European Commission

2016

Annual Activity Report

DG Health and Food Safety (SANTE)

FOREWORD

2016 saw DG Health and Food Safety (DG SANTE) strengthen its contribution to the Commission's strategic agenda through a structural reorganisation which took effect on 1 February. It aims to better deliver DG SANTE's priorities, set out in President Juncker's mission letter to Commissioner Andriukaitis, through modernising and simplifying existing legislation, developing expertise on health systems and building up country knowledge, and supporting the EU's capacity to deal with crisis situations and pandemics. The reorganisation also ensures greater operational efficiency and maximises effectiveness.

As part of the modernisation and simplification of existing legislation, a new legal framework governing the food and feed sector was agreed. This covers Regulations on Animal Health, Plant Health, Official Controls, Animal Breeding and Novel Foods and aims to facilitate greater competitiveness in the EU's food and feed sector while maintaining a high level of consumer protection.

In addition, a dedicated Better Regulation Unit was created underlining DG SANTE's commitment to the application of Better Regulation principles in its policies and activities. Furthermore, a Strategy and Coordination Unit was established to ensure sound coordination and consistency in DG SANTE's policies and policy documents.

DG SANTE also focussed on developing expertise on performance assessments of health systems and building country specific knowledge. This was reflected in a reorganisation of the SANTE Health Directorates. DG SANTE launched the first product of the 'State of Health in the EU' initiative, the joint OECD-Commission report 'Health at a Glance: Europe 2016' which provides a comprehensive overview of the EU's health systems and public health.

Animal, food and plant crisis management was placed within a single Directorate in 2016 to streamline DG SANTE's approach to preparedness and the management of crises. This will help ensure a coordinated response to all aspects of future crises and to enable in particular plant health crisis management to benefit from experience in the animal and food sectors.

Another major achievement in 2016 was the creation of 23 European Reference Networks (ERNs) which will benefit EU citizens suffering from rare diseases. By consolidating knowledge scattered across countries, ERNs will give healthcare providers access to a much larger pool of expertise. This will result in better prospects for patients to receive an accurate diagnosis and advice on the best treatment for their condition.

2016 also saw the creation of a task-force on antimicrobial resistance (AMR) which pooled resources from both health and food Directorates to ensure a true 'one-health' approach to fight this global threat. DG SANTE focused on the preparation of a new One-Health Action Plan to support Member States in the fight against AMR.

A further DG SANTE flagship initiative in 2016 was the establishment of a new EU Platform on Food Losses and Food Waste bringing together different actors to help define measures to prevent food waste, share best practice and evaluate progress towards achieving the relevant Sustainable Development Goal.

Finally, the Commission adopted two draft legal acts to establish scientific criteria for identifying endocrine disruptors, to amend the legislation on plant protection products and on biocides, which now need to be finalised according to the relevant procedures.

By ensuring both policy domains – public health and food safety – function to their full potential and in parallel, DG SANTE seeks to ensure that risks to human, animal and plant health are prevented or contained and that EU citizens are properly protected.

Xavier Prats Monné,

Director-General of DG SANTE

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THE DG IN BRIEF

The mission of DG Health and Food Safety (DG SANTE) is to promote and protect health and food safety and contribute to a well-functioning and fair internal market in food, feed, agricultural and medicinal products. The food production and processing chain accounts for 7.5 % of employment and 3.7 % of total value added in the EU[1]. In 2015, health spending reached 9.9% of GDP and health sector accounted for 11% employment in the EU[2]. Both food and health sectors require a solid policy framework built on science and protecting a high level of consumer, animal and plant health.

DG SANTE's priorities are defined in its Strategic Plan 2016-2020[3] and built around three of the Juncker Commission's ten priorities: (1) a new boost for jobs, growth and competitiveness in the EU, (2) a deeper and fairer internal market, and (3) a reasonable and balanced free trade agreement with the US. Our work also makes an important contribution to the Europe 2020 objectives. It strives to enable the health and food sectors to achieve their full economic potential and foster innovation and growth.

DG SANTE's activities are directly shaped by the Treaty on the Functioning of the European Union (TFEU) and principally linked to Articles 114 (Internal market), 168 (Public Health) and 13 (Animal Welfare). EU health policy is explicitly limited by Article 168 which stipulates that Member States are responsible for defining their health policies and for organising and delivering health services and medical care.

EU action is therefore mainly linked to incentive measures for disease prevention and health promotion, and cooperation measures to improve links between Member State health systems. In food safety, the EU is directly responsible for designing, implementing and enforcing a single, common policy framework that applies across all Member States.

In both policies, the EU plays an important supporting role, providing guidance to Member States and tools to promote cooperation and help national systems operate more effectively. This is important for risk management and crisis preparedness and to protect the EU's citizens, animals and plants from serious cross-border health threats. It depends on the will and commitment of Member States to achieve its objectives and on businesses and Member States to implement and enforce EU rules correctly.

DG SANTE operates under the political leadership of the Commissioner for Health and Food Safety on the basis of multi-annual policies and financial frameworks. The 3rd Health Programme 2014-2020 provides funding for health policy whereas Regulation (EU) No. 652/2014 provides the financial framework for food safety, animal and plant health[4].

In 2016, DG SANTE managed financial operations for two policy areas - Public Health and Food and Feed Safety. In addition, it paid subsidies to agencies and implemented its administrative budget.

DG SANTE works closely with the Executive Agency for Consumers, Health and Food (CHAF-EA) – which helps to implement the EU Health Programme and Better Training for Safer Food initiative. DG SANTE is a partner DG to the following EU decentralised agencies: the European Medicines Agency (EMA), the European Food Safety Authority (EFSA), the European Centre for Disease Protection and Control (ECDC), the Community Plant Variety Office (CPVO) and the European Chemicals Agency (ECHA).

DG SANTE plans and reviews its main priorities and objectives annually, building its annual Management Plan around the resources available and any identified risks which

[1] Agri-food trade in 2015: China boosts EU exports, Monitoring Agri-trade Policy, MAP 2016– 1, Eurostat, p. 3.
[2] This includes employment in following activities: human health, residential care and social work without accommodation, source: Eurostat.
[3] http://ec.europa.eu/atwork/synthesis/amp/doc/sante_sp_2016-2020_en.pdf
[4] A complete overview of the Programmes' key facts and figures, their performance framework and their key achievements of 2016 is given in the Programme Statements prepared for the 2018 draft budget procedure.

may impact on its objectives. Monitoring is done via bilateral meetings between the Director-General, individual Directorates and Unit managers, as well as weekly management meetings involving the Director-General and the Management Team.

DG SANTE delivered its objectives in 2016 using a total of 796 staff. Of these, 58% worked in food and feed safety policy area, 25% on public health and 17% on policy, strategy, coordination and management.

DG SANTE Human Resources[5] by activity area	**Establishment Plan posts**	**External Personnel**	**Total**
Public Health	149	48	**197**
Food and Feed Safety	401	62	**463**
Management of DG SANTE	68	18	**86**
DG SANTE Policy Strategy and Coordination	37	13	**50**
Total	**655**	**141**	**796**

DG SANTE pursues its policies with a focus on prudent management and protection of the related EU financial resources. All financial transactions are carried out under direct centralised management: the Director-General is the authorising officer by delegation who sub-delegates at the level of Deputy Directors-General, Directors and Heads of Units. Risk management helps establish specific internal control strategies focussing on activities and domains representing the highest risks.

The 2016 budget of the two policy areas, public health and food and feed safety was spent under direct management, mainly through grants and procurement. In addition, DG SANTE paid subsidies to agencies.

DG SANTE 2016 budget[6] in EUR million	**Operational Expenditure**	**Administrative expenditure (DG managed)**	**Total Financial Resources**
Public Health	11,0	1,4	**12,4**
Food and Feed Safety	235,7	1,3	**237,0**
Other	0,3	-	**0,3**
Horizontal Administration[7]	0	11,4	**11,4**
Consumers, Health, Agriculture and Food Executive Agency (CHAF-EA)	0	5,5	**5,5**
European Food Safety Authority (EFSA)	79,4	0	**79,4**
European Centre for Disease Prevention and Control (ECDC)	58,2	0	**58,2**
European Medicines Agency (EMA) [8]	17,2	0	**17,2**
European Chemicals Agency (ECHA) biocides[9]	0,9		**0,9**
Total	**402,7**	**19,6**	**422,3**

As in previous years, DG SANTE's centralised on-the-spot controls played a prominent role in the financial control environment, verifying – where applicable – the eligibility of costs claimed at beneficiary level and going to Member States. In 2016, DG SANTE's residual error rate did not exceed the materiality threshold of 2%. In the context of the animal disease eradication programmes in the food and feed policy area, the residual error rate was around 1%, confirming the trend observed since 2013 thanks to a series of mitigating actions DG SANTE has taken to reduce the error rate. Their cumulative effect has reduced it to an acceptable level.

[5] The Human Resource data rely on the snapshot of Commission personnel actually employed in each DG/service as of 31 December of the reporting year. These data do not necessarily constitute full-time-equivalents throughout the year.

[6] Commitments made on the basis of the final available credits taking into account EFTA credits, budget amendments and/or budget transfers; without credits implemented by CHAF-EA.

[7] The horizontal credits include EUR 6,1 million for the Global Envelope and EUR 5,3 million for the building in Grange, Ireland.

[8] The EU contribution to EMA is a balancing grant; EMA's total 2016 budget amounted to EUR 324,7 million, mainly financed by fees.

[9] ECHA's budget for biocides in 2016 amounted to EUR 7,9 million. The EU contribution is a balancing grant.

EXECUTIVE SUMMARY

The Annual Activity Report is a management report of the Director-General of DG Health and Food Safety (SANTE) to the College of Commissioners. Annual Activity Reports are the main instrument of management accountability within the Commission and constitutes the basis on which the College takes political responsibility for the decisions it takes as well as for the coordinating, executive and management functions it exercises, as laid down in the Treaties[10].

a) Key results and progress towards the achievement of general and specific objectives of the DG

In 2016, DG SANTE continued to actively contribute to three of the Juncker Commission's ten priorities set out in its Strategic Plan for 2014-2020: (1) a new boost for jobs, growth and competitiveness in the EU, (2) a deeper and fairer internal market, and (3) a reasonable and balanced free trade agreement with the US.

1. *Promoting sustainable growth, competitiveness and job creation*

Promoting good health at EU level plays an important economic role. It helps the EU to deliver on key priorities linked to competitiveness and growth and reduce pressures on national budgets while helping to keep citizens in good health.

The EU's food and feed policies are supported by a comprehensive legal framework that promotes a well-functioning and safe food chain. The aim is to create the right environment for growth and investment in this important sector – the largest manufacturing sector in the EU in terms of employment and second largest in terms of value added[11] – whilst ensuring a high level of human, animal and plant health and a high level of food safety.

To streamline rules, in 2016 DG SANTE contributed to the successful conclusion of several legislative proposals. 2016 saw the adoption of the new ***Animal Health***, ***Plant Health*** and ***Animal Breeding Regulations***[12] and a political agreement was reached on the ***Official Controls Regulation***. These Regulations together with ***Novel Foods Regulation***[13] adopted in November 2015 aim to contribute to a simpler legal framework, greater competitiveness and sustainability in the EU's agri-food sector, maintaining a high level of safety and protection for EU consumers.

Supporting the EU's capacity to deal with crisis situations

Quick response to outbreaks of diseases and mitigation of their consequences is essential for public health and for the EU's food industry limiting related economic costs.

In 2016, DG SANTE funded through the Health Programme EUR 4,33 million to support the EU's capacity to address serious cross-border health threats. DG SANTE coordinated the response to the ***Zika virus epidemic***, amongst other actions.

In 2016, DG SANTE also provided substantial funds to national veterinary programmes (around EUR 160 million) and plant health survey programmes (EUR 11,4 million) which helped ensure early detection and eradication of disease outbreaks. Moreover, DG SANTE co-funded around EUR 23 million for emergency measures to contain ***animal disease outbreaks*** such as: avian influenza, African swine fever, lumpy skin disease and bluetongue. These outbreaks required rapid detection, treatment and a coordinated

[10] Article 17(1) of the Treaty on European Union.
[11] Eurostat Statistics Explained, Manufacturing statistics – NACE Rev. 2
[12] Animal Health Regulation (EU) 2016/429, Plant Health Regulation (EU) 2016/2031 and Animal Breeding Regulation (EU) 2016/1012
[13] Regulation (EU) 2015/2283

response at EU level to prevent uncontrollable spread and substantial damage. For example, DG SANTE support to the initial response to the outbreak of lumpy skin disease by providing vaccines from the European vaccine bank proved crucial in containing the disease. EUR 5,7 million were committed to contain ***pest outbreaks***. Emergency measures were issued or updated to control outbreaks of *Xylella fastidiosa*, Pine Wood Nematode and *Epitrix*.

Long term EU co-financing led to the improvement of animal health status e.g. in case of bovine spongiform encephalopathy (175 cases in 2007 decreased to 2 cases in 2015) and rabies (814 cases in 2007 decreased to 31 cases in 2016) and containment of outbreaks. This increased confidence in the EU standards reflected in the continued growth of EU export of food and live animals which have risen by 50% from 2010 to 2015.

Helping Member States to tackle increased pressure on health services and on official controls

Antimicrobial resistance (AMR) remains a major global challenge with serious implications for the economy and human health. Drug resistant infections already cause at least 25,000 deaths annually in the EU and an estimated EUR 1.5 billion worth of healthcare and productivity losses.[14] In response to this threat and in line with the June 2016 Council conclusions on AMR and the outcome of the evaluation of the first EU Action Plan on AMR (2011-2016), in October 2016 the Commission published a roadmap for a ***new One-Health Action Plan*** to support Member States in the fight against AMR. The new Plan will be adopted in 2017. DG SANTE also started preparations for the ***"One-Health" network***, which gathers Member States' experts on AMR from the human, the veterinary and the environment sectors.

In 2016, DG SANTE continued to contribute to discussions in the Council on the proposals on ***veterinary medicinal products*** and on ***medicated feed*** legislation. Quick adoption of these proposals is crucial to reduce AMR.

In response to the President Juncker's mission letter to Commissioner Andriukaitis which called for expertise on performance assessments of health systems and country-specific and cross-country knowledge for informed policies, in 2016, DG SANTE launched the first of four products of the 'State of Health in the EU' flagship initiative – the joint OECD-***Commission report 'Health at a Glance: Europe 2016'***. The report provides a quantitative overview of trends in the EU's health systems and public health, and offers a horizontal analysis of key issues. The report together with the country health profiles, which are in preparation and will contain qualitative country specific evidence, will feed into a Staff Working Document that aims to identify common health policy priorities across the EU and reveal potential for actions with EU added value. The first 'State of Health in the EU' cycle will pool expertise and strengthen knowledge and will reveal data and knowledge gaps that subsequent cycles will aim to cover.

DG SANTE continued to contribute to the ***European Semester Country Reports*** aiming to identify challenges in the health systems of Member States, based on the processing of health indicators from DG SANTE's assessment tool and on the intelligence gathered through interaction with national authorities and stakeholders.

Public expenditure on healthcare and long term care accounts for 8.5% of Gross Domestic Product (GDP) in the EU and is expected to increase by an additional 2 to 4 percentage points by 2060.[15] Up to 70% of health expenditure is spent on the ***treatment of preventable chronic diseases*** caused by common risk factors including excessive alcohol consumption, smoking, poor nutrition and physical inactivity. Tackling this challenge remained an important priority in 2016. DG SANTE supported Member State efforts in this area with a significant amount of funding (around EUR 22 million) towards

[14] ECDC/EMA (2009), Joint technical report: ''The bacterial challenge, time to react''

[15] European Commission, Joint Report on Health Care and Long-Term Care Systems & Fiscal Sustainability, Vol 1., Institutional Paper 037, October 2016

health promotion and disease prevention mainly financing actions on chronic diseases, cancer, mental health and refugees' health.

A set of ***tertiary legislation implementing the Tobacco Products Directive*** was adopted on characterising flavours, priority additives and technical standards for refillable cigarettes. The Directive aims to discourage young people from taking up smoking and is estimated to lead to a 2% reduction in smoking in the EU over the next five years - equivalent to 2.4 million fewer smokers.[16]

Another key success for DG SANTE in 2016 was the establishment of 23 ***European Reference Networks*** (ERNs) with a financial commitment of around EUR 12 million. The ERNs will generate clear EU added value by bringing together highly specialised healthcare providers from different EU Member States for a wide range of rare diseases where expertise is scarce and a concentration of knowledge and resources is needed.

Digitalisation and innovation play an essential role in healthcare and more cost-effective healthcare provision contributing to effective, accessible and resilient health systems. In 2016, several DG SANTE's policies were included in the Commission's ***Digital Single Market***, including support to exchange of health data across Member States.

The use of digital technologies is also important in strengthening official controls in the food sector. DG SANTE continued its work on digitalisation of animal and plant health certificates, laboratory tests, animal identifications, tracking and tracing and alert management. In 2016, the ***TRAde Control and Expert System (TRACES)*** continued to grow in terms of geographical usage (with 10 more non-EU countries now using it for their imports to the EU) as well as in scope (the use of TRACES for plants has now reached 100.000 certificates per year).

In 2016, DG SANTE carried out ***208 audits, fact-finding missions and study visits*** in EU countries and non-EU countries exporting to the EU, covering food safety, animal health, animal welfare, plant health and AMR. This work provides for effective and correct implementation and enforcement of EU legislation, maintaining high standards and safety levels and providing a level playing field for business operators within the EU and in relation to EU trading partners. The results feed to evidence-based policy development, and a regulatory environment which facilitates jobs, growth and investment.

Promoting EU values and standards globally

DG SANTE contributed to the Commission-wide efforts to achieve the Sustainable Development Goals (SDG), in particular in relation to the health goal (SDG3) and the goal to halve ***food waste*** (SDG 12) by 2030. In 2016, DG SANTE established a new ***EU Platform on Food Losses and Food Waste*** bringing together Member States, international organisations and food chain actors, to help define measures to prevent food waste, share best practice and evaluate progress, thus supporting all players towards achieving the relevant SDG.

The EU is a global leader in the pharmaceutical industry and the world's major trader in pharmaceutical products (over EUR 170 billion in 2013). It is therefore crucial for DG SANTE to focus its efforts in increasing ***international harmonisation in pharmaceutical products***. In 2016, DG SANTE achieved an important milestone by completing the reform of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and promoting new membership, including Brazil and Korea.

As the largest exporter and importer of food in the world with a well-recognised and respected framework for food safety legislation, the EU must ensure its ***food standards***

[16] Impact assessment for the Tobacco Products Directive, SWD(2012) 452 final, 19.12.2012, page 113

are aligned globally to safeguard its competitive position. DG SANTE continued to promote and defend EU interests in meetings of the International Plant Protection Convention, the World Organisation for Animal Health and Codex Alimentarius.

2. ***Contributing to a deeper and fairer internal market***

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

Strengthening internal market for safe food products

Food and feed safety is ensured in the EU through a wide range of harmonised rules, as well as by EU ***authorisations for products and substances used in the food chain*** i.e. food flavourings, food/feed additives, pesticides, biocides, plastic food contact materials or genetically modified organisms. This framework ensures a high level of health and environment protection across the EU thus helping the internal market to run smoothly, and giving consumers access to safe food products. In 2016, DG SANTE continued to assess and where appropriate, authorise a range of substances used in food and feed production to ensure safe and of high quality products on the internal market.

In 2016, particular attention was drawn to the Commission proposal for two legal acts establishing the ***criteria for identifying endocrine disruptors*** as required by the legislation on plant protection products and biocides. These acts need to be adopted in line with the respective procedures.

Strengthening internal market for safe health products

In the Single Market Strategy the Commission committed to improve the functioning of the internal market for health products and to introduce an initiative of health technology assessments (HTA) to increase coordination to avoid multiple assessments of products across Member States. In 2016, DG SANTE published the ***inception impact assessment on a new HTA initiative*** and launched a public consultation. This will feed into the new initiative anticipated for 2017. HTA supports innovative technologies, encourages innovation and growth in the pharmaceutical and medical devices sectors.

DG SANTE continued its work on the ***authorisation of medicinal products***, the advance therapy medicinal products and particular aspects of the regulatory framework for orphan medicines. This makes an important contribution to a stable legal environment and optimal use of current authorisation procedures to ensure patients' access to safe medicines and a competitive EU pharmaceutical sector. DG SANTE also supported innovation in the pharmaceutical sector by streamlining the procedures for products subject to accelerated assessment and optimising the time taken to authorise innovative medicines of major interest to public health.

3. ***Achieving reasonable and balanced free trade agreement with the US***

In 2016, DG SANTE performed an assessment of the US regulatory system for pharmaceutical products and confirmed the equivalence of standards. Based on this work, the Commission adopted an updated EU-US agreement on ***mutual recognition of inspections of medicine manufacturers*** in March 2017. This agreement will bring cost savings for pharmaceutical industry and regulators by avoiding multiple inspections of the same facilities, and will lead to a better use of respective inspection resources. This will allow both the EU and the US to identify problems earlier and prevent poor quality pharmaceuticals from entering into their markets.

DG SANTE continued working on the negotiation of the ***Sanitary and Phytosanitary (SPS) Chapter of Transatlantic Trade and Investment Partnership (TTIP)***. A number of provisions were agreed with the US, including some areas of importance to the EU, such as import checks and audits and equivalence.

b) Key Performance Indicators (KPIs)

KPI 1: Containment of spread of major epidemic animal diseases after initial outbreak

Specific objective 1.1: Effective preparedness, prevention , reaction and eradication of human, animal and plant diseases			Related to **Food and feed expenditure Regulation (EU) No. 652/2014**
Result indicator 1.1D: Containment of spread of major epidemic animal diseases in the EU after initial outbreak (foot and mouth disease, classical swine fever, African swine fever, avian influenza and Newcastle disease) **Source of data:** Commission internal from several sources			
Baseline 2014	**The latest data** 2016	**Interim Milestone** 2018	**Target** 2020
19/25[17]	21/25	Increasing	Increasing (internal target)

There has been slight improvement of performance of the EU preparedness and control systems under SANTE coordination and management trough legislative (dozens of implementing decisions) and non-legislative tools (technical and financial support) as shown by the overall 2016 score of 21 compared to baseline of 19 in 2014. The situation for foot and mouth disease and classical swine fever remained excellent (scoring 5 each), for African Swine fever slow spread occurred as assessed by EFSA and for Newcastle disease no subsequent spread occurred from any outbreak, indicating good management with good disease containment and minimum spread (scoring 4 each) while for avian influenza year 2016 recorded relatively wide disease spread due to multiple virus introductions from wild birds leading to limited further spread to poultry (scoring 2).

KPI 2: Number of established European Reference Networks

Specific objective 1.5: Increased access to medical expertise and information for specific conditions				Related to **Health Programme; Connecting Europe Facility (CEF) financing programme**
Result indicator 1.5.A: Number of established European Reference Networks **Source of data:** Information system on ERN, minutes of the ERN Board of Member States meetings, licences of the ERN trademark licensed				
Baseline (2015)	**The latest data** 2016	**Interim Milestone** 2016	2018	**Target** 2020 (forecast as the establishment of ERNs dependent on the no. of proposals received to the call for ERN and the no. of approvals decided by the competent body (ERN Board of Member States)
0	23	10	20	30

By the end of 2016, 23 ERNs had been established (which is a higher number than interim milestones for 2016 and 2018) following a call for applicants managed by DG SANTE. The DG SANTE's contract to establish the basic IT structure serving the ERNs was signed in December 2016. A framework partnership agreement, funded by the Commission's Health Programme, was drawn up with the ERNs to ensure that over the next five years, they will reinforce their capacities, improve the diagnosis and clinical outcomes of patients and contribute to the efficiency of the national healthcare systems.

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

Objective 1: Effective and reliable internal control system giving the necessary guarantees concerning the legality and the regularity of the underlying transactions		
Indicator 1: Estimated residual error rate of on-the spot controls (ex-post) for each policy area **Source of data:** Internal follow-up sheet, reported in AAR		
Baseline	**Target** (according to the control strategy approved by the DG)	**The latest data**
2014 and 2015: around 1% (policy area Food and Feed Safety) 2014 and 2015: around 0% (policy area Public Health)	Less than 2% in value of the relevant payment budget (annually or multi-annual depending on the design of the programmes)	2016: around 1% (policy area Food and Feed Safety) 2016: around 0% (policy area Public Health)

DG SANTE's residual error rate amounts to around 1% for the policy area "Food and Feed Safety". Thus, it does not exceed the materiality threshold of 2% and confirms the trend observed since 2014. To reduce the error rate, in the past few years, DG SANTE has taken a series of mitigating actions which reduced the error rate to an acceptable level.

[17] The indicator shows a number composed according to an internal evaluation matrix. The value of the indicator is a number between 25/25 and 5/25, the higher the better. (25/25: no disease spread; 5/25: all five diseases spread vastly). Scoring for the top-5 diseases is in a rage of 1 to 5 (5=perfect and 1=disaster). For 5 diseases the best scenario is 25 and the worse is 5.

c) Key conclusions on Financial Management and Internal Control (executive summary of section 2.1)

In accordance with the governance statement of the European Commission, (the staff of) DG SANTE conducts its operations in compliance with the applicable laws and regulations, working in an open and transparent manner and meeting the expected high level of professional and ethical standards.

The Commission has adopted a set of internal control standards, based on international good practice, aimed to ensure the achievement of policy and operational objectives. The financial regulation requires that the organisational structure and the internal control systems used for the implementation of the budget are set up in accordance with these standards. DG SANTE has assessed the internal control systems during the reporting year and has concluded that the internal control standards are implemented and function as intended. Please refer to AAR section 2.1.3.3 for further details.

In 2016, DG SANTE faced several changes to its control environment mainly brought about by the re-organisation, in force since 1 February 2016. The new organisation aimed at increasing both the effectiveness and the efficiency of the DG. It also addressed effectively several issues related to sensitive posts since it triggered a high mobility of staff. DG SANTE assessed that overall the changes did not bear a high risk thanks to the mitigating actions that have been in place since several years. Please refer to AAR section 2.1.3 for further details.

In addition, DG SANTE has systematically examined the available control results and indicators, including those aimed to supervise entities to which it has entrusted budget implementation tasks, as well as the observations and recommendations issued by the Internal Audit Service and the European Court of Auditors. These elements have been assessed to determine their impact on the management's assurance as regards the achievement of control objectives. Please refer to Section 2.1 for further details.

In conclusion, management has reasonable assurance that, overall, suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated; and necessary improvements and reinforcements are being implemented. The Director General, in his capacity as Authorising Officer by Delegation has signed the Declaration of Assurance.

d) Information to the Commissioner

In the context of the regular meetings during the year between the DG and the Commissioner on management matters, also the main elements of this report and assurance declaration, have been brought to the attention of Commissioner Andriukaitis, responsible for health and food safety.

1. KEY RESULTS AND PROGRESS TOWARDS THE ACHIEVEMENT OF GENERAL AND SPECIFIC OBJECTIVES OF THE DG

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

The table with impact indicators is included in Annex 12.

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

Impact indicator 1.1 monitors the **employment rate of the population aged 20-64**. Public health policies play an important role in this respect, impacting directly on premature mortality and morbidity as well as indirectly on labour force participation and productivity.

Coordinated policies and initiatives targeting key ***health determinants*** contribute to increasing productivity through fewer annual workdays lost as well as fewer long lasting work disabilities linked to chronic conditions. EU action to help Member States prevent and control ***chronic diseases*** can also help reintegrate people with chronic disease into the labour market and reduce disease-related early retirement. DG SANTE activities in 2016 which aimed to address chronic diseases, health determinants and healthy diet are included under the specific objective 1.3.

DG SANTE also supports Member States in their efforts to increase the job-creation potential of the healthcare sector by contributing to ***skills analysis of health professionals and the improvement of labour market intelligence in health sector***. This leads to better understanding of skills needs and informed education and training in the health sector and feeds into an agenda for new skills and jobs, one of the flagship initiatives of Europe 2020.

In 2016, DG SANTE completed a cross-country study of the core competences of healthcare assistants which examined the roles of these health professionals as part of healthcare teams. To increase a better understanding of skills needs, the Joint Action on health workforce planning and forecasting (2013-2016), funded by the Health Programme, published a series of policy briefs on the key drivers of future health workforce skills until 2035. The results were highlighted at a conference closing the Joint Action in Mons, Belgium, on 3-4 May 2016. The European Expert Group on health workforce met twice, and discussed inter alia continuous professional development and the Commission's New Skills Agenda for Europe. The Organisation for Economic Co-operation and Development (OECD) was a key partner in these developments.

SANTE was also involved in establishing the ***European Solidarity Corps*** which aims to provide 100,000 opportunities for young people under the age of 30 to volunteer or work in solidarity related areas which includes health.

DG SANTE policies also help to address people at risk of **poverty or social exclusion** (**impact indicator 1.2**). DG SANTE aims to ***reduce stigma and discrimination***, for example in relation to people with HIV or mental illness, and to ***fight health inequalities*** with a special focus in 2016 on migrants thus contributing to the Europe 2020 strategy flagship initiative on the European platform against poverty and social exclusion.

Fighting stigma and discrimination against people living with HIV was one of the priorities under the existing ***EU HIV/AIDS Action Plan 2014-2016***. The main at-risk group that continues to be disproportionally affected by the epidemic are men having sex with men (MSM). In this context, a project under the Health Programme was launched in 2016 on European Surveys and Trainings to Improve MSM Community Health (EUR 2 million), to better understand the remaining challenges, including stigma and discrimination, which this group may be facing in accessing testing, prevention or linkage to care, including in community-based settings.

As regards ***migrants***, in accordance with the general priorities of the Commission on migration for 2016 and the Action Plan for integration of third country nationals, the activities for 2016 focused on exchanges of best practices for integration of migrants in national health systems.

In 2016, the ***EU Joint Action on mental health and wellbeing*** produced the "European Framework for Action on Mental Health and Wellbeing". Its recommendations for action to fight depression and prevent suicide, to improve mental health at work and in schools, to better develop community-based and socially inclusive mental healthcare and to strengthen mental health in all policies include also measures to fight stigma and discrimination. To implement the framework, a mechanism was established to collect, exchange and analyse information on policy and stakeholder activities in mental health. Its work in 2016 led to recommendations that addressed stigmatisation, discrimination and better inclusion of people with mental disorders.

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

Tables with result indicators and outputs are included in Annex 12.

Epidemics and infections represent a serious health and security risk and a direct economic cost for growth, consumer confidence and international market access if they are not contained or well-managed. Crisis preparedness, prevention and response capacity in the fields of human, animal and plant health and food safety is a critical part of DG SANTE's work. Efforts in 2016 ensured the EU's framework for disease prevention and crisis management remained robust in an ever-evolving context and that the EU's emergency measures could support rapid and effective management of any disease outbreaks.

The following priorities were addressed:

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

DG SANTE's work on responding to serious cross-border threats to health was supported by the ECDC, which provided rapid risk assessments, surveillance and technical support throughout 2016. On major threats, the assessments and input from ECDC was essential to guide the Commission coordination in the Health Security Committee. On the Zika threat for travellers and pregnant women in particular, ECDC assessments and surveillance data proved to be essential to guide national and EU-wide policy development.

DG SANTE's work on preventing, managing and eradicating animal and plant diseases was supported by the European Food Safety Authority (EFSA) and the Community Plant Variety Office (CVPO), which provided rapid scientific and technical support throughout 2016. On animal diseases the input from EFSA was decisive and of direct and immediate use to prepare preventive rules for lumpy skin disease and to lay down new biosecurity

and early warning rules for avian influenza in response to the HPAI H5N8 epidemic. The regionalisation for African swine fever was also based on useful EFSA scientific input provided during 2016. EFSA also provided the essential inputs to support the necessary measures against pests. CPVO contributed to the adoption of measures simplifying and modernising the intellectual protection of plant varieties, and implemented the respective legislation by granting such protection at EU level.

1. Tackling serious cross-border health threats

While preparedness, response planning and implementation are the responsibility of individual Member States, the EU - in particular DG SANTE - has an important role to play in coordinating preparation and response to serious cross-border health threats.

Important activities in 2016 included developing implementing measures under Decision 1082/2013/EU on serious cross-border threats to health, in particular the draft Commission Implementing Decision on the ***procedures for the notification of alerts***, as part of the early warning and response system, and for the ***information exchange***, consultation and coordination of responses. The Committee for serious cross-border threats to health voted in favour of this Implementing Decision by unanimity on 16 December 2016, which was adopted in February 2017.

This implementing measure will address the recommendations made by the ***European Court of Auditors***' special report on cross-border health threats published in December 2016 together with DG SANTE's work to improve the coordination between Commission services and the ECDC and to organise several joint procurements in 2016/17. Please see more information on the European Court of Auditors' report under point 2.1.2. The Joint Procurement Agreement is a basis for voluntary cooperation of Member States to jointly procure medical countermeasures to cope with threats under the Decision on serious cross-border threats to health (so far, 24 Member States have signed up to the Joint Procurement Agreement).

Preparatory work on the implementing act regarding the ***list of communicable diseases*** to be covered by the epidemiological surveillance network and the case definitions of those diseases, as well as the procedures for the operation of the network, is ongoing in close cooperation with ECDC. The updated list of diseases will include Dengue, Chikungunya, and Lyme disease, as well as Zika. Due to the time needed by the ECDC to conclude its scientific opinion on the case definitions and for the consultation process with Member States and stakeholders, it was not possible to adopt the implementing act in 2016. The aim is to have it adopted by the end of 2017.

In 2016, DG SANTE and Member States also worked on the preparation of an ***action plan to strengthen preparedness*** and support the implementation of the International Health Regulations in the EU considering the new developments under the World Health Organisation (WHO) Health Emergencies Programme. The action plan is planned to be endorsed by the Health Security Committee (HSC) in 2017. It aims to improve preparedness and response planning for serious cross-border health threats and to build capacities ensuring coherence and interoperability among sectors at EU level and between Member States. The proposed actions are building upon the lessons learnt from the Ebola outbreak, on the findings of the report on preparedness and on the recommendations of the European Court of Auditors report on dealing with serious cross-border threats to health in the EU.

In 2016, in addition to usual activities, Commission services, in particular DG SANTE, had to coordinate the response to the ***Zika virus*** epidemic, between EU Member States involving expertise from the ECDC, the WHO and the Global Health Security Initiative. DG SANTE provided information to travellers and healthcare professionals and organised workshops with medical associations and the tourism sector to explore needs and to explain the EU activities. DG SANTE also organised a specific workshop on vector (mosquito) control with experts from Member States to assess the state of preparedness in this critical field.

Financial contribution to tackling serious cross-border health threats

In 2016, the Health Programme committed EUR 4,33 million on serious cross-border health threats. In total five grants and contracts were signed which focus on:

- Capacity building against health threats in Member States
- Training programme for first-line health professionals, border officers and trainers working at local level working with migrants and refugees.

In relation to ***HIV/AIDS, viral hepatitis and tuberculosis***, a new Joint Action was announced in 2016 under the EU Health Programme, with foreseen EU co-funding of EUR 2 million, on quality of prevention and linkage to care across these three diseases. This Joint Action is in addition to the on-going Joint Action on prevention and harm reduction and the existing projects on early diagnosis and integrated care of hepatitis and tuberculosis.

2. Managing and isolating outbreaks of major animal diseases

One of the EU's most important tasks in animal health policy is to ensure it can rapidly react to, isolate and eradicate outbreaks of major animal disease and mitigate any consequences for animal health and trade in animals or animal products. This is essential for public health, for the EU's food industry and to limit the significant economic impact of any emergencies and disease outbreaks.

Diseases control is carried out under fully harmonised EU veterinary legislation based on specific disease control Directives.

Preparedness is built on harmonised activities at EU level, such as awareness-raising, surveillance, contingency plans, simulation exercises and harmonisation of diagnosis by the EU Reference Laboratories (EURLs). These actions are managed by DG SANTE.

Concerning ***crisis management***, DG SANTE operates together with the Member States using legislative and non-legislative instruments, mainly: 1) the Animal Disease Notification System, an IT tool managed by DG SANTE; 2) Commission Decisions on the interim (within 24-48h) and definitive safeguard protective measures; 3) the Community Veterinary Emergency Team managed by DG SANTE and networks of animal diseases EURLs which provide immediate technical and scientific support; 4) Commission Decisions on regionalisation to separate infected and disease free areas enabling safe trade; and 5) mobilisation of the EU vaccine banks managed by DG SANTE.

Traceability of live animals is a necessary element of disease control applied uniformly across the EU through specific provisions for each animal species based on legislation managed and updated by DG SANTE.

In 2016, there were ***outbreaks of several major epidemic animal diseases***: African swine fever (in Lithuania, Estonia, Latvia and Poland), lumpy skin disease (in Greece and Bulgaria, affecting also neighbouring non EU Member countries like Serbia , Kosovo, the former Yugoslav Republic of Macedonia, Albania and Montenegro), highly pathogenic avian influenza (Hungary, Poland, Germany, Austria, Denmark, the Netherlands, Sweden, Romania, France, Bulgaria, the United Kingdom, Slovakia, Italy) and Bluetongue (spreading from North Africa and affecting mainly Greece, Italy, Spain, France, Portugal, Slovenia, Croatia and Austria). The management of all these outbreaks required quick detection, control measures, and a coordinated response at EU level to prevent uncontrollable spread and substantial damages.

Major progress in this area was marked with the adoption of a new ***Animal Health Regulation*** (Regulation (EU) 2016/429 of 9 March 2016) and a new ***Animal Breeding Regulation*** (Regulation (EU) 2016/1012 of 8 June 2016). These laws introduce a simpler and more modern framework and will contribute to competitive and sustainable growth within the European livestock sector.

The number of restrictions in the EU caused by outbreaks of major epidemic animal diseases totalled 217 in 2016. This marked an increase compared to previous years mainly due to further spread of African swine fever in wild boar and to the avian influenza (HPAI H5N8) epidemic (**result indicator 1.1.C** of SANTE's Strategic Plan 2016-2020).

There has been a slight improvement of the **result indicator 1.1.D** of SANTE's Strategic Plan 2016-2020 which shows the level of containment of major epidemic animal diseases in the EU after initial outbreak. The situation for foot and mouth disease and classical swine fever remained excellent; for African swine fever and Newcastle disease good with disease containment and minimum spread; while for avian influenza 2016 saw wide disease spread due to multiple virus introductions from wild birds leading to further spread to poultry.

These indicators reflect the effectiveness of Member States – with help and coordination from the Commission – in stopping the spread of epidemic diseases among livestock holdings. Successful disease evolution depends on Member States effectively implementing EU disease control rules and stakeholders properly complying with them.

Financial contribution to sanitary (animal health) measures

EU support for animal disease eradication, control and monitoring programmes aims to progressively eliminate animal diseases and/or implement disease monitoring measures across the EU. It accounts for the largest proportion of spending under the EU's food safety budget.

In 2016, around EUR 160 million was allocated to ***national veterinary programmes*** targeting transmissible and often epidemic animal diseases. The EU also provided co-funding worth around EUR 23 million for ***emergency measures*** to contain animal disease outbreaks quickly.

DG SANTE supported Member States and non-EU countries with the initial response to the lumpy skin disease outbreak providing vaccines form the European ***vaccine bank*** and coordinating vaccination campaigns in all affected countries plus Croatia's preventive vaccination exercise which proved crucial in containing the disease.

In 2016, the ***European Court of Auditors*** published a special report on animal disease eradication and monitoring programmes. All recommendations of the report referred to actions that were already on-going. DG SANTE plans to complete the action plan in response to these recommendations by late 2017. Please see point 2.1.2 for more information on the European Court of Auditors' report.

3. Preventing plant diseases

Globalisation of the plant trade together with climate change have substantially increased the risk of plant pest infestation. Early detection and control is essential to mitigate the trade and economic consequences.

A new ***Plant Health Regulation*** (Regulation (EU) No 2016/2031) entered into force in December 2016 and will become applicable in December 2019. The Regulation introduces a more pro-active approach towards detecting and eradicating plant pests in the Union territory and strengthening rules on imports to prevent the entry into the EU of pests from non-EU countries.

It is based on the assumption that more resources should be allocated at an early stage to avoid much higher costs caused by the devastating damage inflicted by plant pests at a later stage. In this regard, the new Regulation increases the level of responsibility for competent authorities and professional operators; introduces prioritisation of the most risky plant pests which will be subject to stricter provisions; and harmonises and simplifies rules on certification of traded plants to ensure transparency and traceability. It

also sets out more detailed principles on risk assessment and risk management to facilitate a science-based and proportional approach against phytosanitary threats.

Preparatory work also began for the relevant delegated and implementing acts, due to be adopted in the period 2017 to 2019 (e.g. adoption of common formats for plant passports, lists of priority pests, high risk plants and plants to be excepted from phytosanitary certificates for import).

DG SANTE stimulates Member States to do more surveillance and indicates the priorities for surveillance activities by co-financing ***national survey programmes*** which are designed to detect and eradicate priority plant pests on EU territory. Amongst the pests surveyed, pinewood nematode, Xylella fastidiosa, potato diseases (potato brown rot, ring rot and wart disease), Asian lon g horn beetles and citrus greening were the most represented in 2016.

22 programmes were implemented in 2016, bringing the total percentage of EU territory covered by surveys to 90%. This is ahead of the 2017 milestone - 70% - set in **result indicator 1.1.E** of SANTE's Strategic Plan. In 2016, the surveys for pests considered to be most dangerous covered the entire EU territory as targeted in the milestone of **result indicator 1.1 F** of SANTE's Strategic Plan.

Emergency measures were issued or updated as appropriate to control outbreaks of harmful organisms within the EU. More specifically, emergency measures against *Xylella fastidiosa* were updated based on the European Food Safety Authority's (EFSA) input and following new findings reported in Italy, France, Germany and Spain. Moreover, at the request of the Court of Italy for preliminary ruling, the European Court of Justice determined that those measures are justified by the available scientific evidence.

Additionally, as follow-up to the recommendations of the Commission's Task Force on Pine Wood Nematode, the Commission initiated the review process of the respective EU emergency measures. As regards Epitrix, the EU emergency measure was strengthened to ensure effective protection.

Import measures were also introduced for certain non-EU countries, or updated for other non-EU countries, to prevent the entry into the EU of citrus blackspot (measures currently cover Brazil, South Africa and Uruguay).

Following the withdrawal in 2015 of the ***proposal on plant reproductive material***, in 2016, DG SANTE focused on the implementation of the existing legislation (12 Directives) to ensure that Member States achieve the objectives of that legislation.

On ***innovative solutions in seed production***, the legislation was amended for new fodder seed mixtures. New innovative plant varieties were also supported by simplifying and modernising the procedures for variety protection (with regards to intellectual rights). The Commission's new Forest Reproductive Material Information System (FOREMATIS) became publicly available, providing a search tool functioning as a repository of planted forest tree species.

Member States took an average of 49 days in 2016 to notify the Commission of pest outbreaks which is higher than 2015 baseline of 42 days (**result indicator 1.1 G** of SANTE's Strategic Plan 2016-2020). However, the situation should improve gradually as in addition to the EUROPHYT interceptions system, a new electronic system to report pest outbreaks (EUROPHYT Outbreaks) became available to Member States in January 2017 to streamline the transmission of the necessary information. This will help to progressively reduce the time taken to notify and to work towards the 2020 target of 8 days . However, it is unlikely that the 2017 milestone of 20 days will be achieved. In a longer term it will also help to record the data on eradication of pests and contribute to the increase in the eradication success rate. In 2016, the nominal success rate was only 8,4% mainly because with paper reporting the Member States were not updating the status of an outbreak (SANTE's Strategic Plan 2016-2020, **result indicator 1.1 H**).

Financial contribution for plant health measures

National survey programmes for organisms harmful to plants ensure early detection and eradication of pest outbreaks. This is a new funding activity in the food and feed area introduced under Regulation (EU) No 652/2014. The budget for the implementation of the plant health survey programmes in 2016 was EUR 11,4 million.

In 2016, DG SANTE spent EUR 8,5 million on ***pest outbreaks***. Amongst the outbreaks, Asian long horn beetles, pinewood nematode and *Xylella fastidiosa* were those most co-financed by the EU.

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

Tables with result indicators and outputs are included in Annex 12.

The EU's food safety policy ensures consumer confidence in this sector and good functioning of the internal market Food and animal feed throughout the EU is subject to a well-developed legal framework that protects and promotes a high level of safety and quality and encourages free trade, investment and innovation.

In 2016, DG SANTE worked on a number of priorities to deliver safe and sustainable food and feed production systems in the EU.

Modernising and simplifying EU legislation

"Better regulation" is an important part of DG SANTE's work. Regular evaluation and updating of the EU's rules for food and feed production is essential to ensure the framework continues to provide a high level of consumer protection whilst simultaneously encouraging growth and innovation within this very valuable economic sector.

In this respect, a roadmap for an ***evaluation on plant protection products and pesticides residues*** was completed in 2016. The results of the evaluation are expected in late 2018 or early 2019. The roadmap for an ***evaluation on nutrition and health claims*** was published in March 2016 and the study supporting the evaluation is expected to be completed in mid-2017.

Future ***evaluation of the feed additives authorisation system*** was developed with the aim of this being finalised in 2018.

DG SANTE's activities on Better Regulation are described in more details in point 2.2.2.

Food labelling

Following the adoption of a series of reports, DG SANTE worked in 2016 on an implementing act on ***food labelling concerning voluntary origin indications*** (Article 26(3) of the Regulation (EU) No 1169/2011 on the provision of food information to consumers). The implementing act will be adopted in 2017 and will be beneficial in terms of supporting consumer choice and good functioning of the Internal Market.

In order to facilitate the harmonised interpretation and application of this Regulation, DG SANTE prepared, during the course of 2016, a ***Questions and Answers document***, a Guidance document on allergen labelling and a Guidance document on quantitative ingredients' indication. These documents are to be finalised in the first half of 2017 following more extensive consultations than originally foreseen with other Commission services. These documents will provide support for a more harmonised application of the current rules benefiting the Internal Market.

To help food businesses, in particular SMEs, to identify mandatory labelling requirements when they place foods on the EU market, DG SANTE also worked on a user friendly ***IT tool for all mandatory EU and national labelling requirements*** for specific categories of foods, as part of the Better Regulation agenda. The tool should become operational in the fourth quarter of 2017.

DG SANTE also worked on a report about applying a mandatory indication of the list of ingredients and a nutrition declaration on ***alcoholic drinks***, which are currently exempted under Regulation 1169/2011. In the report, the Commission is requesting the sectors concerned to develop, within a year, a self-regulatory concerted proposal to provide the list of ingredients and nutrition information on all alcoholic beverages enabling consumers to make informed choices.

Foods for specific groups

DG SANTE continued working on the implementation of Regulation (EU) No 609/2013 on foods for specific groups (FSG). Two Delegated Regulations, for ***infant and follow-on formula***, ***and food for special medical purposes*** were adopted in 2016. The European Parliament objected to a Delegated Regulation on cereal-based food and baby food. A new draft will be prepared taking into account scientific opinions to be issued by EFSA. The preparatory work is ongoing on a draft Delegated Regulation on total diet replacement for weight control. The adoption of that act was delayed due to the necessity to assess thoroughly a number of technical concerns raised by the industry with regards to the minimum content of certain nutrients that are recommended by EFSA in its relevant opinion.

Two reports analysing whether specific rules are needed for "***follow-on milks" for young children (1-3 years)*** (also known as "young-child formulae") and ***"sports foods"*** to ensure a high level of consumer protection and effective functioning of the internal market were published.

Novel food

In 2016, DG SANTE started preparation of the implementing and delegated acts necessary to allow full implementation of the new ***Regulation on Novel Foods*** (Regulation (EC) 2015/2283) – published in 2015 – which will enter into force on 1 January 2018. This legislation aims to improve efficiency and transparency of the safety evaluation and authorisation procedure, promote innovation and allow a faster and more proportionate safety assessment for traditional foods from non-EU countries with a history of safe food use.

Result indicator 1.2.C of SANTE's Strategic Plan 2016-2020 focuses on DG SANTE's compliance rate with its legal obligations to complete delegated and implementing acts identified as a priority under the new Regulation on novel foods. This allows DG SANTE to measure whether the EU, within the limits of its competences, has fully satisfied its legal obligations to regulate this priority area. In 2016, this rate did not change from 0/0 in 2015 as only preparatory works were done on these obligatory legal acts in view of their adoption in the course of 2017.

Preventing food waste and promoting the Circular Economy

DG SANTE was engaged together with DG ENV and DG GROW in the negotiations on the revision of the Waste Framework Directive with respect to food waste and continued to implement the Circular Economy Action Plan on the prevention of food waste. In June 2016, the Council adopted the ***conclusions on food losses and waste***, supporting the current EU initiatives and urging the Commission to better integrate prevention of food waste and valorisation of biomass in the future examination of EU policies.

In August 2016, DG SANTE established a ***new EU Platform on Food Losses and Food Waste***, bringing together Member States, international organisations and actors in the

food chain, which met for the first time on 29 November 2016. The Platform will help to define the measures needed to prevent food waste, share best practice and evaluate progress over time, thereby supporting all players towards achieving the Sustainable Development Goal of halving food waste by 2030. This initiative is an important part of the Circular Economy package and helps to promote a more sustainable food chain with resulting economic and environmental gains as well as improved food security through the facilitation of food donation. DG SANTE also started work on a guidance document on food donation as well as guidance on how to use food which is safe but cannot be marketed for human consumption for other purposes, for example as a resource for animal feed. It also started work on a methodology, which will illustrate which materials may be quantified as "food waste. These documents will be finalised in 2017. The preliminary elements of a study to better understand the impact of date marking on food waste were also defined.

Market access for safe substances

DG SANTE continued to assess, and where relevant authorise, a range of substances used in food and feed production throughout 2016 to ensure their safety. This helps protect consumer health and supports an efficient internal market in these products.

In 2016, DG SANTE authorised a number of substances (food flavourings, food and feed additives, substances under the Regulation on plastic food contact materials, substances for use in biocidal products, and substances for use in plant protection products), based on applications from food business operators and on safety evaluations carried out by the EU agencies (EFSA, ECHA). Moreover, DG SANTE set Maximum Residue Limits (MRLs) for 86 pesticides and reviewed MRLs for 39 pesticides.

In 2016, DG SANTE proposed the withdrawal or non-approval/non-renewal of certain substances for food use (i.e. pesticides, biocides, food and feed additives) to ensure products circulating on the internal market are safe and of high quality.

In addition, DG SANTE drafted a measure on the use of bisphenol A (BPA) in food contact materials, including a migration limit for plastics as well as coatings, based on the EFSA opinion to harmonise the use of this substance in the EU. This measure is expected to be adopted in 2017.

DG SANTE continued to modernise the authorisation IT system to improve information exchange with EFSA, allow authorities and applicants to save time, improve transparency and make better use of resources. This makes an important contribution to **result indicator 1.2 B** on the compliance rate with legal deadlines for the presentation of a regulatory decision on the approval of food additives (89% in 2016) and on the approval of pesticides (81.5% in 2016).

In 2016, DG SANTE completed the modernisation of the Catalogue of feed materials which improves feed safety and market transparency and improved many dietetic feed specifications.

Genetically Modified Organisms

DG SANTE continued to implement the legislative framework on GMOs by processing the pending ***GM food and feed and cultivation applications***. Authorisations are valid throughout the EU and issued only after scientific evaluation on the risks that the GM food or feed may present for human and animal health and for the environment. In 2016, 11 new GMOs were authorised. In addition, discussion started with the Members States in the regulatory committees on the proposals to authorise two GMOs for cultivation and renew the existing authorisation for cultivation.

Furthermore DG SANTE focussed on three key areas: (1) implementing the newly adopted GM cultivation legislation for authorisations with restricted scopes; (2) contributing to discussions on the possibility for Member States to take account of

national concerns on GMOs; and (3) updating the requirements for environmental risk assessment of GMOs.

On ***emerging techniques in biotechnology***, DG SANTE mandated the Commission's Scientific Advice Mechanism to provide a state-of-the-art explanatory note on these new techniques. The results will be available in 2017 and will feed into a broader debate on modern biotechnology

DG SANTE's initiatives in GMOs area aim to ensure protection of human and animal health and environment and at the same time foster responsible and safe innovation in agriculture contributing to one of the Europe 2020 flagship initiative - An industrial policy for the globalisation era, and in particular, to the investments in innovation pillar.

Sustainable use of pesticides

DG SANTE continued to work with Member States on the implementation of the Directive on the sustainable use of pesticides (2009/128/EC) to reduce risks and impacts of pesticide use and promote the use of integrated pest management and alternative approaches or techniques.

The Expert Group on Sustainable Plant Protection, chaired and facilitated by DG SANTE, presented a report identifying short and long term actions to increase the availability of low-risk plant protection products and accelerate the implementation of Integrated Pest Management in Member States.

DG SANTE decided to delay the ***report on the sustainable use of pesticides*** in 2016, so as to merge it with a report to be published in autumn 2017 summarising the results of the ongoing Survey under the Directive and the results of the series of fact-finding missions to six Member States (March to June 2017) to give a more comprehensive picture.

Endocrine disruptors

DG SANTE has taken actions in response to the serious reputational event of late 2015, when the General Court ruled against the Commission for having failed to set criteria to identify endocrine disruptors (reported in 2015 AAR). Based on the Impact Assessment finalised in 2016, the Commission endorsed ***two draft legal acts establishing the scientific criteria for identifying endocrine disruptors*** as required by the legislation on plant protection products and on biocides. The draft acts are now undergoing adoption processes and were discussed four times in 2016 with Member State experts in addition to being subject to consultation with non-EU countries via the World Trade Organisation (WTO) notification system and with stakeholders.

In order to allow for a smooth implementation of the criteria, DG SANTE mandated in 2016 EFSA and ECHA to develop a joint ***guidance document*** for implementing the criteria. A draft of the guidance is expected to be ready for public consultation as soon as the new criteria are adopted.

For more information on DG SANTE’s critical risk in relation to endocrine disruptors please see point 2.1.3.

Bee guidance document

To ensure that pesticides do not harm the environment, including bees, DG SANTE, together with Member States and EFSA worked on the Guidance Document on bees which aims to improve the current scheme to assess the risk to bees. . Member States were not able to endorse the Guidance document in a consensual procedure at the Standing Committee. The Commission is now considering next step, including adoption of the Guidance Document as a Commission Notice.

Food fraud

DG SANTE established synergies between various networks including the Food Fraud/Administrative Assistance and Cooperation, the Rapid Alert System for Food and Feed (RASFF) and the Trade Control and Expert System (TRACES) to optimise use of existing resources and to enhance efficient detection and coordination of food fraud. DG SANTE coordinated its work on food fraud with other DGs, EUROJUST and INTERPOL to ensure better cooperation with police and justice authorities. DG SANTE coordinated more than 160 food fraud cases in 2016 including a number of large cases (e.g. misuse of additives in fresh fish).

Food hygiene

Human diseases linked with the food/feed chain can seriously affect consumer health and jeopardise confidence in food safety across the EU single market. While it is up to Member States to take control measures against foodborne pathogens, a coordinated EU response is needed in cases of high-profile, multinational outbreaks. DG SANTE plays a key role in this respect. The audits it performed in 2016 (see specific objective 1.6) also assessed contingency planning in Member States for food-borne emergencies and promoted the constant improvement of control systems.

DG SANTE measures successful intervention in this area by the reduction in the number of cases of diseases in humans in the EU linked to food safety or zoonoses (**result indicator 1.2.A** of SANTE's Strategic Plan 2016-2020). In 2015, there were 94625 confirmed cases of human salmonellosis, representing a 5% increase compared to 2012 baseline. It is too early to conclude whether this shows a change in trend, whether the number of cases is stabilising, or if it is accidental. This needs to be assessed against the data collected in the forthcoming years.

Animal welfare

Following calls from several Member States, the European Parliament and stakeholders, DG SANTE worked towards the establishment of an **EU Platform on animal welfare**. The aim of the Platform is to increase stakeholder dialogue on animal welfare, improve the implementation and enforcement of existing legislation and exchange of information and best practices also with the view to promote the existing EU standards on the market and at global level. The first meeting, which will be chaired by DG SANTE, is foreseen for 6 June 2017.

DG SANTE also finalised several outstanding actions of the EU animal welfare strategy adopted in 2012, including a report on systems restraining bovine animals, EU guidelines on the protection of pigs, a report on the application of EU animal welfare rules at farm level and a report on broilers' genetic selection. At the same time, DG SANTE continued to promote EU animal welfare standards at global level and in the EU's free trade agreements.

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

Tables with result indicators and outputs are included in Annex 12.

Up to 70% health expenditure in the EU is spent on the treatment of preventable chronic diseases[18] caused by common risk factors including excessive alcohol consumption, smoking, poor nutrition and physical inactivity. Given population ageing and the corresponding increase in the prevalence of chronic diseases, without action, the cost of

[18] European Union Health Policy Forum, Answer to DG SANCO consultation on chronic diseases, 13 January 2012, page 7

healthcare is expected to double by 2050 with crippling economic consequences. Both the EU and the WHO have identified chronic disease prevention as a priority.

DG SANTE's action in this field includes support for the design and implementation of targeted initiatives in EU countries to promote good health, reduce health inequalities, prevent and manage chronic diseases and encourage best practice exchange. This creates the conditions for more cost-effective health promotion and disease prevention and in turn improves the sustainability of health systems and contribute to boosting jobs, growth and investment.

In 2016, around EUR 22 million were committed from the ***Health Programme*** to health promotion and disease prevention (22 grants and contracts), financing the following major activities: Joint Action on chronic diseases; projects in support to Member States and stakeholders to address the chronic disease challenge; exchanging best practice on measures reducing underage drinking and heavy episodic drinking; and the European Cancer Initiative on Breast Cancer Screening and Cancer Information System.

Assessment of CHAF-EA's work

The Health Programme is managed by the Commission with assistance from the ***Consumers, Health Agriculture and Food Executive Agency (CHAF-EA)***. CHAF-EA also manages the Better Training for Safer Food (BTSF) initiative under the financial framework for food safety, animal and plant health. Cooperation with CHAF-EA was reinforced in 2016 with the adoption of new sets of procedures under a specific Manual of Understanding agreed by all parent DGs (AGRI, JUST and GROW). The policy objectives were achieved thanks to the close collaboration with CHAF-EA and their high level of flexibility, within the limits of the EU financial Regulation. In times where EU was threatened with several animal and plant disease outbreaks, this flexibility has shown its merit in establishing quickly organised, tailor-made, very hands-on training programmes.

2016 was a challenging year for CHAF-EA, having to address differing timelines across different funding mechanisms. The Annual Work Programme (AWP) for 2015 was only adopted in June 2015 and amended again in October to take into consideration specific needs raised by the refugee crisis. As a result several procedures from 2015 were still running at the beginning of 2016, especially the direct grant agreements with international organisations; those with the competent authorities of the Member States (Joint Actions); and procurement procedures.

Conversely, other calls could only be launched at the very end of the year and were still on-going in the first quarter of 2017, such as the specific grant agreements with the European Reference Networks (ERNs) and the call for projects for rare disease registries.

Procurement procedures covering subjects mentioned in the respective work programmes were implemented by the Agency for all tenders for which the parent DGs provided input with regards to the definition of the requested service. For the year 2016, this translated in CHAF-EA launching 24 procurement procedures (22 from the AWP 2016 and 2 pending from the AWP 2015, i.e. 92 % of procedures foreseen). The Agency also signed 19 service contracts (9 from the AWP 2016 and 10 from the AWP 2015).

CHAF-EA also continued throughout the year to support the dissemination of Health Programme implementation results, using platforms of national, EU-wide and international events. The Agency's pop-up stand and dissemination material were present at more than 15 events of national or EU dimension.

In terms of monitoring of the Health Programme, CHAF-EA has introduced, within the IT project management system (COMPASS/SyGMa), a structured questionnaire comprising the Health Programme's indicators. However, only a very limited number of actions were reported as most contracts were signed only in 2015. Nevertheless, once the reporting "pipeline" becomes fully activated, CHAF-EA will be able to contribute to the Health Programme's monitoring scheme.

Chronic diseases

Specific actions in 2016 included:

- A conference on "the prevention and management of chronic diseases" in April 2016 and the first meeting of the Steering Committee on Promotion and Prevention in November 2016;
- The launch and development of Joint Actions with Member States on chronic diseases, rare cancers, dementia and frailty;
- Expert group meetings on cancer control, rare diseases and mental health and dementia, whose work was facilitated by the EU Health Policy IT Platform.

In 2015, 12 Member States had an integrated national plan to address chronic disease in place which implements the WHO non-communicable diseases (NCD) targets (no new data available in 2016) - **result indicator 1.3A**. Concerning the number of EU countries in which a European accreditation scheme for breast cancer services is implemented - **result indicator 1.3C** - in 2016, Member States have not yet implemented the scheme. This scheme is under development as part of the European Initiative on Breast Cancer, cooperation between Joint Research Center (JRC) and DG SANTE, and could be operational in 2017.

Health determinants, healthy diet and food reformulation

The work of the High Level Group on Nutrition and Physical Activity agreed on a ***methodology for monitoring national reformulation initiatives***, an essential step to promote the implementation of reformulation targets on added sugars but also on salt and saturated fat.

The Group, with the support of DG SANTE and the JRC and under the lead of the Maltese Presidency, also prepared the draft of a technical report on ***voluntary public procurement guidelines for food*** – an important tool to promote both healthy diets and the most progressive and innovative companies.

A revised work methodology was also agreed for the EU Platform for Action on Diet, Physical Activity and Health, ensuring the relevance, ambition and rigour of the commitments. Over 50 meetings took place with members of the Platform/stakeholders in 2016 to improve the commitments.

A ***report on the implementation of the Action Plan on Childhood Obesity*** was commissioned in 2016 to meet the request in the 2014 Council conclusions.

The ***Joint Action to Reduce Alcohol Related Harm*** (2014-2016) co-funded by the Commission came to an end in October 2016. As a follow up, the Committee on National Alcohol Policy and Action began to identify the areas that will best help Member States to tackle alcohol related harm. These will be developed into a framework tender contract for 2017-2020.

Result indicator 1.3B of SANTE's Strategic Plan 2016-2020 measures progress on the issues of healthy diet and food reformulation. In 2016, 1) 21 Member States had national initiatives on reduction of saturated fat (no change from 2015); 2) 23 Member States had national initiatives on reduction of salt (increase from 20 in 2105); 3) 20 Member States had national initiatives on reduction of sugar (no change from 2015); and 4) 23 Member States had national initiatives on reduction of alcohol-related harm (increase from 21 in 2105); with the target covering all Member States by 2020. Moreover, 15 Member States have specific initiatives on reduction of added sugars.

Transfats are an important risk factor in the development of heart disease. Yet they are present and consumed at unhealthy levels in certain foods and by certain population groups. In 2016, DG SANTE launched an inception impact assessment to see if setting a legal limit for industrially produced transfats would be the most effective measure to

protect consumers and public health and ensure the compatibility with the internal market. An inception impact assessment was published and a supporting study is under preparation to complement the data for the impact assessment analysis.

DG SANTE continued its work to discourage tobacco consumption. The deadline for Member States to transpose the new ***Tobacco Products Directive*** (2014/40/EU) was 20 May 2016. Ten Member States completed the transposition of the Directive by the deadline and further ten Member States by the end of 2016. The aim of this legislation is to contribute to better health, disease prevention and better functioning of the internal market in tobacco products.

In 2016, key activities included adoption of the implementing acts on the procedure for determining tobacco products with characterising flavours and on the establishment and operation of an advisory panel to help Member States and the Commission assess tobacco products with a potentially characterising flavour; adoption of a list of priority additives subject to enhanced reporting; adoption of an implementing act on technical standards for refillable cigarettes and a report on health risks of refillable electronic cigarettes. Preparations for the remaining implementing and delegated acts on measures against illicit trade are ongoing. A new IT reporting tool for tobacco and electronic cigarettes has been developed. In addition, Commission Decisions were adopted in 2016, allowing Finland and Austria to ban in their territory the sale of certain categories of smokeless tobacco products following their notifications under the Tobacco Products Directive.

SANTE also works closely with OLAF, the Commission's antifraud department to encourage ratification of the WHO's Framework Convention on Tobacco Control (FCTC) Illicit Trade Protocol.

A ***Joint Action on tobacco control*** financed by the Health Programme was launched in 2016 to ensure effective implementation and application of tobacco legislation. It will start its work in 2017.

Inequalities in health

Health is one of the priority topics in the Commission Action Plan for integration of migrants and refugees and is also present in all legislative proposals approved in 2016 in the area of migration.

During 2016, the Expert Group on Social Determinants and Health Inequalities defined the aims of a future Joint Action to tackle health inequalities and promote the responsiveness of health systems to the needs of migrants.

In 2016, four ***projects*** and one direct ***grant*** (with the International Organisation for Migration) providing support to Member States facing increased influx of migrants and refugees were launched. They aimed to support coordination, assessments, planning, access to healthcare and capacity building in Member States under particular migratory pressure, and to provide tools to assess health status and needs of migrants. A first series of training packages for health professionals and law enforcement officials to improve access and quality of health services for migrants were also finalised.

In addition, an agreement with the WHO for common guidelines and resources for training was signed at the end of 2016.

SANTE coordinated these actions with DG HOME and DG ECHO and in collaboration with NGOs and international organisations.

Non-food Scientific Committees

When preparing policy and proposals related to consumer safety, health and environment, DG SANTE and other Commission's departments rely on independent non-

food Scientific Committees to provide sound scientific advice and draw attention to emerging problems. The work of the Scientific Committees contributes to the Europe 2020 flagship initiative - Innovation Union.

The non-food Scientific Committees are managed by DG SANTE. Following reorganisation, two new Committees, the ***Scientific Committee on Consumer Safety*** (SCCS) and the ***Scientific Committee on Health, Environmental and Emerging Risks*** (SCHEER) began their 2016-2021 term in April 2016. The evaluation of the functioning of the Scientific Committees for the 2009-2015 period which was finalised in 2016 made several recommendations which were or are in the process of being implemented.

The Committees published 26 scientific opinions in 2016 linked to risk assessments in public health, consumer safety and environment to support the Commission's decision-making process, e.g. the opinion on tobacco additives by SCHEER looked at specific characteristics of a broad number of tobacco additives and thus provided useful input to DG SANTE in developing the implementing act on priority additives; and the opinion by SCHEER (requested by DG JUST and DG GROW) on biological effects of ultraviolet radiation, with particular reference to sunbeds, will feed into the discussion with Member States on the follow up measures at the EU level.

Country knowledge

The information on country knowledge has been moved to objective 1.4 as it is closely linked to the performance of healthcare systems in the EU.

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

Tables with result indicators and outputs are included in Annex 12.

Healthcare systems need to become more cost-effective, accessible and robust to be sustainable. This requires them to adapt to specific challenges and embrace and make full use of innovative new technologies for more cost-effective and flexible healthcare solutions. DG SANTE's work under this specific objective supports strategic, growth-friendly investment in healthcare, in parallel with necessary health system reforms to improve outcomes for individuals and enhance competitiveness of the economy.

Specific priorities addressed by SANTE in 2016 included:

Country knowledge

President Juncker requested in his mission letter to Commissioner Andriukaitis to develop expertise on health systems performance and to build country-specific and cross-country knowledge. The evidence gained will be used to support policies for cost-effective health promotion and disease prevention.

In response to this request, DG SANTE launched ***'State of Health in the EU***' initiative, which is a new two-year cycle of knowledge gathering and sharing that supports Member States in their evidence-based policy making by creating a means of mutual learning. In order to do so, DG SANTE has initiated a tripartite collaboration between the Commission, the OECD and the European Observatory on Health Systems and Policies.

2016 saw the launch of the first of four 'State of Health in the EU' products, namely the joint OECD-Commission report ***'Health at a Glance: Europe 2016'***. The report provides a comprehensive quantitative overview of the EU's health systems and public health, and offers a horizontal analysis across key issues that are aligned to DG SANTE's agenda of effectiveness, accessibility and resilience. In parallel, extensive preparation took place

regarding the remaining 'State of Health in the EU' products foreseen for 2017: a comprehensive pilot phase was conducted for the twenty-eight country health profiles, which are to focus on country-specific strengths and challenges, and plans were developed for the 2017 Staff Working Document that is to accompany the profiles.

To ensure that relevant EU-level health data is available to generate country knowledge, DG SANTE has also been working with Member States and the Expert Group on Health Information (EGHI), to improve the coordination of health information initiatives in the EU. This includes the BRIDGE Health project which concluded in 2016 with recommendations on how to streamline the generation of health information in the EU, making it more policy-relevant and less burdensome on Member States. DG SANTE will follow up by launching a ***Joint Action on Health Information*** to help Member States put in place the core elements of a future Member States-led European Research Infrastructure Consortium on Health Information.

The new ***EU Health Policy Platform*** was launched in April 2016 and had its first meeting in December 2016. The Platform improves the interaction and exchange of information between the Commission and its health interest groups. It also promotes the work of the Commission's expert and stakeholder groups in the field of health. In the cycle April - December 2016, the EU Health Policy Platform's interest groups successfully delivered four joint statements on mental health, health inequalities, public health workforce and patient safety.

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

Antimicrobial resistance (AMR)

AMR is a major global challenge with serious implications for the economy and human health. Each year, drug resistant infections cause at least 25,000 deaths in the EU and an estimated EUR 1.5 billion worth of healthcare and productivity losses in the EU.[19] Unless tough action is taken, it will continue to have a significant negative impact on health, jobs, growth and investments.

Council conclusions in June 2016 called for reinforced EU measures to combat AMR, including a new and comprehensive EU Action Plan on AMR based on the "one-health" approach. In September 2016, a political declaration was agreed at the ***UN*** General Assembly, committing to a coordinated, multi-sectoral approach to AMR. An ***evaluation of the first EU Action Plan on AMR*** (2011-2016) was finalised in 2016 recognising that continued action was necessary and identifying room for improvement in several areas. To address these calls for action, the Commission published in October 2016 a roadmap for a ***new One-Health Action Plan*** to support Member States in the fight against AMR. This new Plan is planned for adoption in 2017. DG SANTE also started preparations for the "One-Health" network, which will gather Member States' experts on AMR from the human, the veterinary and the environment sectors. The first meeting of the network is to take place in February 2017.

In 2016, the European Parliament adopted its two reports on the Commission's ***proposals on veterinary medicinal products*** and on ***medicated feed*** legislation. In the Council, the discussions continued in the Working Party. These proposals are critically important in the fight against AMR as they introduce a comprehensive set of provisions aiming to minimize the risk to public and animal health arising from the use of antimicrobials in the sector including incentives for development of new antimicrobials.

[19] ECDC/EMA (2009), Joint technical report: ''The bacterial challenge, time to react''. Stockholm: European Centre for Disease Prevention and Control.

DG SANTE continued to contribute to the discussions in the Council and is promoting quick adoption of the proposals.

EFSA, ECDC and EMA continued to make an important contribution to SANTE's work in this area, collecting, analysing and reporting key data on AMR and antimicrobial consumption. In February 2016, EFSA and ECDC published their annual report on AMR in zoonotic and indicator bacteria from humans, animals and food. In October 2016, EMA published the sixth annual report on the sales of veterinary antimicrobials in EU/EEA countries (ESVAC project). These reports inform antimicrobial policy and the responsible use of antimicrobials.

In 2016, work on a pilot project on the prudent use of antimicrobials in human medicine was also completed and ECDC prepared **EU guidelines for prudent use of antimicrobials in human health** to support Member States when developing and implementing national strategies to promote the prudent use of antimicrobials and good practices by healthcare professionals**.** The aim is adopt these guidelines as a Commission Notice in 2017. EMA continued its work to increase the availability of antimicrobials and alternatives..

This work should contribute to a decline in overall EU consumption of antibiotics in humans which is measured by the **result indicator 1.4.B** of SANTE Strategic Plan 2016-2020. In 2015 the EU consumption of antibiotics in humans increased slightly in comparison with the baseline in 2013. However overall there was no statistically significant trend in EU antimicrobial consumption during the period 2011-2015.

Finally, a Joint Action was announced in 2016 under the Health Programme to develop and support best practice exchange on AMR and healthcare-associated infections in 2017-2020.

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

DG SANTE continued to monitor the proper transposition of the Directive on the application of patients' rights in cross-border healthcare[20] to ensure its correct implementation. In addition, work on the Directive focussed on improving Member State cooperation on regional cross-border care, data exchange, better information to patients and healthcare provision via established National Contact Points and the European Reference Networks. This was advanced by the Conference "Towards amplified awareness of EU rights to cross-border care" in October 2016, with Member States and stakeholders.

Innovative health technologies

Five priorities, of which four DG SANTE is responsible for, were included into the ***Digital Single Market*** work in 2016: (1) exchange of health data across Member States, (2) deployment of telemedicine within the European Reference Networks, (3) electronic access of patients to their health data, (4) mHealth (DG CNECT lead) and (5) digitalisation of the pharmaceuticals chain.

DG SANTE continued to work on a new ***Digital Service Infrastructure (DSI)*** financed under the Connecting Europe Facility (CEF), creating the basis for cross-border exchange of patient summary and ePrescription service and increasing access to health services cross-border. This included developing the technical EU level capability needed by Member States and agreements signed at the end of 2016 with 16 countries to set up the ***National Contact Points for eHealth***. These activities contribute to one of the Europe 2020 flagship initiatives - Digital agenda for Europe, in particular to the pillar on ICT-enabled benefits for EU society.

[20] Directive 2011/24/EU of 9 March 2011, Official Journal of the EU, L88/45, 4 April 2011

In 2016, 10 Member States reported the capacity for health data exchange and participated in cross-border eHealth information services (**result indicator 1.4.A** of SANTE's Strategic Plan 2016-2020) – up from 5 Member States in 2015.

The ***Joint Action supporting the eHealth Network*** (JAseHN) focussed its activities in 2016 on improving the interoperability of health systems for exchanging health data supporting cross-border healthcare, in line with building the eHealth DSI. The Joint Action updated the cross-border healthcare guidelines for ePrescriptions and patient summaries. It continued to also work on an agreement between Member States to exchange health data which is expected to be ready in 2017.

Blood, tissues, cells and organs

The supply of blood, tissues, cells and organs is crucial for the EU healthcare systems to support essential and often life-saving treatments and allow many patients to regain or retain an active and productive life.

EU legislation on safety and quality for blood dates from 2002 and for tissues and cells from 2004. Much progress and innovation has taken place since in this dynamic sector. In 2016, the Commission published ***implementation reports*** on the legislations, as well as an economic study on tissues and cells sector and a survey on implementation of national safety (testing) measures. To follow-up on possible issues, an ***evaluation of EU law on blood, tissues and cells*** was launched at the end of 2016. Its results are expected by the end of 2018.

In the organs sector, in 2016 DG SANTE launched a ***study on the impact of the EU Organ Action Plan*** that ran from 2009 to 2015 and initiated two pilot projects from the European Parliament.

In 2016, DG SANTE further strengthened existing EU safety and quality frameworks by developing a preparedness plan to avoid Zika transmission through the blood/transplant systems, by launching an IT-platform to ensure traceability of tissues and cells and by adopting, in collaboration with the Council of Europe, up-to-date guidelines for good blood practices.

Financial contribution from Health Programme

In 2016, the Health Programme committed 11 new grants and contracts were established for EUR 5,32 million related to objective 1.4.

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

Tables with result indicators and outputs are included in Annex 12.

Access to expertise and information on rare and chronic diseases

Databases/registries at European level dedicated to certain diseases have a clear EU added value. They allow health care professionals across Europe to improve their knowledge of these diseases, researchers and academics to develop new treatment and therapies, and patients to find reliable, up-to-date information.

Around 30-35 million EU citizens live with a rare disorder, for which knowledge is often scarce and unevenly distributed. Freely accessible for everyone ***Orphanet database,*** which is co-financed by the Health Programme, provides information about 6 000 rare diseases, including guidance on diagnosis and care. Support for the development and maintenance of the Orphanet database is measured by number of data requests from the

database (**result indicator 1.5B** of SANTE's Strategic Plan 2016-2020). To date, the number of pages viewed per day increased from 90 thousand in 2015 to around 130 thousand in 2016 and the number of diseases annotated with prevalence or incidence data increased from 4726 in 2015 to 5329 in 2016.

DG SANTE continued to manage the ***European Platform on Rare Diseases Registration*** which plays a key role addressing the fragmentation and sustainability of data on rare diseases. The number of stakeholders included in the Platform increased from 39 in 2015 to 56 in 2016. The size of the EU population covered by surveillance networks increased from 30% of EU birth population, approximately 1.5 million people in 2015, to 34% of birth population, approximately 1,8 million people - **result indicator 1.5C**.

DG SANTE also continued to cooperate with national and regional authorities through the ***European Network of Cancer Registries*** (ENCR), the only European repository for epidemiological data for cancers. Nothing similar exists for any other chronic diseases and to date, more than 100 cancer registries from 29 countries are now connected under the Network. To further improve data access and calculations for cancer survival rates, the ENCR and JRC organised a call for data in 2016 calling on all the European Cancer Registries to build a unique ***database of cancer data***. As a result, 7 Cancer Registries are participating and a second call for data will be launched in 2017.

European Reference Networks (ERNs)

Via ERNs, DG SANTE promotes greater access to medical expertise for rare and complex medical conditions, bringing together highly specialised healthcare providers from different EU Member States in areas where a concentration of knowledge and resources is needed. They represent one of the most important and innovative cross-European cooperation initiatives in healthcare, providing important economies of scale and a more efficient use of increasingly stretched EU healthcare resources.

In 2016, DG SANTE provided strong funding, coordination and support to the ERN process to ensure its success in collaboration with other key Commission departments (RTD, CNECT, JRC, EAC) and the Member States. By the end of the year, ***23 ERNs were established*** (**result indicator 1.5A** of SANTE's Strategic Plan 2016-2020). The contract to set up the basic IT structure serving the Networks was signed in December 2016. A framework partnership agreement was drawn up with the ERNs to ensure that over the next five years, they will reinforce their capacities, improve the diagnosis and clinical outcomes of patients and to contribute to the efficiency of the national healthcare systems.

Medicinal Products

DG SANTE continued to work on the assessment report on current shortcomings in the ***summary of product characteristics*** (SmPC) and the ***package leaflet*** (PIL) for medicinal products (as required under Directive 2001/83/EC) suggesting improvements to better meet the needs of patients and healthcare professionals. The report should be adopted in the first quarter of 2017.

Orphan medicinal products are intended for diagnosis, prevention or treatment of life-threatening or very serious rare diseases or disorders. In 2016, DG SANTE looked into streamlining the regulatory framework on orphan medicinal products (Regulation (EC) No 141/2000), working on the revision of the 2003 Communication on orphan medicinal products to adapt it to technical progress and provide interpretative guidance to applicants. The new ***Commission Notice*** was published on 18 November 2016. It covers especially topics related to the designation of a medicinal product as an orphan development and/or orphan medicinal product.

DG SANTE also worked on the ***revision of Commission Implementing Regulation*** 847/2000 on orphan medicinal products - certain definitions in the Regulation needed to

be adapted to technical and scientific progress due to major developments in the field of biological medicines, including advanced therapy medicinal products. This work should be finalised in the first semester of 2017. The adoption of the Regulation is delayed due to technical amendments for which more time is needed taking into account consultations with relevant stakeholders

Advanced Therapy Medicinal Products *(ATMP)* are innovative medicinal products based on cells or tissues and gene-therapy. The sector is represented by SMEs, small developers and university hospitals and characterised by a small-scale production.

To reduce administrative burden without compromising public health, in 2016, DG SANTE has been working on the development of ***guidelines on Good Manufacturing Practice specific to ATMPs***. The guidelines aim to improve the competitiveness of this sector and contribute to new innovative products that will benefit patients. In light of the complex nature of the topic and the relevance of the document, a decision was made to run a second stakeholder consultation. While the additional consultation confirmed the support of stakeholders for the initiative and was useful to refine the document, it also delayed the adoption by the Commission. The Guideline should be finalised in the first semester of 2017.

Financial contribution from Health Programme

In 2016, around EUR 12 million were committed from the Health Programme to finance seven new activities under the specific objective 1.5 which among others include ERNs and new rare diseases registries in the framework of ERNs.

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

Tables with result indicators and outputs are included in Annex 12

Audit and control activities

DG SANTE's audit and analysis work is crucial to ensure the effective and correct implementation and enforcement of EU legislation on food safety, animal health, animal welfare, plant health, some areas of human health and cross-cutting issues, notably antimicrobial resistance (AMR). These audits – which take place in EU countries and non-EU countries exporting to the EU – are essential to ensure our high standards and safety levels are not compromised and that the industry can operate on a level playing field. The results contribute to evidence-based policy development, better regulation and a regulatory environment which facilitates jobs, growth and investment.

In 2016, DG SANTE carried out ***208 audits, fact-finding missions and study visits*** in Member States, candidate countries and non-EU countries exporting to the EU, covering food safety and quality, animal health, animal welfare, plant health and AMR.

In addition, in the human health area DG SANTE conducted ***21 joint assessments of notified bodies in the medical devices sector*** in 2016. Since DG SANTE began this exercise in 2013, 29% of the notified bodies active in this area had to close due to non-conformities.

DG SANTE systematically follows up on actions taken by competent authorities in response to recommendations made in audit reports. In 2016, ***ten general follow-up audits and five administrative desk-based follow-ups*** were performed. From the 3-year reporting cycle 2012-2014, 79% of DG SANTE's audit recommendations were satisfactorily addressed by the Member States at the end of 2016 (**result indicator 1.6.A** of SANTE's Strategic Plan 2016-2020). The desired results and expected outcomes

of audits and best practice identification and dissemination depend strongly on the willingness and vigour of Member States and non-EU country authorities to act.

The follow-up work also serves to update *"**country profiles"*** on each Member State which summarise the state-of-play on their performance in the field of official controls and provide country-specific knowledge, which ensures that transparency of the state of enforcement in each and every Member State.

In addition to individual audit reports, DG SANTE produces ***overview reports*** which summarise the outcome of its audits and analysis work. These reports are also the basis for discussion with Member States of common problems and best practices to share. Eight of such overview reports were published on DG SANTE's website in 2016.

In 2016, DG SANTE worked on a ***report on the operation of official controls*** in the Member States on food safety, animal health and animal welfare and plant health, which is expected to be adopted in March 2017, later than originally planned due to the need for extensive consultation. This report provides an overview of the delivery of official controls in the Member States based on their annual official control reports and controls carried out by the Commission.

Other major activities in 2016 to improve the performance of control systems included: meetings of networks of Member State officials responsible for the multi-annual national control plans; the evaluation of facilities of Border Inspection Posts*;* the evaluation of Member States' and non-EU countries' residue monitoring plans; the management of lists of approved non-EU country establishments for food of animal origin; and the operation of the European Union Notification System for Plant Health Interceptions (EUROPHYT).

Modernising and simplifying EU legislation

Political agreement was reached in June 2016 on the revision of the ***Official Control Regulation***, creating a single framework for all official controls along the entire agri-food chain and strengthening, modernising, harmonising and simplifying the system. The Regulation is expected to be formally adopted before the summer 2017.

The new Regulation addresses most of the recommendations made by the ***European Court of Auditors*** in its 2016 follow-up audit of overview reports on meat imports (2010) and slaughterhouses (2012). In this respect, the new Regulation foresees smarter rules for the enforcement of agri-food legislation; establishes a fully integrated system of border checks; and provides for the independence, quality and accountability of the enforcement actors in the Member States, thus improving the transparency of official controls. For more information on the European Court of Auditors' audit report please see point 2.1.2.

Use of digital technologies to strengthen official controls

DG SANTE continued working on standards to align all electronic transactions from farm to fork, including digitalisation of animal and plant health certificates, laboratory tests, animal identifications, tracking and tracing and alert management.

Integration" was the key word for 2016: the management of IT systems, the Rapid Alert System for Food and Feed (RASFF) and the Administrative Assistance and Cooperation (in relation to food fraud), has been allocated to the same team, resulting in better business flow integration and in a great simplification for our counterparts in the Member States.

The TRAde Control and Expert System ***(TRACES)*** continued to grow in term of geographical usage (***10 more non-EU countries*** are now using it for their imports to the EU) as well as in scope (the use of TRACES for plants has now reached 100.000 certificates per year).

Integration between the IT systems now allows border inspectors to report directly any issue from TRACES to RASFF or EUROPHYT from their TRACES main tool. This represents a very important simplification for the 36.000 users of the system.

The improved links between existing networks also contributed to enhanced and more efficient detection and coordination of food fraud.

In 2016, DG SANTE also proposed to the United Nations Centre for Trade Facilitation and Electronic Business (UN/CEFACT) to standardise electronic exchanges in the context of RASFF. Moreover, DG SANTE was active in the international reflection on electronic certifications in the Codex Committee on Food Import and Export Certification and Inspection (CCFICS) and the Standards and Trade Development Facility (STDF) forums hosted by the WTO.

DG SANTE started discussions with the Member States authorities on how to strengthen official controls of ***food traded via the Internet***, a growing market. Expert meetings and consultations served to identify subjects which can be better dealt with at EU level (coordinated control programs, single contact points of platforms and market places for authorities, administrative assistance of non-EU country authorities).

Financial contribution to official controls related activities

All official control activities carried out in 2016 aimed to enhance the EU's ability to detect violations of food chain requirements and strengthen Member States' capacity to ensure cross-border enforcement. These activities include:

The ***European Reference Laboratories (EURLs)*** supported implementation of EU legislation in the agri-food chain via their state of the art analytical and diagnostic services to national competent authorities and enforcers. ***Funding for 43 EURLs*** was granted in 2016. This helped to maintain the efficiency of the network, capitalise on existing knowledge and maintain the same high level of food safety in the EU. The budget for the EURLs for 2016 was close to EUR 16 million.

The ***Better Training for Safer Food programme (BTSF)*** continued to play a key role in improving the efficiency and reliability of official controls in 2016 and in spreading knowledge and awareness of EU legislation. ***Around 200 training courses*** were carried out for Member States' competent authorities responsible for official controls. More than 10 training activities were also performed for non-EU countries' competent authorities with a view to create the conditions for a level playing field for EU food businesses and to build confidence in the EU regulatory model. The budget for BTSF for 2016, managed by DG SANTE's executive agency CHAF-EA, was EUR 15.5 million.

1.1.7 Specific objective 1.7: Increased EU influence in international fora

Tables with result indicators and outputs are included in Annex 12.

DG SANTE worked closely with its global partners in WTO, WHO, the Codex Alimentarius Commission, the World Organisation for Animal Health (OIE), and the International Plant Protection Convention (IPPC) to ensure its standards were recognised, accepted and promoted at bilateral and multilateral level. This contributes to a high level of health protection as well as growth and employment opportunities in the EU's food and pharmaceutical sectors.

DG SANTE contributed to the Commission-wide efforts to achieve the ***Sustainable Development Goals (SDG)***, in particular highlighting the importance of the health goal (SDG3) and its contribution to shaping a sustainable economy, improving labour market

participation and productivity; and the goal to halve food waste (*SDG 12)* by 2030 (please refer to specific objective 1.2 on SANTE's action to tackle food waste).

Public health

Increased EU influence in global health fora

DG SANTE and the EU Delegation in Geneva continued their efforts to facilitate coordinated EU inputs and positions on topics discussed in ***WHO Governing Bodies***. In 2016, coordinated EU inputs were reflected in 80% of WHO Executive Board's resolutions negotiated, 77% World Health Assembly's resolutions negotiated and 90% WHO Regional Committee for Europe's resolutions negotiated - an increase in comparison to the respective data for 2014 (**result indicator 1.7A** of SANTE's Strategic Plan 2016-2020). DG SANTE participated in three WHO Governing Bodies' meetings in 2016.

On tobacco, the EU is a member of the ***WHO Framework Convention on Tobacco Control (FCTC)***. In 2016, it ratified the FCTC Protocol to Eliminate Illicit Trade in Tobacco Products. FCTC Parties, including DG SANTE, met in November 2016 for the Conference of the Parties (COP) - the governing body of the WHO FCTC. It reviewed the implementation of the Convention and took the necessary decisions to promote its effective implementation, including a decision on how to intensify the work of the Panel of Experts on Illicit Trade to ensure that work on tracking and tracing is taken forward.

To contribute to global efforts to tackle the threat of AMR, DG SANTE collaborated with international partners (see section 1.1.4) in working towards the objectives of the ***WHO Global Action Plan on AMR***.

DG SANTE also reinforced its cooperation with the ***OECD*** with a new cooperation arrangement agreed in 2016.

Increased international harmonisation in pharmaceutical products

The EU is a global leader in the pharmaceutical industry and the world's major trader in pharmaceutical products - amounting to over EUR 170 billion in 2013[21].

The work of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) - of which the Commission is one of the founding regulatory members - plays an essential role in promoting the EU position.

In 2016, DG SANTE represented the Commission in managing the ***reform of the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use*** (ICH) and promoting membership in non-member countries. The European Medicines Agency (EMA) also contributed in the development of ***new ICH guidelines***. Increased harmonisation through the adoption of ICH guidelines facilitates access to multiple markets, including those of US, Switzerland and Japan that are currently the three most important export markets for the EU. The accession of Brazil and Korea in 2016 was a great success paving the way for additional regulatory members.

Result indicator 1.7.B of SANTE's Strategic Plan 2016-2020 monitors the recognition of ICH guidelines at global level and global harmonisation. In 2016, regulatory authorities from two new countries (Brazil and South Korea) and three international industry associations joined ICH as Members. 12 ICH guidelines were implemented by new ICH members in 2016 compared to 26 in 2015. In terms of new or revised ICH guidelines or Questions and Answers (Q&As) which provide additional implementation advice on ICH

[21] EUROSTAT Statistics Explained, International trade in medicinal and pharmaceutical products, http://ec.europa.eu/eurostat/statistics-explained/index.php/International_trade_in_medicinal_and_pharmaceutical_products

guidelines, six revised guidelines and five Q&As were adopted in 2016 (compared to one revised guideline and three Q&As in 2015). These fluctuations in the annual output depend on the speed at which each Working Group is progressing which is closely related to the complexity of the topic.

Animal health, plant health and food safety

As the largest exporter and importer of agri-food in the world with a well-recognised and respected framework for food safety legislation[22], the EU must ensure its standards are aligned globally to guarantee its competitive position is not compromised.

DG SANTE continued to promote EU's safety and quality standards and contributed to global governance based on EU values and a high level of protection.

International Standard-Setting Bodies

DG SANTE represented the EU at meetings of the ***IPPC, OIE and Codex Alimentarius,*** promoting and defending EU interests and ensuring that international standards are as closely aligned as possible with EU standards.

In 2016, DG SANTE contributed to work on a number of important files including:

- dispute settlement cases in IPPC;
- limiting the adoption of standards that authorise the use of substances banned in the EU; and
- building strategic partnerships and alliances with non-EU countries.

Codex Alimentarius Commission

In 2016, DG SANTE, in close cooperation with Member States, represented the EU in 13 Codex Committee meetings and in the Codex Alimentarius Commission where 31 Codex standards were adopted. In addition, with the EU as strong proponent, the Codex Alimentarius Commission agreed to establish an Intergovernmental ***Task Force on Antimicrobial Resistance*** that will update the 2005 Code of Practice to Minimise and Contain Antimicrobial Resistance and develop Guidance on Integrated Surveillance of Antimicrobial Resistance.

As part of its continuous targeted capacity building activities, DG SANTE held a training workshop under BTSF on Codex activities for Latin American countries that was attended by 23 countries. In January 2016, the EU committed to provide a financial contribution to the Codex Trust Fund of EUR 700 000 and intends to provide an additional contribution of EUR 150 000 specifically for scientific evaluations of pesticides residues used to establish Codex Maximum Residue Levels (MRLs). These two contributions that are made for the period 2017-2019 enable DG SANTE to be a core supporter of Codex Alimentarius activities.

WTO SPS Agreement

In 2016, DG SANTE continued to represent the EU at meetings of the ***WTO SPS Committee***. The EU position was prepared in cooperation with Member States through the expert group on SPS chaired by DG SANTE.

Other work linked to specific files included information sessions organised by DG SANTE in the margins of the SPS Committee on the new novel foods Regulation and the proposed EU criteria for defining endocrine disruptors. DG SANTE also submitted proposals to the SPS Committee to enhance the implementation of the transparency

[22] Monitoring Agri-trade Policy, MAP 2016– 1, 'Agri-food trade in 2015: China boosts EU exports', EUROSTAT, http://ec.europa.eu/agriculture/sites/agriculture/files/trade-analysis/map/2016-1_en.pdf

provisions of the SPS Agreement.

DG SANTE contributed to the ongoing ***dispute settlement case raised by the EU against the Russian measures on African swine fever***. The panel issued a report which was to a large extent favourable for the EU. The case is not yet closed as appeal procedures are ongoing.

DG SANTE continued to strive for alignment between international and EU standards and reduce EU exposure to dispute settlements. In 2016 the number of Specific Trade Concerns (STCs) raised by WTO Members against the EU in the SPS Committee was 8 (**result indicator 1.7.C** of SANTE Strategic Plan 2016-2020). There was no change with respect to the baseline year 2014 (8 cases). However, it should be noted that, while the overall number of STCs in 2016 was 8, only two of these were actually new cases, which can be regarded as a positive development.

Improving bilateral trade relations

Bilateral trade negotiations are directly linked to multiple Commission priorities, in particular priority 1 on jobs, growth and investment.

While growth is influenced by various factors, access to foreign markets is critical for the EU economy and heavily conditioned by SPS requirements which often act as barriers. DG SANTE aimed in 2016 to negotiate and maintain fair and lawful export conditions and trade facilitation measures with non-EU countries.

The main activities involved negotiating safe, secure and harmonised export conditions for EU products with non-EU countries and managing, monitoring and implementing existing agreements.

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

The table with impact indicators is included in Annex 12.

Progress under this objective is measured via the contribution of the health sector to the Commission's **impact indicator 2.1** on **the Gross Value Added (GVA) of EU industry in GDP**.

As regards specific data monitored by DG SANTE, GVA of the EU health sector (human health activities) in GDP remained stable since 2009 and oscillates around 4,7% (Table 1 in Annex 12).

SANTE will also monitor its contribution to the Commission's **impact indicator 2.2** measuring the **intra-EU trade in goods as a percentage of GDP** which aims to increase by 2020.

As regards specific data monitored by DG SANTE, the data for intra-EU trade in food (and live animals) as a % of GDP show a steady increase since 2008 reaching almost 1,9% in 2013 and remaining at the same level since (Table 2 in Annex 12). This demonstrates a well-functioning food internal market due to clear and harmonised rules being applied and adhered to across the EU by operators and authorities and being recognised as both proportionate and efficient.

The increase in intra-EU export/import in live animals and food products is expected to continue, in 2015 reaching respectively EUR 275,5 billion and EUR 271.5 billion (Table 4 in Annex 12). This trend will be further supported by ongoing efforts to reduce administrative burden in the sector.

The trust created by harmonised legislation regulating food safety in the EU goes beyond EU borders as figures show. In 2015, both intra-EU exports/imports and extra-EU export/import in food were growing. Intra-EU exports/imports grew respectively by 4,4% and 5% in 2015 and extra-EU export/import respectively by 4% and 10,3% (Tables 3 and 4 in Annex 1). The increase in intra-EU trade shows that the internal market works well whereas the increase in extra-EU trade in food is the result of the recognition of the EU's high standards. The EU brand is known for its quality, especially on foods which thus win markets despite higher production costs in Europe.

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

Food and feed safety is ensured in the EU by a wide range of harmonised rules (e.g. the recently adopted Regulations on official controls, plant health, animal health and novel foods), as well as by EU authorisations for products and substances used in the food chain, such as food/feed additives, pesticides or GMOs (please refer to objective 1.2). This framework helps the internal market run smoothly, providing legal certainty to business operators, supporting the free circulation of food/feed products and giving consumers across the EU access to safe and quality food products.

EFSA and EMA made an important contribution to DG SANTE's internal market priorities and policy making process in 2016. EMA recommended 81 human medicines and 11 veterinary medicines for marketing authorisation by the Commission. This includes 27 new active substances for human use and 6 new active substances for veterinary use. Many of these medicines represent therapeutic innovations that have the potential to make a difference to people's lives across the EU. EMA gives also scientific advice to companies on the appropriate tests and studies in the development of innovative medicines. In 2016 a new scheme PRIME (PRIority MEdicines) was launched by EMA to

enhance support for the development of innovative medicines that target unmet medical needs.

DG SANTE worked towards an enhanced cooperation between EFSA and ECHA on the classification of chemical substances. The absence of harmonised classification can have negative impact on the protection of human health and the environment in the EU. This close collaboration is very important for the proper implementation of EU legislation pertaining to pesticides, such as glyphosate for example.

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

Tables with result indicators and outputs are included in Annex 12.

Health Technology Assessment (HTA) presents information on a health technology, pharmaceutical product, medical device or health intervention in a systematic and unbiased manner to inform decision-makers on its safe and effective use. It is an important tool to achieve best outcome and value for money for patients, health professionals and health systems. HTA supports innovative technologies which bring added value, and provides stimulus for innovation and growth in the pharmaceutical and medical devices sectors.

The Single Market Strategy and the 2015 and 2016 Commission Work Programmes called for a Commission proposal to reduce fragmentation and duplication in the internal market through further cooperation and mutual recognition in the HTA procedures carried out by Member States. DG SANTE prepared the inception impact assessment on a new HTA initiative, launching a public consultation in October 2016. This will feed into a ***new Commission initiative on HTA*** anticipated in 2017.

The **result indicator 2.1** of SANTE's Strategic Plan 2016-2020 shows the number of joint HTA reports which were reflected in national measures. These reports include joint EU rapid assessments of pharmaceutical products and medical devices at the time of licensing, joint reassessments of the same technologies after some years, early dialogues and scientific advice. They depend on the will and resources of Member States to engage in joint work and produce national reports, and of the individual companies carrying out the assessments.

The Joint Action EUnetHTA 2, funded by the Commission Health Programme, ended in March 2016 and delivered 15 Joint Reports (more than the 12 planned). Most Reports were reused in national HTA activities, in particular 15 national adaptations were reported, showing an increase from the baseline scenario (2 reports were reflected in national measures in 2012). It should be however noted that that "national adaptations" vary from very minor changes to reflect the national context to major changes resulting in re-using only small parts of the Joint Reports. As the third Joint Action on HTA ***(EUnetHTA 3)*** started working only at the end of 2016, no Joint Reports were produced in 2016. Nevertheless it is expected that the Joint Action will meet the interim 2018 milestone, possibly with some delay.

In 2016, the Health Programme committed EUR 0,36 million on activities related to Health Technology Assessment.

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

Tables with result indicators and outputs are included in Annex 12.

A vibrant EU pharmaceutical sector is essential to achieve a high level of public health protection and a competitive knowledge-based economy. The EU legal framework for medicinal products for human use guarantees high quality and safety standards for medicinal products and promotes measures which encourage innovation and competiveness in Europe.

The European pharmaceutical sector is still very active, despite the costs-containing efforts of Member States and the gradual migration of economic and research activities from the EU to fast-growing markets, such as India, China and Brazil.

According to the estimates of the European Federation of Pharmaceutical Industries and Associations (EFPIA) the pharmaceutical sector in Europe (including Switzerland, Russia and Turkey) was worth EUR 225 billion in 2015, compared to EUR 220 billion in 2014 and employed about 725,000 people. In the same year, EFPIA indicates a positive trade balance of EUR 87 billion and EUR 32 billion spending on research and development.[23]

In 2016, the third Health Programme committed EUR 2.79 million to 9 new activities related to objective 2.2.

In 2016, SANTE focussed on the following priorities:

Improving access to innovative medicines

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

In 2016, DG SANTE started working on initiatives addressing the Council conclusions: a study and ***report on the Paediatric Regulation*** and – together with DG GROW – a ***study analysing the impact of Supplementary Protection Certificates and pharmaceutical incentives and rewards*** (such as data and market protection, market exclusivity for orphan medicinal products, and paediatric rewards) on innovation, accessibility and availability of medicinal products.

In parallel the ***Expert Group on Safe and Timely Access to Medicines for Patients*** (STAMP) continued to work towards optimal use of existing regulatory tools to support innovation and to provide timely access of patients to innovative medicines (e.g. conditional marketing authorisation) and improve the application of other aspects of the regulatory framework.

A new scheme - ***PRIME (PRIority MEdicines)*** - to support companies and academia in particular SMEs, to develop promising new medicines to address unmet medical needs, was launched in 2016. PRIME will give developers of eligible products access to early dialogue and scientific advice from EMA to ensure that data generated during

[23] Source: http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf

development meets the standards required for regulatory approval. The scheme is expected to support a faster evaluation and authorisation procedure for eligible products ensuring they reach patients sooner.

Marketing authorisations of medicinal products

DG SANTE continued work linked to the authorisation of medicinal products, advance therapy medicinal products and particular aspects of the regulatory framework for orphan medicines. This makes an important contribution to a stable legal environment and optimal use of current authorisation procedures to ensure patients' access to safe medicines and a competitive EU pharmaceutical sector.

In 2016, 89% of new medicines were authorised within the legal deadline which is an increase compared to 85% in 2014. For Commission Decisions for which there was an accelerated assessment (1 out of 8 Commission decisions), 87.5% of medicines were authorised within the legal deadline which is a decrease in relation to 100% in 2014. This decrease relates to procedural steps that are not under the control of the Commission. DG SANTE will continue to work with EMA to meet the 90% and 100% targets for 2017 (**result indicator 2.2** of the SANTE Strategic Plan 2016-2002).

Tertiary legislation to support the new EU clinical trials Regulation and falsified medicines Directive

In 2016 DG SANTE made major progress in preparation of legal obligations stemming from the new clinical trials Regulation[24] and the falsified medicines Directive[25]. This includes the preparation of a Commission delegated Regulation on good manufacturing practices (GMP) for investigational medicinal products for human use, a Commission Directive on GMP for finished products and a Commission implementing Regulation on the detailed arrangements for Good Clinical Practice inspection procedures. Once adopted in early 2017, they will ensure reliable data generation during clinical trials, high quality medicines, correct inter-play with the new data protection Regulation and legal certainty for pharmaceutical companies. DG SANTE has also followed-up, in cooperation with EMA and the Member States, the development of the ***clinical trials portal*** which should be audited in 2018.

DG SANTE made good progress with the Member States and stakeholders to prepare for the implementation of the ***safety features on prescription medicines*** by 2019 and in particular the successful setting up of repository systems.

[24] Regulation (EU) No 536/2014 of 16 April 2014, Official Journal of the EU, L 158/1, 27 May 2014
[25] Directive 2011/62/EU of 8 June 2011, L 174/74, 1 July 2011

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

Tables with result indicators and outputs are included in Annex 12.

In parallel to its work on country-specific knowledge ('State of health in the EU'), DG SANTE increased expertise on the performance of health systems in the EU to identify tools and methodologies that will contribute to better and more accessible healthcare and more efficient and more resilient healthcare systems.

An important part of this is the work done in the ***Commission expert group on Health Systems Performance Assessment (HSPA)***, set up and co-chaired by DG SANTE. In 2016, the expert group focussed on defining the indicators and tools to assess performance, such as quality and access to care.

In 2016, Italy and Slovenia asked the Commission to organise seminars of the HSPA expert group with the aim of using their findings to inform national policy making. These events were officially reported on the websites of their Ministries of Health. The activity of tailored cooperation with Member States will continue in 2017 and is expected to lead to the production of national policy documents referring to the recommendations and findings of the expert group on HSPA (**result indicator 2.3A** of DG SANTE Strategic Plan 2016-2020).

For information on country-specific knowledge ('State of health in the EU') pleases refer to the specific objective 1.4.

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

The table with impact indicators is included in Annex 12.

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

In 2016, DG SANTE worked closely with other Commission departments, Member States and export industries to tackle SPS barriers to trade and to improve market access to non-EU countries.

DG SANTE measures its contribution to the Commission's **impact indicator 3.1 - 'Share US in total EU FDI stocks'** by comparison of data for sectors which are under SANTE policies, namely pharmaceuticals and food. Table 5 (in Annex 12) illustrates that in 2014, as much as 58,7% of the total Foreign Direct Investments (FDIs) in agri-food sector in the EU were from the US (slight decrease from 2013) and as much as 67,5% in pharmaceutical sector (10% decrease from 2013). On the other hand, 19,5% of the EU FDI in agri-food sector were invested in the US (slight increase from 2013) and 56.7% in the pharmaceutical sector (7% increase from 2013). The data show favourable development for the EU which increased its FDIs in both agri-food sector and in pharmaceutical sector.

DG SANTE also measures its contribution to the free trade agreement with the US by looking at the trend in the ***share of US trade in food and live animals of the total EU-extra trade in food and live animals***. This share has been steadily increasing since 2011 (see Table 6 in Annex 12). In 2015 it reached 8,4%. Concluding balanced negotiations on TTIP and making exchange easier between the two sides of the Atlantic would likely contribute to further increases.

DG SANTE also measures its contribution to the free trade agreement with the US by looking at the ***number of inspections on Good Manufacturing Practices (GMP) for pharmaceutical products***. The US conducted 248 GMP inspections in the EU in 2015 and 212 in 2016. DG SANTE would aim at a further decrease in the number of inspections once the mutual recognition of these inspections enters into force. The mutual recognition agreement with the US would allow the EU (with all Member States inspectorates recognised as a single entity) and the US to rely on each other's GMP inspections and exchange confidential information on inspection reports. This would entail significant cost savings for industry and would lead to a better use of respective inspection resources by avoiding the current overlap of inspections carried out by the authorities of different EU, US and non-EU countries.

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

Tables with result indicators and outputs are included in Annex 12.

Public health

In 2016, DG SANTE performed an in-depth assessment of the US regulatory system for pharmaceutical products and confirmed the equivalence of standards. Based on this work, the Commission is working towards finalisation of the mutual recognition agreement on pharmaceuticals with the US.

Animal health, plant health and food safety

A decrease in the number of trade "irritants" on the US side is one of the EU's main aims under the TTIP negotiations. Currently, the EU is excluded either wholly or partially from many important US agri-food markets due to SPS barriers affecting a number of key EU agricultural products including beef, sheep and goatmeat, pasteurised dairy products, egg products, apples and pears. A strong, ambitious SPS Chapter within the TTIP negotiations would very much be in the EU's interest.

2016 was a good year in the negotiation of the SPS Chapter of TTIP. Considerable consolidation of text was done and a reasonable number of provisions were agreed with the US. These included some areas of importance to the EU, such as import checks and audits and equivalence. Some of the more difficult areas for each side have not been agreed and are still to be discussed.

To reduce the number of trade barriers that are not in line with international standards (**result indicator 3.1.B** of DG SANTE Strategic Plan 2016-2020), the Commission continued to negotiate with the US administration to achieve SPS import conditions compatible with international standards that would allow EU products to have access to the US market. In 2016, approximately the same number of barriers overall were in place as for 2015.

Concerning the **result indicator 3.1.A** of DG SANTE Strategic Plan 2016-2020, in 2016, the US market has still not been opened for apples and pears. This is entirely due to delays within the US administration. It was planned to open the market in 2017, but this is not clear due to changes in the US administration. Three Member States are now listed to export beef to the US, up from two in 2015. Two Member States can export egg products, up from one in 2015. It should be noted that given the change in US administration and particularly the expected attitude of the new administration, ambitions for 2017 are at best moderate.

2. ORGANISATIONAL MANAGEMENT AND INTERNAL CONTROL

This section answers to the question *how* the achievements described in the previous section were delivered by the DG. This section is divided in two subsections.

The first subsection reports the control results and all other relevant information that support management's assurance on the achievement of the financial management and internal control objectives. It includes any additional information necessary to establish that the available evidence is reliable, complete and comprehensive; appropriately covering all activities, programmes and management modes relevant for the DG.

The second subsection deals with the other components of organisational management: human resources, better regulation principles, information management and external communication.

2.1 Financial management and internal control

Assurance is an objective examination of evidence for the purpose of providing an assessment of the effectiveness of risk management, control and governance processes.

This examination is carried out by management, who monitors the functioning of the internal control systems on a continuous basis, and by internal and external auditors. Its results are explicitly documented and reported to the Director-General. The reports produced are:

- Annual reports on budget implementation drafted by the Authorising Officers by Sub-delegation;
- Reports of the central financial cell on the results of the second-level ex-ante controls, and of the Public Procurement Committee ("Comité des Marchés Publics" - CMP) on ex-ante controls of public procurement procedures;
- Audit reports and the annual activity report of the on-the spot controls;
- Report of the Internal Control Coordinator on the annual assessment of the implementation of the internal control standards;
- Audit reports of the Commission's Internal Audit Service (IAS) and its annual conclusion on the state of control in DG SANTE;
- Observations and recommendations reported by the European Court of Auditors.
- Reports from Authorising Officers in other DGs responsible for managing budget appropriations in cross-delegation;
- Reports on control results from the Consumers, Health, Agriculture and Food Executive Agency (CHAF-EA);
- Reports on control results from EU decentralised agencies.

These reports result from a systematic analysis of the evidence available. This approach provides sufficient guarantees as to the completeness and reliability of the information reported and results in a complete coverage of the budget delegated to the Director-General of DG SANTE.

This section reports the control results and other relevant elements that support management's assurance. It is structured into (a) Control results, (b) Audit observations and recommendations, (c) Effectiveness of the internal control system, and resulting in (d) Conclusions as regards assurance.

2.1.1 Control results

This section reports and assesses the elements identified by management that support the assurance on the achievement of the internal control objectives[26]. The DG's assurance building and materiality criteria are outlined in the AAR Annex 4. Annex 5 outlines the main risks together with the control processes aimed to mitigate them and the indicators used to measure the performance of the control systems.

In 2016, DG SANTE managed financial operations under two policy areas, Public Health and Food and Feed Safety, under direct management, mainly through grants and procurement. In addition, DG SANTE paid subsidies to agencies.

Table 2.1 DG SANTE's budget of 2016[27]

Type of expenditure	**Operational budget, implemented by (M€)**				**Total (M€)**	**Error rate Ex-post**
Policy area	**CHAF-EA** ("entrusted" entity")	**Other DGs** (cross-delegation)	**DG SANTE** Operational credits	**DG SANTE** Administrative support		(detected estimated)
Food and Feed	15,4	0,0	235,7	1,3	**252,4**	
Public Health	49,7	0,0	11,0	1,4	**62,1**	
Other	-	-	0,3	-	**0,3**	
Subtotal			***247,0***	***2,7***		
Sub-total programmes	***65,1***	***0,0***	***249,7***		***314,8***	**0,6-0,9%**

Subsidy payments to agencies	**DG SANTE** Operational credits	**DG SANTE** Administrative budget	**Total (M€)**	
Executive agency (CHAF-EA) operating budget	-	5,5-	5,5	Around 0%
EU agencies' operating budgets	155,7	-	155,7	Around 0%
Sub-total agencies	***161,2***		***161,2***	
TOTAL operational budget SANTE	**410,9**		**476,0**	Around 0%

Administrative expenditure	**DG SANTE** Operational credits	**DG SANTE** Administrative budget		
Global envelope for administration	-	6,1	6,1	n/a
Building expenditure Ireland, et al.	-	5,3	5,3	Around 0%
Sub-total administrative budget	**-**	***11,4***	***11,4***	
TOTAL budget (commitments)	**422,3**		**487,4**	

EC balance sheet category	**DG SANTE (M€)**	
Assets – inventories of vaccines and antigen stocks for animal diseases	***12,1***	***n/a***

[26] Effectiveness, efficiency and economy of operations; reliability of reporting; safeguarding of assets and information; prevention, detection, correction and follow-up of fraud and irregularities; and adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments (FR Art 32).

[27] Commitments made on the basis of the final available credits taking into account EFTA credits, budget amendments and/or budget transfers. Comparison to Annex 3: (a) Annex 3 shows the subsidies to EU agencies of EUR 154,8 million under "Public Health"; and EUR 0,9 million under "Food and Feed""; (b) Annex 3 includes the subsidies to CHAF-EA of EUR 5,5 million and the administrative support credits on operational budget lines of EUR 2,7 million in "administrative expenditure".

Table 2.1 above shows DG SANTE's budget implementation through direct centralised management (no intermediaries) and through entrusted entities as follows:

- In the policy area Food and Feed Safety, DG SANTE implemented its budget to a large extent through direct grants to Member States based mainly on the co-financing of eligible costs. The main features of this management mode are explained in section 2.1.1.1 below and Annex 5.1.1 shows the corresponding internal control template.
- In the policy area Public Health, public procurement is the most important financial management instrument (see section 2.1.1.2 below for more detail and Annex 5.1.2 for the internal control template).
- DG SANTE implemented about 25% of its 2016 operational credits (EUR 65,1 million out of EUR 249,4 million) through entrusted entities, first and foremost by the Consumers, Health, Agriculture and Food Executive Agency (CHAF-EA). None of DG SANTE's commitment appropriations were implemented by authorising officers of other Directorates General (see section 2.1.1.3 below).
- DG SANTE paid subsidies to finance – partially or in full – the operating budgets of the executive agency, CHAF-EA, and a number of EU decentralised agencies (for more detail see section 2.1.1.3 below; Annex 5.2 shows the corresponding internal control template)
- The administrative support credits (EUR 2,7 million) on the operational budget lines are used mainly for meetings, conferences, IT and communication services. The global envelope (EUR 6,1 million) includes missions, meetings, committees, studies, IT (administrative tools only), training and credits for external staff. The administrative expenditure for Grange, Ireland, (EUR 5,3 million) relates to the office building in Grange which is managed directly by DG SANTE (not by OIB or OIL).
- In its balance sheet, DG SANTE identifies current assets (inventories) of a total value of EUR 12,1 million pertaining to vaccines stocks for animal diseases: food and mouth disease, classical swine fever and lumpy skin disease (see section 2.1.1.4 below).
- DG SANTE's best estimate of the detected error rate during ex-post controls is between 0,6% and 0,9%[28].

Regarding the EU funds managed directly by DG SANTE through grants and procurement, including the administrative related expenditure, DG SANTE can conclude that there are no major control weaknesses affecting assurance in terms of the five Internal Control Objectives. Neither were elements identified that could seriously damage the reputation of DG SANTE. Moreover, none of the issues raised by the auditors were critical or pointed to material deficiencies in the internal control systems of DG SANTE.

Cross sub-delegated authorising officers in other DGs and the Executive Agency, CHAF-EA, have reported reasonable assurance on the delegated budget managed by them on behalf of DG SANTE in 2016.

With regard to the subsidies paid to EU decentralised agencies, no serious control issues were signalled by these services. From the monitoring and supervision work done, which includes regular contacts at operational level as well as monitoring through the participation in the meetings of the agencies' Management Boards and relevant management and audit reports, there are no indications that their reporting would not be reliable.

The coverage of the Internal Control Objectives and their related main indicators are described in greater detail in the following subchapters:

[28] The range is to be understood as DG SANTE's best estimate calculated as the weighted average error rate between the detected error during ex-post controls in the Food and Feed policy area, and, in Public Health, the estimated most likely error of around 0% and the worst case error rate of just under 2%.

2.1.1.1 Control effectiveness as regards legality and regularity

DG SANTE has set up internal control processes aimed to ensure the adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the annual character of programmes as well as the nature of the payments concerned.

One of the key performance indicators of the control objective "legality and regularity" is the residual error rate of DG SANTE's ex-post controls. It should not exceed the materiality threshold of 2%; materiality is assessed in accordance with Annex 4.

In the context of the protection of the EU budget, at the Commission's corporate level, the DGs' estimated overall amounts at risk and their estimated future corrections are consolidated (see section 2.1.1.4 "Conclusion on legality and regularity").

2.1.1.1.1 Grants to Member States in the policy area Food and Feed Safety

In the policy area Food and Feed Safety, DG SANTE follows an integrated approach with the aim to ensure a high level of food safety, animal health, animal welfare and plant health within the European Union through coherent farm-to-fork measures and adequate monitoring.

Provisions for the management of expenditure for the policy area Food and Feed are set out in the Common Financial Framework (CFF)[30]. The years 2015 and 2016 marked the transition to the implementation of the CFF, i.e. the implementation of the national programmes since 2015 are based on grant decisions, while in 2016, some payments made for previous programmes or other veterinary and phytosanitary expenditure of the Member States were still based on the previous Council Decisions 2009/470/EC and 2000/29.

Table 2.2 Food and Feed Safety

Commitment credits implemented by DG SANTE *(without CHAF-EA)*	**2016 M€**	**2015 M€**	**2014 M€**
Animal disease eradication programmes (grants to Member States)	156,9	165,3	166,8
Veterinary emergency fund (grants to Member States)	20,0	16,4	6,9
Phytosanitary expenditure (grants to Member States)	17,1	7,6	5,9
Other veterinary and food-and-feed-safety expenditure (grants to Member States, EURL, etc)	19,1	28,2	31,8
Sub-total grants	**213,1**	**217,5**	**211,4**
Procurement	22,6	19,3	20,1
Other expenditure[29]	0,0	0,0	2,1
Administrative support credits	1,3	1,5	1,5
Total budget implemented	**237,0**	**238,3**	**235,1**

Direct financial contributions to Member States is by far (more than 80%) the most important budget implementation instrument. 28 Member States submitted 130 animal disease eradication and control programmes approved for implementation in 2016.

In addition, a total of 21 files for cost reimbursements were handled in relation to the veterinary emergency fund, to combat, for example, Lumpy Skin Disease (EUR 11,3 million), Avian Influenza (EUR 5,9 million), African Swine Fever (EUR 2,0 million) and Bluetongue (EUR 0,1 million). Other measures to contain animal disease outbreaks are

[29] In 2014, DG SANTE paid indemnities in response to damages claimed regarding a ban on imports of birds from non-EU countries 2005-2007.

[30] Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014

the purchase of vaccines stocks: in April 2016, an EU vaccine bank for Lumpy Skin Disease has been set up (amounts are included under procurement; see sections 2.1.1.2 and 2.1.1.4 below).

Addressing the combat of organisms harmful to plants, 22 Member States submitted their 2016 "pest survey programmes" of a total amount of EUR 11,4 million and 17 Member States submitted emergency plant health measures 2016 for EUR 5,7 million.

Other non-typical grants concern mostly the EUR 15,7 million funding of the European Reference Laboratories (EURL).

The 2016 commitment appropriations at the end of the year of EUR 237,0 million, and the 2016 payment credits of EUR 223,0 million, were each almost fully implemented.

The control process is divided into four distinct stages, each with specific control objectives. The description focuses on the national programmes for animal disease eradication and monitoring which account for around 74% of the grants in the Food and Feed policy are (see table 2.2 above). Other grants in the policy area Food and Feed Safety follow the same control procedures as far as applicable. Procurement procedures are described in part 2.1.1.1.2 below.

Stage 1: Programming and evaluating national programmes

In 2016, DG SANTE paved the way for the award of the 2017 animal disease eradication programmes of the Member States. In compliance with the Commission work programme[31] to implement the Common Financial Framework (CFF)[32], Member States submitted their 2017 disease eradication and control programmes by 31 May 2016. DG SANTE, assisted by external experts, evaluated the national programmes to ensure their good quality and their added value to achieve the policy objectives at reasonable costs. Of the 133 programmes submitted, 5 were rejected as they did not meet sufficiently the eligibility or award criteria as set out in the work programme.

At the programming and evaluation stage the key controls were mostly directive and preventive: application guidelines for the Member States, mandatory IT tool for electronic submission of applications; assessment of the technical quality and financial analysis of the national programmes; and selection of independent external evaluators. On the basis of the evaluation results, DG SANTE facilitated the Member States' finalisation of their programmes.

Stage 2: Approving national programmes and Grant Decision

On 18 January 2017, DG SANTE communicated the list of the 2017 national programmes technically approved and the final EU contribution allocated to each programme to the Standing Committee on Plants, Animals, Food and Feed (PAFF). On 27 January 2017 the authorising officer by delegation took the award decision. The corresponding grant decisions were signed by 31 January 2017. As a simplification measure, only one grant decision per Member State was taken, covering the eradication and control programmes for all diseases for each Member State. As in previous years, in 2016 the deadlines fixed in the legislation were respected allowing a timely launch of the 2017 programmes of the Member States.

[31] Commission Implementing Decision C(2015) 3024 of 30/04/2015 on the multiannual work programme for 2016-2017 for the implementation of veterinary programmes for animal diseases and zoonoses

[32] Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014

Table 2.3a) Indicators for grants	*Targets*	2016	2015	2014
Stage 1: Programming and evaluation				
Ratio of rejected national programmes to total programmes submitted: 5 out of 133 programmes for 2017 submitted in 2016 (11 out of 141 programmes for 2016 submitted in 2015)	*n/a*	4%	8%	8%
Ratio of modified programmes to total programmes retained after evaluation (in 2016: 92 out of 130; in 2015: 46 of 130)	*n/a*	70%	35%	79%
Stage 2: Grant Decision on the national programmes and EU funding				
Communication of the list of programmes to be funded by 30/11 in year N for programmes of year N+1 (Art. 13 of the CFF)	*100%*	100%	100%	100%
Grant decisions taken on-time by end of January year N+1 for programmes of year N+1 (Art. 13 of the CFF)	*100%*	100%	100%	100%

Stage 3: Monitoring national programmes and managing financial transactions

In 2016, DG SANTE monitored the implementation of the 2015 national programmes. Firstly, the progress made by the Member States was assessed on the basis of interim technical and financial reports. The objectives were (i) to ensure that the national programmes are implemented as planned and meet the objectives and conditions, and (ii) to increase the efficiency of the use of the credits. One of the results of the financial monitoring at the interim stage is the in-year redistribution of EU funds between the different national programmes.

Secondly, DG SANTE examined the Member States' final technical reports and checked the correctness of the final cost claims. The depth of control depended on a risk analysis. The controls took place prior to the processing of financial transactions by the operational and financial actors involved in DG SANTE's financial circuit (decentralised in the operational Unit, with counterweight on a sample basis ensured by the horizontal financial Unit: 2nd level control). The aim was to detect and correct errors before authorisation of a financial operation.

Thirdly, on the basis of a risk analysis, a sample of ex-ante financial controls was carried out on-the-spot, in the Member States, to verify cost claims that were assessed as being exposed to a relatively high risk of error. In 2016, this ex-ante "on-the-spot" control took place according to plan, and focused on the high risk areas as follows: (i) plant health surveys, as these are new projects; and (ii) veterinary emergency fund and plant health measures: commitments exceeding EUR 2 million or other exceptionally high amounts. In 2016, all mistakes found during ex-ante controls in Member States' cost claims were corrected prior to the authorisation of the payments.

Table 2.3b) Indicators for grants	*Targets*	2016	2015	2014
Stage 3: Monitoring and financial management				
Member States' interim reports received and analysed	*100%* *100%*	100% 100%	100% 100%	100% 100%
Number of registered **"exception reports"**	*n/a*	0	0	0
Instances of Article 66(2) FR	*n/a*	0	0	0
Percentage of implemented final **commitment** appropriations after global transfers[33]	*99%*	99,6%	100%	99%

[33] Annex 3 shows a commitment implementation rate of 98,4% in the Food and Feed Safety policy area as it includes the subsidies to ECHA (European Chemicals Agency) of EUR 0,9 million; see section 2.1.1.1.3.

Table 2.3b) Indicators for grants	*Targets*	2016	2015	2014
Percentage of implemented **payment** credits after global transfers[34]	*100%*	99,3%	100%	100%
Desk ex-ante 2nd-level verification coverage: % of transactions % of total amounts	*10%* *50%*	17% 70%	14% 75%	10% 55%
Desk ex-ante 2nd-level verification: rejection rate % of amounts with financial errors	*< 2% in value*	0,5%	0,0%	0,0%
On-the-spot ex-ante controls: **correction rate** *(average of all corrections)* - Eradication programmes - EU Reference Laboratories - Other veterinary expenditure - Veterinary emergency fund - Phytosanitary measures	*n/a*	 27,0% - - 20,1% 1,9%	 0,6% - - 27,8% 23,5%	 0,4% 4,8% 17,4% - -

Stage 4: Managing ex-post controls and error corrections for grants

Ex-post controls are carried out on a sample of payments DG SANTE made to the Member States on the basis of their cost declarations. The aim is to provide reasonable assurance on the legality and regularity of expenditure on an annual basis. A key indicator is the estimated residual risk of errors in payments with a materiality threshold of 2% (for more information on materiality see Annex 4).

The 2016 audit work plan was adopted by the Directors' Steering Committee of DG SANTE in March 2016. The aim was to optimise the control impact through a risk based selection of payment transactions to be audited and sufficient audit coverage to lower the residual error rate. Ex-post controls were carried out by DG SANTE's own competent staff, and by an external audit service provider, independent of the operational Directorates and according to professional standards.

The 2016 audit work plan included 20 audit missions of which 95% were carried out and only one audit visit had to be postponed to 2017. As this did not concern a significant file, the postponement had no impact on the assurance building capacity of the ex-post control function in 2016.

The errors detected during the ex-post controls finalised in 2016 resulted in an error rate of 1,2% (EUR 0,4 million) for the audited national programmes for animal disease eradication and monitoring for the years 2011 to 2014. The error rate detected in the Food and Feed policy area as a whole amounted to about 1,3% (EUR 0,5 million). The issues giving rise to corrections were common to a number of audited cost claims of Member States, and were due mainly to ineligible tests. Other corrections were made for ineligible animals, payments delays, errors in the calculation of staff costs, incorrect value of animals.

The residual error rate for 2016 was below 2% for food and feed safety policy, maintaining the downward trend from 2011.

About 72% of the errors detected in audits finalised in 2016 were already corrected in 2016 (EUR 0,4 million) by issuing recovery orders. After correction, the **residual error rate amounted to 1,1%** for the overall ABB activity Food and Feed Safety. This is well below the materiality threshold of 2% and confirms the overall downward trend from 2011. Therefore in 2016, no reservation to the declaration is warranted.

[34] Annex 3 shows a payment implementation rate of 98,0% in the Food and Feed Safety policy area as it includes the subsidies to ECHA (European Chemicals Agency) of EUR 0,9 million; see section 2.1.1.1.3.

Ex-post control in the Food and Feed policy area	2016	2015	2014	2013	2012	2011
Residual error rate	1,1%	1,2%	0,8%	2,3%	3,4%	4,3%

On 26 April 2016, the Court published its Special Report (SR 28/2016) on a performance audit on animal disease eradication programmes and drew overall positive conclusions on DG SANTE's management of the programmes (see section 2.1.2 point (2) below). All recommendations of the Court referred to actions that were already on-going; DG SANTE foresees to complete the action plan by late 2017.

In 2014/2015, DG SANTE's management of funds in veterinary programmes was also audited by DG SANTE's former internal audit capability (now transferred to the Commission's Internal Audit Service (IAS); see section 2.1.2). The auditors considered that in general, there are sufficient and adequate control mechanisms to ensure the sound management of funds for the veterinary programmes. In late 2016, the last two audit recommendations rated "very important" were being implemented, mainly by improving the documentation of the allocation and re-allocation exercises of the veterinary programmes for 2016 and for 2017. Only the finalisation of the IT tool and its full use were still on-going.

Table 2.3c) Indicators for grants	*Target*	2016	2015	2014
Stage 4: Ex-post controls				
Ex-post control **detected error rate** (ABB activity: Food and Feed Safety)	*n/a*	**1,3%**	1,7%	0,9%
Ex-post control **residual error rate** after correction (ABB activity: Food and Feed)	***< 2%***	**1,1%**	**1,2%**	**0,8%**
Amount of net financial corrections identified in year N compared with amount of transactions audited	*n/a*	**0,5 M€** 37,1 M€	**0,8 M€** 47,1 M€	**0,3 M€** 35,6 M€
Financial corrections in year N linked to audits finalised in year N (until March N+1)	*n/a*	0,4 M€ **72%**	0,72 M€ **91%**	0,07 M€ **22%** [35]
Total financial correction of detected errors	*100%*	0,4 M€ 72%[36]	0,75 M€ 95%[37]	0,3 M€ 100%

Conclusion on legality and regularity in grants

In conclusion, the analysis of the available control results, the assessment of the weaknesses identified and that of their relative impact on legality and regularity has not revealed any significant weakness which could have a material impact as regards the legality and regularity of the financial operations. It is possible to conclude that the control objectives as regards legality and regularity have been achieved.

DG SANTE's residual error rate amounts to 1,1% for the ABB activity "Food and Feed Safety" as a whole. Thus, it does not exceed the materiality threshold of 2% and confirms the overall downward trend observed since 2011: residual error rate: 4,3% (2011); 3,4% (2012); 2,3% (2013); 0,8% (2014); 1,2 (2015).

[35] In 2014; the low percentage of financial corrections was due to one audit that was finalised only in December 2014. The recovery process started in June 2015 and the amount was cashed in in late August 2015.

[36] In late March 2017, an amount of EUR 0,1 million was still in the process of being recovered.

[37] An amount of EUR 0,72 million was corrected already before March 2016; an amount of EUR 0,02 million was recovered in November 2016. Further correction of EUR 0,04 million will be made in 2017.

To reduce the error rate, in the past few years, DG SANTE has taken a series of mitigating actions; their cumulative effect has reduced the error rate to an acceptable level.

The audit samples are taken on the basis of a risk analysis rather than following a statistical random selection. Thus, DG SANTE calculates an average error rate rather than a statistically representative one. The detected error rate in the non-representative sample, however, is considered a sufficiently reliable source of information in the assurance building process because, in the last four years, around 50% of the payments made relative to animal disease eradication programmes have been subject to on-the-spot controls, and most of the findings were systemic.

2.1.1.1.2 Procurement in the two policy areas

Provisions for the management of expenditure relative to the policy areas Public Health and Food and Feed Safety are laid down as follows:

1. The third **Programme of the Union's action in the field of health (2014-2020)** was adopted in March 2014[38], lays down the general objective to work with Member States to encourage innovation in healthcare and increase the sustainability of health systems, to improve the health of the EU citizens and protect them from cross-border health threats. The Commission decided on the specific Public Health work programme for 2016 on 1 March 2016[39] with a total programme budget of EUR 58,5 million. DG SANTE implemented 12% (EUR 7,1 million)[40] under direct management, almost exclusively through public procurement[41], mostly using framework contracts, for example for IT products and services and for communication actions; services were provided by the Joint Research Centre (JRC) based on administrative agreements.

Table 2.4 Procurement in the two policy areas

Commitment credits implemented by DG SANTE *(without CHAF-EA)*	**2016 M€**	**2015 M€**	**2014 M€**
Public Health Programme implemented by SANTE	7,1	7,2	8,4
Administrative budget of the PH programme implemented by SANTE	1,4	1,6	1,5
Pilot projects/preparatory actions implemented by SANTE through procurement	0,9	3,1	6,8
Public Health total	**9,4**	**11,9**	**16,7**
Food and Feed Safety: SANTE procurement expenditure	22,6	19,3	20,1
Other procurement	0,3	-	-
Administrative budget Food and Feed implemented by SANTE	1,3	1,5	1,5
Food and Feed Safety total	**24,2**	**20,8**	**21,6**
Total budget implemented	**33,6**	**32,7**	**38,3**

In addition to the funds for the Public Health programme, DG SANTE received EUR 3,8 million in 2016 for eight pilot projects with a contract value varying between EUR 0,1 million and EUR 1,2 million. Of these, DG SANTE implements two Pilot Projects, with a total contract value of EUR 0,9 million, through procurement and six through grants for a total amount of EUR 2,9 million[42].

[38] Regulation (EU)282/2014 of 11/03/2014

[39] C(2016) 1158

[40] The remaining 88% of the 2016 work programme for Public Health is implemented by the executive agency CHAF-EA (see section 2.1.1.3 below as well as CHAF-EA's 2016 AAR).

[41] A direct grant is given to an international organisation (WHO) amounting to EUR 0,2 million. The control system for these grants is not described in detail as the amounts involved account for less than 1% of DG SANTE's total budget

[42] The control system for these grants is not described in detail as the amounts involved account for less than

The 2016 DG SANTE payment credits for the Public Health policy area amounted to EUR 11,6 million and were fully consumed[43], after budget transfers of EUR 13,1 million in September and EUR 2,3 million in December 2016. These funds were not needed for the policy area Public Health in 2016 mainly due to the slower than foreseen closure of several projects, the additional time needed to finalise the open call for joint actions pertaining to the 2015 work programme and the late launch of the 2016 call for joint actions. Thus, much less was spent on pre-financing payments in 2016 than initially foreseen.

2. The 2015/2016 Work Programme in **Food and Feed Safety** policy area was adopted in November 2014 and last amended in April 2016[44]. In addition, the 2016 Work programme for IT tools was adopted in April 2016[45]. The budget for procurement was spent mainly on IT services and communication actions, almost exclusively using framework contracts. In addition, DG SANTE committed credits for the purchase of vaccines for Lumpy Skin Disease and antigens for Food and Mouth Disease for almost EUR 8 million (other expenditure in the Food and Feed policy area are described in section 2.1.1.1 on grants). The payment credits implemented by DG SANTE were fully consumed.

The control process is divided into three distinct stages, each with specific control objectives as described below.

Stage 1: Assessing procurement needs and selecting the offer

DG SANTE starts the planning of a procurement procedure by assessing the procurement needs when preparing the annual work programmes in each policy area. With regard to the choice of the right procurement procedure, the most important criterion is the size of the contract and the kind of service needed.

With a view to achieving a good quality in terms of tender documents, harmonisation and efficiency gains, since mid-2014 DG SANTE has centralised its administrative management of public procurement procedures covering new procurement procedures above EUR 15.000, including specific contracts on Framework Contracts with re-opening of competition. In 2016, a few exceptions to the centralisation still existed for organisational/technical or geographical reasons; these concerned mainly the communication, and the local calls for tender managed by DG SANTE's site in Grange, Ireland.

Striving to reduce administrative burden, DG SANTE published all 2016 calls above the Directive threshold of EUR 135.000 through the e-tendering platform of the Commission. Preparations to also use e-submission have been well advanced although still some adjustments to the security systems of DG DIGIT have to be made to better fit DG SANTE's control environment.

In 2016, several types of procurement procedures have been applied (see the table below and Annex 3).

1% of DG SANTE's total budget.

[43] Annex 3 shows a payment implementation rate of 89,9% in the Public Health policy area; however Annex 3 includes the payment credits for EU agencies in the figures for Public Health (EUR 154,3 million with an implementation rate of 89,2%).

[44] Commission Implementing Decision 2014/C 410/ 04 of 17 November 2014 amended by Commission Implementing Decision C(2015)4262 of 30 June 2015, and for 2016, amended by Commission Implementing Decision C(2016)1926 of 5 April 2016.

[45] Commission Implementing Decision C(2016)1789 of 1April 2016

Table 2.5 Procurement contracts above € 60.000

Type of procedure	2016		2015		2014	
	N° of contracts	Amount M€	*N° of contracts*	Amount M€	*N° of contracts*	Amount M€
Open (Art. 127.2 RAP, FR 2012)	*3*	2,6	*7*	6,3	*6*	5,6
Open (Art. 104(1a) FR 2012)	*2*	0,9	*3*	1,3	-	-
Restricted (Art. 104(1) (b) FR 2015)	*2*	2,4	-	-	-	-
Restricted (Art. 127.2 RAP, FR 2012)	*1*	0,3	-	-	-	-
Restricted (Art. 136.1(a))	-	-	*2*	3,1	*2*	0,1
Negotiated (Art. 134 RAP)	*3*	1,1	*1*	3,3	*2*	2,1
Competitive dialogue Art. 104(1) (e) FR)	*1*	5,0	-	-	-	-
TOTAL	***12***	**12,3**	***13***	**14,0**	***10***	**7,8**

In 2016, as in previous years, DG SANTE made extensive use of framework contracts concluded by itself or other DGs (for example DG DIGIT). In addition to the more than 100 specific contracts, DG SANTE awards every year a rather low number of contracts following an open, restricted or negotiated procedure (table 2.5 above). In this restricted view, the share of different procedures fluctuates significantly from year to year: while in 2016, the negotiated procedure was used in 25% of the limited number of cases included in the table above (3 out of 12), it was 8% in 2015 (1 out of 13) and 20% in 2014 (2 out of 10). Expressed in amounts, the yearly variance is equally high: in 2016, 9% of the contract value was awarded through the negotiated procedure while it was 24% and 27% in 2015 and 2014 respectively. The main reason for using negotiated procedures is DG SANTE's demand driven purchase of vaccines and antigens for animal diseases in which DG SANTE often faces situations such as monopoly or extreme urgency due to unforeseen events.

In 2016, DG SANTE awarded two contracts for purchase and storage of vaccines for Lumpy Skin Disease with a total contract value of about EUR 1,2 million. One negotiated and one open procedure was applied. DG SANTE keeps stocks of two other vaccines for animal diseases: Food and Mouth Disease and Classical Swine Fever. At the end of 2016, the total value of stocks amounted to EUR 12,1 million and is shown in the EC balance sheet under inventories (see section 2.1.1.4 on assets).

The restricted procedures are typically used for DG SANTE's site management in Grange, Ireland: four contracts of a total amount of EUR 4,3 million for services from 2016 to 2020 for security, transport and childcare were awarded through three restricted procedures for EUR 2,7 million and one open procedure for EUR 1,6 million.

In the Public Health policy area, following the open procedure, two contracts were awarded for Pilot Projects of about EUR 0,5 million each and one IT contract for online testing tools for eHealth services (EUR 0,3 million). For the first time, DG SANTE used the procedure of "competitive dialogue" for an IT service contract of EUR 5,0 million for Scalable Software as a Service (SaaS) for a clinical patient management system to support European Reference Networks in the diagnosis and treatment of rare or low prevalence complex diseases or conditions across national borders.

In 2016, DG SANTE has made significant progress in preparing joint procurement procedures under the Joint Procurement Agreement[46]. Several procedures were launched in 2016 and one was successfully concluded in December 2016. The procedure for personal protective equipment was launched in March 2016, but had to be cancelled for administrative reasons and budget consideration; it will soon be re-launched. The preparation of the joint procurement for pandemic vaccines is well advanced following a thorough needs analysis with all participating Member States and the agreement on tender specifications for the call (publication expected in spring 2017). Further procedures are currently under preparation.

Procurement procedures (open calls for tender and negotiated procedures) for contracts above EUR 135.000 are examined by DG SANTE's "Public Procurement Committee" (CMP). The CMP is designed as an ex-ante control prior to an authorising officer by sub-delegation (AOSD) taking an award decision. It gives an opinion on the compliance with Commission rules and procedures for public procurement, including the use of adequate contract provisions. The Committee consists of representatives of the central financial cell, the decentralised financial cells and the legal affairs Unit. Furthermore, at the discretion of the competent authorising officer, the CMP may be asked to review the draft tender documents before the publication of the contract notice in the Official Journal. In 2016, this voluntary additional check was used in only one case for IT services in the Public Health policy area.

Table 2.6a) Indicators for procurement	***Targets***	**2016**	**2015**	**2014**
Stage 1: Assessing procurement needs and selecting the offer				
Rate of open calls for tenders for which - No offer was received - The procedure had to be cancelled *(2 in 2016; 0 in 2015; 3 in 2014)*	*0%* *0%*	0,0% 25%	0,0% 0,0%	0,0% 23%
Rate of negotiated procedures for which - No offer was received *(2 out of 3 in 2015)* - The procedure had to be cancelled *(2 out of 3 in 2015)*	*0%* *0%*	0,0% 0,0%	66% 66%	0,0% 0,0%
Positive/negative opinions of the procurement committee (CMP) (2016: 15 opinions; 2015: 12 opinions; 2014: 5 opinions)	*n/a*	93% (1 negative)	92% (1 negative)	60% (2 negative)
CMP opinions followed by the authorising officers responsible	*100%*	100%	100%	100%

In 2016, two open calls for tender procedures had to be cancelled: in one case the only offer received exceeded by far the maximum amount foreseen, and in another case no admissible bid was received. Both procedures were re-launched with changes to the tender specifications.

In 2016, the CMP provided 15 opinions on procurement contracts with a total maximum value of EUR 17,6 million. One opinion was negative. It referred to a negotiated procedure in which the CMP found an inconsistency in the evaluation report as regards the selection criteria. However, since the issue appeared to be the result of errors in presenting the evaluation results, the negative opinion allowed for an amended report to be submitted for review. The file passed its second presentation to the CMP as adequate actions were taken. Thus, no situation of overruling the negative opinion of the CMP by the authorising officer occurred.

[46] The Joint Procurement Agreement was initially signed by 15 Member States in June 2014 and entered into force on 5 July 2014. By December 2016, 24 EU Member States have signed this agreement.

Stage 2: Monitoring the implementation of procurement contracts and managing financial transactions

The second stage in the control procedure for procurements concerns the technical and financial monitoring of the implementation of the contracts. This is the responsibility of the operational Units and is not part of the centralisation of the procurement procedures. The frequency and depth of the controls depends on the size, complexity and sensitivity of the contract.

The objective is, firstly, to ensure that the contractor meets the objectives, delivers good quality, on time, and complies with the contract provisions. Secondly, DG SANTE aims to detect and correct errors before a financial operation is authorised. The financial circuits foresee a first-level verification of each financial transaction by the responsible financial Unit; a second-level verification is carried out by the central financial Unit on a sample of transactions (commitments, payments and recovery orders).

Checks are done at the desk prior to the authorisation of the transaction (ex-ante). The selection of operations second-level verification is supported by the IT application "MUS-DICE", based on a risk analysis with a set of risk criteria.

Table 2.6b) Indicators for procurement	***Targets***	**2016**	**2015**	**2014**
Stage 2: Monitoring of contract implementatio and financial management				
Ex-ante 2nd-level verifications coverage: % of transactions % of amounts	*10%* *50%*	8% 52%	8% 52%	7% 55%
Ex-ante rejection rate of 2nd-level verifications: % of amounts with financial errors	*< 2% in value*	0,0%	0,0%	0,0%
Late interest payments relative to total value of contracts (*in 2016: 2 cases of a total of €459,25; in 2015: no cases; in 2014: 1 case of €557,41)*	*0%*	0,0%	0,0%	0,0%
Percentage of implemented final commitment appropriations	*99%*	100%	100%	100%
Percentage of implemented payment credits after global transfers	*100%*	100%	100%	100%

As in previous years, in 2016, all detected errors were corrected prior to the authorisation of the transactions.

Stage 3: Supervisory measures

In order to measure the effectiveness of ex-ante controls, DG SANTE has established diverse supervisory measures such as the reporting on exceptions and non-compliance events, defined as control over-rides or deviations from policies and procedures, and the results of other supervisory activities. In addition, DG SANTE's procurement procedures are audited by the Court of Auditors and the IAS on a regular basis (see the IAS audit on "pilot projects and preparatory actions" of 2016 in section 2.1.2 below).

Ex-post controls on procurement contracts at the contractor's site are conducted only in exceptional cases when high risks have been identified during ex-ante controls. In 2016, no such audit was finalised. DG SANTE considers that adequate procurement procedures ensuring a good price-quality ratio as well as the technical and financial checks prior to payment are sufficient to give reasonable assurance that error rates are very low. Therefore, DG SANTE believes, there is little added value to carry out ex-post controls of payments linked to procurement on a systematic basis.

Table 2.6c) Indicators for procurement	*Targets*	2016	2015	2014
Stage 3: Supervisory measures				
Number of registered **"exception reports"** relative to procurement procedures	*n/a*	7	8	9
Instances of Article 66(2) of the Financial Regulation	*n/a*	None	None	None
On-the-spot control: detected error rate in a procurement contract (no audit in 2015; one audit finalised in 2014)	*< 2%*	n/a	n/a	0,0%
Recovery orders of year N: (in number) in amount	*n/a*	(0) n/a	(0) n/a	(7) 0,07 M€
For procurement: **Ombudsman** cases or legal proceedings open in year N	*n/a*	None	None	None

The systematic registration of so-called "exceptions" and internal control weaknesses is a supervisory tool to improve the functioning of the internal control system. The underlying causes behind these exceptions and weaknesses were analysed and reported to the Directors' Steering Committee on 16 February 2017. The seven "exception reports" in 2016 pertain to non-compliance events (for example, à posteriori commitments mainly due to the backlog caused by the late adoption of the 2015 work programmes). They do not impact on the implementation of the budget, and have no bearing on the Director-General's declaration of assurance. Management assessed that, overall, the existing controls are sufficient and that no additional mitigating actions have to be taken except for an earlier adoption of the annual work programmes.

Conclusion on legality and regularity in procurement

In conclusion, the analysis of the available control results, the assessment of the weaknesses identified and that of their relative impact on legality regularity has not unveiled any significant weakness which could have a material impact as regards the legality and regularity of the financial operations. DG SANTE considers it possible to conclude that the control objective as regards legality and regularity has been achieved.

2.1.1.1.3 Budget implementation tasks entrusted to other services and entities

DG SANTE has entrusted parts of its budget for indirect management implementation by a number of cross-sub-delegations and by the Executive Agency CHAF-EA. In addition, DG SANTE finances, partially or in full, the operating budgets of CHAF-EA and a number of EU decentralised agencies. In each case, DG SANTE's supervision arrangements are based on the principle of controlling 'with' the relevant entity. For details, see Annex 5.3 (internal control template).

Cross-delegations to other Authorising Officers by Delegation (AOD)

Table 2.7 Cross-delegations

DG	2016 Appropriations	
	Commitments M€	Payments M€
ESTAT	-	1,5
TOTAL	**-**	**1,5**

In 2016, DG SANTE cross-sub-delegated EUR 1,5 million of payment credits to ESTAT mainly to support data collection in the Public Health area. No other amounts were cross-delegated due to the fact that previous years' cross-delegations to PMO and DGT were replaced by co-delegations.

Being Commission services themselves, the authorising officers in other DGs are required to implement the appropriations subject to the same rules, responsibilities and accountability arrangements as DG SANTE. The cross-delegation agreements signed with

the DGs require the authorising officers to report on the use made of the delegated appropriations. In the reports sent to DG SANTE for 2016, the authorising officer of ESTAT did not communicate any events, control results or issues which could have a material impact on assurance.

Table 2.8 Indicators of control effectiveness as regards legality and regularity	***Targets***	***2016***	***2015***	***2014***
Cross delegations				
Reports of all AODs in other DGs received prior to finalisation of DG SANTE's Annual Activity Report	*100%*	100%	100%	100%
Issues raised by these AOSDs pertaining to the cross-delegated funds	*0*	0	0	0

Consumers, Health, Agriculture and Food Executive Agency (CHAF-EA)

The Consumers, Health, Agriculture and Food Executive Agency (CHAF-EA, formerly the Executive Agency for Health and Consumers – EAHC[47]) was created on 1 January 2005. Since 2014, the agency's mandate includes the implementation of the Public Health Programme and the Better Training for Safer Food (BTSF) initiative, for both of which DG SANTE is the parent DG. DG SANTE pays a subsidy to CHAF-EA to cover its running costs (administrative or operating expenditure) for the implementation of the tasks transferred to it. The other parent DGs (DGs JUST, AGRI and GROW) also pay their share of the total costs to implement the transferred tasks related to the Consumer programme and Agri-promotion respectively.

DG SANTE follows up on the agency's consumption of both the administrative and the operational budget. To this end, DG SANTE carries out supporting and steering activities in relation to the agency, in particular through the quarterly meetings of the Steering Committee, which are chaired by DG SANTE's Deputy Director-General responsible for Health. The Steering Committee consists of five members, out of which one external member (DG HR) and the chair (from DG SANTE). Furthermore, two persons have observer status: a Director in DG GROW and a Head of Unit of DG SANTE's Food and Feed Safety policy area.

Table 2.9 Subsidies paid by DG SANTE to CHAF-EA

CHAF-EA (former EAHC)	**2016 M€**	**2015 M€**
Subsidy for administrative budget	5,5	5,5
Operational budget transferred from SANTE	65,1	63,2

The Steering Committee adopts the agency's annual work programme and administrative budget including the establishment plan. It is regularly informed through the agency's quarterly reports on the achievements of objectives, audit findings and relevant follow-up, as well as of any other important issue relating to internal control, financial management and audit.

Furthermore, regular meetings at the level of the Units concerned in DG SANTE and CHAF-EA ensure the necessary co-ordination of activities. General guidelines for the day-to-day co-ordination between DG SANTE and the agency were adopted by the Steering Committee in February 2013 and revised in 2016 to accommodate to the new situation in

[47] Commission Implementing Decision No 2013/770/EU of 17 December 2013 establishing the Consumers, Health, Agriculture and Food Executive Agency and repealing Decision 2004/858/EC establishing the Executive Agency for Health and Consumer; Commission Decision C(2013)9505 of 20 December 2013 delegating powers to the Consumers, Health, Agriculture and Food Executive Agency with a view to performance of tasks linked to the implementation of Union programmes

which the CHAF-EA became a multi-parent agency. The general guidelines are complemented by more specific guidelines for certain tasks transferred to the agency.

The use CHAF-EA makes of the subsidy is audited every year by the European Court of Auditors, which has given – since the creation of the Agency – a positive declaration of assurance to CHAF-EA. No serious control issue came to the attention of DG SANTE that would warrant a financial or reputational reservation in DG SANTE's 2016 Annual Activity Report. Careful attention was paid to the IAS audit report of December 2015 on the management of grants under 2014-2020 Consumer and Health Programmes in CHAF-EA. The IAS recognises CHAF-EA's efforts in setting up an adequate internal control system for grant management that complies overall with the relevant rules and principles of sound operational management. The weaknesses identified by the auditors refer mainly to CHAF-EA's internal grant management procedures, which were partially incomplete and insufficiently documented. CHAF-EA reports regularly to the Steering Committee on the actions taken to address these issues.

In addition to the audit report on CHAF-EA, the IAS addressed a management letter to DG SANTE referring to the late adoption of the 2015 Public Health work programme and pointing to the impact this delay had on CHAF-EA's implementation of the work programme. The IAS also saw room to improve the design and presentation of certain aspects of the annual work programmes. All aspects were taken into consideration in the 2017 Work programme of the Health Programme[48].

In the CHAF-EA's Annual Activity Report, the Director reported reasonable assurance on the delegated budget managed by the agency on behalf of DG SANTE and made no reservation (see the agency's 2016 Annual Activity Report: as in previous years, CHAF-EA reported a residual error rate of ex-post controls below the threshold of 2% pertaining to the funds DG SANTE transferred to the agency).

Table 2.10 Indicators of control effectiveness as regards legality and regularity	***Targets***	***2016***	***2015***	***2014***
Executive agency CHAF-EA				
Steering Committee meetings with adequate quorum for voting (info: DG SANTE is one of three parent DGs)	*4*	4	4	4
Number of "exception reports" relative to the guidelines on the co-operation between DG SANTE and CHAF-EA	*n/a*	0	0	0
Budget execution rates of the operational budget transferred to the agency: commitments payments	*99%* *100%*	100% 100%	100% 100%	100% 100%
Director's report on control results and error rates endorsed by Steering Committee prior to finalisation of DG SANTE's Annual Activity Report	*yes*	yes	yes	yes
Court of Auditors' assurance on the agency's accounts and implementation of the administrative budget of year N-1 without qualification	*yes*	yes	yes	yes
Discharge granted for year N-1 and discharge recommendations implemented for year N-2	*yes*	yes	yes	yes
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1 (€0,26/€5,5 million)	*n/a*	4,7%	8,5%	9,0%

EU decentralised agencies

In 2016, DG SANTE was responsible for four EU decentralised agencies, of which three received an annual subsidy from the EU budget. In addition, DG SANTE also contributes to the running costs of ECHA for its biocides activities (the responsible DG for ECHA is DG GROW).

[48] C(2017)316 of 26/01/2017

- European Centre for Disease Prevention and Control (ECDC) located in Stockholm, Sweden[49].
  ECDC works to prevent disease outbreaks and to react quickly and effectively to minimise their impact. To this end, ECDC operates dedicated surveillance networks, provides scientific opinions, notably risk assessments, operates the early warning and response system (*EWRS*) and provides scientific and technical assistance and training.
- European Food Safety Authority (EFSA) located in Parma, Italy[50].
  EFSA provides independent scientific opinions and scientific and technical advice on food and feed safety.
- European Medicines Agency (EMA) located in London, UK[51].
  EMA evaluates and supervises medicines for human and veterinary use; it provides the Member States and the institutions of the European Union with independent scientific advice on medicinal products for human or veterinary use. EMA is to a large extent fee-financed.
- Community Plant Variety Office (CPVO) located in Angers, France[52].
  CPVO supports innovation through the patenting of new plant varieties throughout the EU; CPVO is fully fee-financed.
- European Chemicals Agency (ECHA) located in Helsinki[53].
  ECHA's main tasks are to ensure a high level of protection of human health and the environment as well as the free movement of substances on the internal market. Relevant for DG SANTE are ECHA's biocides which are partially fee-financed.

Table 2.11 EU decentralised agencies – subsidies

EU decentralised agencies	*Number of staff* *			EU contribution		
	2016	***2015***	**2014**	**2016 M€**	**2015 M€**	**2014 M€**
ECDC	*291*	*295*	*299*	58,2	58,4	60,5
EFSA	*470*	*477*	*474*	79,4	79,6	79,6
EMA[54]	*811*	*803*	*754*	17,2	33,9	34,3
CPVO[55]	*46*	*46*	*47*	n/a	n/a	n/a
ECHA[56] (biocides)	*55*	*60*	*n/a*	0,9	6,0	n/a
Total	***1.673***	***1.681***	***1.574***	**155,7**	**177,9**	**174,4**

* Total number of human resources authorised under the budget

[49] ECDC was established by Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004; OJ L 142/1, 30.4.2004

[50] EFSA was established by Regulation (EC) No 178/2002 of the European Parliament and of the Council; OJ L 31/1 of 1.2.2002

[51] EMA was established by Council Regulation (EEC) No 2309/93, which was replaced by Regulation (EC) No 726/2004 of the European Parliament and of the Council; OJ L 214/1 of 24.8.1993 and (OJ L 136/1 of 30.4.2004)

[52] The CPVO was created by Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights; Official Journal L 227/1 of 01/09/1994

[53] ECHA was set up by Regulation (EC) No 1907/2006 of the European Parliament and of the Council; OJ L 396, 30.12.2006, p. 1.

[54] EMA's total 2016 budget amounted to EUR 324,7 million (in 2015: EUR 308,1), mainly financed by fees. The EU contribution is a balancing grant (in 2016: 5%; in 2015: 11%).

[55] CPVO does not receive any EU subsidies; its 2016 budget amounted to EUR 15,5 million (2015: EUR 15,1)

[56] Since 2015, DG SANTE contributes to the biocides activities of ECHA in accordance with the Biocidal Products Regulation (EU) No 528/2012, which came into force on 1 September 2013. ECHA's budget for biocides in 2016 amounted to EUR 7,9 million (in 2015: EUR 9,1 million). The EU contribution is a balancing grant (in 2016: 11%; in 2015: 66%).

Overall, the staff numbers and budgets of agencies are decreasing slightly every year as foreseen in the Commission's communication on the programming of human and financial resources for decentralised agencies (2014-2020)[57]. In 2016, the EU contribution to the ECHA budget was much lower than expected thanks to the increase in the fee income in response of the market to the Biocidal Products Regulation deadline of 1 September 2016.

While the Director-General of DG SANTE is accountable for the legality and regularity of the payments of the subsidies to the agencies, the accountability for the regularity and legality of this expenditure resides ultimately with the agencies themselves.

The use made of the EU funds by the agencies is checked – inter alia – by the European Court of Auditors through special reports as well as through annual reports on the agencies accounts. In mid-2016, the Court gave all EU agencies to which DG SANTE is responsible (including CPVO and ECHA) a positive declaration of assurance for the reliability of their 2015 accounts as well as for the legality and the regularity of the underlying transactions. The comments made by the Court on weaknesses in internal control systems did not call the positive declaration into question. The agencies draft action plans to implement the Court's audit recommendations and report on the progress made. Further to the Court's assurance received in mid-2016, DG SANTE cleared all pre-financing payments made to the agencies in 2015 and made the final payments of the 2015 subsidies. Thus no reservation to DG SANTE's declaration is warranted.

DG SANTE, within the limits of its role on the EU agencies' Management Boards, follows up closely the improvements to be made by the agencies. The role of the Management Boards includes the approval of the agencies' annual budgets as well as the adoption of both the annual work programmes and the annual activity reports. They are regularly informed on the achievements of the agencies' objectives as well as on all other important issues relating to operational and financial management, internal control, evaluations and audits. Each of the agencies for which DG SANTE is responsible has developed an anti-fraud strategy adopted by the respective Management Boards.

The control issues that came to the attention of DG SANTE did not affect the legality and regularity of DG SANTE's payments of subsidies to the agencies (Table 2.12 below summarises the indicators of control effectiveness as regards legality and regularity).

While the relevant operational Units in DG SANTE are the primary interlocutors with the agencies, a horizontal Unit takes on a coordination role to promote a coherent approach towards all agencies and to exchange good practices. For example, each agency adopted its rules of "independence" and "conflict of interest"; DG SANTE actively monitored compliance with the Commission's guidelines on independence in DG SANTE's task force with the agencies and through bilateral contacts. In addition to monitoring compliance, DG SANTE identifies and disseminates good practices in collaboration with the agencies.

In May 2016, the IAS submitted its final audit report on DG SANTE's coordination and working arrangements with EU agencies. No critical issue was raised. The main recommendation to reinforce DG SANTE's leverage effect on the agencies' programming was already implemented by October 2016 through DG SANTE's contributions to the Commission Opinions on the agencies' Strategic Programming Documents for 2017 to 2019 (for more detail and other actions, see section 2.1.2.1 below).

[57] COM(2013) 519 final of 10/07/2013

Table 2.12 Indicators of control effectiveness as regards legality and regularity	*Targets*	*2016*	*2015*	*2014*
EU agencies				
Court of Auditors' assurance on EFSA's, EMA's, ECDC's, CPVO's and (since 2015) ECHA's accounts and implementation of their administrative budget of year N-1 without qualification	*Yes* *5 out of 5*	**yes** **5 out of 5**	yes 5 out of 5	yes 4 out of 4
Discharge granted for year N-1 and discharge recommendations implemented for year N-2	*yes*	**yes**	yes	yes
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1 (€21,6/€155,2 million in 2016)	*n/a*	13,9%	3,6%	2,6%

The increase in the amount recovered is due to the fact that in 2016, the EU contribution to the ECHA budget has been much lower than expected thanks to the increase in the fee income in response of the market to the Biocidal Products Regulation deadline of 1 September 2016.

2.1.1.1.4 Conclusion on legality and regularity

In the context of the protection of the EU budget, at the Commission's corporate level, the DGs' estimated overall amounts at risk and their estimated future corrections are consolidated.

SANTE, the estimated overall amount at risk *at payment*[58] (for the 2016 payments of EUR 409,7 million is between EUR 2,3 and 3,7 million. This is the AOD's best, conservative estimation of the amount of *relevant expenditure*[59] during the year not in conformity with the applicable contractual and regulatory provisions at the time the payment is made.

This expenditure might be subsequently subject to ex-post controls and a sizeable proportion of the underlying error is expected to be detected and corrected in successive years. The conservatively estimated future corrections[60] for those 2016 payments made are EUR 2,0 million. This is the amount of errors that the DG conservatively estimates to identify and correct from controls that it will implement in successive years.

The difference between those two amounts leads to the estimated overall amount at risk *at closure* of EUR 1,8.

[58] In order to calculate the weighted average error rate (AER) for the total *relevant expenditure* in the reporting year, the *detected*, estimated or other equivalent error rates have been used.

[59] As per definition of DG BUDG, "*relevant expenditure*" during the year equals payments made, minus new pre-financing paid out, plus previous pre-financing cleared.

[60] Even though based on the 7 years historic average of recoveries and financial corrections (ARC), which is the best available indication of the corrective capacity of the ex-post control systems implemented by the DG over the past years, DG SANTE adjusted this historic average. Any encoding errors, ex-ante elements, one-off events, (partially) cancelled or waived Recovery Orders, were adjusted in order to come to the best but conservative estimate of the expected corrective capacity average to be applied to the reporting year's relevant expenditure for the current programmes in order to get the related estimated future corrections.

Table 2.13 – Estimated overall amount at risk at closure

(1) Type of expenditure	Grants - relevant expenditure (Food and Feed)	Procurement and other expenditure (Public health/ Food and Feed)	Agencies	Overall/ Total
(2) Total payments as per AAR Annex 3	205,5 M€	43,5 M€	160,7 M€	**409,7 M€**
(3) Minus new prefinancing	-10,5 M€	-0,4 M€	-156,5 M€	**-167,4 M€**
(4) Plus cleared prefinancing	9,7 M€	0,3 M€	160,1 M€	**170,0 M€**
(5) Relevant expenditure = (2) – (3) + (4)	**204,7 M€**	**43,4 M€**	**164,2 M€**	**412,3 M€**
(6a) Weighted average error rate (detected; lower limit) in %	1,3%	0,0%	0,0%	**0,6%**
(6b) Weighted average error rate in % (detected; upper limit)	1,3%	2,0%	0,0%	**0,9%**
(7a) Estimated overall amount at risk at payment (lower limit) = (5) * (6)	2,6 M€	0,0 M€	0,0 M€	**2,3 M€**
(7b) Estimated overall amount at risk (upper limit) = (5) * (6)	2,6 M€	0,9 M€	0,0 M€	**3,7 M€**
(8) 7-year average recovery/corrections as % of relevant payments[61]	1,0%	0,0%	0,0%	**0,5%**
(9) Estimated future corrections = (5) x (8)	2,1 M€	0,0 M€	0,0 M€	**2,0 M€**
(10a) Estimated overall amount at risk at closure = (7) – (9)	0,5 M€	0,0 M€	0,0 M€	**0,3 M€**
(10b) Estimated overall amount at risk at closure = (7) – (9)	0,5 M€	09 M€	0,0 M€	**1,8 M€**

2.1.1.2 *Control efficiency and cost-effectiveness*

This section outlines the indicators used to monitor the efficiency of the control systems. The main indicators monitored in 2016 focussed on the timeliness of procedures and the resources employed. The resources employed for control activities encompass DG SANTE's staff carrying out the monitoring tasks through the different stages of the control processes as defined in Annex 5. The costs are calculated on an all-cost basis without including an overhead rate.

The results for 2016 by type of expenditure are as follows:

2.1.1.2.1 Grants to Member States

Based on an assessment of the most relevant key indicators and control results, DG SANTE has assessed the cost-effectiveness and the efficiency of the control system and reached a positive conclusion on the control efficiency in its grant management.

[61] The "corrective capacity" (7-year average) included in DG BUDG's reports amounts to 2,1% for DG SANTE; it includes not only ex-post controls but also other differences between the registered cost-claim/invoice and the actual payments made.

Table 2.14 Indicators of control efficiency – timeliness in grant management

Indicators per stage of the grant procedure	*Targets*	*2016*	*2015*	*2014*
Stages 1 and 2: Programme, evaluation, approval, EU funding				
Ratio of decisions taken on-time (legal deadlines) to allow a timely start of the national programmes	*100%*	100%	100%	100%
Stage 3: Monitoring and financial management				
Payments made on time[62] (in number) in amount	*95%*	(97%) 99%	(97%) 99%	(97%) 97%
Average payment time[63]	*90*	52	n/a	n/a
Stage 4: Ex-post controls and error corrections				
Timely implementation of the annual ex-post control work programme (19 audit visits carried out in 2016; 13 in 2015; 21 in 2014)	*100%*	95%	83%	95%
Percentage of financial audit recommendations accepted by the beneficiaries/Member States	*100%*	100%	86%	100%
"Time to recover": average days from finalising the control to issuing the debit note (12 debit notes in 2016; 11 in 2015; 10 in 2014)	*n/a*	64 days	60 days	72 days

In 2016, DG SANTE did not face any undue delays in its procedures related to grants to Member States in the policy area Food and Feed Safety.

The costs of control cover the annual costs of both DG SANTE staff and external service providers carrying out the control tasks through the different stages of the control procedure. The figures in the table below are calculated on an all-cost basis without including an overhead rate.

Table 2.15 Indicators of control efficiency in grants - resources[64].

Indicators per stage of the grant procedure (average FTE times standard annual costs) [65]		**2016 M€**	**2015 M€**	**2014 M€**
Stages 1 and 2: Programming, evaluation and operational monitoring				
Cost of operational staff in the policy Units concerned	2016: FTE: 6,8	0,9	0,9	0,9
Financial resources spent on external experts assisting in the evaluation of national programmes in the policy area Food and Feed Safety		0,1	0,1	0,1
Stage 3: Monitoring of financial transactions				
Cost of financial staff in the policy Units concerned	2016: FTE: 8,5	1,0	1,0	1,0
Cost of staff involved in second-level ex-ante and other desk controls of the central financial Unit	2016: FTE: 1,5	0,1	0,1	0,1

[62] Time limits for payments were fixed in the specific legislation which was still applicable in 2015 to a large number of payment transactions.

[63] Payments before 2016 were mostly based on the specific legislation in which a fixed payment date was defined; the time-limits set in the Financial Regulation were not applicable. In 2016, still some payments were made based on the previous legislation.

[64] For the costs of control, no targets are defined in monetary terms as the information available is insufficient to analyse the evolution over time and/or to compare the figures with Commission benchmarks.

[65] FTE = full time equivalent; standard annual costs: EUR 138.000 for officials and EUR 70.000 for contractual staff

Indicators per stage of the grant procedure (average FTE times standard annual costs) [65]		2016 M€	2015 M€	2014 M€
Stage 4: On-the-spot controls (ex-ante and ex-post)				
Cost of DG's internal staff dealing with on-the-spot controls	2016: FTE: 4,2	0,6	0,6	0,7
Financial resources spent on external audit services In the policy area Food and Feed Safety		0,1	0,1	0,1
Total annual cost (without overhead rate)		**2,8**	**2,8**	**2,9**
Budget spent on "grants" ("benefit" of the controls)		**212,7**	**217,5**	**211,4**
Total cost as % of total annual budget (commitment appropriations)		**1%**	**1%**	**1%**

Conclusion on control efficiency in grants

DG SANTE quantifies the costs of the resources and inputs required for carrying out the controls described in Annex 5. While most costs of controls are quantifiable in monetary terms, most of their undeniable benefits are not. The evaluation of the proposed national programmes helps ensure that national programmes are compliant with the legislation and of good quality. This control is very significant to ensure value for money through improved quality, but the benefit is not quantifiable. The same can be said for DG SANTE's on-the-spot controls in the Member States: the benefits in non-financial terms include, first and foremost, compliance with regulatory provisions and deterrent effects but also improvements of the reporting systems in the Member States. Therefore, DG SANTE makes the assumption that without these controls, value for money in the grants to Member States could not be ensured. Thus, the benefit is estimated at about 100% of the budget spent.

In addition, for some control indicators, mere numbers and percentages do not give reliable information on the effectiveness of control; only a qualitative analysis of the reasons behind the figures is relevant and useful. For example, simplification measures initiated since 2013 encompass the introduction of unit costs for several elements in the Member States' animal disease eradication programmes; the use of the "grant decisions" such that only one decision is taken for each Member State, grouping together its programmes and including a flexibility clause that allows a Member State to shift up to 20% of the allocated funds between its programmes without the Commission's intervention; the compulsory online submission tool for Member States' applications using predefined templates for each disease. The full effect of these measures on control efficiency is showing in the indicators from 2016 onwards.

Analysing the evolution of the efficiency indicators over time and taking the simplification measures of the past few years into consideration, DG SANTE expects that the cost of control will remain stable around 1% of the annual budget spent through grants to Member States. Therefore, DG SANTE reached a positive conclusion as to the relative efficiency of the controls of these grants.

2.1.1.2.2 Procurement

Based on an assessment of the most relevant key indicators and control results, DG SANTE has assessed the cost-effectiveness and the efficiency of the control system and was not able to conclude on the control efficiency in procurement as 2016 was only the second year after the centralisation of the procurement procedures. Efficiency gains started to show, but a conclusion seems premature.

Table 2.16 Indicators of control efficiency in procurement - timeliness

Indicators on control efficiency in procurem	*Targets*	2016	2015	2014
Stage 1: Rate of timely launched procurement procedures as specified in the annual work programmes	*100%*	85%	61%	100%
Stage 2: Average payment times	*30 days*	24 days	21 days	19 days
Ratio of payments made on time (in number) in amount	*95%*	(87%) (98%)	(91%) (99%)	(99%) 99%
Stage 3: "Time to recover": average days from information/confirmation date to issuing the debit note (in 2016 and 2015, no debit notes related to procurement; in 2014: 7 debit notes)	*n/a*	n/a	n/a	41 days

In 2016, DG SANTE still faced delays in the launch of planned procurement procedures due to the backlog that was created in 2015 further to the late adoption and amendment of the 2015 work programmes for Health as well as for Food and Feed.

The late payments mainly relate to the IT domain, where a high number of invoices were received in quarterly batches each representing a small amount. Further efforts will be undertaken to enhance the situation and to avoid late payments.

The table below shows the costs of control. They cover the annual costs of DG SANTE staff carrying out the control tasks through the different stages of the control procedure and are calculated on an all-cost basis without including an overhead rate.

Table 2.17 Indicators of control efficiency in procurement - resources[66]

Indicators for procurement (average FTE times standard annual costs) [67]		**2016 M€**	**2015 M€**	**2014 M €**
Cost of operational staff in the policy Units concerned	2016: FTE: 3,3	0,5	0,6	1,0
Cost of staff involved in the CMP activities	2016: FTE: 0,2	0,03	0,03	0,1
Cost of staff involved in 2nd-level ex-ante and other controls of the central financial Unit	2016: FTE: 1,5	0,2	0,05	0,1
Cost of central staff involved in procurement and financial procedures	2016: FTE: 8,2	1,1	1,1	0,9
Cost of DG's internal staff dealing with on-the-spot controls	2016: FTE 0,0	0,0	0,0	0,0
Total annual cost (without overhead rate)		**1,8**	**1,8**	**2,1**
Budget spent on "procurement" ("benefit" of the controls)		**33,6**	**32,7**	**45,0**
Total cost as % of total annual budget spent through procurement (commitment appropriations)		**5%**	**6%**	**5%**

[66] For the costs of control, no targets are defined in monetary terms as the information available is insufficient to analyse the evolution over time and/or to compare the figures with Commission benchmarks.

[67] FTE = full time equivalent; standard annual costs: EUR 134.000 for officials and EUR 70.000 for contractual staff

Conclusion on control efficiency in procurement

DG SANTE quantifies the costs of the resources and inputs required for carrying out the controls described in Annex 5. While most costs of controls are quantifiable in monetary terms, most of their undeniable benefits are not. Therefore, DG SANTE makes the assumption that without a proper needs' analysis, well drafted tender specifications and a high quality evaluation process, value for money in procurement could not be ensured. Thus, the benefit is estimated at about 100% of the budget spent through procurement.

DG SANTE analyses the evolution of the efficiency indicators over time and/or compares them with relevant benchmarks to reach a conclusion as of the relative efficiency of the controls. This is not currently possible, as the centralisation of the administrative management of procurement procedures has been implemented only gradually since May 2014. Time and experience was needed throughout 2015 and 2016 to establish mature procedures and guidance. Efficiency gains started to show and a conclusion should be possible in the 2017 AAR.

2.1.1.2.3 Budget implementation tasks entrusted to other services and entities

Based on an assessment of the most relevant key indicators and control results, DG SANTE has assessed the cost-effectiveness and the efficiency of the control system and reached a positive conclusion on the control efficiency with regard to entrusted entities.

Table 2.18 Indicators of "control efficiency" – resources employed

DG SANTE's cost of monitoring the agencies in relation to the subsidies paid (average FTE times standard annual costs)[68]		**2016 M€**	**2015 M€**	**2014 M€**
Cost of staff in the central Unit ensuring co-ordination within DG SANTE and with the agencies	2016: FTE 1,7	0,2	0,1	0,1
Cost of operational staff involved in monitoring the operations of the agencies	2016: FTE 5,0	0,7	0,6	0,7
Cost of staff involved in budgetary, financial, audit matters and evaluation of the agencies	2016: FTE 1,7	0,2	0,1	0,1
Total annual cost (without overhead rate)		**1,1**	**0,8**	**0,9**
Subsidies paid to the agencies		**161,2**	**183,4**	**181,7**
Total cost as % of total annual subsidies paid		**0,7%**	**0,5%**	**0,5%**

Overall, the costs of monitoring and supervision represent 0,7% of the total subsidy payments to the agencies' administrative budget. It is worth noting that none of the EU decentralised agencies for which DG SANTE is responsible carry out budget implementation tasks on behalf of the Commission that would require an in-depth monitoring.

For the costs of control, no targets are defined in monetary terms. As most of the controls are directive and preventive in nature, the overall control benefit is non-quantifiable. However, each agency undergoes an external evaluation on a regular basis.

[68] FTE = full time equivalent; standard annual costs: EUR 134.000 for officials and EUR 70.000 for contractual staff

Conclusion on "entrusted entities"

For the 2016 reporting year, the cross-sub-delegated AODs and the executive agency CHAF-EA have themselves reported reasonable assurance on the delegated budget managed by them on DG SANTE's behalf. They have signalled no serious control issues and no reservation was made . For all five EU agencies (EFSA, EMA, ECDC, CPVO and ECHA (for its biocides activities) for which DG SANTE was responsible in 2016, the Court of Auditors gave a positive declaration of assurance for the year 2015. The comments made by the Court do not call into question DG SANTE's reasonable assurance on the operating budget managed by the EU agencies.

From own monitoring and supervision work as a responsible DG, nothing came to the attention of DG SANTE that would indicate that the reporting from the agencies would not be reliable. The IAS audit on DG SANTE's coordination and working arrangements with the EU agencies gave positive feedback on DG SANTE's role as DG responsible for the agencies.The weaknesses identified by the auditors do not call the Director-General's assurance into question.

Consequently, in view of DG SANTE's residual responsibility for the management of the parts of the budget cross-delegated to authorising officers in other DGs and transferred to the executive agency, CHAF-EA, as well as for the funds paid to the operating budgets of the agencies, DG SANTE concludes that there are no control weaknesses affecting the assurance building in terms of the control objectives.

With regard to DG SANTE's control efficiency, analysing the evolution over time of DG SANTE's supervisory role and related monitoring costs, DG SANTE expects that its cost of control will remain well below 1% of the annual subsidy payments to the agencies.

2.1.1.3 Fraud prevention and detection

DG SANTE has developed and implemented its own anti-fraud strategy since 2013, elaborated on the basis of the methodology provided by OLAF. It is in the process of being updated.

The internal control officer monitored the implementation of the associated action plan and reported the results to DG SANTE management twice a year, at mid-term and at year-end. Actions are well embedded in existing procedures, for example, (i) active participation in the network "Fraud Prevention and Detection" (FPD) chaired by OLAF and systematic feedback given to DG SANTE staff concerned; (ii) ethics awareness raising campaigns addressed to all staff; (iii) standing operating procedures for the handling of allegations of fraud, other irregularities and OLAF cases; (iv) contribution to OLAF's annual report on actions taken in the framework of the anti-fraud strategy.

The controls to prevent and detect fraud are basically the same as those intended to ensure the legality and regularity of the transactions. In 2016, DG SANTE looked into the risk of fraud in the context of its comprehensive risk assessment concerning potential sensitive functions and as part of the annual risk management exercise. The fraud risks are addressed by specific controls designed and implemented to mitigate the risks. Activities and operations that are at a higher risk of fraud are subject to more in-depth monitoring and control such as an independent review of procurement procedures prior to the publication of the call for tender (see table 2.19 below).

The IAS carried out an audit on the adequacy and effective implementation of the anti-fraud strategies (final report issued in July 2015) and concluded positively on DG SANTE's anti-fraud strategy, the method the DG used to develop it and the monitoring of the action plan. It included one recommendation to discuss on a regular basis with other DGs to identify possible common fraud risks which could warrant complementary or coordinated actions to mitigate them. The action is on-going.

Table 2.19 Indicators for fraud prevention and detection

Indicators for fraud prevention and detection	*Targets*	*2016*	*2015*	*2014*
Updated anti-fraud strategy of January 2014	*October 2016*	*Not yet done*	*n/a*	n/a
% of actions listed in SANTE's anti-fraud action plan without delays in the implementation phase (milestone in 2016: 5 actions, in 2015: 15 actions)	*100%*	*40%*	*73%*	90%
% of payments subject to close monitoring or additional controls due to relatively high risk of fraud	*100%*	*93%* *(3,4 M€ paid)*	*81%* *(3,5 M€ paid)*	*91%* *(1,3 M€ paid)*
% of financial officers reached in financial cell network meetings	*100%*	*100%*	*100%*	n/a
% of new-comers reached in training on ethics	*100%*	*n/a*	*100%*	n/a
OLAF recommendations in investigation reports covered by appropriate follow-up and reporting (no new actions since 2013)	*100%*	*n/a*	*n/a*	n/a

In 2016, DG SANTE did not finalise the update of its first anti-fraud strategy of January 2014, mainly due to the substantial organisational changes that affected the DG throughout the whole year 2016. Therefore, management postponed its comprehensive analysis of real residual risks of fraud in the DG's diverse financial and non-financial functions to mid-2016 and adopted the results in October 2016. In addition, the annual risk assessment exercise, finalised in November 2016, feeds into the update of the anti-fraud strategy and its action plan. The adoption of both documents is foreseen in the second quarter 2017.

The three-year action plan of the 2014 anti-fraud strategy foresaw 24 actions out of which 20 (83%) were implemented by the end of 2015. A new action stemming from the IAS audit on the anti-fraud strategy (see section 2.1.2.1 below) was added in 2015 so that five actions remained to be finalised in 2016. Only two (40%) could be completed, mainly due to the late update of the fraud risk analysis (see paragraph above) and given that actions addressing in particular the non-spending legislative initiatives of DG SANTE, for example, legislative fraud proofing in non-financial contexts, are much more complex than expected; DG SANTE is in contact with OLAF on this issue.

Main actions implemented in 2016 were especially (i) the DG internal awareness raising campaign on issues related to food fraud; (ii) the establishment of a contact with another DG to discuss on a regular basis possible common fraud risks which could warrant complementary or coordinated actions to mitigate them (this action stems from an IAS audit recommendation of 2015 and is on-going). Awareness raising and training on ethic topics in which DG SANTE reached the target groups as follows: 16 staff member participated in the in-house training on "Managing Stakeholders in Challenging Meeting" and 14 attended the training on "Dealing Appropriately & Effectively with Lobbyists". Complete statistics to check whether all newcomers attended the compulsory ethics training was not available for 2016 due to the on-going transition to the new corporate IT tool "EU Learn" since November 2016.

In addition, DG SANTE's re-organisation, effective since 1 February 2016, and its middle-management mobility in mid-2016 - both exercises triggered a high mobility of staff and thus addressed effectively several issues related to sensitive posts (see section 2.1.3).

During the reporting year, DG SANTE did not have to transmit any suspicions of fraud to OLAF that implied effects on DG SANTE's budget. From previous cases, all follow-up actions to implement OLAF recommendations were closed since 2013; no new recommendation has been issued since.

To conclude, no control weakness was observed that could have an impact on the assurance given for DG SANTE's activities in 2016.

2.1.1.4 Other control objectives: safeguarding of assets and information, reliability of reporting

In its balance sheet, DG SANTE identifies current assets (inventories) of a total value of EUR 12,1 million pertaining to vaccines stocks for animal diseases in order to carry out emergency vaccination. The stocks include food and mouth disease antigens with a stock value of EUR 11,6 million, classical swine fever vaccines with a value of EUR 0,3 million and lumpy skin disease vaccines accounting for EUR 0,2 million.

The Common Financial Framework[69] provides that a Union financial contribution may be awarded for the establishment of stocks of biological products or the acquisition of vaccines doses if the occurrence or the development in a third country or Member State of one of the animals diseases and zoonoses listed in the Common Financial Framework might constitute a threat to the Union. Reserves of foot-and-mouth disease vaccines were already established in 1991 by Council Decision[70].

DG SANTE signed contracts with different companies for the purchase, storage and delivery of the vaccines mainly through open calls for tender or negotiated procedures (the controls in procurement procedures are described in section 2.1.1.1.2 above). The contracts set forth that the manufacturer shall store the vaccine according to the principles of the last existing update of the Manual of Diagnostic Tests and Vaccines for Terrestrial Animals of the World Organisation for Animal Health (OIE)[71]. The contractors' reports on 2016 did not point to any breaches to these principles.

The stock is determined at the acquisition value (without VAT). At the end of their validity, if still in stock, the vaccines and antigens are bought back by the companies at a price determined in the relevant contracts.

The main aim of accounting controls is to assure the quality and reliability of the accounts and underlying transactions through methodical checks on the accounting records (data) and timely communication and correction of the errors. The controls carried out in 2016 have followed the Annual Accounting Quality Plan. The controls performed are additional to the ex-ante controls performed by Financial Verifying Agents and Authorising Officers by Sub Delegated on each transaction, in compliance with the Financial Regulation.

The Court of Auditors carries out annual audits on DG SANTE's accounts. In the past few years, no observation was made that would affect the vaccines stocks.

In conclusion, DG SANTE considers the current control arrangements for accounting and financial reporting to be sufficient. They work in practice as intended. Proper safeguarding of the DG SANTE assets, EUR 12,1 million vaccines stocks, was ensured throughout the year as stated in the reports received by the contractors.

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[69] Article 6(5) of Regulation (EU) No 652/2014 with Article 7 or 10

[70] Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines (OJ L 368, 31.12.1991, p. 21)

[71] http://www.oie.int/international-standard-setting/terrestrial-manual/access-online/

2.1.2 Audit observations and recommendations

This section reports and assesses the observations, opinions and conclusions reported by auditors in their reports as well as the limited conclusion of the Internal Auditor on the state of control, which could have a material impact on the achievement of the internal control objectives, and therefore on assurance, together with any management measures taken in response to the audit recommendations.

This section includes audits of the European Court of Auditors (Court) and the Commission's Internal Audit Service (IAS).

2.1.2.1 European Court of Auditors

Court's audits of 2016

(1) 2015 DAS – compliance audit

In 2016, the Court finalised its annual report (2015 DAS) on the implementation of the 2015 budget. The structure of the Court's 2015 report is adapted to the budget headings of the Multi-annual Financial Framework (MFF) 2014-2020. DG SANTE is part of the policy chapter to Heading 3: Chapter 8 "Global Europe and Security and Citizenship".

As the Court did not report any major finding related to DG SANTE, DG SANTE is not mentioned in any policy chapter nor in the horizontal chapters on budgetary and financial management. The overpayment of just under EUR 0,1 million found in one payment to a 2014 veterinary programme was based on an erroneous cost-claim. The mistake was due to special circumstances and cannot be extrapolated to other cases. The overpayment was recovered and mitigating actions taken.

(2) Court's special report on the EU implementation of animal disease eradication and monitoring programmes (SR 06/2016)

The Court started this audit in June 2014 and published the report in April 2016. The Court's conclusions do not contain any critical issue neither for the Commission nor for the Member States.

The audit covered Member State's animal disease eradication programmes from 2009 to 2014 and focussed on the Commission’s role and control instruments, objectives, performance indicators, and the amount of EU funds involved. The Court's conclusions were overall positive: the Court assessed that the approach taken by the Commission was generally sound and that Member State programmes were well designed and implemented.

Recommendations to improve the Commission's management of the programmes are acceptable to DG SANTE: (i) facilitate the exchange of epidemiological information between Member States; (ii) examine whether existing indicators should be updated to provide better information on veterinary control activities and the cost-effectiveness of programmes; (iii) include the wildlife aspect in the veterinary programmes more systematically, when relevant; (iv) support Member States in acquiring vaccines, when this is epidemiologically justified.

DG SANTE drafted an action plan to implement all recommendations by the end of 2017. All actions are well advanced, for example, (i) the sharing of epidemiological information in the Standing Committee on Plants, Animals, Food and Feed (PAFF), (ii) the first discussions to examine whether existing indicators could be updated during the annual meeting of the plenary task force on animal diseases eradication on 8 February 2017 and (iii) the systematic reference to the wildlife aspect in the Member States' veterinary programmes for several diseases; (iv) furthermore, in

April 2016, an EU vaccine bank for Lumpy Skin Disease has been set up in addition to the existing vaccines stocks for Food and Mouth Disease and Classical Swine Fever.

(3) Court's special report on the EU framework for protecting citizens from serious cross-border threats to health (SR 28/2016)

The audit fieldwork started in April 2015 and was concluded in July 2016. The Court published its report in December 2016 together with the replies of the Commission. The Court's conclusions do not point to any critical issue neither for the Commission nor for the Member States.

The Court recognises that a key milestone in building a stronger EU health security framework was the adoption in 2013 of a Decision on serious cross-border threats to health; it then aimed at assessing whether it was adequately implemented. The Court recommends to (i) speed up the implementation of the 2013 Decision, notably by developing a strategic roadmap for the Health Security Committee; (ii) upgrade the Early Warning Response System and develop more integrated solutions for risk management; (iii) improve the sustainability of results from co-funded actions for health threat protection and the related performance measurement methodology; (iv) develop a more structured coordination between different Commission services for health security activities.

In early 2017, DG SANTE developed an action plan to implement the recommendations. A number of issues are already being addressed such as modernising the early warning and response system, drafting Implementing Acts foreseen under the decision, improving the coordination between Commission services and with the ECDC as well as organising several joint procurements in 2016 and 2017 (so far, 24 Member States have signed up to the Joint Procurement Agreement).

(4) Court's special report on combating food waste in the EU (SR 34/2016)

The Court started the audit in June 2015 and published its report in January 2017. The audit examined the question "Does the EU contribute to a resource-efficient food supply chain by combating food waste effectively?" The Court examined the role the EU can play in combating food waste and looked at the actions taken thus far and how the various EU policy instruments work to reduce food waste.

The Court's conclusions are not critical neither for the Commission nor for the Member States. However, the Court concludes that currently the EU does not contribute to a resource-efficient food supply chain by combating food waste effectively. It issued the following three recommendations: (i) strengthen and better coordinate the EU strategy to combat food waste; (ii) in coordinating the various policies with the potential to combat food waste, the Commission should consider food waste in its future impact assessments and better align the different EU policies which can combat food waste; (iii) to facilitate the donation of food that would otherwise be wasted, the Commission could usefully clarify the interpretation of legal provisions that can discourage donation. The Commission should encourage further exploitation of existing possibilities for donation and consider how to facilitate donation in other policy areas.

Some of the Court's observations are already being addressed by the Commission through ongoing activities, in particular, (1) the Commission's Circular Economy Package adopted in 2015 in which food waste is singled out as a priority area, (2) the EU Platform on Food Losses and Food Waste launched in November 2016 to bring together both public and private interests and accelerate progress towards the UN Sustainable Development Goals. DG SANTE has developed its action plan with target dates in 2018 and 2019.

DG SANTE's follow-up on Court's audit recommendations

The follow-up of the Court's recommendations as well as recommendations made by the discharge authorities in previous years is organised by DG BUDG through the RAD-database (Recommendations, Audit and Discharge). DG SANTE launches systematic updates at least twice a year (May/June and December/January).

Further to having closed all open recommendations in previous years, DG SANTE has received as "chef de file", four new recommendations related to the audit on animal disease eradication programmes (see point (2) above) and 12 new recommendations related to the audit on cross-border threats to health (see point (3) above). DG SANTE drew up action plans with deadlines mostly in late 2017.

In June 2016, the Court launched a follow-up audit on two performance audits – on "meat imports"[72] of 2010 and "slaughterhouses"[73] of 2012. The Court concluded that DG SANTE addressed most of the recommendations in the Commission proposal of 2013 to revise the Regulation on official controls along the food chain for which political agreement was reached on 16 June 2016. The new Regulation foresees smarter rules for the enforcement of agri-food legislation and establishes a fully integrated system of border checks and provides for the independence, quality and accountability of the enforcement actors in the Member States, thus improving the transparency of official controls.

2.1.2.2 Internal audit service (IAS)

Since March 2015, DG SANTE's internal audit function is centralised in the Commission's Internal Audit Service (IAS). The mutual working arrangements set up by DG SANTE and the IAS ensured good co-operation and information sharing throughout 2016.

Conclusion of the Internal Auditor:

The IAS contributed to DG SANTE's Annual Activity Report for 2016 by submitting a "conclusion on the state of internal control" (Note of 15 February 2017). Based on the audit work performed in the period 2014 to 2016, the IAS concludes that DG SANTE's "internal control systems audited are overall working satisfactorily although a number of very important findings remain to be addressed in line with the agreed action plans". Both the very important recommendations and DG SANTE's actions are explained under point (2) below; they pertain to the audit on DG SANTE's working arrangements with EU decentralised agencies.

IAS audits of 2016 on DG SANTE

(1) Follow-up audit on open audit recommendations of the former internal audit capability

Since the centralisation of the internal audit function in March 2015, the IAS followed up on a total of 21 recommendations stemming from audits finalised by the former internal audit capability of DG SANTE. While having closed 12 recommendations in 2015, nine were still to be implemented in 2016. DG SANTE implemented seven of these recommendations and the IAS closed the audits.

The IAS assessed that two recommendations pertaining to the management of veterinary programmes, initially rated "very important", were partially implemented

[72] Special Report 14/2010: "The Commission's management of the system of veterinary checks for meat imports following the 2004 hygiene legislation reforms

[73] Special Report 14/2012: "Implementation of EU hygiene legislation in slaughterhouses of countries that joined the EU since 2004"

awaiting the finalisation and use of the IT tool supporting audit trail. Nonetheless, in light of the progress made, the IAS downgraded the two recommendations to "important".

(2) IAS audit on coordination and working arrangements with EU decentralised agencies

In accordance with the 2015 IAS Audit Plan, in June 2015 the IAS started an audit on the coordination and working arrangements with EU decentralised agencies in DGs SANTE and HOME. The IAS finalised its audit work in early 2016 and submitted its final audit report in mid-May 2016. No critical issue was raised. DG SANTE produced an action plan in June 2016 and started its implementation. The three main recommendations of the IAS and actions of DG SANTE are

(i) To reinforce DG SANTE's leverage effect on the agencies' programming: DG SANTE has already taken the most important action addressing this recommendation by preparing for each agency the Commission Opinions on the agency's Strategic Programming Documents 2017 to 2019. This new tool was applicable for the first time in 2016.

(ii) To strengthen DG SANTE's monitoring and control approach: as a first action, DG SANTE introduced into its 2017 Management Plan more detailed explanations on how the agencies' activities contribute to the achievement of DG SANTE's policy objectives; this information lays the basis for an improved bottom-up reporting on the agencies' activities.

(iii) To clearly define the roles and responsibilities of and within DG SANTE vis-à-vis the agencies: DG SANTE's actions are well advanced as outlined in a Note to DG SANTE's Management Board, especially to reflect the DG's new organisational structure and the new coordination role of a horizontal Unit (in force since February 2016).

(3) IAS audit on "pilot projects and preparatory actions" in DG SANTE

Further to the 2016 IAS Audit Plan, in June 2016, the IAS launched an audit on "pilot projects and preparatory actions" in DG SANTE. The overall objective of the audit was to assess the effectiveness of the controls covering the financial management of pilot projects and preparatory actions through grants and procurement. The final audit report was issued in December 2016. The IAS made no recommendation rated "critical" or "very important".

DG SANTE drafted its action plan in January 2017 and foresees to implement all actions by the end of 2017. Actions include an update of DG SANTE's control strategy and guidance information on the process for the management of grants pertaining to pilot projects and preparatory actions.

DG SANTE's follow-up on IAS audit recommendations

DG SANTE organises its follow-up work using the corporate IT tool "Issue-track - Governance Risk and Control" (GRC) managed by the IAS. DG SANTE addresses all audit recommendations by proportionate action plans and monitors their implementation regularly. The internal control officer reports on the progress made twice a year, firstly, in the context of the mid-term report on internal control, and secondly, during the annual activity reporting.

DG SANTE's management assesses that the follow-up of audit recommendations is satisfactory given the mitigating actions already put in place and that delays of more than six months were justified by specific circumstances, such as DG SANTE's re-organisation, effective since 1 February 2016, and its middle-management mobility in the second half of 2016. These changes delayed both the update of the Business Continuity

Plan and the re-assessment of the sensitive functions. Both recommendations were closed in late 2016. With regard to DG SANTE's anti-fraud strategy, one action stemming from an IAS audit of 2015 is on-going: to discuss on a regular basis with other DGs to identify possible common fraud risks which could warrant complementary or coordinated actions to mitigate them.

2.1.2.3 Conclusion on audit results and follow-up

Based on the results of its audit and follow-up work as described in the objectives and scope of the engagements carried out in 2016, the Commission's Internal Audit Service (IAS) concludes that DG SANTE's "internal control systems audited are overall working satisfactorily although a number of very important findings remain to be addressed in line with the agreed action plans". DG SANTE management assesses that the mitigating actions already taken have reduced the residual risk to an acceptable level.

None of the issues raised by the auditors met the materiality criteria set out in Annex 4: no critical recommendation was made; no significant repetitive error or material deficiency in the internal control systems of DG SANTE was highlighted. The weaknesses pointed out in the IAS audit on DG SANTE's working arrangements with EU decentralised agencies or issues addressed by the Court of Auditors do not point to significant quantifiable errors; neither were elements identified that could seriously damage the reputation of DG SANTE. Therefore, the identified weaknesses are not likely to have a bearing on the content of the annual declaration of the Director-General of DG SANTE.

DG SANTE's implementation of audit recommendations is in general assessed as positive: auditors find DG SANTE's actions appropriate and do not report any improper delays.

2.1.3 Assessment of the effectiveness of the internal control systems

The Commission has adopted a set of internal control standards, based on international good practice, aimed to ensure the achievement of policy and operational objectives. In addition, as regards financial management, compliance with these standards is a compulsory requirement.

DG SANTE has put in place the organisational structure and the internal control systems suited to the achievement of the policy and control objectives, in accordance with the standards and having due regard to the risks associated with the environment in which it operates.

2.1.3.1 Annual assessment of internal control by management

In its internal control system, DG SANTE embedded monitoring measures to ensure that its management and internal control framework is effective. DG SANTE has also considered the risks and focuses its control resources on those areas where risks are the highest, while ensuring adequate control coverage over all activities.

The annual assessment on the implementation of the Internal Control Standards started in late 2016 and finished in the first quarter 2017 with the endorsement of a summary note by the Directors' Steering Committee on 16 February 2017 and the adoption by the Management Board on 7 March 2017. The assessment was organised by the internal control officer who collected information through the following three main sources:

(a) Desk review of documents produced by DG SANTE to implement the Commission's requirements, action plans stemming from management's risk assessment and the anti-fraud strategy; analysis of the use made of "exception reporting";

(b) Analysis of the 2016 management reports received from the authorising officers by sub-delegation as well as the audit observations of both the IAS and the Court of Auditors in the period of 2014 to 2016;

(c) Interviews with and written contributions of key staff supporting the set up and functioning of internal controls.

In 2016, DG SANTE faced several changes to its control environment mainly brought about by the re-organisation, in force since 1 February 2016. The new organisation ensured a coherent approach and rationale to the responsibilities of each Directorate with the aim to reflect and implement the clear framework set out by President Juncker and Commissioner Andriukaitis. The new organisation chart aimed at increasing both the effectiveness and the efficiency of the DG.

The new organisational structure also addressed effectively several issues related to sensitive posts since it triggered a high mobility of staff. In the transitional phase it warranted a high number of hand-overs to be organised as well as several plans and procedures to be updated. Some of the updates were finalised only at the end of 2016, for example, the Business Continuity Plan (see section 2.1.2.2 above). Other planned updates were postponed to 2017, for example, the anti-fraud strategy (see section 2.1.1.3 above). DG SANTE assessed that the delays did not bear a high risk thanks to the mitigating actions that have been in place since several years.

Throughout the year, the functioning of the internal control systems was closely monitored by the systematic registration of so-called "exceptions" and internal control weaknesses. The underlying causes behind these exceptions and weaknesses were analysed and discussed in the Directors' Steering Committee on 16 February 2017; although some issues were recurrent (mainly due to the backlog caused by the late adoption of the 2015 work programmes), management assessed that overall, the existing controls are sufficient and that the procedures in place function well. In the meeting, the importance of exception reporting was underlined to ensure that all instances that constitute an exception are covered by an appropriate report.

In the past few years, DG SANTE put special emphasis on enhancing the effectiveness of the control standard on "Objectives and Performance Indicators" (ICS 5) with the aim to improve performance measurement not only of spending programmes but also of non-financial political activities. DG SANTE is responsible for an extensive regulatory acquis covering the different policy areas. During the re-organisation in early 2016, DG SANTE created a new Unit "Better Regulation". Its main objective is to ensure that DG SANTE's policies and activities are implemented, reviewed and updated consistent with the requirements of the Commission's Better Regulation Guidelines. A set of comprehensive standard operating procedures was established and methodological support provided to identify data availability and a definition of indicators for the development of monitoring systems (for more detail see section 2.2.2 below).

Due to the continuous need for economy measures, since several years, DG SANTE makes special efforts to simplify its administrative procedures to realise efficiency gains. In 2016, DG SANTE started an efficiency exercise "Towards Excellent SANTE" to identify heavy or complicated workflows for optimisation. The objective is to achieve a streamlined, slimmer and more balanced DG SANTE (for more information see section 2.2.1 below). On 7 November 2016, the Management Board endorsed a list of workflows susceptible of simplification, identified the project leaders and, in early February 2017, received the first progress reports outlining the concrete solutions found for each workflow. The Management Board endorsed the proposed solutions and implementation has been launched in February 2017.

With regard to budget implementation in 2016, all authorising officers by sub-delegation prepared their annual reports for the Director-General. No significant risk impacting on the Director-General's declaration was identified.

Furthermore, the feedback received from the Court of Auditors did not reveal any significant internal control issues and no OLAF investigation or IDOC report was addressed to DG SANTE that would point to serious control weaknesses. The audit observations of the IAS rated "very important" are related to DG SANTE's planning and monitoring of its EU decentralised agencies; however, the main weaknesses have already been addressed in 2016 through actions that mitigate the risks pointed out by the auditors.

2.1.3.2 Risk management and reputational events

Risk management in DG SANTE facilitates the establishment of specific internal control strategies focussing on the activities and domains representing the highest risks. To be effective, risk management is fully integrated into DG SANTE's planning and control cycle. Since 2010, this is achieved by including the identification of risks and mitigating actions into the harmonised template for Unit Management Plans (UMPs).

The risk assessment exercise for the 2017 Management Plan started in October 2016. Further to the input received from all Units, the results of the risk assessment were discussed in the Director's Steering Committee to identify DG SANTE's critical risks to be reported in the 2017 Management Plan.

With a view to monitoring the implementation of the action plans, each year in August/September a progress report is prepared and communicated to the Commissioner in the context of the mid-term report. The 2016 report was discussed with the Commissioner in a meeting on 18 October 2016. DG SANTE has taken actions in response to the serious reputational event of 2015, when the General Court ruled against the Commission for having failed to set criteria to identify endocrine disruptors (reported in 2015 AAR). DG SANTE finalised the Impact Assessment, which was launched in 2013. On this basis, the Commission adopted the draft delegated and implementing acts on 15 June 2016 setting criteria to identify endocrine disruptors which were under discussion with the Member States at the end of 2016.

In 2016, no major event impacting the Director-General's declaration of assurance occurred.

2.1.3.3 Conclusion on the effectiveness of the internal control systems

DG SANTE has assessed the internal control systems during the reporting year and has concluded that the internal control standards are implemented and functioning as intended.

No instances of ineffective controls came to management's attention that would have exposed the DG to serious risks. The weaknesses pointed out by auditors do not call the overall control effectiveness into question; they will be addressed by appropriate actions in the coming months.

2.1.4 Conclusions as regards assurance

This section reviews the assessment of the elements reported above (in Sections 2.1.1, 2.1.2 and 2.1.3) and draws conclusions supporting the declaration of assurance and whether it should be qualified with reservations.

The information reported in section 2.1 stems from the results of management and feedback received in audit reports listed above. These reports result from a systematic

analysis of the evidence available. This approach provides sufficient guarantees as to the completeness and reliability of the information reported and results in a full coverage of the budget delegated to the Director-General of DG SANTE.

Given the results of its on-the-spot controls, with a residual error rate of around 1% in the ABB activity Food and Feed, DG SANTE does not deem it necessary to introduce a reservation to the Director-General's declaration. Since 2010, the cumulative effect of all measures taken has reduced the error rate to an acceptable level, i.e. below the materiality threshold of 2%.

The results of internal control reviews, risk management, ex-ante and ex-post on-the-spot controls, second level verification and follow-up on audit reports as described above indicate that in 2016, DG SANTE's system of internal control has functioned effectively, as intended, and has in general not identified material weaknesses.

In particular, DG SANTE's best estimate of the risks relating to the legality and regularity of the expenditure authorised during the reporting year[74] is between 0,6% and 0,9%. This is the weighted average detected error rate which implies an overall amount at risk at payment between EUR 2,3 and 3,7 million. This is the best, conservative estimation of the amount of relevant expenditure during the year not in conformity with the applicable contractual and regulatory provisions at the time the payment is made. A sizeable proportion of the underlying error is expected to be detected and corrected in successive years. The conservatively estimated future corrections[75] are EUR 2,0 million. This is the amount of errors that the DG conservatively estimates to identify and correct from controls that it will implement in successive years. The difference between those two amounts leads to the estimated overall amount at risk at closure of EUR 1,8 million.

Taking into account the conclusions of the review of the elements supporting assurance and the expected corrective capacity of the ex-post controls to be implemented in subsequent years, DG SANTE assesses that it has an effective, efficient, robust and reliable internal control system at its disposal. None of the issues raised by internal and external auditors met the qualitative materiality criteria: based on the audit engagements performed, their objectives and scope, no critical recommendation was made; no significant repetitive error or material deficiency in the internal control systems of DG SANTE was highlighted; neither were elements identified that could seriously damage the reputation of DG SANTE.

Therefore, the identified weaknesses are not likely to have a bearing on the content of the annual declaration of the Director-General and thus, it is possible to conclude that the internal control system provides sufficient assurance with regards to the achievement of the other internal control objectives and no reservation to the declaration is warranted.

Overall Conclusion

In conclusion, management has reasonable assurance that, overall, suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated; and necessary improvements and reinforcements are being implemented. The Director General, in his capacity as Authorising Officer by Delegation has signed the Declaration of Assurance.

2.1.5 Declaration of Assurance

[74] Total amount of payments made in 2016: EUR 409,7 (see Annex 3, table 2).

[75] The "corrective capacity" included in DG BUDG's reports amounts to 1,9% for DG SANTE; it includes not only ex-post controls but also other differences between the registered cost-claim/invoice and the actual payments made.

DECLARATION OF ASSURANCE

I, the undersigned,

Director-General of DG SANTE

In my capacity as authorising officer by delegation

Declare that the information contained in this report gives a true and fair view[76].

State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the self-assessment, ex-post controls, the limited conclusion of the Internal Audit Service on the state of control, the observations of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for years prior to the year of this declaration.

Confirm that I am not aware of anything not reported here which could harm the interests of the institution.

Brussels, 31 March 2016

Signed

Xavier Prats Monné

Authorising Officer by Delegation

[76] True and fair in this context means a reliable, complete and correct view on the state of affairs in the DG.

2.2 Other organisational management dimensions

Examples of economy and efficiency

Since several years, DG SANTE makes special efforts to simplify its procedures to realise efficiency gains. In 2016, DG SANTE started a new efficiency exercise called "Towards Excellent SANTE" (for more information see section 2.2.1 below).

As an example of economy and efficiency, in its 2016 Management Plan, DG SANTE mentioned that it is in the process of implementing the AGORA IT tool for "meetings". The aim is to manage the entire process from planning an external meeting to reimbursing experts in one single electronic tool. In 2016, the AGORA tool was renamed "AGM" and the AGM Steering Committee informed DG SANTE that it would be one of the priority Directorates General for January 2018.

Other examples of economy and efficiency are reported in section 2.1.1.1.2 ('Procurement in the two policy areas'), such as employing the e-tendering platform of the Commission. Preparations to also use e-submission have been well advanced although some adjustments to the security systems of DG DIGIT still have to be made to better fit DG SANTE's control environment related to procurement.

2.2.1 Human resource management

Tables with result indicators and outputs are included in Annex 2.

DG SANTE implemented in the beginning 2016 its new structure and organisational model to respond better to the general challenges of the Juncker College, and the specific priorities set out in the Mission letter to Commissioner Andriukaitis. This delivered not only a more efficient and effective organisation but also a leaner DG taking account of the geographical constraints of Directorates in Grange and Luxembourg. The reorganisation also implemented significant mobility among DG SANTE managers, many of whom have particular specialist skills.

The reorganisation fulfilled the following objectives:

- To reinforce DG SANTE's crisis management capacity;
- To reinforce and organise expertise to strengthen country-specific and EU-wide knowledge in the field of health;
- To ensure a stronger emphasis on better regulation;
- To increase focus on removing international trade barriers as regards food;
- To create a streamlined, slimmer and more balanced DG SANTE ensuring a better-balanced workload among Units and Directorates while remove unnecessary satellite Units.

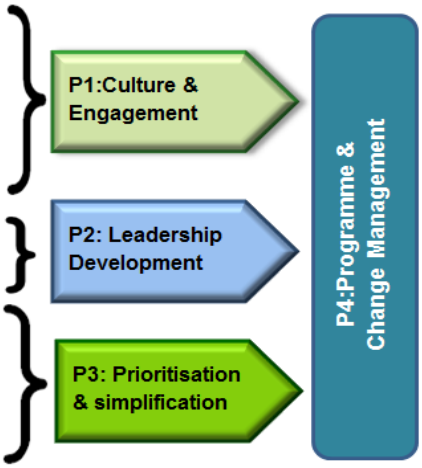
The reorganisation was the first step of DG SANTE’s overall strategic objective towards achieving organisational excellence as announced in its Strategic Plan 2016-2020.

As a result, the main focus was shifted to specific measures to develop, empower and engage staff within a supportive and healthy working environment.

During the March 2016 Management Seminar, the Middle and Senior Management teams of DG SANTE gathered to collectively discuss and decide – with the assistance of external experts – the road towards improving organisational excellence guided by the detailed analysis prepared in 2015 of the 2014 Staff Survey results.

The solutions to the prioritised work-packages were combined into 3 programmes, with a 4th transversal one as follows:

DG SANTE Strategy Work Packages	Key STEPS identified at the Management seminar
Define and drive organizational culture	Define the DG we want to be
Improve staff engagement and empowerment, respect and recognition	Time for direct discussion with management and open feedback
Improve Well-being at the workplace and allow better professional v. private life balance	Change the mentality of the managers to support New Ways of Working
Effective internal communication and collaboration	Recognize the time effort for collaboration
Leadership development	Do a 360° for Senior & Middle Management
Improve senior management communication and outreach to staff	
Plan, implement and allocate tasks and resources in accordance with DG SANTE needs	Dynamic review of priorities and stick to them
Make SANTE a modern, flexible and leaner organisation	Simplification of the heavy and complicated workflows
More efficient information, data and knowledge management	Less work for better briefings
Provide professional talent management to staff	HR support for middle management



The interaction and the discussions of both days were important steps towards creating a new DG SANTE culture and a better way of collaborating between units and directorates, and also between middle and senior management.

The results were discussed by DG SANTE's management board, whose members took full ownership and responsibility for the follow up. Leaders were assigned to the 4 programmes.

The leaders proposed next steps, together with a feasible timeline, and will engage other senior and middle managers in their implementation. Deloitte, the consultancy that has supported the process, will be involved where needed, and notably on the work on 360° evaluation of managers under the "Leadership Development" programme.

Special attention was also given to the progressive increase and the uneven and disproportionate distribution of the workload which was identified in the Staff Survey as being excessive leading to a more stressful and unpleasant working environment and leading to poor results.

Although the implementation of the new organisation chart already included some rationalisation of the HR allocation, SANTE engaged in March 2016 in an in-depth planning exercise to reflect deeper strategic thinking on the organisation of the work to ensure the objectives and the deliverables agreed with the Commissioner could be achieved while ensuring an indicative staff reduction target of 5%. This would allow:

- Initiating a change in DG SANTE's management's mind-set in view of achieving more flexibility in DG SANTE's internal allocation of resources over time;
- Identifying a pool of posts which could be redeployed rapidly to priority areas within DG SANTE.

Each Director, and the DDGs for their pillar overall, were asked to present clearly how they proposed to organise their Directorate to achieve the objectives and the deliverables agreed with the Commissioner, while ensuring the theoretical 5% cut in posts.

During the management discussions, it soon transpired that it would be very difficult to achieve the full 5% of savings in all activity areas of the DG. Some activity areas in the DG are already under particular stress and savings would only be possible after first undertaking an upfront investment in modernising and harmonising some of the processes and procedures. Important work has already been started in the food safety area.

However, the exercise resulted in net savings amounting to 17 Full Time Equivalent (FTEs) and the internal redeployment of 23 FTEs. These savings came on top of the net savings amounting to 72 FTEs already carried out since 2012.

A similar exercise was carried out in the context of the 2017 management plan and resulted in the redeployment of an additional 7 FTEs.

The above actions have significantly contributed towards increasing the overall organisational fitness of DG SANTE, ready to tackle the many challenges set out in the 2017 management plan and beyond.

2.2.2 Better regulation

Tables with result indicators and outputs are included in Annex 2.

Strengthening DG SANTE capability to deliver Better Regulation compliant initiatives

DG SANTE is responsible for an extensive regulatory acquis covering the different areas of its portfolio. The DG's commitment to efficient and valued-added management and the continuous update of its acquis, in line with the Better Regulation principles[77], was translated in 2016 with the creation of a dedicated "Better Regulation" team. The new Unit is mandated to support the establishment of a strong Better Regulation regulatory mind-set across DG SANTE and to provide internal practices and tools to ensure that DG SANTE policies and activities are implemented, reviewed and updated consistent with the requirements of the Better Regulation Guidelines. The team also advises on the application of the Better Regulation principles in the performance of ex-post evaluations of existing legislative acts and impact assessments of future legislative proposals.

Integrating the BR principles in SANTE methods of working

In 2016 DG SANTE established a set of ***comprehensive standard operating procedures*** (including appropriate screening and quality checks) for regulatory activities to ensure compliance with BR principles and rules. The procedures cover all steps of the policy cycle (from forward planning, to screening for evaluation needs, impact assessments, and stakeholder consultation, etc.) and include the direct involvement of the BR team in priority and major initiatives in DG SANTE.

The Better Regulation team provides advice and methodological support in the identification of data availability and the definition of indicators for the development of monitoring systems.

New internal validation processes ensure that the production of tertiary legislation (a significant share of DG SANTE's policy output) is closely scrutinised during preparation with the twofold objective of a) ensuring compliance with BR principles and b) identifying as early as possible in the decision-making process any issue that might require specific attention by the political validators. The new procedures, in use since the autumn 2016, will also enable DG SANTE to closely screen the considerable number of delegated and implementing acts to be adopted following the recent reviews of legislation in the plant and animal health and official controls areas.

New standard operating procedures were adopted in relation to studies performed or outsourced by DG SANTE, to ensure that financial and human resources engaged in such activities are used in accordance with and for the pursuit of agreed policy priorities.

[77] Better regulation principles entail quality evidence based policy choices by ensuring that its proposals meet policy goals at minimum cost and deliver maximum benefits to citizens, businesses and workers while avoiding all unnecessary regulatory burdens.

The terms of reference for DG SANTE's new *Framework contract for the provision of services in the areas of evaluation, impact assessment, monitoring and implementation and of other related services, in relation to the Health and Food policies*' were amended to ensure that procured services are in line with Better Regulation principles and quality standards.

Mapping DG SANTE acquis and policies

A comprehensive screening of all of DG SANTE's initiatives was conducted in 2016 to identify legislation or activities that might need to be subjected to an ex-post evaluation in 2017 or the following years. The outcome of this fed into the draft Management Plan 2017 of DG SANTE. This comprehensive mapping will enable a more systematic update of the DG's evaluation rolling plan, will increase the transparency and predictability, and thus contribute to a more efficient use of resources.

Awareness raising and knowledge sharing of Better Regulation principles and rules includes a monthly Better Regulation bulleting and specific training offered by the Better Regulation team (e.g. on the principles of Better Regulation, on how to establish your intervention logic). A dedicated functional mailbox was set up allowing colleagues to provide feedback and new ideas.

Better Regulation items in 2016

Items finalised in 2016

Evaluation of the functioning of the non-food scientific committees for the 2009-2015 period - The objective of the evaluation was to assess how the Committees carried out their mission and performed their tasks, and looked at opportunities for changes in the organisation or in the functioning of the committees. Most of the recommendations for improvement have been already or are in the process of being implemented. An action plan including the remaining actions to be taken is currently being implemented.

Evaluation of the EC Action Plan against the rising threats from antimicrobial resistance - The existing Action Plan (COM (2011) 748) covered a five-year period to 2016. The evaluation produced an evidence-based report assessing the impact of the Action Plan's implementation.

The evaluation's results support work currently underway towards a new Commission Action Plan against AMR, which will build on the results of this evaluation, as well as expand towards innovative approaches, focusing on activities with a clear EU added-value, and on measurable and concrete outcomes.

The comprehensive ***impact assessment on endocrine disruptors*** analyses different options for defining the criteria for the identification of endocrine disruptors. The impact assessment was based on the screening of available evidence of approximately 600 chemicals, covering active substances used in plant protection and biocide products, as well as a selection of substances falling under the REACH Regulation, the Cosmetic Products Regulation and the Water Framework Directive. The options were compared using Multi-Criteria Analysis, used comprehensively for the first time in an Impact Assessment. On the basis of the impact assessment, the Commission proposed the draft delegated and implementing acts setting criteria to identify endocrine disruptors, which were under discussion with the Member States at the end of 2016.

Important items ongoing or launched in 2016

Impact Assessment on Health Technology Assessment (HTA) – The DG started an Impact Assessment analysis aimed to assess the added value on the public health policies and the industry. The IA encompasses supporting studies to establish a robust baseline scenario and to gather data on alternative policy options have been launched

together with consultation activities involving all relevant actors. The analysis and the drafting of the Impact Assessment Report are expected to be completed in 2017.

Mid-term evaluation of the Common Financial Framework (CFF) for the management of the expenditure in the food chain area in the period from 2014-2020 *(Regulation* (EU) No 652/2014) - It covers the spending for animal health measures, plant health measures and official control activities. The evaluation will assess at mid-term the results and impacts of the EU funding of – among others - veterinary and phytosanitary programmes and emergency measures, European Union reference laboratories and training activities in the agri-food chain area.

Evaluation of the EU legislation on plant protection products and pesticides residues *(Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005)* - The general objective of the evaluation is to perform an evidence-based assessment of the implementation of the legislation on plant protection products and pesticides residues, including by assessing the efficacy of enforcement action and by identifying problems of compliance.

Evaluation of a) Regulation (EC) No 1924/2006 on nutrition and health claims made on food with regard to nutrient profiles and health claims made on plants and their preparations and of b) the general regulatory framework for their use in foods - The purpose of this evaluation is to assess whether two specific elements required for the implementation of the Regulation have proven to be "fit for purpose" and whether the Regulation, to date, with respect to these elements, has achieved, at minimum burden, its overall objectives.

Thus the evaluation will look at whether **nutrient profiles** (provided for in the Regulation, not yet been adopted) are warranted and adequate to ensure the objectives of the Regulation. It will also examine the current rules concerning health claims on plants and their preparations used in foods and look at how the use of claims for those products interacts with other existing rules.

Evaluation of EU law on blood, tissues and cells - The evaluation will provide a comprehensive assessment of EU rules on blood and tissues and cells - Directives 2002/98/EC1 and 2004/23/EC2 respectively and of their implementing Directives. The evaluation will assess the extent to which the legislation in place has met its original objectives and whether it remains fit for purpose. The evaluation is expected to provide a sound evidence base upon which to consider the need for any changes to the legislation.

2.2.3 Information management aspects

Tables with result indicators and outputs are included in Annex 2.

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

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

DG SANTE's eGovernment policy is toward full e-government i.e. in an open and digital manner. For some systems, DG SANTE has reached the highest level of eGovernment

maturity level, namely Transformed Government, with fully automated activities, full electronic case handling and electronic signatures for the processes implemented for interaction with Member States, business and citizens. The policy aims towards the digital economy by raising the maturity level for as many applications as possible, using standards and providing high value e-services, reducing bureaucracy where possible. We actively promote and publish available information in the European Union Open Data Portal (ODP) in human and machine readable formats.

2.2.4 External communication activities

Tables with result indicators and outputs are included in Annex 2.

DG SANTE communication priorities for 2016 were in line with the President's political guidelines, his mission letter to Commissioner Vytenis Andriukaitis, the general and specific objectives of DG SANTE in the Strategic Plan and the Commission work programme. The external communication activities launched aimed to raise awareness and build on the benefits and savings of effective protective systems in the Health and Food Safety sectors in the EU.

In 2016, a separate communication work plan was prepared by DG SANTE in line with the objectives and targets identified in the Strategic and Annual Management Plan. With this approach, communication was integrated upstream in the policy making process and communication priorities followed closely the political agenda. Communication plans on each priority were also developed, implemented, monitored and evaluated in close coordination with policy units.

The activities described below are the ones for which most of the human and financial resources have been used. However, this does not represent an exhaustive overview of all internal and external communication activities of the DG. Among the external communication activities DG SANTE intensively used its communication resources to provide timely, proactive and reactive media material in relation to sensitive files such as pesticides and endocrine disruptors or to crisis management (in particular during the Zika virus epidemic), as well as on regular media requests and requests for articles for the Commissioner.

a) In the context of the preparation of a **new EU Action Plan on Antimicrobial Resistance** and the importance to measure knowledge and raise awareness about this global threat, two Eurobarometers (in the 28 MS and in third countries) were published on 16 June 2016[78] and 18th November 2016[79], on the occasion of the European Antibiotic Awareness Day. Communication focused this year on keeping the momentum and interest in EU's role and added value on AMR in view of the adoption of the new Action Plan in 2017[80].

b) **Communication in the health sector** supported dissemination of and awareness on health innovation (focusing on access to safe and innovative medicines, Health Technology Assessment, e-health and European Reference Networks) and on effective, sustainable and resilient health systems (collecting evidence on country health profiles, reduce the burden of major chronic diseases, use of structural funds for investment in health). Proactive communication was also ensured in view of the transposition deadline for Member States for the Tobacco Products Directive (TPD), which completes an important action carried out before the TPD was launched with the Ex-Smokers campaign, which was completely phased out in 2016.

c) DG SANTE was part of the subgroup of the Communication Network in charge of the **2016 Corporate Communication Action "The Investment Plan and other Jobs and Growth initiatives".** A selection of health projects funded by

[78] http://ec.europa.eu/dgs/health_food-safety/amr/docs/eb445_amr_generalfactsheet_en.pdf
[79] http://ec.europa.eu/health//sites/health/files/antimicrobial_resistance/docs/ebs_407_en.pdf
[80] http://europa.eu/rapid/press-release_IP-16-3805_en.htm

the European Fund for Strategic Investments (EFSI) strengthened DG SANTE's links with the Investment Plan and other health-related initiatives contributing to the creation of growth and jobs.

d) Our communication activities in 2016 also stressed the importance and economic relevance of a strong and efficient **EU preparedness, prevention and response to crises in the health and food safety sectors**. In addition to the media work referred to above, , a series of four videos on the role of audits in the food safety area[81] were produced with the aim to increasing confidence in the EU control systems and recognition of the EU added value in this area, key for trade and with a big economic impact.

Regarding the **communication infrastructure**, the rationalisation of SANTE websites has started to migrated to the new Drupal platform in the framework of the Digital Transformation programme. SANTE web content will be further optimised according to the user test data and gradually integrated within a common Commission structure.

Our social media (the two DG SANTE dedicated Twitter accounts on food safety and health)_also boosted the visibility of the political priorities as well as the portfolio. The targeted social media buying allowed for increased impact of the priority communication actions with minimal financial resources and, in some cases with outstanding results: i.e. more than 300 000 views of the health cycle video in two weeks and at a cost of EUR 0.01/view.

[81] Videos will be released in the first half of 2017