European Commission

2015

Management Plan

Health & Food Safety

Directorate-General

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1. MISSION STATEMENT

"*Making healthy and safe EU citizens the engine of sustainable economic growth*"

DG Health and Food Safety (DG SANTE) mission is to improve the health and safety of European citizens and contribute to the Commission's Agenda for Jobs, Growth, Fairness and Democratic Change. This goal is central to the idea of European values; it is firmly embedded in the Treaty on the Functioning of the European Union and it has an important role to play in helping the EU achieve its 2020 objectives of smart, sustainable and inclusive growth. DG SANTE is responsible for several important sectors including food and pharmaceuticals which are heavily dependent on a well-functioning and fair internal market, conditioned by the paramount principle of safety.

In practice, our mission requires that we:
- improve and protect human health;
- ensure that all food and medicinal products are safe;
- protect animal health and welfare, and plant health.

DG SANTE works towards these objectives by:
- developing and maintaining sound and proportionate policies, laws and programmes that follow the Commission's principles of "Better Regulation",
- ensuring compliance with existing legislation, and
- communicating clearly and effectively with citizens and stakeholders.

In doing so, through our high safety standards we aim to achieve worldwide competitiveness, to contribute to the European economic recovery, to support the creation of jobs, to stimulate innovation, and to attract more investments while also maintaining mutually beneficial relations with the EU's international partners.

DG SANTE policies address issues that concern citizens and governments inside and outside the EU. By pooling knowledge, experience and resources we can help tackle problems shared by a number of countries and in doing so, generate large economies of scale, strengthen the single market and deliver benefits to European businesses and consumers alike.

Human capital is an indispensable generator of economic growth and sustainable development depends on the health of the population. A healthy population and well-functioning health systems are preconditions for economic prosperity and social cohesion. An appropriate regulatory framework and enforcement measures are needed to ensure a high level of public safety, which has significant implications for a healthy economy that generates prosperity for businesses and citizens.

Safe food is essential to public health and to long-term economic development. Ensuring safety impacts in two ways; reducing the economic and social costs associated to inappropriate standards causing diseases, and recognition in international trade of our high standards which promotes our exports, generates growth and reduces poverty.

The policies and laws for which we are responsible touch the daily lives of individual citizens and contribute *inter alia* to a healthy European workforce. DG SANTE ensures that our policies are designed, applied and enforced to deliver the best results, benefiting citizens and increasing the efficiency of an essential resource of any business, its employees.

2. THE CHALLENGES THIS YEAR AND BEYOND

Over the past years, Europe suffered the worst financial and economic crisis since World War II, the effects of which are still taking their toll. Substantial reductions in public spending to decrease debt or deficit levels have put increased pressure on the health and food safety area whose vital role in the creation of economic growth is sometimes underestimated. In line with the stock-taking of the Europe 2020 strategy, ageing of the population, migration, social inequalities, globalisation, the fast evolving technologies, the capacity to increase overall productivity, and pressure on resources are among challenges that need to be addressed by the EU in the forthcoming years. By addressing them, the Health and Food Safety policies contribute to the Commission's Agenda for Jobs, Growth, Fairness and Democratic Change.

Indeed, as stressed by President Juncker "all policies, decisions and initiatives [should] respect and apply the Treaty provisions on public health, in line with Article 168 [of the Treaty]", who also committed to "make sure that public health will be at least as important in [the Commission] policies as internal market considerations." Health and Food Safety policies are uniquely placed to address issues of fundamental concern to citizens and governments.

Against this background, we will be facing in 2015 challenges that have a long-term character and others that can be dealt with in the short to medium term, in line with the mission letter addressed by President Juncker to Commissioner Andriukaitis for the Health and Food Safety portfolio:

- develop EU policies as regards medicines and pharmaceutical products,
- review the decision-making process for GMOs, and
- develop expertise on health system performance assessment to usefully inform the work of the European Semester.
- support the EU capacity to deal with crisis situations,

DG SANTE will thus work to reinforcing Europe's ability to deal with the Ebola virus disease, will be at the forefront of food safety issues in relation to Russia and Ukraine, will review the existing decision making process to GMOs, and will ensure that health and food safety questions are appropriately addressed during trade negotiations. DG SANTE is prepared to face any health or food safety crisis that might arise in the course of the year. We will support Member States to finalise the important structural reforms to help them cope with the budgetary constraints and assist them in implementing measures conducive to sustainable development.

In the long term, an ageing Europe poses challenges to providing the EU businesses with a healthy workforce that is essential to prosperity. We will support innovation as a catalyst for economic growth and will inspire confidence in new technologies in both policy areas. To better serve citizens' interests, we will continue to integrate our work into other EU policies and will increase our efforts to understand lifestyle and behaviours in such a diverse European Union.

In both policy areas, we strive to achieve the highest level of protection, the greatest degree of efficiency and the greatest value for money. Over the course of the new spending programmes under the 2014-20 multi-annual financial framework, DG SANTE will endeavour to support ambitious, cross-cutting initiatives that provide real benefits and represent good value-for-money.

The DG will review its detailed planning and internal organisation in the first quarter of 2015 against the background of the changes in the DGs competences and staffing, and the 2015 tax obligations, to ensure that the DG can deliver on the key policy priorities while maintaining the DG's critical functions.

Public Health Policy

Good health is a pre-condition for smart, sustainable and inclusive growth and social cohesion in an ageing Europe, where resources are increasingly stretched. By investing in health promotion, health protection and disease prevention, we can help to deliver better value for money, enabling people to remain active for longer and limiting the costs linked to the treatment of preventable diseases.

Based on the subsidiarity principle, EU health policy complements and supplements national policies to tackle today's key challenges; it helps EU countries to achieve structural reform of their health systems to ensure their effectiveness, accessibility and resilience. This will be the clear main focus of the DG's activity in response to the mission letter addressed by President Junker to Commissioner Andriukaitis which requires him to "develop expertise on performance assessment of health systems (…) to usefully inform the work of the European Semester". DG SANTE will play its part in supporting the EU's capacity to safeguard health across the borders in the EU, and notably deal with crisis situations such as pandemics. In addition, DG SANTE will respond to the manifold challenges of globalisation and increased movement of persons, goods and services by fostering innovation and safety in health to ensure high quality and safety standards, and to support European research excellence and the competitiveness of industry.

Protecting citizens from health threats

Serious cross-border health threats, including infectious diseases, biological and chemical agents and environmental hazards, pose significant risks to public health and international travel and trade. As learnt from past and current events (Ebola, poliomyelitis, *E. coli* etc.), they may spontaneously emerge at any time – anywhere – and have consequences for the EU. Crisis coordination and management will therefore continue to address the unprecedented challenges we are facing. Moreover, a threat posed by existing and new communicable diseases, such as HIV/AIDS, tuberculosis and hepatitis, persists and there are gaps in immunisation coverage in many Member States. The EU plays a key role in coordinating with the WHO and other UN organisations. Increasing emphasis will be put on helping not just the EU but also third countries in tackling global health threats.

Promoting effective, accessible and resilient health systems

Over the last decade, European health systems have faced growing common challenges: increasing cost of healthcare, ageing population associated with a rise of chronic diseases and multi-morbidity leading to growing demand for healthcare, shortages and uneven distribution of health professionals, health inequalities and inequities in access to healthcare.

Building on the Communication on effective, accessible and resilient health systems (COM(2014)215), the Commission will continue working with Member States towards strengthening the effectiveness and resilience of health systems, and increasing the accessibility of healthcare. Notably, it will develop expertise on performance assessments

of health systems, drawing lessons from recent experience, and from EU-funded research projects to build up country-specific and cross-country knowledge which can inform policies at national and European level. A newly established Commission expert group on health systems performance assessment will identify tools and methodologies. This expertise will also usefully inform the work of the European Semester of economic policy coordination. Finally, work on health system reform will be further considered as an integral part of the European Semester, including work on reform measures set out in economic adjustment programmes.

Encouraging innovation in health

The Commission will continue to promote the use of safe, innovative and cost-efficient health products, technologies and systems and ensure the quality and safety of new health products (pharmaceuticals, substances of human origin), and smooth functioning of the internal market. Health technology and innovation in health are drivers of competitiveness and have the potential to address the challenges health systems face. Health Technology Assessment can assist national authorities in achieving best value through identification of the most effective and safe health interventions. The EU has developed and maintained a favourable regulatory environment for medicinal products which guarantees a high level of protection of public health, and fosters a stable and predictable environment for innovation in medical technology. Over the years flexibilities have been built within the regulatory system with the aim to accelerate authorisation of innovative medicines for patients with unmet medical needs. Also, eHealth is a key tool to provide high quality and universal healthcare as health systems face increasing pressure. The Commission will build the legal, organisation and technical infrastructure for services providing real added value for citizens within the eHealth Network.

Foster good health in an ageing Europe

Ageing populations can be drivers of economic growth. The market driven by the needs and purchasing power of older consumers is estimated to be worth €12tn by 2020. The Commission has already launched a number of measures to stimulate the Silver Economy and help European industry (and SMEs in particular) become more competitive. For SANCO these include the eHealth Action Plan and the European Innovation Partnership on Active and Healthy Ageing. But there is also enormous potential in the development of personalised care, healthy age-friendly environments as well as addressing un-met needs in research and disease management. SANTE therefore plans to work together with other DGs, Member States and stakeholders to stimulate this Silver Economy and leverage quality of life and economic benefits arising from population longevity.

Investing in prevention and health as human capital

The EU needs new approaches to investing in health, moving beyond limiting expenditure to addressing the demand for health and social services. Reducing the burden of chronic diseases would generate huge savings to society and the economy. Many chronic diseases are linked to a few common risk factors: tobacco use, the harmful use of alcohol, unhealthy diets and lack of physical activity. Disease and death from these risk factors can be prevented, thus saving health care expenditure and contributing to healthier lives. EU health policy will continue to tackle these key risk factors, particularly by supporting the Member States' actions.

Reducing health inequalities and fighting discrimination

The level of disease and the age at which people die is strongly influenced by various factors, including employment, income and access to healthcare. To reduce inequalities in health status, a multi-sectorial approach is required, with a focus on achieving greater gains in groups that are less advantaged than the average to close the gap. Key measures need to improve the quality of and access to health systems, address the underlying risk factors in health behaviours, boost investments in the prevention of chronic diseases and ensure adequate incomes and living and working conditions.

Mobility of health professionals – a potential opportunity for jobs in the future

An increasing interaction between healthcare systems in Europe generates benefits as well as challenges. Supply, skills and the mobility of healthcare workers are crucial for the effectiveness, accessibility and resilience of healthcare systems. By 2020 the EU will suffer from a shortage of about 1 million healthcare professionals overall, which creates pressures for new ways in recruitment, retention and the planning or workforce needs.

Globalisation of health issues

People, medical products, and services (*e.g.* outsourcing of certain services, *e.g*. diagnostic ones) but also pathogens and unhealthy lifestyles are increasingly moving across the globe. Global supply chains for health products and for pharmaceutical ingredients are becoming more complex with increased risks for security and safety of supply. At the same time globalisation creates significant new market opportunities for a sector with high added value where the EU is a world leader. There are a number of challenges related to globalisation, such as the emergence of other players like the BRIC and other countries which will influence global norm-setting and exert new regulatory and market pressures on the EU – particularly in Free Trade Agreement negotiations - to reduce the level of protection and quality and safety standards; misuse of antimicrobial medicines and pesticides that increases the risk of antibiotic resistance; and climate change. It will therefore be important for the EU to press for EU norms being accepted as global norms both to maintain high standards and to reduce costs for exporters, , and to continue to promote high levels of safety, quality and health protection in multilateral and bilateral trade agreements.

Food Safety

A well-functioning and safe food chain remains a key public health and economic priority. Maintaining a high level of safety is a key contributor to competitiveness, growth and jobs in Europe, including small and medium size enterprises. It ensures that the food industry, Europe's largest manufacturing sector and biggest employer, is supported with its related agricultural sectors, by a regulatory environment which promotes high and uniform levels of safety throughout Europe. The EU food safety standards are also an asset for European producers to compete on the global market. In 2015, the focus will remain on ensuring the EU rules are implemented correctly and in time to support an innovative, competitive and high value added food industry founded on high levels on consumer confidence.

Maintaining a high level of food safety

This will remain a priority in the future, against the challenges posed by increasing globalisation and the potential for rapid transmission of diseases. Lessons learnt from previous foodborne incidents will keep contributing to the improvement of our preparedness. Success in this respect will be measured by the reduction in the incidence of the main food-borne diseases in the EU such as BSE and salmonellosis.

Risk management – controlling animal diseases and plant pests.

EU measures have been successful in tackling risks to food safety and controlling and eradicating certain animal diseases and plants pests. A coordinated pan-European approach offers more effective protection against the introduction into and the potential cross-border spread of diseases and pests within the EU. Day-to-day management will continue to focus on prevention, reducing the incidence of animal diseases and minimising the impact of outbreaks when they occur.

Inspiring confidence in new technologies as drivers of economic development

Innovation is a catalyst for growth and DG SANTE aims to support innovation and inspire confidence in new technologies linked to food and feed. In 2015, the Commission will bring to completion the institutional discussions on proposals to give EU countries greater freedom to decide on GMO cultivation. It will also review the GMO authorisation system to take account of situations where a clear majority of Member States oppose. On novel food, the Commission will aim at contributing to the successful conclusion of the legislative procedure, so that innovation in technology can be translated faster and more coherently into access to the Single Market, while ensuring any safety concerns are fully taken into account.

Streamlining the rules – a legal framework that is fit-for-purpose

Given the size, sophistication and complexity of the food chain and the high cost of system failures, it is essential to ensure the EU's legal framework remains fit-for-purpose. Food, animal and plant legislation is under constant review and the Commission will continue to innovate, adapt and, where necessary, consider any necessary modifications, based on thorough impact assessment, of the legal framework to ensure it can achieve its aims.

In improving the effective implementation of the regulatory framework we aim to maximize benefit and minimize burden, apply the principle of subsidiarity, and demonstrate the added value and necessity of EU action.

Inter-institutional discussions on the 2013 package of proposals to review EU animal health law, the EU plant health and plant reproductive materials law and the approach to official controls will continue in 2015. They aim to ensure Europe continues to have a safe and nutritious feed and food supply adapted to new challenges and changed circumstances.

Improving enforcement to ensure a level playing field

Strict enforcement of rules on food safety, animal health, plant health and animal welfare will remain essential to ensure that standards are not compromised by poorly implemented controls and that industry can operate on a level playing-field. The trainings organised under the 'Better Training for Safer Food' (BTSF) initiative and the Food and Veterinary Office's (FVO) audits will remain crucial in this regard, to ensure more uniform, objective and efficient controls throughout the EU and therefore effective enforcement.

The Commission will pay attention to the enforcement of plant health legislation and its continuous adaptation to new threats and the real situation of pest presence in the EU. The Commission will also maintain and develop enforcement of the animal welfare legislation through various means from legal proceedings (ban of battery cages or sow stalls), the development of guidelines (protection of pigs, animal transport) as well as regular audits, expert meetings and trainings. This year will be also dedicated to develop additional tools for monitoring Member States' efforts in implementing EU animal welfare rules.

Tools for a rapid response to food safety and animal and plant health threats

To ensure rapid responses from Commission and Member States, advanced electronic systems are available to swiftly collect, transmit and store relevant data and to enable consultation (RASFF - Rapid Alert System for Food and Feed; Europhyt; ADNS - Animal Disease Notification System; TRACES - TRAde Control and Expert System). A comprehensive set of tools enables the EU to react promptly to emergencies resulting from food or feed and those which threaten the health of animals or plants. The necessary decisions to contain or eliminate any risk, irrespective of its source, can be taken swiftly. The remaining challenge is to better coordinate the response of the EU control system to fraudulent practices along the food chain.

Working together with international partners

Stronger international relations will remain our objective and we will continue to promote the European policy model and safety and quality standards, to contribute to global governance based on our values and to secure a high level of protection. In promoting the European model, trade opportunities for European industry can be enhanced. DG SANTE has a high quality technical input to offer in the Sanitary and Phytosanitary (SPS) field and, through the BTSF programme, is the only donor providing concrete hands-on information on EU import requirements on a wide range of SPS issues. Such activities which will continue counter restrictive measures, create goodwill and facilitate and support regulatory cooperation with our trading partners.

Key Performance Indicators (KPI)

Impact indicator KPI-1: Number of Healthy Life Years at birth (European Innovation Partnership on Active and Healthy Ageing) *Source of data: Eurostat*		
Baseline 2010	Milestone (2018)	Target 2020 (agreed in the EIP on Active and Healthy Ageing)
Males: 61.9 Females: 62.7	Increase by 1 year	Increase by 2 years
Impact indicator KPI-2: Reduction in the incidence of main food-borne disease in the EU –BSE & Salmonella (Regulation (EU) 652/2014 on expenditure in the field of the food chain, animal health and welfare and on plant health and plant reproductive material) *Source of data: EU BSE surveillance programme and ECDC surveillance data on human cases published in the annual joint EFSA/ECDC report on zoonoses*		
Baseline (2012)	Milestone (2018)	Target (2020)
18 BSE cases	10 cases	5 cases
90000 confirmed cases of human salmonellosis	67,000 confirmed cases of human salmonellosis	(60,000 cases) continuous reduction / no eradication possible

Impact indicator (KPI-3): Reduction of restrictions in the EU due to outbreaks of major epidemic animal diseases (foot and mouth disease, classical swine fever, African swine fever, avian influenza and Newcastle-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		
Baseline (2014)	Milestone (2018)	Target (2020)
New indicator (baseline to be established at the end of 2014)	Decreasing trend	Decreasing trend

Impact indicator KPI-4: Time between finding and notification for pests not known to occur in the Union (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme) *Source of data: Notification of outbreaks by MS (electronic system planned to be put in place)*			
Baseline (2012)	Milestone (2015)	Milestone (2017)	Target (2020) (agreed in Commission proposal COM(2013)327 final)
10 days	8 days	4 days	3 days

Impact indicator KPI-5: Residual error rate of on-the spot controls (ex-post) for each ABB activity *Source of data: Internal follow-up sheet, reported in the Annual Activity Report*	
Baseline (2012)	Target
3,4% (Food & Feed); < 1% (Public Health and Food Safety)	Less than 2% in value (approved by Management Team)

3. GENERAL OBJECTIVES WITH A MULTI ANNUAL PERSPECTIVE

The actions of DG SANTE contribute towards smart, sustainable and inclusive growth and make a tangible and positive difference to the lives of European citizens.

3.1. Health

Health systems and public health policy are essential towards achieving the targets of the Europe 2020 strategy. Smart, sustainable and inclusive growth depends upon a healthy population and the proper functioning of financially sustainable health systems.

The EU Health Strategy sets out an over-arching framework for EU action on health through legislation, cooperation between EU countries and via the financial support provided by the EU Health Programme. The Strategy was complemented in 2013 by the "Investing in Health" approach and in 2014 by the Communication on effective, accessible and resilient health systems[1]. The three objectives of the EU Health Strategy are:

– Fostering good health in an ageing Europe;

– Protecting citizens from health threats;

– Supporting dynamic health systems and new technologies.

The objectives of the Health Programme are far reaching and encompass most areas of Public Health in Europe. The evaluations planned on the finalised Health Programme 2008-2013 and on the third Health Programme (2014-2020) will help to improve the quality of interventions and projects funded under the three objectives mentioned above.

<table>
<tr><td colspan="2">General objective 1 Complement, support and add value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.</td><td>☒ Spending programme
☒ Non-spending</td></tr>
<tr><td colspan="3">External factors: The health of EU citizens is not only driven by health care related determinants, but is also linked to individual lifestyles and behaviour (smoking, alcohol consumption, employment status, housing tenure and so on) as well as environmental factors.</td></tr>
<tr><td colspan="3">Impact indicator 1.A (KPI-1): Number of Healthy Life Years at birth (European Innovation Partnership on Active and Healthy Ageing)
Definition and relevance: Healthy Life Years (HLY) also called disability-free life expectancy at birth is defined as the number of years that a person is expected to continue to live in a healthy condition at birth. We are looking at HLY instead of life expectancy because it's a crucial question whether extra years of life gained through increased longevity are spent in good or bad health. Moreover, HLY also monitor health as a productive or economic factor. An increase in HLY would lead to lower public healthcare expenditure and would likely increase the possibility that people continue to work later into life.
(Source of data: Eurostat)</td></tr>
<tr><td>Baseline 2010 (estimates 2011)</td><td>Milestone (2018)</td><td>Target 2020
(agreed in the EIP on Active and Healthy Ageing)</td></tr>
<tr><td>Males: 61.9 (61.8) Females: 62.7 (62.2)</td><td>Increase by 1 year</td><td>Increase by 2 years</td></tr>
<tr><td colspan="3">Planned evaluations</td></tr>
<tr><td colspan="3">Ex-post evaluation of Health Programme 2008-2013 (31 December 2015)</td></tr>
<tr><td colspan="3">Evaluation of the implementation 2009 Commission Communication on reducing health inequalities and 2010 Council Conclusion on equity and health in all policies (30 June 2016)</td></tr>
<tr><td colspan="3">Mid- term evaluation report on the achievement of the objectives of the Health Programme 2014-2020 (30 June 2017)</td></tr>
</table>

[1] COM(2014)215 final

3.2. Food and feed safety, animal health and welfare, and plant health

A high level of safety over the entire food chain is essential towards achieving key public health and economic objectives. It is also vital for the food industry and its related agricultural sectors – Europe's largest manufacturing sector and biggest employer – to operate in a marketplace protected from the massive disruption which can result from unsafe food.

The EU's food safety policy has four general objectives:
– ensuring food and feed are safe and nutritious;
– ensuring a high level of animal health and welfare and plant health;
– ensuring adequate transparent information about issues of interest to consumers, such as origin, content and use of foods;
– enhancing the sustainability of the food chain.

These general objectives are pursued through a holistic approach to the food chain, encompassing legislation, enforcement, communication, scientific advice and international cooperation, and contributing to competitiveness and a sustainable environment.

The safety of food and feed is achieved by clear and predictable procedures for marketing authorisations which apply to products and substances used in the production and processing of primary products. For many products (pesticides, additives, flavourings) the EU has put in place harmonised authorisation processes including the establishment of regulatory limits of those substances that allow the relevant industry to plan and predict their market activities.

EU safety standards are among the highest in the world: as a result, a level playing-field enables and promotes job creation, economic growth and trade in an integrated market.

<table>
<tr><td colspan="2">General objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs</td><td>☒ Spending programme
☒ Non-spending</td></tr>
<tr><td colspan="3">External factors: The EU status of animal/plant diseases can be jeopardised by the introduction of agents of animal/plant disease through illegal imports of commodities from third countries. In addition, implementation on the ground is done by the authorities in the Member States. For third countries neighbouring EU Member States we are dependent on their efforts, which are not always of the same level as in the Union.</td></tr>
<tr><td colspan="3">Impact indicator 2.A (KPI-2): Reduction in the incidence of main food-borne disease in the EU –BSE & Salmonella (Regulation (EC) No 652/2004 on expenditure in the field of the food chain, animal health and welfare and on plant health and plant reproductive material)
Definition and relevance: Maintaining effective control measures on two of the major food-borne diseases, based on sound scientific evidence, ensures the continued reduction in the incidence of these diseases in animals and gives greater protection to the public.
Source of data: EU BSE surveillance programme and ECDC surveillance data on human cases published in the annual joint EFSA/ECDC report on zoonoses</td></tr>
<tr><td>Baseline (2012)</td><td>Milestone (2018)</td><td>Target (2020)</td></tr>
<tr><td>18 BSE cases</td><td>10 cases</td><td>5 cases</td></tr>
<tr><td>90000 confirmed cases of human salmonellosis</td><td>67,000 confirmed cases of human salmonellosis</td><td>(60,000 cases) continuous reduction / no eradication possible</td></tr>
</table>

Impact indicator 2.B (KPI-3): Reduction of restrictions in the EU due to outbreaks of major epidemic animal diseases (foot and mouth disease, classical swine fever, African swine fever, avian influenza and Newcastle-disease) **Definition and relevance:** The indicator is synthetic number[2] composed of the sum of the number of regions[3] which are restricted for each of these diseases. This indicator measures the deviation from the ideal situation where there are no outbreaks hence no regions are restricted from normal domestic or intra-EU trade of live animals and their products due to any of these diseases. It captures spatial elements on a yearly basis relevant to the burden they cause to livestock competitiveness and unhindered movements. **External factors:** The Member States are responsible for the implementation of the EU rules to fight these diseases (i.e. import requirements and rules on eradication of the disease) in doing so they also rely on compliance by stakeholders and citizens. Moreover the management of the animal health situation outside of the EU is not bound by EU legislation and policies. **Source of data:** Commission internal from several sources: safeguard and regionalisation decisions, eradication and monitoring programmes against these diseases, Animal Disease Notification System (ADNS).		
Baseline (2014)	Milestone (2018)	Target (2020)
New indicator (baseline to be established at the end of 2014)	Decreasing trend	Decreasing trend
Impact indicator 2.C: Maintenance of EU territory free from Citrus Black Spot and Citrus Canker **Definition and relevance:** EU is one of the few areas free from these two severe pests of citrus fruit and having an important production of citrus. Maintaining the freedom of EU territory from this pest is a decisive factor for the competitiveness of this production and associated EU exports. **External factors:** Member States are responsible for timely implementation of the relevant EU legislation and swift co-operation in order to agree on the measures to be taken. **Source of data:** Notification of outbreaks by MS: EPPO data		
Baseline (2012)	Milestone (2018)	Target (2020)
No confirmed cases of outbreaks of Citrus Black Spot and Citrus Canker in the EU	Keep disease freedom	Keep disease freedom

3.3. Cross-cutting objectives

3.3.1. Crisis management

Early warning and crisis preparedness are essential in order to deal effectively with human, animal or plant health emergencies. In recent years much of the focus has been on communicable diseases and the preparation for a possible pandemic. With the 2013 Decision 1082/2013/EU on serious cross border threats to health the scope for health security has been extended to threats arising from other biological threats, chemical events and environmental hazards with an impact on public health. The generic and specific preparedness structures are constantly strengthened in terms of planning and coordination, monitoring and assessment, prevention and containment, health system response and communication, together with our partners such as EFSA, EMA, ECDC.

Rapid alert and traceability systems provide fast and user-friendly information on food, feed, plants and public health alerts and support trade in the relevant products (food, animals etc.). The functioning of EU-wide mechanisms for information exchange, consultation, coordination and operation related to the handling of health-related emergencies need to be maintained.

Where an audit by SANTE's Food and Veterinary Office (FVO) identifies an immediate threat to consumer, animal or plant health, the Commission may take emergency ("safeguard") measures.

[2] a number between 0 (no outbreaks anywhere, theoretical minimum: optimum scenario) and 7.800(the 1.560 EU regions in Member States restricted during the year for all five diseases) as an absolute high

[3] as defined in Directive 64/432/EEC

The newly developed Rapid Alert on Tissues and Cells (RATC) strengthens the safety and quality of tissue transplantations and offers the prospect, in future, to roll out adapted systems in the fields of organ transplantation and blood transfusion.

We ensure sustainable and flexible business continuity mechanisms covering both normal working arrangements – dealing with the management of relatively low level food and feed crises – and specific arrangements that may be needed in emergency situations, such as a serious outbreak of animal or human disease.

<table>
<tr><td colspan="3">General objective 3: Respond rapidly and efficiently to any outbreak potentially endangering the health and safety of citizens, animals, or plants in Europe, through adequate reaction capacities, appropriate preparedness and efficacious tools for quick alert and exchange of information.</td><td>☐ Spending programme
☒ Non-spending</td></tr>
<tr><td colspan="4">External factors: The degree of preparedness and the ability to identify rapidly a hazard are crucial and heavily rely on the structure and capacity in place in Member States and third countries</td></tr>
<tr><td colspan="4">Impact indicator 3.A: Ability to quickly react to any alert and isolate/circumvent any outbreak of a given disease
Definition and relevance: EU safety and health status is among the highest in the world. Preserving it is crucial not only as a goal in itself but also for its side effect on our ability to trade products or on tourisms activities.
Source of data: WHO/OIE, EPPO-IPPC, EFSA, EWRS (Decision 1082/2013/EU)</td></tr>
<tr><td>Baseline (2014)</td><td>Milestone (2016)</td><td colspan="2">Target (2020)</td></tr>
<tr><td colspan="4">African Swine Fever</td></tr>
<tr><td>5 EU MSs affected</td><td>3 EU MSs affected</td><td colspan="2">0 EU MS affected</td></tr>
<tr><td colspan="4">Citrus black spot</td></tr>
<tr><td>0 MS affected</td><td>0 MS affected</td><td colspan="2">0 MS affected</td></tr>
</table>

3.3.2. Better regulation

We constantly strive to achieve better regulation and will continue to do so. Our legislation can only work effectively if it is well designed, transparent, easy to implement and up-to-date. In the context of the 2013 Commission Communication on Regulatory Fitness, SANTE will continue to review its legislation to make sure it is fit for purpose; that it poses the least burden possible, notably when it comes to SMEs; and that it is both coherent and proportionate. Better implementation and enforcement of existing legislation are also crucial: a very considerable proportion of DG SANTE's resources are devoted to this in any given year. Proper enforcement is key to both ensuring a high level of safety and to avoid problems in trade. Transparency and communication are extremely important, especially where uncertainties arise during the risk assessment/decision-making process. We will continue to develop participative processes involving stakeholders at all stages of the policy-making process.

<table>
<tr><td colspan="3">General objective 4: Maintaining a high level of health and safety on the EU territory while allowing competitiveness of the economic sectors under SANTE policies through proportionate, fit for purpose legislation</td><td>Spending programme
☒ Non-spending</td></tr>
<tr><td colspan="4">External factors: Co-legislators may affect during the policy making process the initial intentions of the Commission. Furthermore, at the time of implementation, the Member States can also impact this approach either through stricter national standards or by not using flexibility provisions.</td></tr>
<tr><td colspan="4">Impact indicator 4.A: Intra-EU trade of food products
Definition and relevance: Globalisation requires finding the right balance between the need to keep the EU level of safety and the ability of our industry to compete on international markets, or of SMEs to simply grow on the EU or national/local markets. Both are not mutually exclusive and on the contrary are mutually reinforcing as high quality products contribute to economic sustainability. The challenge is to offer the right regulatory environment to achieve this goal.
Source of data: COMEXT, 2012 data (CN codes: 2 – 8, 10, 15 – 21, 23, 35), 27 MSs (without Croatia)</td></tr>
<tr><td>Baseline (2012)</td><td>Milestone (2017)</td><td colspan="2">Target (2020)</td></tr>
<tr><td>Quantity: 240 million tonnes
Value: 260 billion euro</td><td>260 million tonnes
270 billion euro</td><td colspan="2">280 million tonnes
290 billion euro</td></tr>
</table>

4. POLICY ACTIVITIES

4.1. Health

ABB activity: Health							
Financial resources (€) in commitment appropriations					**Human resources**		
Operational expenditure		Administrative expenditure		Total	Establishment plan posts[4]	Estimates of external personnel (in FTEs)	Total
DG Health and Food Safetys	ECDC, EMA, EFSA	Heading 5 appropriations	Other budget lines				
57.301.000	164.694.000	2.034.000	5.709.000	229.738.000	165	47	212
221.995.000		7.743.000					

EU health policy contributes to the Agenda for Jobs, Growth, Fairness and Democratic Change by making Europe smarter, more inclusive and more sustainable, and contributing to the objectives of the overall EU growth strategy, Europe 2020. In 2015 the Commission will pursue actions linked to these objectives, in particular by contributing to "A Connected Digital Single Market" and "A Deeper and Fairer Internal Market with a Strengthened Industrial Base". The EU health policy will play its part in supporting the EU's capacity to safeguard health across EU borders, notably through dealing with crisis situations such as pandemics. It will also help Member States address the challenge of increased calls on health services and more complex technological choices at a time of intense pressure on public finances. The Commission will continue to support an integrated approach to health through legislation, cooperation and with financial support from the EU Health Programme.

[4] Figure includes two frozen posts

THE CHALLENGES

- increasingly challenging demographic context threating the sustainability of health systems

- fragile economic recovery limiting the resources available for investment in healthcare

- increase of health inequalities between/within Member States

- increase in chronic diseases prevalene

GENERAL OBJECTIVES

- Complement, support and add value to the policies of Member States

- to improve the health of EU citizens *and*

-reduce health inequalities

SPECIFIC OBJECTIVES

1) Promote health, prevent disease and foster supportive environments for healthy lifestyles: *Identify, disseminate and promote the up-take of evidence-based good practices for cost-effective disease prevention and health promotion measures by addressing in particular the key lifestyle related risk factors with a focus on the Union added value.*

2) Protect citizens from serious cross-border health threats: *Identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies.*

3) Contribute to innovative, efficient and sustainable health systems: *Identify and develop tools and mechanisms at Union level to address shortages of resources, both human and financial, and facilitate the voluntary up-take of innovation in public health intervention and prevention strategies.*

4) Facilitate access to better and safer healthcare for Union citizens: *Increase access to medical expertise and information for specific conditions also beyond national borders, facilitate the application of the results of research and develop tools for the improvement of healthcare quality and patient safety through, inter alia, actions contributing to improve health literacy.*

Budget: €449.4 million (2014-2020)

Management mode: Centralised direct and indirect management

Programming and implementation on the basis of adoption of Annual Work Programmes through implementing acts

Monitoring and reporting

Mid-term review in 2017Annual implementation report sent to EP& Council

ACTIONS (see annex I of the Programme Regulation)

1.1 *Risk factors such as use of tobacco and passive smoking, harmful use of alcohol, unhealthy dietary habits and physical inactivity.*
1.2. *Drugs-related health damage, including information and prevention.*
1.3. *HIV/AIDS, tuberculosis and hepatitis*
1.4. *Chronic diseases including cancer, age-related diseases and neurodegenerative diseases*
1.5. *Tobacco legislation*
1.6. *Health information and knowledge system to contribute to evidence-based decision making*
2.1 *Risk assessment additional capacities for scientific expertise*
2.2. *Capacity building against health threats in Member States, including, where appropriate, cooperation with neighbouring countries*
2.3. *Implementation of Union legislation on communicable diseases and other health threats, including those caused by biological, and chemical incidents, environment and climate change*
2.4 *Health information and knowledge system to contribute to evidence-based decision making*
3.1 *Health Technology Assessment*
3.2 *Innovation and e-health*
3.3 *Health workforce forecasting and planning*
3.4 *Setting up a mechanism for pooling expertise at Union level*
3.5 *European Innovation Partnership on Active and Healthy Ageing*
3.6 *Implementation of Union legislation in the field of medicinal products and cross-border healthcare*
3.7 *Health information and knowledge system including support to the Scientific Committees set up in accordance with Commission Decision 2008/721/EC*
4.1 *European Reference Networks*
4.2 *Rare diseases*
4.3 *Patient safety and quality of healthcare*
4.4 *Measures to prevent Antimicrobial resistance and control healthcare-associated infections*
4.5 *Implementation of Union legislation in the fields of tissues and cells, blood, organs*
4.6 *Health information and knowledge system to contribute to evidence-based decision making*

RESULTS

1. Increased use of evidence-based practices at the appropriate level in Member States

2. Coherent approaches integrated in the Member States preparedness plans; improved surveillance of cross-border health threats and their protection and management

3. Increased production of advice and use of developed tools and mechanisms by MS in the reform of their health systems

4. Establishment of the European Reference Networks (for rare or low prevalence and complex diseases), and increasing number of healthcare providers joining the European Reference Networks

Intervention logic: EU Public Health Policy

Fostering good health in an ageing Europe

Legislation

The new Tobacco Products Directive (2014/40/EU) must be transposed by Member States by 20 May 2016. In 2015, a priority will be the implementation of the Directive, through supporting and monitoring transposition by Member States, as well as developing the implementation legislation concerning mainly the ingredients and labelling of tobacco products.

Cooperation

The Commission will continue to support activities on key health determinants including social and environmental determinants and health inequalities, nutrition and physical activity, alcohol, and tobacco control. Particular emphasis will be placed on communicating with all stakeholders and a specific electronic platform will be developed to boost interaction between stakeholder groups and the Commission on public health issues, and among the various stakeholder groups, to increase information sharing and coherence.

Cooperation developed within the "European Innovation Partnership on Active and Healthy Ageing" will continue in 2015: DG SANTE will pursue work to disseminate and further develop evidence around the community and clinical interventions identified under the European Innovation Partnership, addressing the prevention of frailty (in the context of a Joint Action under the EU health programme), complex co-morbidities and the twin challenges of adherence to medical plans and poly-pharmacy.

Cooperation in the context of the "Strategy for Europe on Nutrition, Overweight and Obesity related health issues" will continue in 2015. The Action Plan on childhood obesity will continue to be implemented and monitored with the High Level Group on Nutrition and Physical Activity, in line with the conclusions on obesity prevention in children. The Commission will also support the Joint Action under the EU Health Programme to take forward work on common priorities (expected to begin May 2015).

To support Member States' efforts to reduce alcohol related harm, the Action Plan on Youth Drinking and on Heavy Episodic Drinking endorsed by the Committee on National Alcohol Policy and Action will be implemented and monitored. The aim is to strengthen the capacity of EU countries to reduce harmful alcohol consumption and related harm, as well as the related costs to health systems and society.

To follow-up the 2006-2012 EU strategy to support Member States in reducing alcohol-related harm, the Commission will consider various policy options, where necessary by means of an impact assessment. Other actions will include the Commission's contribution to an Action Plan on youth/binge drinking and continued work on rare diseases, cancer, mental health and antimicrobial resistance.

Work will continue to support EU countries in activities to improve access to health care – in particular for vulnerable people – and combatting discrimination in health. This will include participating in discussions with stakeholders on tools to measure access, identifying and exchanging good practices on policies and tools used to improve access, support for training health professionals, raising awareness of effective actions in this area and support for the implementation of national strategies on Roma integration. A specific angle on health inequalities will be supported in both the alcohol and nutrition and physical activity Joint Actions.

In parallel, work on major chronic and rare diseases will continue in 2015. Chronic diseases represent the major part of the disease burden in the EU and place a high burden on patients and health and social care systems.

In 2015, work with Member States will also continue on the Joint action with EU countries on chronic diseases and by setting up an expert group on patient empowerment in chronic disease management. A cooperative structure on chronic diseases with Member States and stakeholders will be created, in full respect of the principles of subsidiarity and proportionality, to take specific actions with an impact on health outcomes in response to selected chronic diseases. This will lead to a coherent policy approach on chronic diseases prevention and management.

EU action on rare diseases brings together fragmented resources from across Member States to improve diagnosis and treatment. The Commission's communication on rare diseases, Europe's challenges and the Council recommendation on action in the field of rare diseases provide the framework for activities which will continue in 2015. The Commission has put forward a report on the Implementation of the Commission Communication and Council Recommendation on rare diseases which details the implementation activities to date and takes stock of achievements and lessons learnt.

Dementias are among the major health challenges linked to demographic change. Building upon the Staff working paper on the implementation of the EU strategy for Alzheimer's disease and other dementias published in 2014, and linked to broader work on ageing and the silver economy, addressing dementia will be a key working area in 2015. A second Joint Action on Dementia will be launched. Inter-service collaboration and work with Member States will be strengthened. The Commission will contribute to a WHO global ministerial conference on dementia (March 2015). This event will build on G7 work on dementia, which was launched in December 2012 and which included the Commission.

The EU Compass for Action on Mental Health and Well-being will be developed into a mechanism inviting reporting on activities by Member States and stakeholders and disseminating good practices, and this will include a forum event. A report on EU action on mental health will be prepared to take stock on achievements to date and point out the gaps and needs for future action.

Cancer is the second biggest cause of death for both men and women. 2015 marks 30 years of EU cancer action. During 2015, the new Joint Action financed under the EU health programme on cancer control guidelines will strengthen cooperation between Member States and open debates on additional cancer screening measures. A new Joint Action on rare cancers financed under the EU health programme will be launched. On-going work on cancer registries will be the basis for the consolidation of the European Cancer Information System. The European Breast Cancer Initiative will be developed with the creation of collaborative structures working on new breast cancer screening guidelines and a quality assurance scheme – taken forward by JRC. The new Expert Group on cancer control will take a more prominent role in this area. The report on the implementation of the Council recommendations on cancer screening and the European partnership for Action on Cancer published in 2014 will serve as a guidance document for the further development of EU cancer policy.

Relevant general objective 1: Complement, support and add value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.

Specific objective 1.1: In order to promote health, prevent diseases, and foster supportive environments for healthy lifestyles: Identify, disseminate and promote the up-take of evidence-based and good practices for cost-effective health promotion and disease prevention measures by addressing in particular the key lifestyle related risk factors with a focus on the Union added value **External factors:** The desired results and expected outcomes depend strongly on the cooperation of Member State authorities and stakeholders (including the relevant and large involvement of all Member States), and on the efficient and effective implementation of the Health Programme by the Consumers Health and Food Executive Agency (CHAFEA).	☒ Spending programme ☒ Non-spending

Result indicator 1.1.A: Number of Member States involved in health promotion and disease prevention, using evidence-based and good practices through measures and actions taken at the appropriate level in Member States. (Health Programme 2014-2020)

Definition and relevance: The health programme provides support to Member States and stakeholders for the identification, validation and dissemination of good practices, through Joint Actions and other means, linked to policy priorities to prevent chronic diseases – including cancer – and rare diseases, and to address health determinants and common risk factors. The number of Member States using the validated good practice measures represents a good proxy for effective coordination and contacts developed in order to take up the experiences across borders.

Source of data: Health programme implementation statistics (CHAFEA)

Baseline	Milestones		Target (2020)
(2013)	2015	2018	(agreed in Health Programme 2014-2020)
0	7	23	28

Result indicator 1.1.B. Number of MS involved in projects of promoting health and preventing diseases (as deriving from indicator 1.1.A from Health Programme 2014-2020)

Definition and relevance: The health programme provides support to Member States and stakeholders for work on promoting health and preventing diseases, through projects and other means, linked to policy priorities to promote investment in prevention. The number of Member States and the degree of their involvement in projects and joint actions presents a good proxy for Member States coordination and contacts to develop and take up the experiences across borders.

Source of data: Health programme implementation statistics (CHAFEA)

Baseline	Milestones	Target
2013	2017	2020
0	14	28

Result indicator 1.1.C: Number of EU countries with a national initiative on the reduction of saturated fat (White Paper on a strategy for Europe on Nutrition, Overweight and Obesity related health issues – COM (2007)279 final)

Definition and relevance: In Europe today, 6 of the 7 biggest risk factors for premature death – blood pressure, cholesterol, Body Mass Index, inadequate fruit and vegetable intake, physical inactivity and alcohol abuse – relate to how we eat, drink and move. Multi-stakeholder's approach within and between Member States in particular for food reformulation campaigns is core in the strategy for Europe on Nutrition, Overweight and Obesity related health issues and the Member States endorsed on 3 February 2011 the High Level Group (HLG) agreed on the EU Framework for National Initiatives on Selected Nutrients with a first focus on saturated fat.

Source of data: High Level Group on Nutrition and Physical Activity

Baseline (2013)	Milestones		Target (2020)
	2015	2018	(target agreed in the programme statement)
12	18	24	28

Result indicator 1.1.D: Number of EU countries in which a European accreditation scheme for breast cancer services is implemented (Programme Statement attached to the Budget 2014)

Definition and relevance: The European Accreditation system should be in place in 2016/2017 and will provide a good proxy for Member State uptake of guidance and good practice tools developed at EU level

Baseline (2013)	Milestone (2017)	Target (2020) (target agreed in the programme statement)
0	10	28

Result indicator 1.1.E: Percentage respondents which currently smoke cigarettes, cigars or a pipe
Definition and relevance: Tobacco consumption is the single largest avoidable health risk in the European Union. It is the most significant cause of premature death in the EU, responsible for nearly 700,000 deaths every year. Around 50% of smokers die prematurely (on average 14 years earlier). In addition, smokers have more life years in poor health. Many forms of cancer, cardiovascular and respiratory diseases are linked to tobacco use, which causes more problems than alcohol, drugs, high blood pressure, excess weight or high cholesterol.
Source of data: Eurobarometer (latest data: Special Eurobarometer 385, 2012)

Baseline (2012)	Milestones 2018	Target (2021) (according to the Impact assessment of the Tobacco Products Directive)
28%	27,70%	27.44%

Main outputs in 2015

Description	Indicator	Target
A well-functioning cooperative structure with Member States and stakeholders to realise actions with health impact on selected chronic diseases	A cooperative structure in place	cooperative structure to be operational
Follow-up to the adoption of Tobacco Products Directive:		
- support and monitor the transposition by the Members States (by 20 May 2016)	Transposition	Support and monitoring
- develop the implementation legislation concerning mainly the ingredients and labelling of tobacco e-cigarettes, such as a common reporting format and adaptation of the health warnings on tobacco packs (Commission output)	Implementing legislation	Preparation
- report on potential risks from electronic cigarettes and their refillables	Report	Publication

Planned evaluations

Evaluation Ex-Smokers communication campaign (March 2015)
Ex-post evaluation of Health Programme 2008-2013 (31 December 2015)
Mid- term evaluation report on the achievement of the objectives of the Health Programme 2014-2020 (30 June 2017)

Protecting citizens from health threats

Legislation

Outbreaks of communicable diseases such as Poliomyelitis, Middle East Respiratory Syndrome Corona Virus (Mers CoV) and most topically Ebola Virus Disease (EVD) underline the vulnerability of the international community as regards such threats and the need for consistent and coordinated monitoring and responses. Decision 1082/2013/EU on serious cross border health threats provides the solid framework to address, coordinate and manage these threats in cooperation with the Member States, WHO, the ECDC and other international partners. It also extends the existing framework for communicable diseases to hazards caused by other biological, chemical and environmental events. Work will continue in 2015 to implement the Decision, further strengthen preparedness and support, where possible, Member States in their efforts to contain, mitigate and fight health scourges. As a formal consultation body, the EU Health Security Committee will continue to provide cooperation on risk management of specific threats.

Further work on procedures for information exchange under the Early Warning and Response System (EWRS) and procedures for mutual information, consultation and coordination to coordinate responses to a health threat need to be implemented in 2015.

The Joint Procurement agreement is now established as a basis for voluntary cooperation of Member States to jointly procure medical countermeasures to cope with threats under the Decision. A specific initiative for the procurement of pandemic vaccines will be launched in 2015.

Implementing legislation for verifying the equivalent standards of quality and safety for human tissues and cells imported from third countries will be adopted early 2015 in order to harmonise current practices in EU countries and ensure that the same high-quality standards apply to all tissue and cell products circulated in the EU.

To strengthen traceability at EU level, implementing legislation setting out the mechanism for the application of the Single European Code for human tissues and cells intended for human application will be adopted early 2015.

Two reports are planned for 2015 following an analysis of Member States' replies to surveys on the implementation of EU legislation on blood (Directive 2002/98/EC) and on tissues and cells (Directive 2004/23/EC) to ensure our legislation remains effective and efficient in ensuring safety and quality.

Cooperation

The EU Health Security Committee will continue to provide for cooperation on risk management of specific threats. Within this Committee, officially nominated representatives from EU countries will continue to coordinate their preparedness activities, measures taken to contain or mitigate serious cross-border health threats and their risk and crisis communication activities.

International cooperation in preparing for and reacting to serious cross border health threats will be continued both at the WHO and through the Commission's membership of the Global Health Security Initiative, in which the UK, US, Germany, France, Italy, Japan, Canada, Mexico, WHO and the Commission work together to improve health security at global level. Links to the Global Health security agenda, where States take leadership to support the implementation of the International Health Regulations are also established. In this context, addressing the issues that emanate from the Ebola outbreak in Africa will be among the areas of focus of the Commission in 2015.

Disease specific activities

Discussion on the way forward as regards the future policy framework for HIV/AIDS, Hepatitis and Tuberculosis will also start in 2015. Antimicrobial resistance, health care associated infections and vaccination will also attract close attention.

Antimicrobial resistance (AMR) will remain a high priority in 2015. The EU-US Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) will continue to share information and strategies on AMR. A review of the implementation of the Council recommendation on the prudent use of antimicrobials will be carried out and the results will be made available by SANTE on its web site, to the EU Health Security Committee and to relevant working groups.

The results of an external evaluation of the HIV/AIDS strategy will inform the development of options for a future EU policy framework. The Commission will continue its work with the Civil Society Forum, the Think Tank on HIV/AIDS,

international organisations and other stakeholders in the definition and implementation of policies combating HIV/AIDS and co-infections such as tuberculosis and hepatitis. These actions will be supported by projects under the Public Health Programme.

A coordination strategy on human laboratories in the EU was elaborated in consultation with stakeholders. Continued activities related to vaccination against measles and rubella will be implemented in order to contribute to reaching the WHO European Region target to eliminate measles and rubella by 2015. EU countries will continue to be supported to increase vaccination coverage at national level.

On the basis of the progress report on the implementation of the Council Recommendation on seasonal influenza vaccination (2009/1019/EU) a hearing/conference with stakeholders will be organised in 2015 with a view to achieving a consensus on proposed steps for improvement and a commitment to accelerated actions. A cost-benefit analysis will also be conducted to consider the cost-effectiveness of seasonal influenza vaccination. These exercises will serve as the basis for an evaluation of the Council Recommendation on seasonal influenza vaccination.

Relevant general objective 1: Complement, support and add value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.

Specific objective 1.2: In order to protect citizens from serious cross-border health threats: Identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies. **External factors:** The desired results and expected outcomes depend strongly on the cooperation of Member State authorities and stakeholders (including the relevant and large involvement of all Member States), and on the efficient and effective implementation of the Health Programme by the Consumers Health and Food Executive Agency (CHAFEA).	☒ Spending programme ☒ Non-spending

Result indicator 1.2.A: Number of Member States integrating the developed common approaches in the design of their preparedness plans (source: Commission Staff Working paper impact assessment, accompanying the Decision of the European Parliament and Council on serious cross-border threats to health)
Definition and relevance: The number of Member States integrating the developed common approaches in the design of their preparedness plans is a clear indicator that directly allows for a proper assessment of the ways Member States identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies. The legal basis that defines how these data will be achieved is already laid down in Commission Implementing Decision 504/2014/EU adopted on 25 July 2014.
Source of data: Report on the state of preparedness of Member States (by 7 November 2014 and then every three years afterwards, according to Article 4 of Decision 1082/20137EU)

Baseline (2013)	Milestones		Target (2020) (agreed in the programme statement attached to the Budget 2014)
	2015	2017	
0	4	14	29

Result indicator 1.2.B: Number of Member States ensuring common EU traceability of tissues and cells.
Definition and relevance: MS will ensure traceability by implementing the Single European Coding system, and ensuring the compendium of tissue establishments is kept up to date. While the legal obligation only enters in 2016, all IT tools are available to implement the system earlier.
Source of data: Utilisation logs of compendia (IT).

Baseline (2013)	Milestones		Target (2020) (Source: Eurocet128)
	2015	2018	
0	5	28	28

Main outputs in 2015		
Description	Indicator	Target
Decision on serious cross-border threats to health	Implementing acts on (EWRS) and procedures for mutual information, consultation and coordination to coordinate responses to a health threat	Adoption by Commission
Pandemic preparedness	Joint procurement agreement	conclusion
Joint procurement of pandemic vaccines	Framework contracts	conclusion
Anti-Microbial Resistance roadmap	Deliverables	Implementation
Stakeholder consultation on reference laboratories for human pathogens	Report	Adoption
National Competent Authorities who are actively updating the Single European Coding system. (While the legal obligation only enters in 2016, all IT tools are available to implement the system earlier.)	Nr of up to date compendia of authorized tissue establishments	5
Planned evaluations		
Evaluation of the European Centre for Disease Prevention and Control (ECDC) (March 2015)		
Ex-post evaluation of Health Programme 2008-2013 (31 December 2015)		
Evaluation of the implementation 2009 Council recommendation on seasonal influenza vaccination (30 June 2016)		
Evaluation of 2011 Council conclusions on childhood immunisation (July 2016)		
Mid- term evaluation report on the achievement of the objectives of the Health Programme 2014-2020 (30 June 2017)		

Support dynamic health systems and new technologies

In 2015, the Commission will monitor and assess whether EU countries are properly enforcing the rules of the Directive on patients' rights in cross-border healthcare, and encourage cross-border cooperation on information to patients, patient safety, integration of care, health workforce, health technology assessment, e-Health, health information and European Reference Networks.

The Commission will continue to work for a consistent representation of health system reforms within the framework of the European Semester, building on the policy framework laid out in the Communication on effective, accessible and resilient health systems[5]. The goal is to support the development of cost-effective and sustainable health systems, able to provide the patient with high-quality care and access to appropriate and effective health services. The Commission will provide support to identify areas where reforms are most needed, and will help monitoring the implementation of such reforms.

Legislation

The Directive on patients' rights in cross-border healthcare, which had to be transposed by Member States by 25 October 2013, helps facilitate access to high-quality and cost-effective healthcare for patients, giving them the right to receive high quality, safe and efficient healthcare in other EU countries and be reimbursed for it.

In 2015, the Commission will assess whether Member States are properly enforcing its rules and will adopt a first report on the operation of the Directive. In implementing the Directive, instruments are being put in place to encourage EU countries to work closely together on areas such as health technology assessment and e-Health. The Commission will continue to promote the exchange of best practices in healthcare, with a view to improving the quality and value for money of all European health systems.

[5] COM(2014) 215, as available at http://ec.europa.eu/health/healthcare/docs/com2014_215_final_en.pdf

In 2015, the Commission will prepare the call for proposals for the establishment of European Reference Networks, in accordance with the provisions of Decision C(2014)1411. These networks will enhance cooperation between healthcare providers across the EU, with the aim of improving patient access to the highest quality care available in a given field.

In 2015, the Commission will continue implementing the Action Plan for the EU Health Workforce adopted in April 2012 as part of the Communication on job-rich recovery (COM (2012) 173 final). The Action Plan puts forward 4 areas of action to help EU countries cope with the challenges faced by the health workforce:

– improve health workforce planning and forecasting in the EU;
– better anticipate skills needs in the healthcare sector;
– stimulate exchange on recruitment and retention of health workers; and
– cooperate with the WHO on the implementation of the Global Code on the international recruitment of health workers.

The Commission will also continue working towards the implementation of the Directive on falsified medicinal products adopted in June 2011, and in particular on the unique identifier and the anti-tampering device, on the logo for the online sales of medicines, and the assessment of applications of 3rd countries in the context of importation of active pharmaceutical ingredients into the EU

Following the adoption of Regulation (EU) No 536/2014 on clinical trials in 2014 the Commission will, in 2015, continue the preparation for the application of this new Regulation. In this respect, the Commission is starting the preparatory work of a number of implementing and delegated acts and updating relevant guidance documents to bring them in line with the provisions of the new Regulation. The Commission will also continue its close collaboration with the European Medicines Agency and the Members States on the preparation of the EU Clinical Trials Portal and Database.

Another priority for 2015 will be to further facilitate innovation for the benefit of patients. For this reason DG Health and Food Safety has initiated discussions with Member States and the European Medicines Agency on how to improve and maximise the effective use of the current regulatory tools e.g. conditional marketing authorisation. This will build on the experience acquired from the implementation of the legislation and national initiatives.

In addition, DG SANTE will follow closely EMA's pilot project on adaptive pathways, which is a new approach to marketing authorisation aiming at an early authorisation of medicines in a restricted indication where there is an unmet medical need, followed by iterative phases of evidence-gathering and adaptation of the authorisation to broader patient populations. The focus of adaptive pathways is not only on the authorisation but also on a medicines added value, reimbursement potential, monitoring and the utilisation plan. This approach requires cooperation among a wide range of stakeholders, including regulators, the pharmaceutical industry, HTAs, payers as well as patients, healthcare professionals, researchers and academics. The applicability of adaptive pathways within the current legal framework will be also examined with the Member States. In addition, optimisation of the use of current regulatory tools such as conditional marketing authorisation and accelerated assessment is discussed with the Member States.

The Commission, through a joint action, will continue to facilitate EU countries' exchange of experience and knowledge for organising and running their pharmacovigilance systems with the view to monitor the safety of authorised medicines

and detect any change to their risk-benefit balance in the context of the new pharmacovigilance legislation.

The Commission will continue to work with the European Medicines Agency to ensure that medicinal products placed on the EU market conform to EU standards for quality, safety and efficacy.

Relevant general objective 1: Complement, support and add value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.

Specific objective 1.3: In order to support public health capacity building and contribute to innovative, efficient and sustainable health systems: Identify and develop common tools and mechanisms at EU level to address shortages of resources, both human and financial, and facilitate the voluntary uptake of innovation in public health intervention and prevention strategies **External factors**: The desired results and expected outcomes depend strongly on the cooperation of Member State authorities and stakeholders (including the relevant and large involvement of all Member States), and on the efficient and effective implementation of the Health Programme by the Consumers Health and Food Executive Agency (CHAFEA).	☒ Spending programme ☒ Non-spending

Result indicator 1.3.A: Advice produced, *in particular the number of Health Technology Assessments produced per year* (Health Programme 2014-2020 and Report from the Commission to the EP and Council on the evaluation of the Union4s finances on the results achieved COM(2014)383 final and Overview of the Monitoring and Evaluation Frameworks for the MFF 2014-2020 pp. 186-189 SWD(2014) 201 final)
Definition and relevance: The number of Health Technology Assessment reports produced as a consequence of EU collaboration indicate the degree of joint work done by the Member States. The assessments are counted as any types of reports (early dialogues, full HTA reports etc) produced.
Source of data: Information from EUnetHTA and other EU funded projects.

Baseline	Milestones		Target
2012	2015	2017	2020 (agreed in the programme statement)
2	6	10	50

Result indicator 1.3.B: Number of Member States using the tools and mechanisms identified in order to contribute to effective results in their health systems: patient summaries data/ ePrescription in line with the EU guidelines (Health Programme 2014-2020 and Report from the Commission to the EP and Council on the evaluation of the Union4s finances on the results achieved COM(2014)383 final and Overview of the Monitoring and Evaluation Frameworks for the MFF 2014-2020 pp. 186-189 SWD(2014) 201 final)
Definition and relevance: Patient summaries contain personal and health data for healthcare delivery. Patient summary data and ePrescription alignment is necessary to allow cross-border exchange. The uptake of eHealth instruments such as Electronic Health Records (EHR) and ePrescriptions (eP) contributes to better developing and monitoring of health technologies, better serving patients needs and possibly reducing the costs of health care
Source of data: eHealth network and joint action supporting the eHealth

Baseline	Milestones		Target
2013	2015	2017	2020
0	5	12	28

Main outputs in 2015

Description	Indicator	Target
HTA reports	Number produced	6
Organisation for building the eHDSI (eHealth Digital Service Infrastucture) for the exchange of patient summaries and e-prescriptions under the Connecting Europe Facility	eHealth DSI Project	Set-up completed and advancing according to the work plan
Patient summary data/ePrescription in line with EU guidelines - Number of Member States	Number of Member States	5
Expert Panel opinions	Number produced	6

Planned evaluations

Ex-post evaluation of Health Programme 2008-2013 (31 December 2015)
General evaluation of the performance of the Paediatric Regulation (Regulation (EC) No 1901/2006) (January 2016)
Evaluation of Regulation No 1394/2007 on advanced therapy medicinal products (2016)
Mid- term evaluation report on the achievement of the objectives of the Health Programme 2014-2020 (30 June 2017)

Health systems in Europe continue to be under financial pressure and the challenge to provide high quality and universal healthcare has never been greater. In 2015, the Commission – together with Member States – will begin joint activities on health system performance assessment drawing on the conclusions of the reflection process on the future sustainability of health systems.

The eHealth Network has laid down the basis for EU-wide deployment of two basic building blocks in cross-border healthcare: the guidelines on transfer of patient summaries and e-prescriptions, which will bring concrete benefits to citizens. Working within the eHealth Network, the Commission will focus on building the legal, organisational and technical infrastructure necessary to achieving the key objectives spelled out in the Cross-Border Healthcare Directive.

The Expert Panel on investment in health will through its independent advice and opinions provide country-specific and cross-country knowledge that can inform policies at national and EU level and support the Commission on promoting quality and effectiveness of public expenditure.

The network of national authorities and bodies for Health Technology Assessment endorsed in 2014 the European strategy that will put in place the building blocks for carrying out joint work at EU level for the better use on methodologies, data and best practice. The strategy sets the basis for joint pilots and reports which will be possible by concerted work of the Member States' agencies.

The 2015 priority is to set up the new way of doing joint work between national HTA actors to provide EU added value by identifying those treatments that benefit patients and are sustainable.

A newly established Commission expert group on health systems performance assessment (HSPA) will identify tools and methodologies for developing HSPA. It will also define criteria and procedures for selecting priorities areas for HSPA in order to illustrate and better understand variations in the performance of national health systems. The expert group will provide participating Member States with a forum for exchange of experience on the use of HSPA at national level.

The Commission's second report on the implementation of the Council Recommendation 2009/C 151/01 suggested a number of actions to better address patient safety. They include: developing guidelines on how to provide information to patients on safety and quality of care; development with Member States of an EU template on patient safety and quality of care standards to achieve common understanding of this concept in the EU; encouraging the development of training for patients, families and informal carers using also ICT tools; encouraging reporting as a tool to spread a patient safety culture. The Commission will initiate in 2015 work on these topics with Member States and EU stakeholders.

Relevant general objective 1: Complement, support and add value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.

Specific objective 1.4: In order to facilitate access to better and safer healthcare for Union citizens: Increase access to medical expertise and information for specific conditions also beyond national borders, facilitate the application of the results of research and develop tools for the improvement of healthcare quality and patient safety through, inter alia, actions contributing to improve health literacy **External factors:** The desired results and expected outcomes depend strongly on the cooperation of Member State authorities and stakeholders (including the relevant and large involvement of all Member States), on the efficient and effective implementation of the Health Programme by the Consumers Health and Food Executive Agency (CHAFEA) and on the available financial resources.	☒ Spending programme ☐ Non-spending

Result indicator 1.4.A: The number of approved and functioning European Reference Networks established in accordance with Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patient's rights in cross-border healthcare (Health Programme 2014-2020)

Definition and relevance: The networks will be approved by the ERN Board of Member States and will need the Commission support for the development of the assessment procedures, IT platform for ERN, studies and project grants. ERNS will contribute to better and safer healthcare for Union citizens suffering from rare or low-prevalence and complex diseases by increasing access across the EU to medical expertise and information, which will be achieved by bringing together and pooling the knowledge of highly specialised healthcare providers from different Member States. They will help to provide affordable, high-quality and cost-effective healthcare (diagnosis and treatment) in case of need of a particular concentration of resources or expertise in medical domains where expertise is rare.

Source of data: Information system on ERN, minutes of the Board of Member States on ERN meetings, licenses of the ERN trademark licensed.

Baseline	Milestones		Target
2013	2015	2017	2020 (Health Programme 2014-2020)
0	0	10	22

Result indicator 1.4.B: Number of healthcare providers and centres of expertise joining European Reference Networks (Health Programme 2014-2020)

Definition and relevance: ERNs will help Member States with insufficient number of patients to provide highly specialised care and therefore the greater number of members will maximise the speed and scale of diffusion of innovations in medical science and health technologies. ERN will also contribute to the objective acting as focal points in medical training and research, information dissemination and healthcare evaluation.

Source of data: Information system on ERN, minutes of the Board of Member States on ERN meetings, licenses of the ERN trademark licensed.

Baseline	Milestones		Target
2013	2015	2017	2020
0	0	120	266

Result indicator 1.4.C: Number of Member States using the developed tools *such as, having adopted and implemented a national strategy for the prevention and control of health-care associated infections (Commission report (COM (2012) 658 final) on the implementation of the Council Recommendation 2009/C 151/01)*

Definition and relevance: The increase of Member States adopting and implementing national strategies for the prevention and control of health-care associated infections will reduce the risk of acquiring a healthcare-associated infection when seeking healthcare, hence facilitate access to better and safer healthcare for Union citizens.

Source of data: ECDC country summary sheets on HAI

Baseline	Milestones		Target
2013	2015	2018	2020
9	15	20	28

Main outputs in 2015

Description	Indicator	Target
Assessment manual	One manual	Manual finalisation
Selection of assessment bodies	Number of assessment bodies selected	At least one
Development of a pilot IT infrastructure	One IT platform	Platform finalised
Communication campaign	Number of medical journals with inserted ERN ads	20 or more
Second ERN conference	One conference	Conference organised by October 2015
First call for ERN	One call for tender	Call launched no later than December 2015

Planned evaluations

Ex-post evaluation of Health Programme 2008-2013 (31 December 2015)

Mid- term evaluation report on the achievement of the objectives of the Health Programme 2014-2020 (30 June 2017)

Crisis preparedness

Early warning and crisis preparedness is essential to deal effectively with human, animal or plant health emergencies that may arise, and to ensure the rapid withdrawal of unsafe products from the market.

<table>
<tr><td colspan="4">Relevant general objective 3: Respond rapidly and efficiently to any outbreak potentially endangering the health and safety of citizens, animals, or plants in Europe, through adequate reaction capacities, appropriate preparedness and efficacious tools for quick alert and exchange of information.</td></tr>
<tr><td colspan="3">Specific objective 3.1: In order to complement public health preparedness and response planning and contribute to innovative, efficient and sustainable health systems: identify and develop shared tools and mechanisms[6] for sharing best practices, promoting inter-operability and inter-sectoral dimension and supporting the implementation of core capacity requirements[7].</td><td>☐ Spending programme
☒ Non-spending</td></tr>
<tr><td colspan="4">External factors: The desired results and expected outcomes depend strongly by the Member State authorities, who are asked to timely share their preparedness and response plans and by non-forecasted events which will happen in the future.</td></tr>
<tr><td colspan="4">Result indicator 3.1.A: Yearly base notifications by MS of the following items: (a) core capacity standards for preparedness and response planning; (b) description of the measures or arrangements aimed at ensuring interoperability between the health sector and other sectors including the veterinary sector, that are identified as being critical in the case of an emergency, in particular: (i) coordination structures in place for cross-sectoral incidents; (ii) emergency operational centres (crisis centres); (c) description of the business continuity plans, measures or arrangements aimed at ensuring the continuous delivery of critical services and products.
Definition and relevance: The above are essential elements for health preparedness which are enshrined in the Decision 1082/2013/EC.
Source of data: Notification by MS under Art 4 of Decision 1082/2013/EU</td></tr>
<tr><td>Baseline (2015)</td><td colspan="2">Milestone (2018)</td><td>Target (2021)</td></tr>
<tr><td>All MS for (a), (b), (c)</td><td colspan="2">All MS for (a), (b), (c)</td><td>All MS for (a), (b), (c)</td></tr>
<tr><td colspan="4">Main outputs in 2015</td></tr>
<tr><td>Description</td><td colspan="2">Indicator</td><td>Target</td></tr>
<tr><td>Implementation of Decision 1082/2013/EU</td><td colspan="2">Report of the Commission to European Parliament and Council</td><td>Adoption in 2015</td></tr>
</table>

International relations in health

The Commission also participates in multilateral fora aimed at converging regulations in the field of medicinal products. These include the International Conferences on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and that for veterinary medicinal products (VICH).

Bilateral relations: bilateral agreements in all our policy areas are implemented in a way to ensure effective co-operation.

Canada: In September 2014, the EU and Canada concluded the negotiations of a Comprehensive Economic and Trade Agreement that is now submitted for ratification by both parties. It will be the first free trade agreement between the EU and a G8 country. The provisions of the Mutual Recognition Agreement related to Good Manufacturing Practices (GMP) inspections of manufacturing sites of medicinal products have been incorporated into the EU Canada CETA.

Russia: The Russian Federation is the EU's primary trade partner in medicinal products. Together with Customs Union (CU) partners (Belarus and Kazakhstan), they form a region that represents both opportunities and challenges. Russia has recently joined the WTO and is still adjusting to its new obligations, whilst also pursuing its modernisation

[6] according to Article 4 of Decisions 1082/2013/EU
[7] according Art 5 and 13 of the International Health Regulations

objectives. Continuous discussions aim to enhance mutual understanding and resolve multiple trade impediments and to share EU experience in management of health threats.

United States: The talks on the Transatlantic Trade and Investment Partnership with the US were launched in summer 2013 with the aim of removing trade barriers in a wide range of economic sectors to make it easier to buy and sell goods and services between the EU and the US. The negotiations cover pharmaceuticals amongst many other issues. For medicinal products, the main objectives are to achieve mutual recognition of Good Manufacturing Practice (GMP) inspections and a functional US framework for biosimilars. We will continue to build on the strong bilateral relations with FDA in view of developing harmonised or compatible requirements for the oversight of medicinal products and foster coordinated responses to global challenges related to the efficacy, quality, safety and availability of medicinal products.

Free Trade Agreements (FTA)

There are several on-going FTA negotiations, including chapter on medicinal products, with countries outside of the EU, notably Japan, Malaysia, Vietnam, Thailand (Association of Southeast Asian Nations – ASEAN countries), India, the Mercosur group and Morocco. We will continue to ensure the proper implementation of the existing agreements with a medicinal products component notably with South Korea, Mexico, Chile, Switzerland, the Veterinary Agreement with New Zealand and the European Economic Area Agreement (EEA).

Enlargement and Neighbourhood Association Agreements

During 2015, we will continue to ensure the implementation of the association agreements with countries currently candidates to EU accession (Turkey, Serbia, Montenegro, the former Yugoslav Republic of Macedonia) and with potential candidates (Albania, Bosnia and Herzegovina, Kosovo[8]). In addition, we will continue to monitor the adequate implementation of the relevant transitional measures granted to Croatia in its Treaty of Accession to the EU. In this period we will also continue to work on the implementation of the recently signed and ratified association agreements with Ukraine, Moldova and Georgia. In addition we will continue to work with other neighbourhood countries with the view of approximating their health legislation with the EU *acquis* and supporting their health systems.

[8] This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

Relevant general objective 1: Complement, support and add value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats

Specific objective 1.5: Increase the voice and influence of the EU in global health fora **External factors:** Agreeing coordinated EU inputs at WHO and other UN Bodies depends on a consensual willingness of the EU MS to coordinate their positions. Reasons used in the past by MS for refusing include: they consider the topic as exclusive MS competence, as being irrelevant, that they do not have the capacity to coordinate on a large number of items, that there is a red line issue in the text for them, that the text is already acceptable etc.	☐ Spending programme ☒ Non-spending

Result indicator 1.5.A: Percentage of the total number of WHO Governing Body Resolutions adopted annually which contain coordinated EU inputs.
Definition and relevance: Historically, EU Member States have negotiated texts individually at WHO governing bodies. The above indicator will (i) indicate a growing move from EU MS individual action to coordinated EU action, and (ii) a real impact of EU inputs to the texts of agreed resolutions
Source of data: reports of WHO governing body meetings

Baseline	Milestone	Target
2014	2017	2021 (internal decision based on the year coinciding with the end of the posting of the next SANCO official to be sent 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%

Main outputs in 2015

Description	Indicator	Target
EU-level Mapping exercises for topics on agendas of the three annual WHO governing body meetings	Percentage of EU-relevant issues mapped Number of mapping meetings	100% 9
Coordinated EU statements at WHO and UNGA on EU-relevant health topics	Percentage of total EU-relevant topics for which statements are agreed in coordination Number of coordination meetings	50% 20
EU positions on WHO governing body resolutions and health-related resolutions at the UN	Percentage of total EU-relevant topics for which EU negotiating inputs are prepared and agreed at EU level.	100%

4.2. Food and feed safety, animal health and welfare, and plant health

ABB activity: Food and feed safety, animal health and welfare, and plant health						
Financial resources (€) in commitment appropriations				**Human resources**		
Operational expenditure	Administrative expenditure		Total	Establishment plan posts	Estimates of external personnel (in FTEs)	Total
	Heading 5 appropriations	Other budget lines				
256.136.000	6.039.900	2.670.000	264.845.900	414	59	473
	8.709.900					

Intervention logic: EU policy for food and feed safety, animal health and welfare, and plant health

COMMON FINANCIAL FRAMEWORK FOR FOOD AND FEED (CFF)

For a better understanding by non-experts readers, this logic of intervention is presented in a simplified way.

- Tackling and preventing animal diseases
- Tackling and preventing pest of plants;
- Safeguarding public health;
- Reducing human health costs;
- Ensuring protection and information of consumers;
- Preserving the environment;
- Ensuring animal welfare;
- Ensuring more uniform, objective and efficient official controls in food and feed, animal health and welfare and plant health areas
- Favouring competitiveness and creation of jobs;
- Protecting the economic value of the food and feed sector;
- Contributing to market stability all along the food chain;
- Guaranteeing fair practices in trade;
- Ensuring safe trade;
- Increasing extra-EU trade;

OBJECTIVES

PROCESSES

Funding modalities	Mainly grants (Annual or multiannual programmes, Emergency measures, Technical activities) Payments to international organisations
Management modes	Centralised direct and indirect

INTERNAL PROCESSES:

- **Programming and implementation**
  - Annual and Multiannual work programmes
- **Monitoring and reporting**:
  - Mid-term evaluation report no later than 30 June 2017 / Ex-post evaluation by 30 June 2022
  - Annual intermediate financial reporting on implementation of programmes
  - Annual financial and technical reporting on implementation of programmes.

IMPACTS

OUTCOMES (RESULTS)

EXOGENOUS FACTORS

In 2015, DG SANTE will strive to strengthen the food chain framework by:

– Placing the consumer first, whilst promoting the competitiveness of business operators of the food chain;

– Setting the right standards at EU level to protect people, plants and animals whilst enhancing a competitive market by adopting Smart Regulation;

– Assuring effective and efficient control systems and compliance with EU standards in the food and feed safety, food quality, animal health, animal welfare, animal nutrition, plant reproductive material and plant health sectors within the EU, and in third countries in relation to their exports to the EU;

– Promoting transparency to better enable consumers to make informed and nutritionally relevant food choices, supported by comprehensive impact assessments where appropriate;

– Promoting sustainability as an opportunity to create jobs and growth;

– Exploring how food chain policy can be adapted to sustainability imperatives for example by contributing to preventing food waste along the food chain

– Monitoring, evaluating, managing threats, and where necessary, alerts and identified risks, in a proportionate manner;

– Fostering innovation so as to encourage new technologies and investments in research.

– Promoting EU standards at international and multilateral levels;

– Strengthening relations with the European Food Safety Authority (EFSA) and the Community Plant Variety Office (CPVO).

Official controls and enforcement along the food chain

Official controls are key elements to assure consumers and operators that the measures put in place along the food chain for a safer, more competitive and sustainable market are implemented properly.

The audits of DG SANTE's audit service, the Food and Veterinary Office (FVO), are crucial for ensuring proper implementation in the fields of food and feed safety, food quality, animal health and welfare, plant health and some areas of human health. During 2015, the FVO in accordance with its audit programme will carry out approximately 250 audits in Member States, candidate countries and third countries exporting to the EU. The results of FVO activities assist in ensuring that our legislation is kept up to date, relevant and fit for purpose. The 2015 programme contains a number of priorities for projects affecting more than one sector or bringing together different aspects of a sector normally audited separately, like, for example post-slaughter traceability of meat and meat products, food additives, composite products, aquaculture and anti-microbial resistance monitoring (as part of the AMR roadmap)[9]. In addition to its audit reports, the FVO also produces overview reports to ensure that the results of audit series are presented in a manner which facilitates understanding of the state of implementation of EU legislation and the problems and good practices identified across the MS.

In May 2013, the Commission adopted its proposal reviewing Regulation 882/2004 on official controls. The aim of the proposal is to simplify and streamline the existing legal

[9] Full programme to be found at http://ec.europa.eu/food/fvo/inspectprog/index_en.htm

framework, in order to improve the efficiency of official controls performed by the Member States along the food chain while minimising burdens for operators. Discussions between the Commission and the co-legislators will continue in 2015.

Based on the latest scientific advice provided by EFSA, the Commission will also prepare draft regulations on meat inspection of poultry, ruminants, horses and farmed game for adoption during 2015.

As a complementary tool to FVO's audits, the Better Training for Safer Food programme plays an important role in spreading knowledge and awareness of EU legislation, in promoting harmonisation and uniformity of control activities across the EU and in improving the ability of control staff to detect fraud and non-compliance on the EU market but also at its borders.

<table>
<tr><td colspan="4">Relevant general objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs</td></tr>
<tr><td colspan="3">Specific objective 2.1: Contribute to improve the effectiveness, efficiency and reliability of official controls and other activities carried out in view of the effective implementation of, and compliance with, EU rules
External factors: The desired results and expected outcomes depend strongly on the willingness and vigour of Member States and third country authorities to act.</td><td>☒ Spending programme
☒ Non-spending</td></tr>
<tr><td colspan="4">Result indicator 2.1.A: Percentage of FVO recommendations following FVO audits that Member States have satisfactorily addressed with corrective action
Definition and relevance: The FVO carries out audits to verify (a) compliance with EU rules and (b) that official controls are carried out in line with EU law. The FVO makes recommendations to the country's competent authority to deal with any shortcomings revealed during the audits. The competent authority is requested to present an action plan to the FVO on how it intends to address any shortcomings. Together with other Commission services, the FVO evaluates this action plan and monitors its implementation through a number of follow-up activities. The indicator is therefore a measurement of the improvement of official controls.
Source of data: Commission internal (FVO)</td></tr>
<tr><td colspan="2">Baseline (2013)</td><td colspan="2">Target (2015)</td></tr>
<tr><td colspan="2">60% for recommendations from reporting cycles 2010 - 2012</td><td colspan="2">70% of all recommendations from these reporting years to be addressed</td></tr>
<tr><td colspan="4">Result indicator 2.1.B: Ratio of satisfaction of participants in BTSF training programmes (training quality) and steady state of annual participants (minimum training target)
Definition and relevance: Satisfaction ratio is an important tool to measure the training quality from a technical and organisational point of view, the relevance of the training in terms of addressing participants' expectations and needs in the workplace. In order to ensure effective, efficient and reliable controls, high quality training contributes to the better understanding and harmonised enforcement of the rules in place. Taking into account the 'trainee-trainer principle', the participants will disseminate this knowledge in their respective Member States. Therefore the need to ensure and maintain a critical mass of participants to the BTSF trainings. The satisfaction rate as measurable indicator provides a tool to evaluate the appropriateness and relevance for the daily work of the officials attending the training.
Source of data: BTSF Annual Report 2013</td></tr>
<tr><td>Baseline (2014)</td><td>Milestone (2018)</td><td colspan="2">Target (2020)</td></tr>
<tr><td>85% satisfaction rate/6000 participants trained</td><td>85% satisfaction rate/ 6000 participants trained</td><td colspan="2">87% satisfaction rate/ 6000 participants trained</td></tr>
<tr><td colspan="4">Main outputs in 2015</td></tr>
<tr><td>Description</td><td colspan="2">Indicator</td><td>Target</td></tr>
<tr><td>Report on the operation of official controls along the food chain</td><td colspan="2">Report</td><td>Adoption</td></tr>
<tr><td>Overview reports on FVO audit series</td><td colspan="2">Number of reports</td><td>22</td></tr>
<tr><td>FVO audits in the fields of food and feed safety, animal health and welfare and plant health
- audits on imports from third countries of active pharmaceutical ingredients for medicinal products for human use
- audit on organic production and labelling of organic products
- audits on geographical indication schemes (MoU with DG AGRI)</td><td colspan="2">(1) Completion rate of programmed audits
(2) Overall use of audit capacity
Number of audits
Number of audits
Number of audits</td><td>(1) 80%
(2) 90%
2 – 3 (depending on applications)
11
3</td></tr>
</table>

Cross-sector projects	Number of projects	8
Mandatory joint assessments (with designating authorities) of notified bodies in the medical devices sector in MS, EFTA and ESA countries	Number of assessments	Approx. 25
Series of study visits to exchange information and best practice between MS on strategies and actions to improve slaughter hygiene (mammals), including the establishment of an expert group.	Number of study visits Interim overview report Organisation of expert group meetings	6 By end 2015 2
Residue control plans from MS and from third countries exporting food of animal origin to the EU	Number of evaluations	28 MS plans and 85 TC plans
Approved third country establishments for the production of food of animal origin	Management of establishment lists	127 lists by country (27 lists by sector)
Evaluation of Border Inspection Post plans	Number of evaluations	On average 50
Harmful organisms outbreak annual report	Number of reports	1
Plant pest surveys	Number of surveys	3
EUROPHYT Annual report	Number of reports	1
Network meetings with Member State experts to identify problem areas and exchange good practices (e.g. animal welfare, national audit systems and multi-annual national control plans and others)	Number of meetings organised	up to 10
Robust impact indicators to measure BTSF participants' post-training performance	Study to be carried out	Completion in 2015
Management of BTSF programmes	Number of contracts, Evaluation of reports & offers Organisation of meetings with contractors	15 100% evaluated within required timescale 100% organised as required

Plants and seeds

Plants and plant reproductive material (including seeds) are essential sectors for the safety and security of the agri-food chain. DG SANTE intends to promote in particular innovation by ensuring that this is applied by respecting safety rules, by reducing administrative burden and fostering a smart and greener economy. The following actions are planned for 2015.

For Plant Health, the priorities will relate to the continuation of the work started in 2014 for updating the Annexes of the current Directive 2000/29/EC and to the updating of lists of quality pests included in the Directives on seed and plant propagating material in order to create the conditions for their smooth adoption under secondary legislation within the new Plant Health Regulation. Support studies will be contracted out for this preparatory work. In parallel, the trilogue concerning the new legislative proposals for Plant Health is expected to start in September 2015, with possible adoption of the proposed Regulation in 2016.

For Plant Reproductive Material, work in 2015 will continue on updating the Common Catalogues of varieties of agricultural and vegetable species and the development and update of the secondary legislation. The proposal on the production and marketing of plant reproductive material has been withdrawn by the Commission in March 2015 following its earlier rejection by the European Parliament. It will be examined whether the existing legislative framework (12 Directives) should be included in a following REFIT exercise.

The Commission, the European Parliament and the Council succeeded to adopt in March 2015 the Directive giving the possibility to Member States to restrict or ban the cultivation of GMOs, authorised at EU level, on other grounds than risks for health or the environment. Discussion will also continue on the updating of the legal framework for the environmental risk assessment of GMOs.

As regards plant protection products, the work on implementing measures under the Regulation concerning the placing on the market of plant protection products will continue. In 2015 the Commission will continue the work on an impact assessment on the setting of scientific criteria for the identification of endocrine disruptors, as requires under the legislation on plant protection products as well as biocides. In the first stage of this assessment, substances falling under various regulatory options (and published in the relevant Roadmap) will be identified. Subsequently, in a second stage the socio-economic and environmental impacts of these options will be assessed.

A facility to co-ordinate the work of Member States in the area of minor uses of plant protection products with financial support from the Commission and initial involvement in the organisation will be established in 2015. A report will be submitted to the European Parliament and the Council on the national action plans submitted by Member in the context of the Directive 2009/128 on the sustainable use of pesticides.

<table>
<tr><td colspan="4">Relevant general objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs</td></tr>
<tr><td colspan="3">Specific objective 2.2: Contribute to timely detection of pests and their eradication, where they have entered the EU</td><td>☒ Spending programme
☒ Non-spending</td></tr>
<tr><td colspan="4">Result indicator 2.2.A: 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)
Definition and relevance: Survey programmes are an essential tool for early detection of pests enabling early actions for their control. Currently, Regulation (EU) No 652/2014 sets out an incentive for carrying out such programmes through the possible co-financing. Annual survey programmes will become compulsory only through the new Plant Health proposal.
External factors: MS financial and administrative capacity of introducing relevant survey programmes; adoption of the new PH Regulation by the EP and Council without any substantial changes to its provisions.
Source of data: Survey programmes submitted by MS</td></tr>
<tr><td>Baseline</td><td colspan="2">Milestones</td><td>Target</td></tr>
<tr><td>2012</td><td>2015</td><td>2017</td><td>2020 (agreed in Commission proposal COM(2013)327 final)</td></tr>
<tr><td>5%</td><td>50%</td><td>70%</td><td>100%</td></tr>
<tr><td colspan="4">Result indicator 2.2.B: 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)
Definition and relevance: Pests considered most dangerous are usually subject to EU measures, including the obligation of monitoring their presence and reporting monitoring results. It gives the possibility of following on a regular basis the evolution of these pests in EU.
External factors: Compliance of MS with EU measures
Source of data: Monitoring results for pests subject to EU measures.</td></tr>
<tr><td>Baseline</td><td colspan="2">Milestones</td><td>Target</td></tr>
<tr><td>2012</td><td>2015</td><td>2017</td><td>2020 (agreed in Commission proposal COM(2013)327 final)</td></tr>
<tr><td>100%</td><td>100%</td><td>100%</td><td>100%</td></tr>
</table>

Result indicator 2.2.C (KPI-4): Time between finding and notification for pests not known to occur in the Union (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme)
Definition and relevance: The reduction of time between finding of pests and its notification is influencing the timely adoption of eradication measures. The current legal framework is not clearly defining the obligation of notification in terms of days. The new PH proposal is introducing a 3 days period.
External factors: adoption of the new PH Regulation by the EP and Council without any substantial changes to its provisions; agreement of MS on the new deadline proposed for 2015 in the draft Commission implementing decision; successful implementation of the electronic system of outbreak notifications.
Source of data: Notification of outbreaks by MS (electronic system planned to be put in place)

Baseline	Milestones		Target
2012	2015	2017	2020 (agreed in Commission proposal COM(2013)327 final)
10 days	8 days	4 days	3 days

Result indicator 2.2.D: 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)
Definition and relevance: Successful eradication of notified outbreaks is ensuring the protection of crops, forests and green landscapes from extensive damages (economic and environmental)
External factors: administrative capacity of MS for putting in place the necessary measures and finance/co-finance them as needed.
Source of data: Electronic system of outbreaks notification

Baseline	Milestones	Target
2013	2017	2020 (agreed Commission proposal COM(2013)327 final)
0[10]	60%	95%

Main outputs in 2015

Description	Indicator	Target
Amendment of Council Directive 2000/29	1 amendment covering the necessary up-dates concerning the status of pests and associated requirements in the Annexes	Adoption
Amended Proposal on Regulation on plant reproductive material	Amended proposal prepared	Adoption
Draft ToRs for the Plant Reproductive Material EU Reference Centres	Draft ToRs prepared	Conclusion
Updates of the Common Catalogues of varieties of agricultural and vegetable species	12 updates and 2 consolidated versions	Carry out
Emergency measures for Plant Health as needed	100%	Adoption
Proposal for a Regulation of the EP and Council amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation of GMOs on their territory (beyond the control of the Commission)	Amendment	Adoption
Decision-making process applied to GMOs	Review	Carry out
Document clarifying whether products resulting from some new techniques of modification fall under the GMO legislation	Clarification document	Adoption
Act by the Commission modifying the annexes of Directive 2001/18/EC regarding environmental risk assessment of GMOs	Draft discussed with MS and stakeholders	Adoption

Planned evaluations

Evaluation of Regulation 1107/2009 concerning the placing on the market of plant protection products

Ex-post Evaluation on pesticides Maximum Residue Levels legislation (Regulation 396/2005) (2016)

[10] So far no official figures available up to the entry into force of the future EU Regulation on protective measures against pests of plants (COM(2013)267 final)

Animal health

DG SANTE will continue to work under the motto "Prevention is better than cure" in several legislative and non-legislative streams.

In recent years preventive approach has been stepped up and existing mechanisms strengthened. In addition an overarching legal framework is being established by way of a new Regulation on animal health. This will provide increased support to a competitive and sustainable European livestock sector and to a safe and smooth EU market of live animals and their products. After extensive work in 2014 in the EP and Council, negotiations will continue in 2015: the co-legislators may reach an agreement soon. Work on its implementation will immediately follow.

Other actions concern the continuing development of the future ADIS (Animal Disease Information System) system and update of the existing TRACES[11] which also takes into account of the need of other sectors, such as import of food of non-animal origin or plant health. Developments in applied scientific knowledge are also requested and followed to enable DG SANTE staff to help Member States and economic operators achieve a competitive and healthy livestock sector. These will continue in 2015. Communication is important part of our work and 4 high level conferences will provide the opportunity to discuss key issues for the benefit of a sustainable livestock sector.

In the animal health area, one important task is the constant preparedness for and prevention of emergencies due to disease outbreaks. This requires the continuous fine-tuning of numerous animal health rules and the management of many evolving situations. Such actions are too small and numerous to list in the Management Plan and often cannot be foreseen.

An example is the successful management of the African swine fever situation along the eastern EU borders which remains a clear priority in 2015. This previously exotic disease spread during 2014 from eastern neighbouring countries into and within Lithuania, Latvia, Estonia and Poland, both in wild boar and domestic pigs. Significant efforts are being devoted both on the part of the Commission and by those Member States to contain the situation and eradicate the disease. The recent increase of bluetongue cases will also merit close attention in 2015, especially as regards appropriate vaccination campaigns.

The EU financial contribution for animal diseases eradication, control and monitoring programmes aims to progressively eliminate animal diseases and/or implement disease monitoring measures in the Member States and the EU as a whole. It represents by far the largest amount of expenditure under the EU food safety budget[12].

The area of EU zootechnical rules is important for the smooth operation of the EU market of several species of breeding animals (including bovine, horses and pigs) and their germinal products. Its main elements are being aligned to the provisions of the Lisbon Treaty and streamlined into one modern basic set of rules, fully taking into account the principles of better regulation. The legislative procedure is underway in the Parliament and Council following two 2014 Commission proposals[13]: 2015 may see agreement of the co-legislators on this file.

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11 http://ec.europa.eu/food/animal/diseases/traces/about/index_en.htm

12 Over the period 2005-2011, more than 1,17 billion EUR were spent by the EU to co-finance the implementation of programmes for thirteen diseases

13 COM(2014) 4 final and COM(2014) 5 final, respectively

Animal welfare

The broad aim is to ensure that animals do not endure avoidable pain or suffering, to make sure that the owners/keepers of animals respect minimum welfare requirements and to ensure proper information and education of citizens and operators on animal welfare issues.

The Commission is holding an internal debate on the possible initiatives for animal welfare. It will also analyse the outcome of a study on the welfare of dogs and cats and of a study on information to consumers and education. A conference on the welfare of dogs will also be organised.

Furthermore, the Commission will continue the cooperation on animal welfare with the EU's trading partners in the appropriate international fora to build a common understanding on internationally recognised animal welfare standards. In this framework training initiatives will be also developed to improve the welfare in slaughterhouses especially in third countries.

DG SANTE will first concentrate its efforts in 2015 on ensuring that enforcement of the legislation on animal welfare is applied strictly and in time. In particular, we will launch an ambitious pilot project on guidelines on animal transport that will last three years. In addition, the Commission will continue to check the proper implementation of the grouping of sows and work on developing guidelines for the welfare of pigs – an area where non-compliance is often reported. Finally in 2015, the Commission, in cooperation with the Federation of Veterinarians, will continue the training programme for veterinary practitioners with two or three workshops on animal welfare.

<table>
<tr><td colspan="2">Relevant general objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs</td></tr>
<tr><td>Specific objective 2.3: To contribute to a higher animal health status in the Union and to support the improvement of the welfare of animals
External factors: The EU status of animal diseases can be jeopardised by the introduction of agents of animal disease through illegal imports of commodities from third countries. For animal welfare, incorrect implementation by operators and not sufficient controls by the competent authorities on the animal welfare rules can influence negatively the welfare of animals in the EU.</td><td>☒ Spending programme
☐ Non-spending</td></tr>
<tr><td colspan="2">Result indicator 2.3.A: the increase of the number of Member States or regions thereof which are free from Aujeszky disease or with an approved eradication programme
Definition and relevance: This indicator represents results of significant, planned, long-term eradication efforts by Member States, to achieve higher animal status (and hence reduced direct losses from this disease) and more competitiveness of their swine sector both on the internal EU market and for exports to third countries.
Source of data: Annual reports under Directive 64/432/EEC</td></tr>
<tr><td>Baseline[14] (2011)</td><td>Target 2015 (Commission internal target)</td></tr>
<tr><td>17 MS and 98 regions</td><td>Increase in the number of free regions</td></tr>
</table>

[14] Source: annual reports from the Member States under Directive 64/432/EEC

Result indicator 2.3.B: Disease parameters such as number of outbreaks and number of Member States or regions thereof which are free from animal diseases for which a financial contribution is granted
(Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme)
Definition and relevance: The indicators are fundamental to achieve the general and specific objectives as they indicate if the disease has been reduced or even no more present in the concerned animal population and region/Member States (free)
Source of data: annual reports from the Member States under Directives 64/432/EE, 91/68/EEC and (EU) Regulation No. 999/2001 and Animal Disease Notification System (ADNS)

Disease/ programme		**Baseline (2012)**	**Milestone 2015**	**Milestone 2017**	**Target 2020**
ERADICATION PROGRAMMES					
Bovine brucellosis		4 MS with co-financed programmes	4 [15] MS with co-financed programmes 1 MS free[16]	2 MS with co-financed programmes 2 additional MS free	1 MS with co-financed programmes 3 additional MS free
Bovine tuberculosis		5 MS with co-financed programmes	6 MS [3] with co-financed programmes 0 MS free	5 MS with co-financed programmes 1 MS free	2 MS with co-financed programmes 4 additional MS free
Ovine and caprine brucellosis (*Brucella melitensis*)		5 MS with co-financed programmes	4 MSs with co-financed programmes 2 MSs free	4 MS with co-financed programmes	1 MS with co-financed programme
Rabies		No of cases in wild animals			
		527 [17]	384 [18]	246	100
CONTROL AND ERADICATION PROGRAMMES					
Classical swine fever (domestic pig and wild boar)		3 outbreaks in 1 MSs in domestic pigs 17 cases in 1 MSs in wild boars	0 outbreak in domestic pigs	0 outbreak in domestic pigs	0 outbreak in domestic pigs
African swine fever (domestic pig and wild boar)		74 outbreaks in 1 MS in domestic pigs 17 cases in 1 MS in wild boars	Less than 25 outbreaks in domestic pigs in 5 MSs	Less than 10 outbreaks in domestic pigs in 4 MSs	Less than 10 outbreak in domestic pigs in 1 MS
TSE	Classical BSE	11 cases	Less than 5 cases	Less than 5 cases	Less than 3 cases
	Classical scrapie Free MSs	16 MSs	16 MSs	At least 19 MSs	At least 22 MSs
Bluetongue		23 MSs free	23 MSs free	24 MSs free	26 MSs free

[15] Croatia has joined the EU in July 2013
[16] See NB2 at the end of this table
[17] In MSs where a co-financed programme for the disease is implemented (12 MSs) - Bats not included (source EFSA/ECDC 2012 zoonoses report)
[18] -10% per year from 2012 to 2015

Main outputs in 2015		
Description	Indicator	Target
Framework Regulation on animal health[19]	Final rule by co-legislators	Adoption
Detailed rules under the Regulation[20]	implementing act on listing of diseases	Preparation
Conferences on key building blocks of EU animal health policy (on animal health and wild life, emerging diseases/One health, international trade standards, information technology)	Number of conferences	4
World Organisation for Animal Health	Representation of Commission	EU position for General Session of June 2015
Communication targeted to EU livestock sector	Number of participation at major EU agricultural fairs in Berlin, Paris	2
International cooperation with EuFMD	Participation at its General Session, new Agreement with EuFMD	Both completed
Supporting studies for delegated and implementing rules under the Regulation on animal health (aquaculture, on-farm biosecurity)	Number of studies started	2
New EP/Council rules on zootechnics[21]	final rules by co-legislators	Adoption
Welfare at slaughter	Report on restraining bovine by inversion FVO overview report on welfare at slaughter and possible BTSF on this Network meeting for welfare at slaughter	Adoption Produce report third semester 2015
Information to consumers on the stunning of animals	A study	Finalisation of the study
Education of veterinary practitioners on animal welfare	Number of foreseen workshops	2-3
Education of persons keeping or handling farmed animals	Series of audits on animal welfare training programmes (farm transport and slaughter in MSs).	Finalisation of audits
Welfare of dogs and cats	A study + conference	Finalisation of the study Organisation of conference
Protection of animals during transport	Pilot project on best practices	Launching the project
Bovine tuberculosis eradication	Number of foreseen programmes	7
Bovine brucellosis eradication	Number of foreseen programmes	5
Sheep and goats brucellosis eradication	Number of foreseen programmes	5
Blue tongue control and eradication	Number of foreseen programmes	18
Salmonella control	Number of foreseen programmes	22
Swine diseases (classical and African swine fever control and eradication	Number of foreseen programmes	16
TSE control and BSE/Scrapie eradication	Number of foreseen programmes	28
Rabies eradication	Number of foreseen programmes	13
Avian influenza survey	Number of foreseen programmes	28

Food and feed

DG SANTE will take action to maintain a high level of food and feed safety, to address consumer interest in food information and to boost innovation as a driver for smart growth.

[19] This is beyond the full control of the Commission
[20] Timing of these depend on the timing of the final Regulation
[21] This is beyond the full control of the Commission

As regards Food Information to Consumers, the Commission will carry out the follow up actions set out in Regulation (EU) No 1169/2011 such as the reports on the presence of trans fats in foods and on origin labelling of certain categories of food.

In the area of food contact materials, based on the roadmap on how to address the safe use of materials not harmonised at EU level, a baseline study to map the current situation as regards markets, barriers to trade and enforcement will be carried out to define the areas where action is needed.

Following the priorities set by the Commission on encouraging innovation, the definition of nanomaterials as set out in the Commission Recommendation of October 2011[22] will be adapted to the food sector to ensure effective implementation from the food safety and consumer information point of view and allowing innovation, taking into account the position of the EP.

The Regulation on Food for Specific Groups (FSG)[23] adopted by the Parliament and Council in June 2013 revises and simplifies the legislation covering foods for particular nutritional uses (dietetic foods). The Commission will continue the implementation work required by the Regulation in 2015, and in particular will finalise the delegated acts regarding the categories of foods covered by the scope of the Regulation, and will present to the European Parliament and to the Council two reports required by the Regulation – one on young-child formulae and one on food intended for sportspeople.

The Commission has reviewed within the first six months of its mandate the existing decision-making process applied to GMOs, in line with the President Juncker's Political Guidelines.

A document will be presented to Member States and stakeholders clarifying whether products resulting from some new techniques of modification fall under the GMO legislation to give a clearer picture of the legal framework.

The Commission published on 17 July the results of the study on voluntary GM free labelling. The Commission will look at reactions by Member States and stakeholders

A study to analyse data from stakeholders on the likely impacts of harmonisation/non-harmonisation of sampling and testing methods for pending/obsolete GMOs for food use is being carried out.

A proposal to reform of the legislation on the use of Medicated Feed was adopted by the Commission on 10 September 2014. The current Directive dates from 1990 and is widely seen as vague and outdated. The discussion with the Council has already started.

Amendments and implementing rules on the hygiene package will be considered based on new scientific advice and experience gained from its practical implementation. They may include provisions on food of non-animal origin and decontamination of food.

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22 OJ L 275/38, 20.10.2011, p38-40

23 Regulation (EU) No 609/2013 of the European Parliament and of the Council of 12 June 2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control and repealing Council Directive 92/52/EEC, Commission Directives 96/8/EC, 1999/21/EC, 2006/125/EC and 2006/141/EC, Directive 2009/39/EC of the European Parliament and of the Council and Commission Regulations (EC) No 41/2009 and (EC) No 953/2009, OJ L 181, 29.6.2013, p. 35–56

Amendments to annexes of the TSE Regulation and related acts will be introduced based on new scientific advice or developments as well as changes in international standards, focusing on the changes envisaged in the Commission TSE Roadmap 2 (Strategy Paper on TSEs for 2010-2015).

An amendment of Regulation (EC) 2160/2003 on zoonoses control isbeing considered, aiming at a proportional approach for Salmonella control for SMEs in order to allow direct marketing of poultry meat from small farms.

Relevant general objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs

Specific objective 2.4: Contribute to a high level of safety of food and food production systems and of other products which may affect the safety of food, while improving the sustainability of food production **External factors:** Safety of food can be jeopardised by the illegal imports of commodities from third countries.	☒ Spending programme ☐ Non-spending

Result indicator 2.4.A: The number of cases of diseases in humans in the EU linked to food safety or zoonoses (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme)
Definition and relevance: Maintaining effective control measures on Salmonella, based on sound scientific evidence, ensures the continued reduction in the incidence of it in animals and gives greater protection to the public.
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 2.4.B: Bring new additives to the market faster, within the established timelines, ensuring fast market access
Definition and relevance: New uses of food additives (i.e. new additives or extension of existing uses) need an authorisation. .Product authorisations within established timelines (9months for EFSA, 9 months for Commission, 4 months for procedural time) provides legal certainty and predictability, resulting in better planning and faster return on investment and,. It can therefore reduce the total cost of product development. Moreover, competitiveness is increased and companies use the latest research in their improved or new generation of products for consumers. New developments will impact positively the safety of the food chain.
Source of data: Commission food additives database

Baseline (2013)	Target (2015) (as foreseen by legislation)
27 months new additives (including risk assessment) 13 months for extension of use (no risk assessment)	22 months 13 months

Main outputs in 2015

Description	Indicator	Target
Preparation of proposal on food hygiene.	Commission Proposal to the EP and the Council	Adoption by the Commission and support discussions in the EP and Council
Preparation of proposal on feed hygiene.	Commission Proposal to the EP and the Council	Adoption by the Commission and support discussions in the EP and Council
Preparation of proposal on ionising radiation	Commission Proposal to the EP and the Council	Adoption by the Commission and support discussions in the EP and Council
Alignment of the TSE Regulation (EC) 999/2001	Commission Proposal to the EP and the Council	Adoption by the Commission and support discussions in the EP and Council
Medicated Feed Regulation	Council position (expected by the end of 2015)	Support the discussion
Authorisation of feed additives in the framework of Regulation (EC) No 1831/2003	Number of decisions on authorisations	35-40 legal acts (individual authorisations)
Improve legal framework for feed use of safe by-products from vegetable food and biofuel industries	Legislative proposal	Support the discussion and possible adoption of the act
Timely processing of applications by the Commission of new uses of food additives upon receipt of an application from EFSA opinion (when an opinion is needed)	Percentage of authorisations submitted in time to the regulatory committee	90%

Timely processing by the Commission of EFSA conclusion on active substances to be used as pesticides	Percentage of conclusions processed in time	90%
Decision-making process applied to GMOs Document on clarification whether products resulting from some new techniques of modification fall under the GMO legislation Publication of the study on voluntary GM free labelling Study on the likely impacts of harmonisation/non-harmonisation of sampling and testing methods for pending/obsolete GMOs for food use, to be followed by an impact assessment	Review Preparation of the document Study Study	Completion Finalisation Publication Publication

Relevant general objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs

Specific objective 2.5: Strengthen a basis for consumers to make informed choices to make safe use of food **External factors:** Lack of appropriate consumer education with a significant negative impact on consumer behaviour, leading ultimately to consumers taking decisions without being knowledgeable about their impacts. Additionally, purchasing power plays an important role in consumer food choices.	☐ Spending programme ☒ Non-spending

Result indicator 2.5.A: Change in consumer behaviour through increased health awareness reflected in their purchasing habits and consumption of food

Definition and relevance: The change in consumer behaviour towards healthier choices demonstrates that they have or can easily access the information that allows them to take informed decisions and to understand how their food choices impact their lives.

Source of data for baseline: Flabel EU funded project (2008-2012)

Baseline (2012)	Milestone (2017)	Target (2020)
25 - 100 milliseconds (average attention to nutrition labels)	positive trend	positive trend

Main outputs in 2015

Description	Indicator	Target
Reporting on origin indication of: -meat other than beef, pig, poultry, sheep/goat -milk -milk used as ingredient in dairy products -unprocessed food -single ingredient products -ingredients representing more than 50% of a food	Report foreseen in Regulation (EU) 1169/2011 on the provision of Food Information to consumers – Art. 26 (5)	Adoption –follow-up discussions with EP/Council
Reporting on Trans fatty acids	Report foreseen in Regulation (EU) 1169/2011 on the provision of Food Information to consumers – Art. 30 (7)	Adoption – follow-up discussions with EP/Council
Report in alcoholic beverages	Report foreseen in Regulation (EU) 1169/2011 - Art. 16(4)	Adoption – Follow-up discussions with EP/Council
Providing guidance on the presence of certain contaminants	Guidelines document as foreseen in Directive 2009/54/EC on the exploitation and marketing of natural mineral waters	Preparation
Authorisation and refusal of authorisation of health claims following authorisation procedures as foreseen by Regulation (EC) No 1924/2006.	Commission Decisions to be adopted in 2015	4-6
Exemption of generic descriptors (denominations) from the scope of Regulation (EC) No 1924/2006.	Commission Decisions to be adopted by 2015	1-2
Infant formula and follow-on formula, cereal based foods and other baby foods, foods for special medical purposes, total diet replacement for weight control	delegated acts foreseen by Regulation (EU) No 609/2013	Preparation and completion of eventual adoption
Milk-based drinks and similar products for young children and food for sportspeople	Reports required by Regulation (EU) No 609/2013	Presentation

Crisis management

The General Food Law (Regulation 178/2002) establishes the overall framework for crisis management as regards food and feed, establishing the Rapid Alert System for Food and Food (RASFF) allowing for emergency (so-called "safeguard") measures and establishing the general crisis management plan. It allows the Commission to set up a crisis unit to coordinate response to outbreaks of food-borne pathogens and contamination incidents which seriously undermine the high EU level of consumer safety. The results of the fitness check of the General Food Law and on the functioning of the RASFF and crisis procedures will be delivered during 2015 and the necessary follow-up will be ensured.

Crisis management in the field of animal health is mainly based on Directives 89/662 and 90/425, which aim to ensure a high level of health within the single market in animals and food of animal origin. Highly contagious diseases of major concern, such as foot-and-mouth disease, classical and African swine fever and highly pathogenic avian influenza may cause direct losses in the affected holdings, undermine the overall basis for the smooth functioning of agricultural production and lead to serious disruptions of trade.

Directive 2000/29 establishes for plant health a parallel mechanism as described above for food/ feed and animal health, which allows for safeguard measures to be taken if necessary. The rules protect the EU against the introduction and the possible spread of plant pests (pinewood nematode, xylella on live trees, citrus black spot, citrus Tristeza virus, etc.), which may originate in third countries or which may have been introduced into the EU territory. The EUROPHYT system identifies plant health risk on imported products. Coupled with development of MS reporting on Harmful organism outbreaks this enables us to monitor and if necessary enforce MS control of plant health pests.

The competent authorities of Member States are primarily responsible for control measures on their territory. Member States can obtain EU financial support for costs of control measures they have taken, also as an incentive to ensure an early notification of a suspicion of an outbreak.

Relevant general objective 3: Respond rapidly and efficiently to any outbreak potentially endangering the health and safety of citizens, animals, or plants in Europe, through adequate reaction capacities, appropriate preparedness and efficacious tools for quick alert and exchange of information.		
Specific objective 3.2: Develop the ability to react swiftly to and isolate/circumvent any outbreak of a given disease with appropriate budget support **External factors:** The degree of preparedness and the ability to identify rapidly a hazard are crucial and heavily rely on the structure and capacity in place in Member States and third countries		☐ Spending programme ☒ Non-spending
Result indicator 3.2.A: 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 Newcastle-disease) **Definition and relevance:** The indicator shows a synthetic number[24] composed according to a matrix and is indicative of how containment of those diseases functioned during the year. This indicator is related to the effectiveness of the Member States with the coordination and technical and financial assistance of the Commission to halt the spread of these major diseases once they occur. While occasional outbreaks are almost inevitable, their swift containment is key priority of the veterinary services of the Member States and the EU. **Source of data:** Commission internal from several sources: Animal Disease Notification System (ADNS), safeguard decisions, other information by the Member States		
Baseline (2014)	Milestone (2018)	Target (2020)
New indicator (baseline to be established at the end of 2014)	Decreasing trend	Decreasing trend
Specific objective 3.3: Provide fast and user-friendly information on food and feed and public health alerts through RASFF notifications External factors: Reliance on Member States Contact Points to inform and transmit information on potential risks		☒ Spending programme ☐ Non-spending
Result indicator 3.3.A: Follow-up given by the Competent Authorities in the Member States on RASFF Alert notifications within 24 hours of receipt **Definition and relevance:** Alert notifications are sent when food, feed or food contact materials presenting a serious risk are on the market and rapid action is required in other countries than the notifying country. Source of data: RASFF		
Baseline (2012)	Milestone (2018)	Target (2020)
100%	100%	100%
Main outputs in 2015		
Description	Indicator	Target
Timely reaction to an alert	Measures (including safeguard measures adopted on time)	100% timely adoption but only if necessary
Management of RASFF	All notifications dealt with	100%
Safeguard cell	Organisation of meetings	100% when shortcomings with severe effects on human health are identified (eg by FVO)
BTSF Training	Cross-sectoral training on Foodborne outbreak investigations	100% implementation of courses planned

Better regulation

Regulatory fitness and simplification

On the basis of the overview achieved with the mapping of the *acquis* (Commission Staff Working document: 'Regulatory Fitness and Performance Programme (REFIT): Initial Results of the Mapping of the Acquis', COM(2013)401) and with the Fitness Check for the Food Chain (SWD(2013) 516 final), we will pursue our efforts, in particular by performing a fitness check of the General Food Law (Regulation (EC) No 178/2002). Two external studies, one on the definitions, general principles and requirements of the EU food law, and one on the functioning of the Rapid Alert System for Food and Feed and the procedures for emergencies/crisis will support this fitness exercise. The first

[24] A number between 25 (successful containment, no disease spread, theoretical maximum: optimum scenario) and 5 (all 5 diseases spread vastly across EU borders affecting large areas: an absolute low).

exercise is a meta-evaluation aiming to assess several areas including nutrition and health claims made on foods on EU food law (Regulation 1924/2006) in order to allow the Commission to decide on changes needed in the field of food legislation. This fitness check will also include an evaluation of the RASFF and crisis management. It aims to assess the effectiveness and efficiency of the RASFF, its relevance in delivering EU added value, its coherence with wider EU policy priorities and the procedures and tools that were created in order to better prevent and manage emergencies and crisis, as well as to focus on simplification and the reduction of regulatory costs and burdens. The final report will be ready after summer 2015.

As part of a possible review of the Directive[25] on food and food ingredients treated with ionising radiation, an evaluation will be carried out. . The aim is to harmonise the list of foods authorised for ionising treatment based on published EFSA advice and to simply the annual reporting by Member States on checks carried out in facilities and at retail level.

In line with the 5-year Action Plan on Antimicrobial Resistance (AMR), SANTE plans to implement the legislative framework for the harmonised monitoring of AMR in food and animals and has launched the tender for an evaluation report, to be published in 2016, on the impact and effectiveness of the measures taken and the goals achieved by the Action Plan.

The reception of the requests and subsequent re-evaluation of all feed additives is the major task and will last for at least 4 years. Innovation in the area of feed additives can support the replacement of the use of antibiotics in livestock farming and improve the resource efficiency.

Implementation

The improvement and simplification of the regulatory framework for the use of safe and valuable feed materials should decrease the carbon footprint of animal production.

Implementation of the legislation and managing the authorisation for food additives, enzymes, flavourings, food contact materials, GMOs and the future new Regulation on novel food[26]. The legislation will be managed to facilitate harmonised implementation, both for routine and emerging issues. This permanent and systematic work contributes usefully to a good functioning of the Internal Market by authorising the products requested by industry in an effective manner while ensuring a high level of safety throughout the Union.

Continuing with the implementation of the Regulation on nutrition and health claims, in particular, we will continue the work on individual applications and advance work on the list of permitted 'function' health claims which was first adopted in May 2012 and started to apply from 14 December 2012.

Relevant general objective 4: Maintaining a high level of health and safety on the EU territory while allowing competitiveness of the economic sectors under SANTE policies through proportionate, fit for purpose legislation	
Specific objective 4.1 Provide a proportionate legal framework that aims at achieving a high level of food safety while maintaining the competitiveness of the second	☐ Spending programme ☒ Non-spending

[25] Directive 1999/2 of the European Parliament and of the Council of 22 February 1999 on the approximation of the laws of the Member States concerning foods and food ingredients treated with ionising radiation (OJ L 66, 13.3.1999, p. 16)

[26] Proposal for a Regulation of the European Parliament and of the Council on novel foods.

employer of Europe, the food sector **External factors:** The proposals made by the Commission are ultimately amended and adopted by the Council of Ministers and the European Parliament and the Commission cannot stay fully in control of the measures taken	

Result indicator 4.1.A: Food safety legislation is not identified by SMEs among the Top 10 most burdensome legislation

Definition and relevance: Safety rules can be perceived as burdensome, but are on the contrary a way to promote the competitiveness of the food industry through the recognition worldwide of the European standards, which can compensate for disadvantages such as labour costs and make EU products competitive on the international market.

Source of data: TOP10 list of most burdensome EU legislative acts for SMEs

Baseline (2013)	Milestone (2017)	Target (2020)
Food safety legislation is not included in the TOP10 most burdensome EU legislative acts for SMEs	Food safety legislation is not included in the TOP10 most burdensome EU legislative acts for SMEs	Food safety legislation is not included in the TOP10 most burdensome EU legislative acts for SMEs

Main outputs in 2015

Description	Indicator	Target
Revision of Regulation (EC) No 852/2004 on the hygiene of foodstuffs and Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin	Revised proposal	Adoption by the Commission
Proposal for a Regulation of the European Parliament and of the Council on Animal Health	Legislative proposal	Adoption by co-legislators
Proposal on the production and making available on the market of plant reproductive material (plant reproductive material law)	Proposal consolidating 12 Directives	Adoption by co-legislators
Proposal for a Regulation on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products	Legislative proposal	Adoption by co-legislators
Proposal for a Regulation of the EP and of the Council on protective measures against pests of plants.	Legislative proposal	Adoption by co-legislators
Codification of 11 Union acts regulating zootechnics in the EU amending Directives 89/608/EEC, 90/425/EEC and 91/496/EEC as regards references to zootechnical legislation	Codification of 11 acts	Adoption by co-legislators

Planned evaluations

Two external evaluations have been commissioned to support the Fitness check of the General Food Law:
Evaluation on the definitions, general principles and requirements of the EU Food Law
Evaluation on the functioning of the RASSF and management of emergencies/crisis

International relations

Work in the field of international relations will continue to ensure the proper representation of EU views and interests in international fora. The EU's role in multilateral organisations will be maintained, in particular in terms of its obligations arising under the World Trade Organisation. In the spirit of transparency, information will be provided to trading partners of EU measures that are likely to affect trade. Simultaneously, the EU will actively participate in a number of multilateral standard-setting bodies to mould the international norms that will affect the trade in EU products. These include: the Codex Alimentarius, Commission (CAC), the World Organisation for Animal Health (OIE) and the International Plant Protection Convention (IPPC). EU interests will also be safeguarded and promoted in fora such as the International Union for the Protection of New Varieties of Plants (UPOV), the Cartagena Protocol on Biosafety, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), and the OECD. Furthermore, the management of the EU's bilateral agreements in the field will be pursued.

Actions at bilateral level will be twofold: on the one hand, the EU will continue to negotiate international agreements with key trade partners (such as the USA and Japan) and to manage the agreements already concluded and, on the other hand, will maintain

dialogues, structured or unstructured, with the other most important trade partners. EU high food safety standards will be promoted and new market opportunities for EU exports will be sought.

Multilateral rule-making and governance cooperation

As part of its global health policy the Commission collaborates with the World Health Organisation (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 WHO and the OECD.

We will keep up our efforts to properly represent EU interests in the World Trade Organisation (particularly under the Agreement of Sanitary and Phytosanitary measures) and in the international standard-setting bodies (Codex Alimentarius Commission, World Organisation for Animal Health (OIE) and International Plant Protection Convention). We will continue our efforts to ensure that all the obligations derived from our membership of the WTO are fulfilled, including defending our interest when trade disputes arise.

Bilateral relations: bilateral agreements in all our policy areas are implemented in such a way as to foster effective co-operation and a smooth trade in safe products.

Brazil: The EU has a large institutional cooperation with Brazil based on the EC-Brazil Consultation Mechanism on SPS issues. This implies annual meetings of the EU-Brazil Joint Committee (Comista) and frequent meetings with the Brazilian authorities to discuss specific SPS problems. Furthermore, since the Administrative Memorandum of Understanding on technical cooperation in the area of animal welfare was signed between the EU and Brazil in 2013, a process for dialogue, collaboration and increased relations with Brazil has been established. Future actions under this framework will take place during 2015 in order to enhance animal welfare and the competitiveness of the EU's farming production systems.

Canada: In October 2013, the EU and Canada reached a political agreement on the key elements of a Comprehensive Economic and Trade Agreement. It will be the first free trade agreement between the EU and a G8 country. The EU/Canada Veterinary Agreement has been incorporated into the EU Canada CETA.

China: The partnership between the EU and China in food safety and sanitary and phytosanitary (SPS) measures was formalised in 2006 with a Memorandum of Understanding (MoU) between the DG Health and Consumers and the General Administration of Quality Supervision, Inspection and Quarantine of People's Republic Of China (AQSIQ). Despite difficulties in gaining access to the Chinese market, the joint efforts of the Commission, EU national authorities and industry operators now means China is one of the EU's biggest partners in terms of EU agricultural and fishery exports. We will continue to implement a pilot project with AQSIQ to facilitate EU exports to China, by pursuing harmonised and science-based import requirements, eliminating the clause "born and bred" (in a single EU country), the application of systems audit and pre-listing of establishments producing goods of animal origin.

Russia: The Russian Federation is the EU's primary trade partner in agricultural products and pharmaceuticals. Over the past decade Russia has increasingly used sanitary and phytosanitary measures as a pretext to unduly restrict trade from the EU. Following the conclusion of the negotiations of its accession to the WTO, in August 2012, the situation

significantly worsened through unjustified blanket bans against the whole EU for various products (potatoes since July 2013, pork since January 2014 etc.). Following an unjustified EU-wide ban on pork and other commodities imposed by Russia due to a few cases of African swine fever in certain EU MS bordering Russia, the EU opened a dispute settlement case against Russia in the WTO in April 2014. This is ongoing. In August 2014 Russia introduced a ban for one year on many agricultural products from the EU and other countries in response to the western sanctions in relation to the developments in Ukraine. The value of exports affected by the ban is approximately 5 billion EUR yearly. We will continue to provide our technical support to the overall political discussion concerning EU relations with Russia.

United States: The talks on the Transatlantic Trade and Investment Partnership with the US were launched in summer 2013 with the aim of removing trade barriers in a wide range of economic sectors to make it easier to buy and sell goods and services between the EU and the US. The negotiations cover sanitary and phytosanitary issues, intellectual protection and pharmaceuticals among other issues. The Commission intends to incorporate the relevant elements of the EU/US Veterinary Agreement concluded in 1998 into the TTIP.

Free Trade Agreements (FTA)

In addition, there are several on-going FTA negotiations, including a sanitary and phytosanitary (SPS) chapter, with countries outside of the EU, notably Japan, Malaysia, Vietnam, Thailand (Association of Southeast Asian Nations – ASEAN countries), India, the Mercosur group and Morocco. From 2015, progress is also expected in relation to the Free Trade Agreements already finalised between the EU and countries in the Eastern Neighbourhood (Moldova, Ukraine and Georgia), and Singapore. All these Agreements include a comprehensive SPS Chapter.

We will continue to ensure the proper implementation of the existing agreements with an SPS component notably with South Korea, Mexico, Chile, Switzerland, the Veterinary Agreement with New Zealand and the European Economic Area Agreement (EEA). In 2015, we will work to ensure the implementation of Agreements recently entered into force and having an important SPS component namely the Central America (Costa Rica, El Salvador, Honduras, Nicaragua and Panama), Colombia and Peru Agreements.

Association Agreements

During 2015, we will continue to ensure the implementation of the association agreements with countries currently candidates to EU accession (Iceland, Turkey, Serbia, Montenegro, the former Yugoslav Republic of Macedonia, Albania) and with potential candidates (Bosnia and Herzegovina, Kosovo[27]).

Training and technical co-operation

We will continue to step up our work on the provision of technical assistance to developing countries, through training seminars on EU food safety standards and rules organised through the initiative "Better Training for Safer Food" (BTSF).

[27] This designation is without prejudice to positions on status, and is in line with UNSCR 1244/1999 and the ICJ Opinion on the Kosovo declaration of independence.

Contributions to the preparation of candidate countries for EU accession (e.g. via TAIEX) and to regional initiatives and processes (such as the European Neighbourhood Policy) will continue.

SANTE also financially supports capacity building activities of the OIE and actively contributes to the work of the Mediterranean Animal Health Network (REMESA) and the FAO/OIE Global Framework for the progressive control of Transboundary Animal Diseases (GF-TADs).

Training on the RAPEX system is also an established part of our capacity enhancing efforts and demand is still growing.

<table>
<tr><td colspan="4">Relevant general objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs</td></tr>
<tr><td colspan="3">Specific objective 2.6: Promote EU standards at the international and multilateral levels and to assist safe, predictable and uninterrupted trade between the EU and third countries and to avoid SPS measures being used as unjustified barriers to trade
External factors: The achievement of the objective relies on negotiations which are held with up to 185 countries at any one time. Therefore we are dependent on these countries' approach to discussions.</td><td>☐ Spending programme
☒ Non-spending</td></tr>
<tr><td colspan="4">Result indicator 2.6.A: Increase of the number of actions having export facilitating effect in the Sanitary and Phytosanitary area
Definition and relevance: Actions on which we have a documented role (be it a lifting of a trade barrier or the conclusion of a harmonised export certificate) with an export (and therefore growth and jobs creating) effect.
Source of data: Commission internal</td></tr>
<tr><td>Baseline (2014)</td><td>Milestone (2017)</td><td colspan="2">Target (2020)</td></tr>
<tr><td>5</td><td>20
(+5/year)</td><td colspan="2">35
(+5/year)</td></tr>
<tr><td colspan="4">Main outputs in 2015</td></tr>
<tr><td>Description</td><td colspan="2">Indicator</td><td>Target</td></tr>
<tr><td>Opening of new markets in third countries for UE products of animal/plant origin</td><td colspan="2">Number of countries lifting protectionists measures against EU products</td><td>30</td></tr>
<tr><td>Active participation at all Codex Committees – international standards adopted in line with EU legislation</td><td colspan="2">Meetings in 2015</td><td>18 (100%)</td></tr>
<tr><td>Regular attendance at WTO SPS Committee – rebuttal of attacks on EU measures, attack of third country measures hindering market access for EU business</td><td colspan="2">Meetings in 2015</td><td>3 (100%)</td></tr>
<tr><td>Actions with trade (export) facilitating effect in the Sanitary and Phytosanitary area</td><td colspan="2">Market access authorisations/harmonised EU export health certificates</td><td>5 (100%)</td></tr>
</table>

5. HORIZONTAL ACTIVITIES

5.1. Policy Strategy and Coordination for DG Health and Food Safety

<table>
<tr><th colspan="6">ABB activity: Policy strategy and coordination</th></tr>
<tr><th colspan="4">Financial resources
(€) in commitment appropriations</th><th colspan="2">Human resources</th></tr>
<tr><td>Operational expenditure</td><td colspan="2">Administrative expenditure</td><td>Total</td><td>Establishment plan posts</td><td>Estimates of external personnel (in FTEs)</td><td>Total</td></tr>
<tr><td rowspan="3">0</td><td>Heading 5 appropriations</td><td>Other budget lines</td><td rowspan="3">86.000</td><td rowspan="3">41</td><td rowspan="3">10</td><td rowspan="3">51</td></tr>
<tr><td>86.000</td><td>0</td></tr>
<tr><td colspan="2">86.000</td></tr>
</table>

The "Policy Strategy and Coordination for DG Health and Food Safety" Activity includes all actions that support, guide or co-ordinate the policies for which DG Health and Food Safety is responsible. The actions under this activity contribute directly to the success of our policies.

This Activity supports and drives the policy definition, preparation and implementation in order to achieve the overall mission of the DG within the timescales laid down. It promotes a strategic planning culture within the DG in accordance with the Commission's strategic planning and programming cycle. It actively promotes the policies of the DG through information, internal and external communication, and awareness-raising with stakeholders. It supports the coherence of the different activities within the DG, ensuring liaison with central Commission services, the Cabinet of the Commissioner and with other Institutions. It provides legal advice so that DG Health and Food Safety policies are legally sound and comply with the relevant procedures. It aims to develop an administrative culture of independence, objectivity and fairness founded on principles of proportionality and better regulation.

This Activity includes the following functions:
– Policy strategy definition and coordination, better regulation including impact assessment;
– Strategic planning and programming;
– Internal and external communication;
– Coordination of institutional affairs;
– Management of legal issues and coordination of legal processes.

Policy strategy definition and coordination, better regulation including impact assessment

The better regulation practices of the DG will be further improved through the provision of enhanced assistance to policy sectors in the preparation of internal information documents ensuring effective management and delivery of new initiatives (Roadmaps) for a better strategic vision of policy making, and of help to produce quality Impact Assessments (IA).

Further to the Regulatory Fitness Commission Communication of 16 June 2014, the DG will initiate work to respect the relevant Commission commitments, notably through rationalisation of reporting obligations. DG Health and Food Safety will continue its work on further coordination and coherence in the supervision of the four Regulatory

Agencies for which it is the Commission's main interlocutor[28]. This will involve exploring new governance tools with the Agencies, e.g. codes of conduct, improved performance indicators, harmonised conflict of interest policy as well as developing SANTE positions in the Secretariat General led overall dialogue between the Commission and EU Agencies.

Specific objective: Support the decision making process through impact assessments to ensure the mission of DG Health and Food Safety is fulfilled	
Result indicator: Percentage of impact assessments resubmitted to the Impact Assessment Board (IAB) (European Commission – Secretariat General)	
Baseline	Target
60% (2014)	57% (Commission average)
Result indicator: Percentage of stakeholder consultations that respect the 12 week minimum consultation standard (European Commission – DG Health and Food Safety)	
Baseline	Target
100% (2014)	100% (in accordance with Commission rules on stakeholder consultations and the SANTE Guide for Stakeholder Consultations)

Science based policy making

Four decentralised agencies, one executive agency and three scientific committees participate and support the Commission in achieving its objectives linked to public health and safety of the food chain:

– the Community Plant Variety Office (CVPO) grants intellectual protection for new plant varieties throughout the EU,
– the European Centre for Prevention and Disease Control (ECDC), works to prevent disease outbreaks and to react quickly and effectively to minimise their impact,
– the European Food Safety Authority (EFSA), provides independent scientific advice and support on food and feed safety, nutrition, animal health, animal welfare and plant health,
– the European Medicines Agency (EMA), evaluates and supervises medicines for human and veterinary use;

The Consumer, Health and Food Executive Agency (CHAFEA) implements the EU Health Programme, the Consumer Programme and the Better Training for Safer Food (BTSF) initiative.

Apart from the recurrent evaluations that are to be carried out to assess the agencies' performance, an evaluation of Regulation 297/95/EC on fees payable to EMA is also planned in order to verify the costing model for technical assistance to Member States.

The European Commission's Scientific Committees: the Scientific Committee on Health and Environmental Risks (SCHER), and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR), provide independent scientific advice.

The functioning of these scientific committees is to be evaluated in order to assess the value of their advice in the Commission decision-making process. This evaluation will also guide the services for the renewal of the mandate of the Scientific Committees in 2016 in support of the update of the Commission Decision.

[28] The European Centre for Disease Control "ECDC"; the Community Plant Variety Office "CVPO"; the European Food Safety Authority "EFSA"; and the European Medicines Agency", "EMA".

Sound scientific knowledge is the basis for our risk management decisions. Risk assessment is a challenge shared by these decentralised agencies [except CPVO] and the three Scientific Committees. We have revised our procedures to enhance coordination and coherence on governance regarding the decentralised agencies. Follow-up of the joint statement issued by the three EU institutions is included in the overall coordination.

The role of scientific evidence in the decision making process for public health is becoming increasingly important on all levels of decision-making. Evidence-based public health means integrating the best available evidence with the knowledge and considered judgements from stakeholders and experts to benefit the needs of a population. This work is done through the Commission Scientific Committees, the European Medicines Agency, the European Food Safety Authority, and the European Centre for Disease Control and Prevention.

Strategic Planning and Programming

This ensures the implementation of the Commission planning and programming process using the planning tool to support daily management, and providing a better overview and coherence from the Commission-wide Work Programme to Unit specific implementation.

Specific objective: Implement the Commission's planning and programming process so that the Directorate General delivers its policy objectives and contributes to the overall Commission strategy in an effective, timed, efficient and coherent manner	
Output indicator: Percentage of contributions linked to the planning cycle delivered on time (European Commission – DG Health and Food Safety)	
Baseline	Target (agreed internally)
CWP 2014 (100%) MP 2014 (100%) AAR 2012 (100%)	CWP 2015 (100%) CWP 2016 (100%) MP 2016 (100%) AAR 2014 (100%)

Internal communication

This action encompasses the contribution to an effective Internal Communication within the Directorate-General across the three sites as a key element for efficient external communication.

Specific objective: Develop, implement, monitor and adapt internal communication in the DG and establish direct communication, consultation and feedback channels between management and staff to ensure staff understand and share the vision and objectives of their department and work effectively together.	
Output indicator: Number of "knowledge hours" (source: European Commission – DG Health and Food Safety)	
Baseline	Target 2015
20 (2014)	20
Result indicator: migration and rationalisation of the intranet to satisfy user needs and expectations (source: European Commission – DG Health and Food Safety online survey 2014)	
Baseline	Target 2015
60% (2014)	80%
Result indicator: Staff satisfaction on management communication (Source: European Commission: staff survey 2014)	
Baseline	Target 2015
60%	65% of staff judging as good or above that DG Health and Food Safety's' mission and policies are clearly communicated

External communication

Communication priorities for 2015 have been defined in line with political guidelines and resulting policy priorities for DG SANTE. On each of those, communication plans will be developed and implemented, in close coordination with policy units, using the most appropriate tools and channels (media relations, web, audio-visual materials, events, publications, social media, etc.) to reach our agreed communication objectives.

Regarding the communication infrastructure, the web rationalisation process and migration to Documentum initiated in 2013 will be finalised and shift towards digital transformation. This new corporate process will see our content optimised according the user test data and gradually integrated within a common Commission structure. Media relations will be coordinated in close liaison with the Commissioners' Spokespersons' office.

All strategic communications will be designed and carried out in agreement with the communication adviser in the Cabinet

<table>
<tr><td colspan="3">Specific objective: Develop, implement, monitor and adapt an external communication strategy to actively promote the main policies and initiatives of the DG in a clear and visible manner</td></tr>
<tr><td colspan="3">Output indicator: Percentage of integrated communication actions based on a communication plan developed jointly by the policy and communication units (source: DG Health and Food Safety)</td></tr>
<tr><td>Baseline</td><td colspan="2">Target</td></tr>
<tr><td>90% (2014)</td><td colspan="2">90% (2015) - Maintain</td></tr>
<tr><td colspan="3">Result indicator: Number of hits on the DG Health and Food Safety website (source: DG Health and Food Safety)</td></tr>
<tr><td colspan="2">Baseline</td><td>Target 2015</td></tr>
<tr><td colspan="2">Public health: 4 376 691 (2014)
Food safety: 2 225 670 (2014)
DG Health and Food Safety homepage: 393 876 (2014)</td><td>Maintain or slightly increase current levels (due to ongoing web rationalisation including revamp of several sections we intend to attract more users to our pages under Food Safety)</td></tr>
<tr><td colspan="3">Output indicator: Media requests handled within 24 hours (source: DG Health and Food Safetys)</td></tr>
<tr><td colspan="2">Baseline</td><td>Target 2014</td></tr>
<tr><td colspan="2">83.7% (2014))</td><td>85%</td></tr>
<tr><td colspan="3">Result indicator: Further development of social media outreach – Twitter (source: DG Health and Food Safetys)</td></tr>
<tr><td colspan="2">Baseline</td><td>Target 2015</td></tr>
<tr><td colspan="2">EU_health account: 11 267 followers (2014)</td><td>Increase</td></tr>
</table>

Institutional Affairs

This encompasses the co-ordination of the relations of the DG with the European Parliament, the Council, the Economic and Social Committee and the Committee of the Regions, including notably preparation of European Parliament and Council sessions/meetings, ensuring reports/follow-up, handling of questions from Members of the Parliament, petitions, Ombudsman's complaints, and preparing and overseeing the preparation of speeches and briefings for the managerial and political hierarchy on institutional matters.

2015 will be the first year of the new Commission, with a recently elected European Parliament. We will work to develop good relationships with the new Parliament and with the Council formations relevant to the portfolios to promote the new College's priorities of the Health and Food Safety policy portfolios, and seek the timely and successful completion of our initiatives.

Specific objective: Establish and maintain dialogue and cooperation channels with other EU institutions so that legislative and non-legislative proposals put forward by the DG make smooth and efficient progress through the institutions.	
Output indicator: Percentage of Parliamentary questions replied to within the deadline (European Commission – DG Health and Food Safety)	
Baseline 2013 (17/12/2013)	Yearly target
80.10% (Of a total of 1330 PQs on 17/12/2013)	100% (The Commission should respect its institutional commitments and respond in time to Parliamentary questions)
Output indicator: Number of preparatory meetings organised with forthcoming and current Council Presidencies (European Commission – DG Health and Food Safety)	
Baseline	Target
19 (2013)	At least 6 per year (one per policy area and per Presidency)

Legal Affairs

This encompasses both the coordination of legal affairs, to ensure the provision of coherent legal advice in close collaboration with operational units and the Legal Service, and to support the Management Team and the Cabinet in the management of legal issues. DG SANTE will process complaints and infringements, as well as contribute to improving legislation, on the basis of the principles of proportionality and better regulation. This work includes also ensuring that each action is based on a sustainable legal basis and that good administrative practices and general principles of law are followed.

This action includes the following functions:
– drafting legislation;
– processing complaints and infringements as part of the Commission's role as guardian of the Treaties; and
– legal advice on the relevant issues in the management and control of the DG.

Drafting Legislation – support to policy units in applying uniform principles of presentation and legislative drafting, so that legal acts are intelligible, well-thought-out and coherent.

Complaints and infringements – processing DG's complaints and infringements according to established benchmarks.

Legal advice - in particular issues of interpretation of the DG's legislation.

Specific objective: to provide legal advice in close collaboration with the Commission's Legal Service as well as to contribute to the development of sound, clear, simple and effective new legislation.	
Result indicator: Percentage of set deadlines met for requests to provide legal advice or review (European Commission – DG Health and Food Safety)	
Baseline	Target: The new Rules of Procedure and the Implementing Rules - C(2010)1200 – Article 23
100% response on time (October 2014)	Response rate of 100% for all Commission Work Programme items by set deadline. 80% of written requests for legal assessment or review of proposals with set deadlines responded on time.
Specific objective: to effectively process complaints and infringements on the basis of good administrative practice and prioritisation**.**	
Output indicator: Percentage of complaints/infringements processed in DG Health and Food Safety that meet Commission benchmarks (when there are no grounds to justify slower processing) (European Commission – DG Health and Food Safety)	

Baseline October 2013	Milestone	Target Benchmarks established by Commission Communication on "A Europe of results – applying community law" - COM(2007) 502 final; see also COM(2010) 70 final and COM(2012) 154 final)
100% compliance to established benchmarks for processing complaints or infringements, except justified slower processing cases.	Bi-annual coherence exercise of the European Commission in 2015.	At least two-thirds of SANTE caseload to meet established benchmarks during coherence exercises 2014-2015.

5.2. Administrative support for DG Health and Food Safety

<table>
<tr><th colspan="6">ABB activity: Administrative support</th></tr>
<tr><th colspan="4">Financial resources
(€) in commitment appropriations</th><th colspan="2">Human resources</th></tr>
<tr><th>Operational expenditure</th><th colspan="2">Administrative expenditure[29]</th><th>Total</th><th>Establishment plan posts</th><th>Estimates of external personnel (in FTEs)</th><th>Total</th></tr>
<tr><td rowspan="3">0</td><td>Heading 5 appropriations</td><td>Other budget lines</td><td rowspan="3">389.196</td><td rowspan="3">71</td><td rowspan="3">21</td><td rowspan="3">92</td></tr>
<tr><td>389.186</td><td>0</td></tr>
<tr><td colspan="2">389.196</td></tr>
</table>

This Activity includes actions that are necessary for the functioning of the organisation as such and are indirectly linked to the policies for which the DG is responsible.

This Activity promotes and maintains sound and efficient management of human, financial and IT resources within the DG, and ensures that resources are allocated to achieve the policy objectives of the DG. It ensures the soundness of internal control established in the DG's operational management and its financial accounting and reporting systems, and provides internal audit advice within the DG.

The Activity includes the following functions:
– Human resource management;
– Financial management;
– Management of information and communication technologies (ICT);
– Document management;
– Internal audit;
– Internal control and risk management.

Human Resource Management

The DG seeks to attract, deploy, develop and retain sufficiently qualified and experienced staff. The Commission's Human Resources (HR) policies are tailored to the needs of the DG as an organisation and to its staff. HR processes are carried out in Units, with the Human Resources Unit operating as a centre of competence for the whole DG.

In 2015 special attention will focus on the organisation to ensure that the DG can respond effectively to the mandate given by the new College. All HR processes in the DG will need to pro-actively support the establishment and acceptance of the new policy

[29] Covers missions, horizontal units A3, A4, A5, Unit 01, training expenditure and housing (Grange)

orientations, organisation, leadership/management and chain of command, as well as to continue the effort to adapt working methods and organisation and to review and adopt HR policies to ensure staff motivation and engagement remains at a high level despite the further decrease of the overall staffing numbers.

The main objectives are to:
- Ensure appropriate support for quick and smooth adaptation and development of the organisation and of the working methods to the benefit of the Commission overarching objectives of 'Growth and Jobs';
- Ensure that the DG has qualified and experienced staff and makes use of their full potential;
- Ensure that the DG supports working conditions that are conducive to high productivity and are sustainable;
- Ensure the DG allows individuals to reconcile private and professional lives.

Specific objective: ensure that the DG has qualified and experienced staff and makes use of their full potential.	
Result indicator: Percentage of vacant posts (source: European Commission HR Report)	
Baseline 7,3% (October 2014)	Target <6,5% (Less than Commission average)
Result indicator: Percentage of female AD officials, non-management (source: European Commission HR Report)	
Baseline 44,4% (October 2014)	Target >43% (Above 2014 Commission target)
Result indicator: Percentage of female middle managers (source: European Commission HR Report)	
Baseline 34,1,7% (October 2014)	Target >30% (Above 2014 Commission target)
Result indicator: Percentage of staff with a job description (source: European Commission - SYSPER2)	
Baseline 99,13% (October 2014)	Target 98% (Above Commission average)
Specific objective: ensure that the DG supports working conditions that are conducive to high productivity	
Result indicator: Percentage of positive training evaluations (source: European Commission - SYSLOG)	
Baseline 86,5% (October 2014)	Target >85% (Commission target)
Output indicator: Percentage of Annual Appraisal Reports completed on time (source: European Commission - SYSPER)	
Baseline 100% (07/04/2014)	Target 100% (Commission target)
Specific objective: ensure the DG allows individuals to reconcile private and professional lives	
Result Indicator: Staff satisfaction level (source: European Commission - Staff survey)	
Baseline 75,6% (2013 Staff survey)	Target >70% (Above Commission average)

Financial Management

The main objectives of this function are to ensure that DG SANTE obtains the financial resources it needs to meet its policy objectives, and to ensure that operational and financial activities are legal and regular, that financial regulation requirements are met and that financial and management reporting is reliable.

This is achieved by co-ordinating the implementation of the budget, performing risk-based ex-ante verifications and on-the-spot financial controls on funding provided by the DG, and by co-ordinating and reporting on the implementation of the internal control and management standards in the DG.

Specific objective: Plan, perform, monitor and report on the spending of financial resources to ensure sound financial management in all the DG's activities	
Output indicator: Percentage of executed commitment appropriations managed by DG Health and Food Safety (without credits transferred to CHAFEA) (source: European Commission - ABAC, reported in AAR)	
Baseline	Target 2015
2013: 99%	99% (approved by Management Team)
Output indicator: Percentage of executed payment appropriations managed by DG Health and Food Safety (without credits transferred to CHAFEA) (source: European Commission - ABAC, reported in AAR)	
Baseline	Target 2015
2013: 100%	100% (approved by Management Team)
Output indicator: Percentage of payments made on time (source: European Commission - ABAC, reported in AAR)	
Baseline	Target 2015
2013: 97%	95% (approved by Management Team)
Output indicator: Percentage of total budget (without credits transferred to CHAFEA) included in the scope of on-the-spot controls (source: European Commission - ABAC and internal calculations)	
Baseline	Target 2015
2013: 60%	60% (approved by Audit Committee)
Output indicator: Percentage of recovery orders due to ex-post controls issued within three months of year n+1 (period between notifying the final audit report to the auditee and issuing the debit note) (source: European Commission - ABAC and internal calculations)	
Baseline	Target 2015
2013: 87%	100% (approved by Management Team)

The principle of efficiency concerns the best relationship between resources employed and results achieved. The principle of economy requires that the resources used by the institution in the pursuit of its activities shall be made available in due time, in appropriate quantity and quality and at the best price.

Specific objective: Ensure a cost efficient implementation of the Budget	
Output indicator: Overall cost of control for cost reimbursements compared with annual budget (without credits transferred to CHAFEA)	
Baseline 2013	Target
1 %	Not more than 1%
Output indicator: Overall cost of control for procurement compared with annual budget dedicated to procurement (without credits transferred to CHAFEA)	
Baseline 2013	Target
7 %	Not more than 7%

Management of Information and Communication Technologies (ICT)

The main objective is to promote and use Information Technologies capabilities to better serve the policy objectives of the DG and of the Commission.

Until 2020, the focus will continue on implementing the rationalisation of information systems in the Commission, within the framework of the Commission's overall IT governance. The DG has an active role in an important portfolio of systems, with the cross-DG family of TAXUD, AGRI, ENV and ENTR systems, while ensuring maintenance of the necessary day-to-day services to DG SANTE staff.

The main focus will be on the major systems families: Administrative Cooperation, Food Safety, e-Health building blocks, European Reference Networks and the rationalisation of internal Food and Feed systems to TRACES/IMSOC. Systems will be constructed with a maximum reuse of existing building blocks as prepared by various programmes

(ISA, CEF), and they will, together with the more limited maintenance and evolution of existing systems, mobilise most of the human, financial and IT resources. An active participation in the Open Data Portal has led to the publication of almost all SANTE public data and the initiative has allowed the DG to share data more efficiently with SANTE's numerous stakeholders, it will be completed with pharmaceutical data.

Specific objective: define, plan, set up, maintain and develop high quality ICT infrastructures, tools and services to adequately support staff in their work	
Output indicator: Percentage of systems implemented on time (Source: European Commission)	
Baseline 2014	Target IT Master Plan
90%	90%
Result indicator: Increase in the number of streamlining business processes linking DG Health and Food Safety and associated agencies (and/or FVO) (Source: MoU DG SCIC-DG SANTE)	
Baseline October 2014	Target
10 business processes (through 800 video conferences)	More than 20 videoconference with interpretation with FVO (agreed with DG SCIC in the MoU)
Output indicator: Percentage of helpdesk calls resolved within one day (Source: Monitoring report of contractor)	
Baseline (October 2014)	Target
98%	95%
Output indicator: Information Systems support - Percentage of calls resolved in less than 3 days (Source: Monitoring report of contractor)	
Baseline	Target
99% (15 000 up to October 2014)	95%

Document Management

The main objective of this function is to improve the efficiency of the DG's functions by optimising and rationalising the internal document flows and processes.

The focus in 2015 will be on consolidating the use of the document management system (ARES), the external repository, and the DG's transparency project (access to documents management project) to use ARES not only as a central register, but also as a major tool to streamline the management of electronic and paper documents and mail (simplification of circuits, electronic visas, very low probability of loss, and acceleration of the document flow). A particular emphasis will be on the filing and archiving processes. On document knowledge management, SANTE intends to deploy tools in order to make better use of the knowledge contained in the document portfolio of the DG.

Specific objective: put in place and maintain effective document management so that any document connected with the DG's official functions can be electronically filed, stored and retrieved at any given moment**.**	
Output indicator: Percentage of documents registered in DG SANTE and filed in ARES (Source: ARES reports)	
Baseline 2012	Target
95%	98%

Protection of Personal Data

The main objective of this function is to ensure that all the DG's processes and information systems are in line with the regulations in this domain, through advice and support to services. Permanent contact is maintained with the Data Protection Officer of the Commission, as well as a constructive dialogue with the European Data Protection Supervisor's services.

Specific objective: ensure that all the measures are in place in order to comply with the relevant regulation	
Output indicator: Percentage of new systems involving processing of personal data reviewed and notified to the DPO (Source: IT Master Plan 2013-2014 and DPO-2 IT system)	
Baseline 2013	Target
95%	96% (compliance rate fixed by the Data Protection Officer)

Internal audit and evaluation

The main objective of the internal audit function in 2015 is to complete their work programme for 2014 and provide the Director-General with the IAC opinion on the state of control for 2014 by the end of February 2015 at the latest. Thereafter the Internal Audit function will be assumed by the DG IAS.
As regards evaluation, the main objective of the evaluation unit is to provide support and advice to the Director General as well as to Senior Management via independent, objective opinions in order to develop and maintain high standard of management practices and management controls. The activities are performed in line with the guidelines provided by the Secretariat General, for carrying out evaluations. Furthermore, evaluations are performed to provide the basis for informed policy initiatives in line with the guidelines provided by COM(2013)686[30], and useful input to ensure sufficient and improved quality of the policy development and implementation in the DG.

Specific objective: Ensure evaluation, monitoring and evaluative methods more generally are integrated into the decision-making process of DG Health and Food Safety and that they are a useful, accepted and broadly applied resource	
Output indicator: percentage of evaluation reports that are finalised in relation to number of requests in line with planning (Source: Multi Annual Evaluation Plan)	
Baseline	Target
2015	100% of reports that are finalised
Output indicator: for the FWC on evaluation, percentage of finalised terms of reference in relation to requests for assistance.	
Baseline	Target
2015	100% of finalised ToR with 01's support on Evaluation Framework contract
Result indicator: level of implementation and compliance with the 8 quality steps as per the Annex to COM(2013)686 final for DG SANTE evaluations	
Baseline	Target
2015	Dec-2015: 75% (Progressive target as these 8 steps are still to be implemented)

[30] COM(2013)686 final

Internal Control and Risk Management

This activity encompasses the coordination and update of risks and action plans and communication on the progress of the implementation of action plans and the emergence and management of new risks with a special focus on critical risks. It also contains development, update and review of guidelines and documentation related to Internal Control Standards, Baseline Requirements and how to measure and demonstrate control effectiveness.

<table>
<tr><td colspan="4">Specific objective: To implement, maintain and report on an effective and reliable internal control system</td></tr>
<tr><td colspan="4">Output indicator: Percentage of mitigating measures for critical risks implemented within the deadlines set in the action plan (Source: 2014 mid-term report on internal control)</td></tr>
<tr><td>Baseline</td><td colspan="3">Target</td></tr>
<tr><td>2014: 87%</td><td colspan="3">100% (approved by Management Team)</td></tr>
<tr><td colspan="4">Specific objective: To provide reasonable assurance that the resources assigned are used according to the principles of sound financial management.</td></tr>
<tr><td colspan="4">Output indicator: Percentage of audit recommendations (from the IAS, IAC, ECA and Discharge Authority) rated "critical" or "very important" implemented within a period of 6 months past the initial deadlines set in the action plans (Source: 2014 mid-term report on internal control)</td></tr>
<tr><td colspan="3">Baseline</td><td>Target 2015</td></tr>
<tr><td colspan="3">2014: Critical recommendations: N/A
2014: Very important recommendations: 100%</td><td>100% (approved by Audit Committee)</td></tr>
<tr><td colspan="4">Specific objective: To ensure the risk of errors in operations is minimised</td></tr>
<tr><td colspan="4">Result indicator: Rate of correction to be done following the 2nd level ex-ante verification (Source: 2013 AAR)</td></tr>
<tr><td>Baseline</td><td colspan="3">Target 2015</td></tr>
<tr><td>2013: 0.2%</td><td colspan="3">Less than 2% in value (approved by Internal Control Coordinator)</td></tr>
<tr><td colspan="4">Specific objective: To ensure the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions</td></tr>
<tr><td colspan="4">Result indicator (KPI-5): Residual error rate of on-the spot controls (ex-post) for each ABB activity (Source: Internal follow-up sheet, reported in AAR)</td></tr>
<tr><td colspan="3">Baseline</td><td>Target</td></tr>
<tr><td colspan="3">2013: 2,3% (Food & Feed);</td><td>Less than 2% in value (approved by Management Team)</td></tr>
<tr><td colspan="4">Specific objective: To prevent, identify and report on cases of suspected fraud</td></tr>
<tr><td colspan="4">Output indicator: Percentage of actions listed in the anti-fraud action plan of DG Health and Food Safety without delays in the implementation phase
(Source: Internal follow-up sheet)</td></tr>
<tr><td colspan="2">Baseline</td><td>Milestone</td><td>Target 2015</td></tr>
<tr><td colspan="2">2014: 87%</td><td>2015: 15 actions to be finalised</td><td>100%
(approved by Management Team)</td></tr>
<tr><td colspan="4">Output indicator: Percentage of OLAF investigations covered by appropriate follow-up and reporting (Source: Internal follow-up sheet, reported in AAR)</td></tr>
<tr><td>Baseline</td><td colspan="3">Target 2015</td></tr>
<tr><td>2013: n/a</td><td colspan="3">100% (obligation for each DG, no specific approval necessary)</td></tr>
</table>

5.3. Examples of specific efforts to improve economy and efficiency of financial and non-financial activities

In 2015 DG SANTE will continue further developing its four main projects targeted at improving efficiency and bringing economies:

– **"Making SANTE a Leaner Organisation"** which aims at attracting, deploying, developing, motivating and retaining appropriately qualified and experienced staff, as well as at making the DG a more efficient organisation, striving to further improve its motivating atmosphere for its staff. Special part of this project for 2015 will be given to new leadership/management for its establishment and smooth start, and to the integration of the colleagues joining the Safety of the food chain Directorate.

– **"SANTE Simplification Group"** that aims at rationalising and simplifying the working of the DG mostly in the financial area. In 2015 the intention is to roll out the pilot project of the electronic payments throughout the DG which will not only speed up the process of payments but will also bring saving in both human and financial resources.

– **"Transparency initiative" –** the project that started in 2014 will also continue in 2015 by presenting an action plan which should cover DG SANTE's internal procedures and practices related to information management which should bring major savings in the treatment of the many requests for information and access to documents.

– **Unit Management Tool** – this planning tool has been used in SANTE since 2008. After the audit the tool will be further adjusted to reflect better alignment to the Commission's and SANTE's priorities and objectives. In 2013 this tool was agreed by the Secretariat General as the corporate Commission planning tool, in the context of the Commission IT rationalisation. In 2015 SANTE will continue providing assistance to all other Directorates General to roll it out across the Commission.

6. SANTE COMMUNICATION PRIORITIES FOR 2015

Health

Sustainable Health Systems

European health systems face increased costs of healthcare, growing demands from an ageing population, associated with higher risks of preventable chronic diseases, as well as a shortage and uneven distribution of health professionals. The financial crisis has limited the resources and further endangered health systems sustainability**.**

In a 2014 communication, the Commission proposed **an agenda for action at EU level on effective, accessible and resilient health systems**. Several of those actions will see progress in 2015 This agenda also sets the policy line to be followed for the Commission's assessment of health systems and the contribution to **European Semester recommendations**, which also reviews the impact of various health determinants such as nutrition, physical activity, alcohol and tobacco consumption on healthcare systems and on the **quality and productivity of EU workforce**.

The use of eHealth can enable better and safer care for patients**,** more efficient and sustainable healthcare systems and create new opportunities for European industries. In 2015 deliverables of the EU e-Health Action Plan 2012-2020 and of the eHealth Network co-chaired by the Commission will provide communication opportunities.

Growth potential of Innovation in health

Innovation is a key element in the Commission growth agenda. In this respect, health technologies can benefit from appropriate policies to maximise their innovation potential. This requires for example an innovation friendly **regulatory framework for medical products**, as well as use tools such as the **Health Technology Assessment Network** which will ensure the fastest possible uptake and deployment of cost-effective innovative solutions.

High on the political agenda (both with Parliament and selected Member States) is a discussion on how access to innovative medical goods (medicinal products and medical devices) can be balanced with the need to ensure sustainable budgets and a proper reward for therapeutic advances. The Italian Presidency is preparing Council conclusions to be adopted in December 2014 on Innovation for the benefit of the patients.

Also, DG SANTE has initiated reflection with the Member States in the Pharmaceutical Committee on ways to maximise the effective use of the **existing regulatory tools in the EU** pharmaceutical legislation to facilitate innovation and earlier patient access to innovative medicines.

Access to high quality healthcare

The **European semester** gives recommendations among others for health systems reforms. The aim is to contribute to more effective, accessible and resilient health systems **– D2**

European law gives all patients the right to access safe and high quality **cross-border healthcare** and to be reimbursed for it. One year after entry into force of the cross-border healthcare Directive, DG SANTE will continue to monitor and support implementation on the ground and communicate to citizens about their rights. We will also communicate on the launch of the **European Reference Networks**, aiming to pool and further develop highly specialised expertise from all EU countries, while providing better service to patients. .

The EU has one of the safest and most advanced systems for monitoring the safety of medicines. Medicines authorised in the EU are of high quality and undergo a detailed assessment regarding their benefits and risk before being placed on the market. 2015 marks **50 years of pharmaceuticals legislation in the EU**. The anniversary in January will launch a series of communication actions related to the safety of medicines in the EU.

Related to patient safety and development of new innovative products, **antimicrobial resistance**, a growing danger in the EU and worldwide, will remain a priority for SANTE. In 2015, besides the annual European Antibiotics Awareness Day in November, a report on the current Action Plan will be presented.

Food Safety

Genetically Modified Organisms

Currently the authorisation of **GMOs for food and feed** uses at EU level is science-based - the EC proposes authorisation only when there is favourable risk assessment from EFSA. In accordance with the mission letter, by April 2015 DG SANTE will work to review the decision making process closely involving the European Parliament, Member States authorities, relevant organisations and civil society. Regarding **GMOs cultivation** and after successful trilogue negotiations, Member States might be able to decide on cultivation of EU authorised GMOs in their territory, based on reasons other than risk on health and the environment.

Safe food

The **EU control system**, joining Commission and Member States efforts, works well to ensure that food in Europe is safe. Rapid alert and traceability systems and an EU network of national food safety authorities allow us to deal swiftly with any food safety risks across the EU. 2015 communications will aim to secure consumer's confidence in the food sector, one of Europe's biggest economic sectors. The new regulation on **controls on food products at imports** –to be approved mid-2015- will also aim to put an end to the increasing presence on the market of non-compliant (unsafe or fraudulent) products from Third Countries.

Agreement on the **food chain package** is foreseen in the first semester of 2015. Communication will promote the new regulatory framework, which fits into the Better Regulation agenda of the new Commission.
The focus will also be on the revised rules on **food labelling** which are applicable as of December 2014. These revised rules give consumers access to comprehensive and reliable information regarding origin of meat, allergens amongst the ingredients and indication of nanomaterials. Reports on trans-fats, voluntary and mandatory origin labelling and nutrient profiles will be also presented in the first half of 2015.

Further **modernisation and simplification of food legislation** as well as all significant new scientific assessments relevant both to the industry and the consumers will also be highlighted. In this context, 2015 communication will emphasise the ongoing work on a proposal for science-based criteria for **endocrine disruptors** (summary of public consultation to be published by mid-2015), given the increasing attention that their potential impact in health is raising in society and the media.

Innovative and sustainable Food Systems

In the EU, food waste is estimated to have reached 103 million tonnes (205 kg/capita) were wasted in 2013. **Food waste** is an ethical, economic and environmental issue. All actors in the food chain have a role to play in preventing waste. DG SANTE will seek to further raise awareness of the issue among all actors involved including consumers, support Member States in the development of national food waste prevention programmes and sharing best practices, engage in dialogue with industry for example on streamlining of date marketing practices and optimisation of shelf-life and facilitate food donations by retailers and producers. The Expo 2015 in Milan will be a notable communication opportunity. The new circular economy package, probably to be presented by the end of 2015, will give us the possibility to start communication on how the future of this policy will evolve.

To facilitate innovation in the food sector while maintaining food safety, the Commission put forward a proposal on **novel food** in December 2013. The new legislation, likely to be adopted in 2015, would improve efficiency and transparency, remove burden from national administrations, secure faster safety approvals and promote innovation. A transition period of two years is provided for and will allow all actors to become acquainted with the new procedures, which deserve to be well communicated and promoted.

New food technologies allow for healthier, safer and more sustainable food, stimulate innovation and competitiveness in the agro-food chain, therefore contributing to growth. However, consumer's perception of innovative food processing technologies and food packaging is becoming more negative. Research shows that a balanced, clear, concise communication about food safety, safe packaging, the processes and product attributes can increase confidence in food technologies and trust in innovative businesses. In 2015 DG SANTE will pursue such communication, in particular in the context of the Expo Milan.

Animal welfare remains a sensitive issue in SANTE's portfolio, for several aspects impacting on different policy areas. The Commission will seek to respond to high public concerns with this issue while debating possible next policy steps taking into account the recent scientific and technical achievements in the EU.

Potential food crisis and health pandemics

The EU has a coordination role in case of high-profile, multi-national **outbreaks of foodborne pathogens**. The Rapid Alert System for Food and Feed in an essential tool to gather information in times of crisis. The EC coordinates the response, manages the overall communication and dissemination of information to Member States, third countries and other organisations, adopts legislation to regulate trade from affected countries and sends experts to help control outbreaks.

Under the Serious Cross Border Health Threats directive, the Health Security Committee, where all Member States and the Commission are represented, has the mandate to coordinate **public health emergencies** and deliberate on communication to health professionals and the public. The Ebola outbreak will continue to focus attention in 2015.

Public communication efforts accompany such crisis management measures to the extent messages relate to DG SANTE's area of responsibility.