator 1: conclusion reached on cost effectiveness of controls **Source of data:** Internal calculation sheet, reported in AAR	
Baseline (year)	Target
2014: No	2017 AAR: Yes
Indicator 2: overall cost of control to total annual budget (commitment appropriations) per control system (grants and procurement) **Source of data:** Internal calculation sheet, reported in AAR	
Baseline (year)	Target *(none)*
2014: 1% (grants) 2014: 5% (procurement)	*Comment: a percentage figure does not give reliable information on the control effectiveness; only a qualitative analysis of the reasons behind the figures and considering the importance of meeting legal deadlines is relevant and useful.*

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.		
Indicator 1: Updated anti-fraud strategy of the DG elaborated on the basis of the methodology provided by OLAF[12]		
Baseline	Interim Milestone	Target
Date of first adoption: January 2014	First comprehensive update: October 2016	Update every 3 years
Indicator 2: Fraud awareness is increased for target population(s) as identified in the DG's AFS **Source of data:** DG's AFS		
Baseline	Interim Milestone	Target
2015: financial officers reached in financial cell network meetings	2 meetings per year	100% financial officers reached
2015: new-comers training on ethics		100% new-comers reached

C. Better Regulation (only for DGs managing regulatory acquis)

Better Regulation is a key horizontal priority for the Commission. The Commission commits to submit the entire regulatory cycle to systematic quality scrutiny and transparency through i.e. impact assessments, public consultations, ex-post evaluations and Fitness Checks. Through the Regulatory Fitness (REFIT) programme, the Commission ensures that EU law achieves its objectives with the least cost and minimal burden to business, citizens and administrations.

[12]The methodology can be found on the FPDNet website: https://myintracomm.ec.europa.eu/serv/en/fraud-prevention/ToolBox/Documents/Methodology%20and%20guidance%20for%20DGs%20anti-fraud%20strategies.pdf. In particular paragraph 3 of the methodology is relevant.

Objective: Prepare new policy initiatives and manage the EU's acquis in line with better regulation practices to ensure that EU policy objectives are achieved effectively and efficiently.

Indicator 1: Percentage of Impact assessments submitted by DG to the Regulatory Scrutiny Board that received a favourable opinion on first submission.

Explanation: The opinion of the RSB will take into account the better regulation practices followed for new policy initiatives. Gradual improvement of the percentage of positive opinions on first submission is an indicator of progress made by the DG in applying better regulation practices.

SANTE did not submit any new impact assessments in 2014 and 2015. Therefore we have decided to take for a baseline an average success rate between years 2011 and 2013. In 2016, SANTE will aim to maintain the positive opinion rate at the baseline level. This will be a challenge given the increased standards introduced by the Better Regulation rules and the specific nature of SANTE policies whose impacts are very difficult to quantify and the complexity of some of our upcoming impact assessments. In the long-term, we aim to increase our positive opinion rate to 60%.

Baseline: average from 2011-2013	Interim Milestone 2016	Target 2020
50%	50%	60%

Indicator 2: Percentage of the DG's regulatory acquis covered by ex-post evaluations and Fitness Checks not older than five years.

Explanation: Better Regulation principles foresee that regulatory acquis is evaluated at regular intervals. As evaluations help to identify any burdens, implementation problems, and the extent to which objectives have been achieved, the availability of performance feedback is a prerequisite to introduce corrective measures allowing the acquis to stay fit for purpose. DG SANTE has identified 37 legal acts (Regulations and Directives) in its acquis. 11 legal acts are covered by evaluation/assessment/review and have already been evaluated in the last 5 year period. Soft policies or evaluations under FR rules are not covered by this indicator.

Relevance of Indicator 2: The application of better regulation practices would progressively lead to the stock of legislative acquis covered by regular evaluations to increase.
Source of data: Planning of Evaluations and studies (2008; 2016); Commission Reporting obligations under the SANTE legislation (own source)

Baseline 2015	Interim Milestone 2016	Target 2020
Percentage of the DG's regulatory acquis covered by evaluations and Fitness Checks not older than five years (2010-2015). Baseline: 30% of SANTE legislation has been evaluated in the last 5 years.	Positive trend compared to baseline (further 24% of SANTE legislation will be evaluated) For more specific information on planned evaluations, please see Annex 3	Positive trend compared to baseline

Indicator 3: Percentage of evaluations planned and finalised in the last year (2015)

Explanation: Evaluations might cover not only regulatory acquis but also soft policies that need to be evaluated. This indicator includes the following evaluations: legal act, legal base of MFF instrument, financial regulation (activities where the resources mobilised exceed EUR 5 000 000), REFIT evaluation, Commission Work Programme - 'evaluate first', or other evaluations

Relevance of Indicator 3: This indicator assesses planning performance of the evaluated areas.
Source of data: Planning of evaluations and Studies 2015

Baseline	Interim Milestone 2016	Target 2020
Number of evaluations planned in the next 5 years (until 2020) Planned: 26	Percentage of evaluations with final report 27% (7 evaluations - please see Annex 3)	100% of evaluations planned are finalised (final report)

D. Information management aspects

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 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, 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, reducing bureaucracy where possible. We actively promote and publish 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 registered by us documents, 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, because we have realised that some units have not protected their files and because of an eventual integration which may increase the number of protected files.

Objective: Information and knowledge in your DG is shared and reusable by other DGs. Important documents are registered, filed and retrievable		
Indicator 1: Percentage of registered documents that are not filed[13] (ratio) **Source of data:** *Hermes-Ares-Nomcom (HAN)[14] statistics*		
Baseline 2015	Target (2020)	
1.24%	0%	
Indicator 2: Number of HAN files readable/accessible by all units in the DG **Source of data:** *HAN statistics*		
Baseline 2015	Target (2020)	
98%	75%	
Indicator 3: Number of HAN files shared with other DGs **Source of data:** *HAN statistics*		
Baseline 2015	Target (2020)	
98%	75%	
Indicator 4: Percentage of units using collaborative tools to manage their activities		
Baseline (2015)	Interim Milestone (2018)	Target (2020)
20% (9 out of 40 Units plus DG and Direction levels)	60%	100%

[13] Each registered document must be filed in at least one official file of the *Chef de file*, as required by the e-Domec policy rules (and by ICS 11 requirements). The indicator is to be measured via reporting tools available in Ares.
[14] Suite of tools designed to implement the e-Domec policy rules.

Indicator 5: Percentage of briefings managed in accordance with a uniform business process and using a common tool **Source of data:** Briefings and Speeches Information System (BASIS)		
Baseline (2015)	Interim Milestone (2015)	Target (2020)
100%	100% (in total 512 requests)	100%
Indicator 6: Percentage of information systems and processes at the highest level of maturity (transformed government) operating as e-services for the digital single market. **Source of data:** Information systems follow up and annual IT Master Plan		
Baseline (2015)	Interim Milestone (2018)	Target (2020)
20%	60%	90%

E. External communication activities

DG SANTE communication for the period 2016-2020 is in line with the President's political priorities listed in the Strategy section, the mission letter to Commissioner Vytenis Andriukaitis and the general and specific objectives described in this Plan. Our communication will aim to improve the image of the Commission by building on the benefits and savings of competitive protective systems in the Health and Food Sectors for the EU citizens.

DG SANTE's communication strategy for 2016-2020 will contribute to the three main priorities:

1. A new boost for jobs, growth and investment in the EU

Given the economic importance and potential of the health and food sectors, DG SANTE communication will aim to:

- raise awareness on emerging threats with serious economic implications for our healthcare systems and livestock sectors, such as antimicrobial resistance (AMR). Successive Eurobarometer reports will help us keep track of public awareness and effectiveness of policy actions. Results and monitoring will also help better target communication at national, EU and international level.
- highlight the economic importance of a strengthened EU preparedness and crisis management in public health, food safety and plant health, including information on efficient, reliable controls.
- increase confidence in the effective, accessible and resilient healthcare systems in the EU, as a key condition for economic prosperity and social cohesion.
- regarding corporate Communication, DG SANTE will participate in the 2016 Action "The Investment Plan and other Jobs and Growth initiatives". At least four health projects to be funded by the European Fund for Strategic Investments (EFSI) will benefit from reinforced corporate communication and will strengthen DG SANTE's links with the Investment Plan and other health-related initiatives contributing to the creation of growth and jobs.

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

DG SANTE will highlight its contribution to encourage innovation and free trade in the internal market, in particular in food and a competitive pharmaceutical sector. Communication will also focus on the benefits provided by Heath Technology Assessment (HTA) and health systems performance assessments in order to promote efficient and sustainable healthcare systems, but also to bring direct benefits for patients.

3. A reasonable and balanced free trade agreement with the U.S.

DG SANTE will communicate, mainly through reactive media relations, its sectorial contribution to the ongoing Transatlantic Trade and Investment Partnership (TTIP) negotiations. It will in particularly try to achieve a better understanding of the Sanitary and Phytosanitary (SPS) measures, in particular in its food safety dimension, as well as the pharmaceutical aspects of the file.

DG SANTE will prepare a separate communication strategy every year during the period 2016-2020, in line with the objectives and targets identified in the Strategic and Annual Management Plans. With this approach, communication is integrated upstream in the policy making process and communication priorities follow closely the political agenda. Communication plans on priorities included in the Annual Management Plans will be also developed, implemented, monitored and evaluated in close coordination with policy units. DG SANTE will also continue to actively engage in the next corporate communication actions to be organised in the period 2016-2020.

Media relations will continue playing a key role in DG SANTE communication in order to provide timely, proactive and reactive information about scientific evidence and the measures taken in specific crises or policy developments. DG SANTE will continue building up a network of journalists covering Health and Food Safety policies, ensuring high quality and accurate coverage of those topics via the organisation of media seminars and media study trips.

In the framework of the Commission-wide Digital Transformation programme, DG SANTE web content will become part of the central Commission website by the end of 2017. SANTE content is foreseen under two classes – "Live, Work, Travel in EU" (Public Health) and "Food and Farming". Once fully integrated from 2018 onwards, Health and Food Safety content will be updated according to the ongoing communication needs and in line with central web governance rules. On social media DG SANTE will continue to develop a strong social media presence, map & engage with influencers in food safety and public health fields, monitor social conversations and trends and make strategic recommendations for the best use of current social media platforms (Twitter, Facebook, Instagram) as well as emerging/new ones, considering the dynamism and constant innovation in the field.

<table>
<tr><td colspan="2">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.</td></tr>
<tr><td colspan="2">Indicator 1: Percentage of EU citizens having a positive image of the EU
Definition: Eurobarometer measures the state of public opinion in the EU Member States. This global indicator is influenced by many factors, including the work of other EU institutions and national governments, as well as political and economic factors, not just the communication actions of the Commission. It is relevant as a proxy for the overall perception of the EU citizens. Positive visibility for the EU is the desirable corporate outcome of Commission communication, even if individual DGs' actions may only make a small contribution

Source of data: Standard Eurobarometer</td></tr>
<tr><td>Baseline: November 2014</td><td>Target: 2020</td></tr>
<tr><td>Total "Positive": 39%; Neutral: 37 %; Total "Negative": 22%</td><td>Positive image of the EU ≥ 50%</td></tr>
<tr><td colspan="2">Specific objective: To improve the image of the Commission by building on the benefits and savings of competitive protective systems in the Health and Food Sectors for the EU citizens[15]</td></tr>
<tr><td colspan="2">Indicator 2: Percentage of EU citizens who are informed about antimicrobial resistance and awareness raising campaigns</td></tr>
</table>

[15] This will be achieved through communication around the priorities mentioned in the narrative (Antimicrobial Resistance, modernisation of Health systems, crisis preparedness/management, notably in Plant Health and the EU as a global health and food safety player)

Source of data: Eurobarometer on AMR	
Baseline: 2013[16]	Target[17]
- 33% received information about unnecessary use of antibiotics - 36% changed behaviour after receiving information	- 40% respondents receive information about unnecessary use of antibiotics - 40% changed behaviour after receiving information
Indicator 3: Number of contacts made as a result of communication actions supporting SANTE's policy priorities **Source of data:** Collated monitoring data collected by SANTE from website visitors, social media reach, events participants and visitors their actions, from monitoring and evaluation contractors; from opinion pools	
Baseline: 2015[18]	Target
222.710.099	50.000[19]

[16] 2013 AMR EB Results

[17] Trends are based on previous EB results on AMR 2009-2013 and targets are an indicative extrapolation based on the joint policy effort to be made in the period 2016-2020 (new Action Plan, increased coordination with MS including communication)

[18] Reach of communication activities in 2015 includes DG SANTE Web unique visitors (8.279.784), Twitter (4.957.000 impressions over the year – 1.255.400 for @Food_EU and 3.702.000 for @EU_Health according to Twitter Analytics), visitors to stands at IGW, SIA (171.360) and JPO (4.000), Video on Food Technologies (19.658 views), European Reference Networks (676.469 including reach of print & online media buying and social media of #ERN hashtag), Ex-Smokers campaign (199.369.004 overall potential reach combining media, social media paid and organic, iCoach downloads and exsmokers.eu clicks), EU Health Award (486.267 average of articles in media outlets & social media reach), reach of 4 media seminars (8.400.000 overall potential reach), Press Releases and Memos (227.543 page views), e-news (12.000 subscribers), publications (26.069 printed copies distributed and 53.268 online views) and Infographs & Factsheets (27.277 page views). Note on the reach of media seminars: this figure was calculated by taking the average reach of the big media invited (around 33% of the journalists came from big media) and the reach of the small media (remaining 66%). The reach is the addition of the average reach of all the media invited and is based on the assumption that they all publish at least one article, or in the case of TV and Radio, one news feature). Media seminars in 2015 included one seminar held in EXPO.

[19] To be noted that the end of Ex-Smokers campaign is foreseen in 2016 (which represents 90% of 2015 reach baseline). No other campaign is expected for the period 2016-2020.

ANNEX 1: SANTE performance tables

General Objective 1: A new boost for jobs, growth and investment in the EU

Selected Commission impact indicators:

General objective 1 : A new boost for jobs, growth and investment in the EU	
Impact indicator 1.1: Employment rate population aged 20-64 **Source of the data**: Eurostat	
Baseline (2014)	**Target** (2020) Europe 2020 target
69.2%	at least 75%
Impact indicator 1.2: People at risk of poverty or social exclusion **Source of the data**: Eurostat	
Baseline (2013)	**Target** (2020) Europe 2020 target
121.6 million	At least 20 million people fewer: 96.6 million

Result indicators:

Specific objective 1.1: Better preparedness, prevention and response to human, animal and plant health threats

Specific objective 1.1: Effective preparedness, prevention , reaction and eradication of human, animal and plant diseases		Related to spending programme(s) Health Programme
Result indicator 1.1A: Number of Member States which have improved preparedness and response planning in accordance with Article 4 of Decision 1082/2013/EU on serious cross border health threats, in particular with regards to the implementation of the core capacity standards under the International Health Regulations (IHR) **Source of data:** Progress reports based on information provided by Member States in line with Article 4 § 2 of Decision 1082/2013/EU of the European Parliament and Council on serious cross-border threats to health		
Baseline 2015	**Interim Milestone** 2017	**Target** 2019 The first report was developed by SANTE C3 in June 2015 and presented to the Health Security Committee. The deadline for the implementation of IHR was set by WHO for 2009, however a number of Member States asked for extension of the deadline. Under Article 4 of Decision 1082/2013/EU Member States are obliged to consult each other with the aim to support the implementation of core capacity requirements under the IHR
0	14	28
Planned evaluations: The next report on preparedness is due in 2018. In the meantime outputs from regular meetings and workshops with Member States (Health Security Committee, Working Group on Preparedness and Response Planning, and Communicators' Network) should help evaluate the progress made		
Result indicator 1.1B: Number of Member States with improved preparedness and response planning addressing - arrangements aimed at ensuring interoperability between the health sector and other critical sectors , in particular: (i) coordination structures in place for cross-sectoral incidents; (ii) emergency operational centres (crisis centres);		

- (iii) measures or arrangements aimed at ensuring the continuous delivery of critical services and products. **Source of data:** Progress report on preparedness based on information provided by Member States in line with Article 4 § 2 of Decision 1082/2013/EU of the European Parliament and Council on serious cross-border threats to health**.**		
Baseline 2015	**Interim Milestone** 2018	**Target** 2020 The first report has been developed by SANTE C3 in June 2015 and has been presented to the Health Security Committee. The targets have been agreed internally within the Health threats Unit. Under Article 4 of Decision 1082/2013/EU Member States are obliged to consult each other with the aim to address the inter-sectoral dimension of preparedness and response planning at Union level.
1.2.B. (i): 18 1.2.B. (ii): 22 1.2.B. (iii): 16	24 25 22	28 28 28
Planned evaluations: The next report on preparedness is due in 2018. In the meantime outputs from regular meetings and workshops with Member States (Health Security Committee, Working Group on Preparedness and Response Planning, and Communicators' Network) should help evaluate the progress made**.**		

Managing and isolating outbreaks of major animal disease

Specific objective 1.1: Effective preparedness, prevention , reaction and eradication of human, animal and plant diseases		Related to spending programme(s) **Food and feed expenditure Regulation (EU) No. 652/2014**
Result indicator 1.1C: Reduction of restrictions in the EU caused by outbreaks of major epidemic animal diseases (foot and mouth disease, classical swine fever, African swine fever, avian influenza and lumpy skin disease) **Source of data:** Commission internal from several sources: safeguard and regionalisation decisions, eradication and monitoring programmes against these diseases, Animal Disease Notification System (ADNS), other information by MS		
Baseline 2014	**Interim Milestone** 2018	**Target** 2020
152/7800[20]	Decreasing value	Decreasing value (internal target)
Result indicator 1.1D: Containment of spread of major epidemic animal diseases in the EU after initial outbreak (foot and mouth disease, classical swine fever, African swine fever, avian influenza and lumpy skin disease) **Source of data:** Commission internal from several sources: safeguard and regionalisation decisions, eradication and monitoring programmes against these diseases, Animal Disease Notification System (ADNS), other information by MS		
Baseline 2014	**Interim Milestone** 2018	**Target** 2020
19/25[21]	Increasing	Increasing (internal target)

Preventing plant disease

Specific objective 1.1: Effective preparedness, prevention ,	Related to spending programme(s)

[20] Cumulative number between 0/7800 (optimum scenario: no outbreaks of the five diseases in the 1560 EU regions) and 7800/7800 (theoretical worst case with outbreaks of all the five diseases in every region). Major diseases (FMD, ASF, CSF, AI, LSD) multiplied by 1560 regions in the EU (according to the list of regions as laid down in Directive 64/432) equals 7800

[21] The indicator shows a synthetic number composed according to an internal evaluation matrix. The value of the indicator is a number between 25/25 and 5/25, the higher the better. (25/25: no disease spread, successful containment, theoretical maximum: optimum scenario; 5/25: all five diseases spread vastly and uncontrollably across EU borders, affecting large areas). The EU ability to contain the top-5 diseases is in a rage of 1 to 5 on control scoring with 5=perfect and 1=disaster. In the best scenario: 5 (perfect) for 5 diseases is 25, in the worse scenario 1 (disaster) for 5 diseases is 5

reaction and eradication of human, animal and plant diseases		Food and feed expenditure Regulation (EU) No. 652/2014
Result indicator 1.1E: Percentage of the EU territory covered by surveys for pests, in particular for pests not known to occur in the Union territory (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme) **Source of data:** Data can be procured using the Survey programs submitted by MS		
Baseline 2015	Interim Milestone 2017	Target 2020 (agreed in Commission proposal COM(2013)327 final)
50%	70%	100%
Result indicator 1.1F: Percentage of the EU territory covered by surveys for pests considered to be most dangerous, as defined under Directive 2000/29/EC (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme) **Source of data:** Monitoring results for pests subject to EU measures.		
Baseline 2015	**Interim Milestone** 2017	**Target** 2020 (agreed in Commission proposal COM(2013)327 final)
100%	100%	100%
Result indicator 1.1G: Time between finding and notification for pests not known to occur in the Union (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programmes **Source of data:** Data can be procured using notification of outbreaks by MS (electronic system planned to be put in place).		
Baseline 2015	**Interim Milestone** 2017	**Target** 2020
42 days	20 days	8 days
Result indicator 1.1H: Success rate in eradicating such pests -for pests not known to occur in the Union, the success rate of eradication of pests - 2012 (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme) **Source of data:** Data can be procured using the electronic system of outbreaks notification.		
Baseline 2013	**Interim Milestone** 2017	**Target** 2020 (agreed Commission proposal COM(2013)327 final)
0%	60%	95%

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

Specific objective 1.2: Safe and sustainable food and food production systems		Related to spending programmes : **No**
Result indicator 1.2.A: The number of cases of diseases in humans in the EU linked to food safety or zoonoses **Source of data:** ECDC surveillance data on human cases published in the annual joint EFSA/ECDC report on zoonoses		
Baseline (2012)	**Milestone (2018)**	**Target (2020[18])**
90.000 confirmed cases of human salmonellosis	67.000 cases	60.000 (sustained negative trend in incidence cases)
Result indicator 1.2.B: Compliance rate with legal deadlines for authorisations and re-approvals of substances used in food (food additives and pesticides). **Source of data:** Operational Units to provide data on the compliance rate regarding legal deadlines of authorisations of food additives and pesticides.		
Baseline 2015 Substances that should have been approved in 2015 following deadlines as defined by legislation.	**Interim Milestone** 2017	**Target** 2020 Target: the ratio of the described fraction should

		be 1
Compliance rate of approvals: $\frac{\textit{Number of substances that were actually approved within deadline in the reference year}}{\textit{Number of substances that should have been approved in the reference year}}$ **32/42 = 76%**	80%	85%

Result indicator 1.2.C: Compliance rate with legal obligations as regards EU legislation on novel foods (Regulation (EU) 2015/2283) by means of implementing acts/delegated acts.
Source of data: Data can be procured using the list of legal obligations compiled at DG level following the relevant exercise lead by the SANTE legal Unit. Furthermore, data on the compliance rate with legal obligations can be extracted and quantified using the relevant IT tool.

Baseline 2015	**Target** 2018
0/0	4/4
number of completed legal obligations identified as a priority [Delegated acts + Implementing acts]) / (divided by) number of pending legal obligations identified as a priority [Delegated acts + Implementing acts])	Same formula as for 2015 using 2019 as reference year

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

Specific objective 1.3 : Cost effective health promotion and disease prevention		**Related to spending programme(s) Health Programme**
Result indicator 1.3.A: The number of Member States having an integrated National Plan to address (major) chronic diseases in place, implementing the WHO non-communicable diseases (NCD) targets. **Source of data:** Member States reporting		
Baseline 2015	**Interim Milestone** 2017	**Target** 2019 Baseline information based on mapping exercise of WHO Europe.
12	19	28
Planned evaluations: Regular reporting		
Result indicator 1.3.B: Number of EU countries with a national initiative on: 1) the reduction of saturated fat, 2) the reduction of salt, 3) the reduction of sugar 4) reduction of alcohol-related harm. **Source of data:** country questionnaires and High Level Group		
Baseline 2015	**Interim Milestone** 2017	**Target** 2020 Gradual coverage of all MS as final target
1) 21 2) 20 3) 20 4) 21	1) 26 2) 26 3) 26 4) 26	1) 28 2) 28 3) 28 4) 28
Planned evaluations: reporting to the Council on the updates on the EU strategy and the Childhood Obesity Action Plan (2017 and 2020); annual questionnaires to MS via High Level Group		
Result indicator 1.3.C: Number of EU countries in which a European accreditation scheme for breast cancer services is implemented **Source of data:** Member State reporting on implementing the European Commission Initiative on Breast Cancer		
Baseline (2017: guidelines under development	**Interim Milestone** 2018	**Target** 2019 "Communication from the commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on action against cancer: European

until 2017)		partnership"
0	18	24
Planned evaluations: Reporting from Member States		

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

Specific objective 1.4: Effective, accessible and resilient healthcare systems in the EU		Related to spending programme(s) **Connecting Europe Facility**
Result indicator 1.4.A: Number of countries having capacity to the health date exchange and join the Cross-Border eHealth Information Services **Source of data:** Reported number of National Contact Points for eHealth set up, eHealth Network		
Baseline 2015	**Interim Milestone** - set up a NCPeH	**Target** **2020 (**The first year after the ending of the CEF financing programme)
	2017	2019
4	8	12
Planned evaluations: The JAseHN Joint Action will assess in their work package Monitoring and Assessment report on the implementation of the eHealth Guidelines in 2015-2017		
Result indicator 1.4.B: Level of average EU consumption of antibiotics in human **Source of the data**: ECDC		
Baseline 2013	**Interim Milestone** 2017	**Target** 2021
23.9 Defined daily doses/1000 inhabitants/day consumed in the Community and hospital sectors combined	overall decline in EU consumption of antibiotics in human achieved with respect to 2013 less than 23.9/ Defined daily doses/1000 inhabitants/day consumed in the Community and hospital sectors combined	30% reduction in EU consumption of antibiotics in human less than 16.7 Defined daily doses/1000 inhabitants/day consumed in the Community

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

Specific objective 1.5: Increased access to medical expertise and information for specific conditions			Related to spending programme(s) **Health Programme; CEF financing programme**
Result indicator 1.5.A: Number of established European Reference Networks **Source of data:** Information system on ERN, minutes of the Board of Member States on ERN meetings, licences of the ERN trademark licensed			
Baseline (2015)	**Interim Milestone**: 2016	2018	**Target** 2020 (forecast as the establishment of ERNs dependent on the no. of proposals received to the Call for ERN and the no. of approvals decided by the competent body (ERN Board of MS)
0	10	20	**30**
Planned evaluations: Exhaustive evaluation of ERNs every 5 years and yearly monitoring of work plans of the Networks			
Result indicator 1.5B: Number of data requests from the database **Source of data:** Orphanet database			
Baseline 2015	**Interim Milestone** 2018		**Target** 2020
On average around 90,000 pages viewed per day 4,726 diseases annotated with prevalence or incidence data	Maintain number of the website requests To increase number of annotated diseases		Increase number of website requests Majority of rare diseases annotated
Result indicator 1.5C: Number of supported rare diseases stakeholders and the size of the EU population covered by surveillance networks			

Source of data: The European Platform on Rare Diseases Registration		
Baseline 2015	**Interim Milestone**	**Target**
	2018	2020
Number of stakeholders included in the Platform: 39 EU birth population covered: 30% (approx. 1.5 million)	Keep and consolidate the existing parameters	Extend inclusion to all interested parties

Specific objective 1.6: Effective, efficient and reliable controls

Specific objective 1.6: Effective, efficient and reliable official controls	Related to spending programme(s) **Food and feed expenditure** **Regulation (EU) No. 652/2014**
Result indicator 1.6.A: Percentage of DG SANTE's recommendations following its audits that Member States (MS) have satisfactorily addressed with corrective action. **Source of data:** Commission internal (DG SANTE)	
Baseline (2014)	**Target** (2016) (agreed on the basis of available data to DG SANTE; the target for 2017 will be based on recommendations from DG SANTE's reporting cycles of the years 2012 – 2014 etc.)
60% for recommendations from reporting cycles 2011 - 2013	70% of all recommendations from these reporting years to be addressed

Specific objective 1.7: Increased EU influence in international fora

Specific objective 1.7: Increased EU influence in international fora		Related to spending programme(s) **No**
Result indicator 1.7.A: Percentage of the total number of WHO Governing Body Resolutions adopted annually which contain coordinated EU inputs. **Source of data:** Reports of WHO governing body meetings		
Baseline 2014	**Interim Milestone** 2017	**Target** 2021 (internal decision based on the year coinciding with the end of the posting of the next SANTE official to the UN in Geneva)
WHO Executive Board: 85% resolutions negotiated	90%	95%
World Health Assembly: 60% resolutions negotiated	75%	90%
WHO Regional Committee for Europe: 50% resolutions negotiated	70%	90%
Result indicator 1.7.B: Number of countries which recognise ICH guidelines **Source of data:** ICH		
Baseline 2015	**Interim Milestone** 2018	**Target** 2020 The new ICH Association was established in 2015. Implementation of guidelines take time and a 5-year implementation plan will be requested from new ICH members

		for guidelines that are considered to be a priority
Expansion of ICH membership The current members of ICH are US, EC, Japan, Canada and Switzerland. With the establishment of the association, new regulators and industry association have the opportunity to apply. **Number of new members: 0**	5 new ICH members	10 new ICH members
Implementation of ICH guidelines by new members ICH members will have to gradually implement the corpus of ICH guidelines and associated harmonisation documents. **ICH has until now (since 1990) developed more than 60 guidelines**.	70 % of guidelines implemented by new ICH members	85 % of guidelines implemented by new ICH members
Increased harmonisation through Guideline development. Adoption of ICH Harmonisation documents (new or revision of existing ICH guidelines, questions and answers and implementation guides). These ICH harmonisation documents are implemented by current ICH members (EC, US, Japan, Canada, Switzerland) and are expected to be implemented by new members. **Number of ICH harmonisation documents adopted in 2015: 3**	15 new or revised ICH guidelines	25 new or revised ICH guidelines

Result indicator 1.7.C: WTO cases brought against the EU **Source of data:** WTO		
Baseline (2014)	**Interim Milestone** 2017	**Target** 2020 A diminishing number of cases brought against the EU by other WTO Members is in line with our policy to align EU legislation to international standards.
8	7	5

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

Selected Commission impact indicators:

General objective 2: . A Deeper and Fairer Internal Market with a strengthened industrial base	
Impact indicator 2.1: Gross value added of EU industry in GDP **Source of the data**: Eurostat	
Baseline (2014)	**Target** (2020)
17.1%	20%
Impact indicator 2.2: Intra-EU trade in goods (% of GDP) **Source of the data**: Eurostat	
Baseline (2014)	**Target** (2020)
20.8%	Increase

SANTE specific data

Table 1 Gross value added of EU health sector (human health activities) in GDP (%)

	2008	2009	2010	2011	2012	2013
EU28	4,3	4,64	4,63	4,59	4,64	4,65

Source: Eurostat

Table 2 Intra-EU trade in food (and live animals) as a % of GDP

PERIOD	2008	2009	2010	2011	2012	2013	2014
	1.60	1.61	1.66	1.76	1.82	1.89	1.87

Source: Eurostat

Table 3 Extra-EU trade in food products and live animals (EU28) value in euros

	Jan.-Dec. 2010	Jan.-Dec. 2011	Jan.-Dec. 2012	Jan.-Dec. 2013	Jan.-Dec. 2014
IMPORT	73.873.810.214	84.397.252.688	85.521.342.073	86.040.097.156	90.740.146.811
growth (%)	9,6	14,2	1,3	0,6	5,5
EXPORT	54.305.778.283	63.354.408.561	70.079.581.181	75.419.468.601	78.796.408.251
growth (%)	22,8	16,7	10,6	7,6	4,5

Source: Eurostat

Table 4 Intra-EU trade in food products and live animals (EU28) value in euros

	Jan.-Dec. 2010	Jan.-Dec. 2011	Jan.-Dec. 2012	Jan.-Dec. 2013	Jan.-Dec. 2014
IMPORT	210.873.860.699	229.579.682.171	241.875.888.532	254.110.249.728	258.566.443.087
growth (%)	7,3	8,9	5,4	5,1	1,8
EXPORT	214.951.377.690	234.162.503.257	245.847.867.870	259.054.423.353	263.655.451.888
growth (%)	8,1	8,9	5,0	5,4	1,8

Source: Eurostat

Result indicators:

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

Specific objective 2.1: Effective EU assessment of medical products and other treatment			Related to spending programme(s) **Health Programme**
Result indicator 2.1: Number of health technology assessments produced by Joint Action EUnetHTA and of their national adaptations **Source of data:** EUnetHTA Joint Action			
Baseline	**Interim Milestone**		**Target**
2012	2016	2018	2019
2	12	22	29
Planned evaluations: yearly reporting from EUnetHTA JA3			

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

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) **No**
Result indicator 2.2: New medicines authorised within the legal deadlines, particularly innovative medicines of major interest for public health **Source of data:** Commission services' database on product specific authorisation	
Baseline 2014	**Target** 2017
85% all Commission decisions for marketing authorisations (MA) of new centrally authorised medicinal products for human use adopted 100% Commission decisions adopted in 2014 for new centrally authorised MA for medicines for human use that had an accelerated review by European Medicines Agency (EMA)	90% All new centrally authorised MA decisions The target allows for certain steps in the procedures that are not under control of the Commission that might lead to a delay in the Commission decision making process. 100% new MA Commission decisions for which there was an accelerated assessment by EMA

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

Specific objective 2.3: Common Member States' tools and methodologies used for EU health systems performance assessments		Related to spending programme(s) **Health programme**
Result indicator 2.3A: Number of Member States that refer in national policy documents to the recommendations and findings of the expert group on HSPA **Source of data:** Commission analysis		
Baseline 2015	**Interim Milestone** 2017	**Target** 2020 explanation how the target was agreed: decided by the Semester Core DGs
0	5	15
Planned evaluations: internal evaluation to be carried out by Commission services on the bases of the information collected in the expert group on health systems performance assessment**.**		

General objective 3: A reasonable and balanced free trade agreement with the US

Commission impact indicator:

General objective 3 : A Reasonable and Balanced Free Trade Agreement with the U.S.	
Impact indicator 3.1: Share US in total EU FDI stocks (US trade / extra trade) **Source of the data**: Eurostat	
Baseline (2014)	**Target** (2020)
Inwards 35.6% Outwards 33.1% Total 34.4% The figures were calculated subtracting "Special Purpose Entities" FDI from "Total" FDI in order to have "non-SPE" FDI figures that can be comparable with other international data.	Increase

SANTE specific data

Table 5 Share of US in total FDI for selected sectors (2013, EU 28)

		Direct investment abroad (DIA)	Direct investment in the reporting economy (DIRE)
		Net FDI outward	Net FDI inward
Extra EU-28	Manufacture of food products; beverages and tobacco products	237.347,8	92.404,3
Extra EU-28	Manufacture of basic pharmaceutical products and pharmaceutical preparations	145.602,4	35.745,4
Extra EU-28	**All FDI activities 2013**	**5.344.436,7**	**4.179.660,0**
Extra EU-28	**All FDI activities 2014**	5.748.568,4	4.582.548,5
United States	Manufacture of food products; beverages and tobacco products	42.445,6	55.600,8
United States	Manufacture of basic pharmaceutical products and pharmaceutical preparations	90.480,2	27.904,3
United States	**All FDI activities 2013**	**1.812.638,2**	**1.756.031,2**
United States	**All FDI activities 2014**	1.985.269,7	1.810.771,8
Share US in total EU FDI in manufacture of food products; beverages and tobacco products		17,9	60,2%
		Average inward/outward: 39,0%	
Share US in total EU FDI in manufacture of basic pharmaceutical products and pharmaceutical preparations		62,1	78,1%
		Average inward/outward: 70,1%	
Share US in total EU FDI 2013		33,9%	42,0%
		Average inward/outward: 37,9%	
Share US in total EU FDI 2014		34,5%	39,5%
		Average inward/outward: 37,0%	

Source: Eurostat – the data in the table includes "Special Purpose Entities" FDI

Table 6 Share (%) of US trade in food (food and live animals) in total of EU extra trade on food and live animals (EU28)

	2008	2009	2010	2011	2012	2013	2014
SHARE US/EXTRA	7,3%	6,8%	7,1%	7,0%	6,9%	7,3%	7,7%

Source: Eurostat

Result indicators:

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

Specific objective 3.1: A balanced agreement with the US on pharmaceutical products and in SPS area			Related to spending programme(s) **No**
Result indicator 3.1.A: Number of Member States which are authorised for export of beef, sheep/goat meat, Grade A (pasteurised) Dairy Products and Egg Products to the US **Source of data:** Market access database of DG TRADE			
	Baseline	**Interim Milestone**	**Target**
	2015	2017	2020
Beef	2	8	20
Sheep/Goat meat	1	2	4
Grade A Dairy Products	0	3	9
Apples and Pears	0	8	8 (current number of applications)
Egg Products	1	3	9
Result indicator 3.1.B: Number of barriers not in line with international standards, linked to Sanitary and Phytosanitary (SPS) measures **Source of data:** Market access database of DG TRADE			
Baseline 2015	**Interim Milestone** 2017	**Target** 2020 In 2020 the TTIP should be agreed between both sides	
4	3	1	