2017

Annual Activity Report

DG Health and Food Safety (SANTE)

FOREWORD

In 2017, DG Health and Food Safety (DG SANTE) continued to deliver the priorities set out in President Juncker's mission letter to Commissioner Andriukaitis and to strengthen its contribution to the Commission's broader strategic agenda. It worked intensively to provide an **effective policy framework** that **protects human**, **animal** and **plant health**, guarantees a high level of food safety and ensures the EU's public health and food and feed sectors achieve their full economic potential.

Important priorities in 2017 included the mid-term evaluations of the 3rd Health Programme and the Common Financial Framework for the Food Chain 2014-2020. They confirmed the EU's significant added value in these areas and the conclusions will feed into future policy discussions. Preparedness and crisis management also remained a core part of our work with particular challenges posed by epidemics of African swine fever, avian influenza and Xylella. **DG SANTE assured a coordinated response to contain and limit their wider impact.**

Significant progress was made in several areas of our legislation. The Fitness Check of the EU's General Food Law was positively reviewed (and published in January 2018). The revised Official Controls Regulation was adopted; implementation of the new Plant Health Regulation began and various supporting acts were adopted to support the new Novel Foods legislation, the Animal Health Law and the Animal Breeding Regulation.

Important work linked to **plant protection** and **biocidal products** was also completed, in particular regarding the adoption of the criteria to identify endocrine disruptors. The plant protection product criteria are undergoing Parliamentary scrutiny until early April 2018. A proposal to renew approval for **glyphosate** use in the EU for a **further 5 years was adopted**. At the same time, the Commission responded to broader citizen concerns in this area by committing to a new legislative proposal in 2018.

Efforts to tackle **Antimicrobial Resistance** continued. The Commission presented a new EU One Health Action Plan and adopted EU Guidelines on the prudent use of antimicrobials in humans – the Plan's first deliverable. Progress was also made on a range of actions related to vaccines most notably with a view to presenting a Council Recommendation in 2018. At the same time, we continued to develop expertise on EU health systems as part of the **"State of Health in the EU"** initiative, in partnership with the **OECD** and the European Observatory on Health Systems and Policies. Country profiles for all 28 EU Member States were presented in 2017, along with a **companion report**. Further steps were also taken to improve cooperation and coordination between EU countries and to promote more cost-effective and sustainable healthcare delivery. Notable achievements included the adoption of a proposal on Health Technology Assessment; the launch of 24 European Reference Networks to consolidate EU-wide expertise on rare diseases; and the Commission adoption of implementing legislation creating a system for tracking and tracing of tobacco products. In a broader global context, DG SANTE continued to promote EU standards in various international fora and to ensure they are respected by its trading partners.

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].Health spending has reached 9.9%[2] of GDP and health sector accounted for 11% employment in the EU[3]. 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**[4] 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 balanced and progressive trade policy to harness globalisation. DG SANTE's work 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 43 (agricultural policy), 114 (internal market), 168 (public health) and 13 (animal welfare).

EU health policy is mainly 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 in health is therefore mainly linked to incentive measures for **disease prevention** and **health promotion**, and cooperation measures to improve links between Member State health systems. Several legal instruments are however based on Article 114 (internal market).

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[5].

DG SANTE works closely with the **Executive Agency for Consumers**, Health and Food (CHAFEA), 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

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

[2] Source: Companion report State of Health in the EU page 10

[3] This includes employment in following activities: human health, residential care and social work without accommodation, source: Eurostat, figure for 2016.

[4] https://ec.europa.eu/info/publications/strategic-plan-2016-2020-health-and-food-safety_en

[5] A complete overview of the Programmes' key facts and figures, their performance framework and their key achievements of 2017 is given in the Programme Statements prepared for the 2018 draft budget procedure.

(EFSA), the European Centre for Disease Prevention 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 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 2017 using a total of **780** staff.

DG SANTE Human Resources[6]	**Staff of DG SANTE Establishment plan posts At 31/12/2017**
Administrators	426
Assistants and secretaries	213
Contractual agents	97
National experts	44
Total	**780**

DG SANTE pursues its policies with a focus on prudent management and protection of the related EU financial resources. For the budget implemented under direct management, mainly through grants and procurement, the Director-General is the authorising officer by delegation who sub-delegates at the level of Deputy Directors-General, Directors and Heads of Units. The part of the budget implemented through indirect management consists of the subsidies paid to EU decentralised agencies for their running costs. Risk management helps establish specific internal control strategies focussing on activities and domains representing the highest risks.

DG SANTE 2017 budget[7] **in EUR million**	**Operational Expenditure**	**Administrative expenditure (DG managed)**	**Total Financial Resources**
Public Health	9,9	1,4	11,3
Food and Feed Safety	241,5	1,3	242,8
Other policy areas	3,3	4,2	7,5
Horizontal Administration[8]	-	12,6	12,6
Consumers, Health, Agriculture and Food Executive Agency (CHAF-EA)	-	5,5	5,5
European Centre for Disease Prevention and Control (ECDC)	58,0		58,0
European Chemicals Agency (ECHA) biocides[9]	3,9		3,9
European Food Safety Authority (EFSA)	79,2		79,2
European Medicines Agency (EMA) [10]	29,3		29,3
Total	**425,1**	**25,0**	**450,1**

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.

[6] The Human Resource data rely on the snapshot of Commission personnel (establishment plan posts) in each DG/service as of 31 December of the reporting year. These data do not necessarily constitute full-time-equivalents throughout the year.

[7] 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 CHAFEA.

[8] The horizontal credits include EUR 7,4 million for the Global Envelope and EUR 5,2 million related to the building in Grange, Ireland.

[9] The EU contribution to ECHA-biocides activities is a balancing grant; 62,5% of ECHA's budget for biocides in 2017 (EUR 10,4 million) is financed by fees from industry.

[10] The EU contribution to EMA is a balancing grant; about 90% of EMA's total 2017 budget of EUR 322,1 million is financed by fees from industry.

In 2017, DG SANTE's average residual error rate of 2,5% exceeded the materiality threshold of 2% following three consecutive years when it was down to around 1%. The higher average error rate is due to one particular audit in the context of the animal disease eradication programmes in the food and feed policy area. An exceptionally high amount will be recovered in 2018 as one Member State submitted cost claims for 2014 and 2015 programmes which were overstated by about 37%. This error happened in the context of structural changes this Member State made to its management and controls of the cost claims in the audited period and is not applicable to other cost claims or other Member States. As it is an isolated error, it cannot be extrapolated to other animal disease eradication and monitoring programmes. If it is excluded from the calculation, the residual error rate drops to just under 1% which was the rate in previous years.

Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance. Nevertheless, DG SANTE will pay special attention to similar circumstances in other Member States' cost claims related to the same type of programme in the 2018 ex-post control programme.

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[11].

a) Key results and progress towards the achievement of general and specific objectives of the DG (executive summary of section 1)

In 2017, 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 balanced and progressive trade policy to harness globalisation.

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

Promoting good health at EU level plays an important economic role, helping it to deliver on key competitive and growth priorities while reducing pressures on national budgets.

The EU's food and feed policies are supported by a comprehensive legal framework that promotes a well-functioning and safe food chain. They aim 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 value added[12] – whilst ensuring a high level of food safety and human, animal and plant health.

A key priority for this is to ensure that the relevant financing programmes are fit for purpose. In 2017, SANTE completed the mid-term evaluation of the 3rd Health Programme, which finances health-related actions with a total budget of EUR 449.4 million in 2014-2020. It concluded the Programme is highly relevant to Member States' needs and that its management has become increasingly effective.

SANTE also completed its mid-term evaluation of the Common Financial Framework (CFF) for the food chain 2014-2020. It found the current framework "functions well within its policy context" and that activities funded under it contribute to a safe, secure, prosperous and sustainable EU in a global context. Both programmes were considered to be responsive and flexible in the face of emerging needs e.g. the refugee crisis of 2015 or new outbreaks of disease. The results of these evaluations feed into the preparations of the next Multiannual Financial Framework (post 2020).

Supporting the EU's capacity to deal with crisis situations

Quick response to outbreaks of diseases and mitigation of their consequences is essential to protect human, animal and plant health. In 2017 the Commission adopted 47 emergency Decisions to help Member States control outbreaks of several major **animal diseases** including avian influenza, African swine fever and lumpy skin disease. At the same time, it provided funding of EUR 150 million to support 130 national eradication programmes targeting, amongst others, Rabies, Salmonellosis and Bovine Tuberculosis. Emergency measures were also adopted or updated to control outbreaks of organisms threatening **plant health**, notably *Xylella* fastidiosa, Epitrix and Pine Wood Nematode.

DG SANTE also effectively dealt with the incident of fipronil contamination in eggs and poultry meat in summer 2017. Lessons learned were discussed at a high level Ministerial meeting in September and the follow-up measures are carried out.

[11] Article 17(1) of the Treaty on European Union.
[12] Eurostat Statistics Explained, Manufacturing statistics – NACE Rev. 2

On the **human health** side, DG SANTE contributed to a Health Security Committee action plan to strengthen preparedness and acted on the recommendations of the European Court of Auditors' special report on cross-border health threats published in December 2016. In reply to this, implementation of the Decision on serious cross-border threats to health was continued, inter alia through implementing acts and an upgrade of the Early Warning and Response System.

To tackle vaccine-preventable diseases, DG SANTE hosted a high-level workshop on vaccination in May 2017. In December, it launched a public consultation on strengthened cooperation against vaccine preventable diseases, all with a view to preparing a Council Recommendation on vaccination in 2018. Work also continued on the joint procurement of pandemic influenza vaccines, where DG SANTE plays a key role in tendering, negotiation and implementing the framework contracts.

Tackling increased pressure on health services

Non-communicable diseases cause the majority of the pressure on health and social systems (70-80% of healthcare costs, or EUR 700 billion in the EU). In 2017, DG SANTE continued operating the Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases as part of a new approach to maximise joint efforts with EU countries. In 2017, the Group selected the first set of best practices whose implementation will be funded. SANTE also launched several Joint Actions, pilot projects and tenders to transfer good practice and test new care models promoting more cost-effective health and disease prevention to support more sustainable health systems.

Antimicrobial Resistance remains a major global challenge with serious implications for the economy and human health. In response to this and in line with the June 2016 Council conclusions on Antimicrobial Resistance, SANTE presented a new EU One Health Action Plan against Antimicrobial Resistance. It foresees over 75 actions built on three main pillars: a) making the EU a best-practice region, b) boosting research, development and innovation, and c) shaping the global agenda through multilateral and bilateral collaboration. SANTE also secured the adoption of Action Plan's first deliverable: EU Guidelines on the prudent use of antimicrobials in human health, aiming to promote more prudent use of antimicrobials in humans. At the same time, it organised the first meeting of the One Health Network in February, gathering government experts to share innovative ideas, it launched a new series of Better Training for Safer Food workshops specifically on Antimicrobial Resistance and supported the implementation of national One Health action plans through joint visits with the European Centre for Disease Prevention and Control.

DG SANTE continued work on the two-year cycle **State of Health in the EU,** responding to President Juncker's mission letter to Commissioner Andriukaitis to develop expertise on performance assessments of health systems and country-specific and cross-country knowledge. 2017 saw the presentation of 28 country health profiles and their Companion Report. The profiles, published in partnership with the Organisation for Economic Cooperation and Development and the European Observatory on Health Systems and Policies, provide an in-depth analysis of the situation in each EU country, looking at population health and important risk factors, as well as the effectiveness, accessibility and resilience of health systems.

DG SANTE continued its work to discourage **tobacco** consumption by promoting the transposition and implementation of the Tobacco Products Directive. In December 2017, it adopted tertiary legislation outlining new measures for tobacco tracking and tracing that EU Member States and economic operators will need to enact. This legislation caps a multi-year effort by the Commission to tackle illicit tobacco trade and decrease access to cigarettes and other tobacco products, which remain the biggest avoidable cause of premature death in the EU.

SANTE also promoted the uptake of **innovative health technologies**. As part of the Commission's Digital Single Market Strategy, three priorities for health-related actions were identified in the Digital Single Market mid-term review adopted in May 2017: a) enable citizen's secure access to and use of health data across-borders; b) support a cross-border data infrastructure to advance research and personalised medicine; and c) facilitate feedback and interaction between patients and health care providers. Following

the review and a public consultation, SANTE prepared a Communication on enabling the digital transformation of health and care which is scheduled for adoption in April 2018.

2017 also saw an important and visible step towards ensuring that these new technologies are applied to urgent patient needs. The **European Reference Networks** use technology to bring together highly specialised medical expertise on rare, low prevalence and complex diseases affecting EU citizens. In 2017, 24 European Reference Networks were formally launched, with SANTE providing funding and coordination. Clinical operation began in November 2017 when the Clinical Patient Management System started functioning. This is the software for data sharing and virtual panels that DG SANTE developed with funding from the Connecting Europe Facility. With this tool, the Networks are now developing the potential to offer patients and doctors timely access to the best expertise and life-saving knowledge in the EU.

Safe and sustainable food and feed systems

In 2017, DG SANTE carried out 199 **audits** and fact-finding missions in EU and non-EU countries covering food safety, animal health, animal welfare and plant health, and 18 visits and assessments in public health covering Antimicrobial Resistance and medical devices. This work ensures effective and correct implementation and enforcement of EU legislation, maintains high standards and safety levels and provides a level playing field for business operators. The results feed evidence-based policy development, and contribute to a regulatory environment which facilitates jobs, growth and investment.

Continuing the Commission's efforts towards "Better Regulation", the **Fitness Check of the EU's General Food Law** was positively reviewed by the Regulatory Scrutiny Board in October and published in January 2018. Building on this, preparatory work began on a proposal to amend the legislation in 2018 to increase transparency and ensure the EU's risk assessment model remains sustainable.

Continued progress was also made in implementing the new **Novel Food legislation** which applies from 1 January 2018. Three implementing acts were adopted in 2017 and an e-submission system developed to ease the submission of applications and notifications.

Other legislative progress included the adoption of four delegated and implementing acts under the EU's animal breeding Regulation and preparation of several delegated and implementing acts linked to the **Animal Health Law** (adoption expected by April 2019). Also, the revised **Official Control Regulation** was adopted on 15 March and DG SANTE began the preparatory work for the first tertiary acts.

The EU's **Platform for Animal Welfare** was established and met twice in 2017. It aims to promote dialogue on animal welfare and better legislative implementation and enforcement. DG SANTE also continued with the implementation of the existing Animal Welfare Strategy and launched a call for the designation of the first EU Reference Centre for Animal Welfare. These processes will be concluded in 2018.

The implementation of the new **Plant Health Regulation** has began. In December, the Commission adopted the harmonised format specifications of plant passports.

On **pesticides**, the Commission continued to support Member State efforts to implement the Directive on their sustainable use. However, a report it published in October found that while some progress has been made, overall implementation needs to be further improved in future. To this end, SANTE launched a new web portal to link Member State websites and improve information exchange.

On 4 September, the Commission adopted the criteria to identify **endocrine disruptors** in the context of the biocides Regulation which entered into force on 7 December. A draft Implementing Regulation containing the criteria to identify endocrine disruptors in the context of pesticides received a favorable opinion in the Standing Committee on 13 December. It is now under a scrutiny period until early April 2018.

Glyphosate remained a prominent topic in 2017 and in December, its approval for use in the EU was renewed for a further 5 years. At the same time, the Commission adopted a Communication in reply to the European Citizens' Initiative on glyphosate and committed to a new legislative proposal in 2018 to address broader citizen concerns in this area.

In terms of broader Commission objectives, DG SANTE continued to implement initiatives to prevent food waste as part of the EU's Circular Economy Action Plan. To support this process, the **EU Platform on Food Losses and Food Waste** met twice, in June and November. The EU food donation guidelines were adopted on 16 October. In December, a political agreement was reached with co-legislators on the Commission proposal to revise the Waste Framework Directive which provides the legal basis for the Commission to adopt a methodology for the measurement and reporting on food waste levels in the EU.

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 the internal market for safe food and feed products

Food and feed safety is ensured in the EU through a wide range of harmonised rules and 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 environmental protection across the EU, giving consumers access to safe food and feed products and helping the internal market to run smoothly. In 2017, DG SANTE continued to assess and where appropriate, authorise substances used in food and feed production to ensure safe and high quality products on the internal market.

Strengthening the internal market for innovative medicines and treatments

Health Technology Assessment (HTA) is an important tool to achieve best outcome and value for money for patients, health professionals and health systems. In 2017, SANTE worked on a Commission proposal to reduce fragmentation and duplication in the internal market through further cooperation and mutual recognition in the Health Technology Assessment procedures carried out by Member States. Following an Impact Assessment and public consultation, a legislative proposal was developed and adopted on 31 January 2018.

Patient access to affordable medicines and the balance between pharmaceutical innovation and health systems' sustainability is one of DG SANTE's focus areas. The development of innovative medicines is supported by a variety of incentives. In 2017, DGs SANTE and GROW analysed current incentive schemes and aim to present results in 2018. DG SANTE also continued to work on the authorisation of medicinal products, including advanced therapy medicinal products and particular aspects of the regulatory framework for orphan medicines, making an important contribution to a stable legal environment and optimal use of current authorisation procedures.

In October 2017, DG SANTE presented a report on progress made in children's medicines since the Paediatric Regulation came into force 10 years ago. It concluded that positive advances in the development of paediatric medicines could not have been achieved without specific EU legislation supporting e.g. the authorisation of 260 new medicines.

3. A balanced and progressive trade policy to harness globalisation

In 2017, DG SANTE advanced the EU's broader trade agenda by contributing significantly to the provisional application of the Comprehensive Economic and Trade Agreement (**CETA**) between the EU and Canada. Sanitary-phytosanitary technical discussions were concluded with **Japan** in the context of Free Trade Agreement negotiations.

Tangible results have been achieved with **China** where the EU has recorded the highest increase on export of EU agricultural and fishery products. China is now the leading destination for EU exports of meat and edible offals, dairy, eggs and honey.

EU-Mercosur negotiations intensified in 2017 with a view to concluding an Association Agreement in 2018. The negotiation of the SPS Chapter progressed very well and large part of it is now agreed.

Through many of the activities in 2017, DG SANTE contributed to Commission-wide efforts to achieve the Sustainable Development Goals (SDG), in particular health (SDG3) and halving food waste by 2030 (SDG 12) and sustainable use of pesticides (SDG 15).

DG SANTE worked closely with its global partners in the World Trade Organisation, the World Health Organisation, the Codex Alimentarius Commission, the International ouncil for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, the Food and Agriculture Organization, the World Organisation for Animal Health, and the International Plant Protection Convention 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 which is crucial as the EU is the world's major trader in pharmaceutical products (over EUR 170 billion in 2013) and the largest exporter and importer of food in the world.

DG SANTE also continued to reinforce cooperation with the Organisation for Economic Cooperation and Development in the framework of the 2016 cooperation arrangement and worked closely with the G7 and G20 on global health security issues.

On pharmaceuticals, in 2017, the Commission and the United States Food and Drug Administration successfully concluded the **Mutual Recognition Agreement on Good Manufacturing Practices inspections** which allows the EU and the US to rely on each other's inspections and exchange confidential information on inspection reports.

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**	**Interim Milestone**	**Target**
	2017	2018	2020
19/25[13]	**18/25**	Increasing	Increasing (internal target)

2017 saw a slight deterioration in this indicator (down to 18/25 from last year 21/25) due to changes in the EU's epidemiological situation. DG SANTE coordinated and managed preparedness and control systems through dozens of implementing decisions and technical and financial support. The situation for foot and mouth disease, Newcastle disease and classical swine fever remained excellent (scoring 5/5, 5/5 and 4/5 respectively). African Swine fever however, scored 2/5 and saw a slow spread occur in part due to the human factor. Similarly, avian influenza also scored 2/5, occurring relatively widely in 2017 due to multiple virus introductions in poultry farms from wild birds which led to limited further spread to other farms.

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**	**Interim Milestone**	**Target**
	2017	2016 2018	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	24	10 20	30

In 2017, 24 ERNs had been established (exceeding interim milestones for 2016 and 2018). 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

[13] 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.

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, 2015 and 2016: 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)	2017: 2,5% (policy area Food and Feed Safety) 2017: around 0% (policy area Public Health)

In the policy area "Food and Feed Safety", DG SANTE's residual error rate amounts to 2,5%. Although this exceeds the materiality threshold of 2%, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance as the relatively high error rate of 2,5% is due to an isolated error which cannot be extrapolated to the whole policy area Food and Feed (see explanations in 'DG in Brief' and section 2.1.1.1.). If this isolated error is excluded from the calculation, the residual error rate drops to just under 1% which was the rate in previous years.

c) Key conclusions on Financial management and Internal control (executive summary of section 2.1)

In accordance with the governance arrangements 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/principles, 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/principles. 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 Annual Activity Report 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 internal auditors 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) Provision of 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

DG SANTE delivers its strategic vision with support from two programmes financed by the EU budget: the EU Health Programme and the Common Financial Framework 2014-2020 in the food chain area.

EU'S 3RD HEALTH PROGRAMME 2014-2020

The EU's Third Health Programme runs from 2014-2020 with a total budget of EUR 449.4 million. It is implemented via annual work plans which identify priority areas in line with the Political Guidelines and the criteria for funding. The Health Programme is managed by the Commission with assistance from the Consumers, Health Agriculture and Food Executive Agency (CHAFEA) and national contact points in EU and other participating countries.

The work programme for 2017 focused on the following actions:

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

The **mid-term evaluation** of the Third Health Programme was published in October 2017 and concluded that the Health Programme is a small Programme with big EU-added value and where most of the funded actions are well on their way to delivering promising results, some others have only just started. Other conclusions suggest that the Programme is highly relevant to Member States needs and the objectives set are clear, explicit and specific; that Programme management has become increasingly effective; that the Programme demonstrated its responsiveness and flexibility in the face of emerging needs such as the refugees' crisis in summer 2015.

The lessons learned from this mid-term review will feed into the reflection on future EU action in health within the next Multiannual Financial Framework after 2020.

The Health Programme puts forward actions in areas where there is evidence of **EU added-value**. As noted by the Health Programme's Statement prepared for the draft budget procedure 2017[14] and 2018[15], the Programme produced **tangible results**:

- generated useful knowledge and evidence to serve as a basis for informed policymaking and further research into key health issues;

- supported the collection of comparable data across the Union, covering many Member States and providing information for policymaking purposes. In 2017 the Programme contributed to the publication of the first iteration of the so-called "State of Health in the EU" cycle elaborated in cooperation with the Organisation for Economic Cooperation and Development, World Health Organisation, and Eurostat and consisting of 28 country health profiles as well as a cross-country

[14] http://ec.europa.eu/budget/library/biblio/documents/2017/DB2017_WD01_en.pdf
[15] http://ec.europa.eu/budget/library/biblio/documents/2018/DB2018_WD01_en.pdf

analysis which also contributed to inform discussion in the European Semester. In addition work continued on European core health indicators (ECHIs), the ORPHANET database on rare diseases and others;

- provided resources for implementing the EU's political commitments and legal obligations in health (e.g. implementation of the tobacco or health threats legislation, the EU regulatory framework for medicinal products and medical devices, for substance of human origin, and cross border health care) contributing to reaching Sustainable Development Goal 3 on Health

- contributed to support Member States action in addressing cross-border challenges and health threats such as Antimicrobial Resistance (AMR), by defining common approaches to fight AMR and to control healthcare-associated infections in line with ongoing EU and international policies.

- supported public-health capacity-building at various levels by avoiding duplication and improving capabilities (e.g. by fostering Member States' preparedness in the event of health emergencies) through training and exchange of knowledge between healthcare institutions in the Member States;

- supported potential for innovation and economies of scale in health and healthcare through supporting actions on Health Technology Assessment (HTA) and the European Reference Networks (ERNs);

- identified best practice, tools and methodologies that help to secure benefits for both the public-health communities and citizens directly (e.g. with regard to improving diagnostic tests, supporting Member States in developing national actions plans on cancer, improving patient care, etc.);

- supported awareness and sustained networking activities (e.g. by co-funding pan-European conferences and networks such as those in the field of public health and health promotion);

- produced training/educational materials (e.g. to train health professionals on migrant and ethnic minority health) and guidance.

In December 2017, DG SANTE adopted the Health Programme's **Work Programme** for 2018 setting out the priorities and actions to be undertaken during the coming year.

The two non-food **scientific committees***,* (the Scientific Committee on Consumer Safety - SCCS and the Scientific Committee on Health, Environmental and Emerging Risks - SCHEER; funded by the Consumers and Health Programme respectively) continued to make an important contribution to policy decisions in 2017. When preparing policy and proposals related to consumer safety, health and environment, DG SANTE and other Commission's departments request the Scientific Committees for scientific advice and to draw attention to emerging problems.

The Committees published 18 final and six preliminary scientific opinions in 2017 to support the Commission's decision-making process. For example, the two scientific advices on breast implants and health by the Scientific Committee on Health, Environmental and Emerging Risks in September 2017 looked at new scientific information on the safety of PIP breast implants and the possible association between breast implants and anaplastic large cell lymphoma. In 2017, the Scientific Committee on Health, Environmental and Emerging Risks also played a role in rapid risk assessment of chemical threats by preparing a guidance document and participating in two exercises.

The Health Programme is managed by the Commission with assistance from the **Consumers, Health Agriculture and Food Executive Agency** (CHAFEA). CHAFEA also manages the Better Training for Safer Food (BTSF) initiative under the financial framework for food safety, animal and plant health. The policy objectives were achieved thanks to close collaboration with CHAFEA and a high level of flexibility, within the limits of the EU

Financial Regulation. In a time where EU is threatened by several animal and plant disease outbreaks, this flexibility has demonstrated its utility in establishing swiftly organised, tailor-made, and hands-on training programmes.

Procurement procedures in line with the work programmes were implemented by the Agency for all tenders where the parent DGs provided the required input defining the requested service. For the year 2017, this translated into CHAFEA launching in public health area 13 procurement procedures (i.e. 60% of procedures foreseen) and signing five service contracts. In relation to BTSF, CHAFEA launched nine procurement procedures (i.e. 50 % of procedures foreseen) and signed 12 service contracts.

CHAFEA also launched a call for proposals for operating grants addressed to non-governmental bodies pursuing one or more of the specific objectives in the Health Programme. This call was aimed at concluding four-year Framework Partnership Agreements (FPAs) covering the years 2018 - 2021. Successful beneficiaries granted an FPA are then invited to submit applications for the award of (annual) Specific Grant Agreements (SGAs).

Five direct grants with international organisations were also signed, including work on the "Country health profiles", in cooperation with the OECD and the European Observatory on Health Systems and Policies; cooperation on the European Pharmacopeia with the Council of Europe; work on migrant health in collaboration with the International Organisation on Migration (IOM); and work on tobacco control, through collaboration with the World Health Organisation on the Framework Convention on Tobacco Control (FCTC).

CHAFEA also continued to support the dissemination of Health Programme implementation results, using national, EU-wide and international events as platforms. The Agency's pop-up stands and dissemination material were present at more than 10 national and EU events. CHAFEA also organised cluster meetings, bringing together projects in a given policy area, and conferences. It also recently introduced a structured questionnaire which monitors project indicators in the Health Programme.

COMMON FINANCIAL FRAMEWORK (CFF) 2014-2020 IN THE FOOD CHAIN AREA

EU funding for food and feed safety contributes to a high level of health and safety across the food chain from production through to point of sale. It promotes a competitive food industry, operating with high and uniform levels of safety and contributes to the stability of the EU's internal and export markets.

Activities and actions in this area are governed by Regulation (EU) No 652/2014 and expenditure covers animal health measures, plant health measures, emergency measures linked to animal and plant disease outbreaks, official controls activities and relations with relevant international organisations. The total budget of the CFF 2014 – 2020 is EUR 1,892 billion euro.

The CFF finances actions under the specific objective 1.1 in relation to preparedness, prevention and eradication of animal, foodborne and plant diseases and the specific objective 1.1.6 on official controls.

As outlined in the CFF's Programme Statement prepared for the draft budget procedure 2018[16], there is a clear **EU added value** within the Programme, as it ensures that there is a well-functioning and safe food chain in place which is a key public health and economic priority. Outbreaks of serious animal and plant diseases may spread between Member States and involve the entire EU market. An EU intervention allows to minimise the impact on human, animal and plant health, as well as on the industry and the markets with a view to reducing risks and bringing improvements all along the food chain through preventive actions and management of crises.

[16] http://ec.europa.eu/budget/library/biblio/documents/2018/DB2018_WD01_en.pdf

In 2017, veterinary measures (**animal health**) continued to represent the largest share of the food chain budget, as animal diseases remain a major priority for Member States for health, trade and political reasons. As in previous years veterinary measures mostly covered the prevention, eradication or control of diseases through veterinary programmes, emergency measures, crisis management and permanent availability of EU vaccine banks. For more details please refer to point 1.1.3

For **plants**, phytosanitary measures are becoming increasingly important due to increased globalisation and trade, being accompanied by new threats. For 2017, the CFF continued to cover phytosanitary programmes and phytosanitary emergency measures. For more details please refer to point 1.1.4.

DG SANTE also continued to provide support to the Member State's **official control activities** to implement measures in animal health, plant health and food safety. These control measures covered EU databases, alert and notification tools, testing and training activities carried out by the EU Reference Laboratories (EURLs) and training activities carried out under the Better Training for Safer Food (BTSF). For more details please refer to point 1.1.6.

As noted by the CFF's Programme's Statement prepared for the draft budget procedure 2017[17] and 2018[18], the CFF co-financed a number of measures which produced tangible results:

- significant progress in eradication of diseases such as Bovine spongiform encephalopathy (BSE), rabies, and brucellosis through the implementation of national programmes;

- containment and management of outbreaks of animal diseases, e.g. lumpy skin disease through vaccination or avian influenza and African swine fever through the implementation of tailor-made emergency measures;

- containment and management of outbreaks of plant diseases, e.g. the Asian long horn beetles, pinewood nematode and Xylella fastidiosa;

- supported better implementation of the EU legislation through funding the work of the EU Reference Laboratories (EURLs) and training activities carried out under the Better Training for Safer Food (BTSF).

In 2017, DG SANTE completed a **mid-term evaluation** of the Common Financial Framework for Food and Feed (CFF) 2014-2020. Its purpose was to assess the results and impacts of the veterinary and phytosanitary programmes and emergency measures, EU reference laboratories and training activities in the food chain area. The results of this evaluation feed into the preparations of the next Multiannual Financial Framework (post 2020).

A study to develop a methodological approach to implement an analysis of cost-effectiveness in the areas of food safety spending started in 2017; the final report should be available in April 2018. This methodology will be used for the preparation of the next food chain funding instrument and in the ex-post evaluation of the CFF.

WORKING IN PARTNERSHIP WITH THE EU'S DECENTRALISED AGENCIES

DG SANTE's work was supported by five decentralised EU agencies: the Community Plant Variety Office (CVPO), the European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), the European Medicines Agency (EMA) and the European Chemicals Agency (ECHA). Collectively, these bodies represent a wealth of scientific resources, expertise and network opportunities that support SANTE's process of evidence-based policy making.

[17] http://ec.europa.eu/budget/library/biblio/documents/2017/DB2017_WD01_en.pdf
[18] http://ec.europa.eu/budget/library/biblio/documents/2018/DB2018_WD01_en.pdf

DG SANTE's work under the specific objective 1.1 on effective preparedness, prevention, response to and eradication of human, animal and plant diseases is supported by ECDC (on human diseases), EFSA (on animal and plant diseases) and CVPO (on plant diseases).

EFSA, ECDC and EMA continued to make an important contribution to SANTE's work on AMR (see section 1.1.4.).

ECHA, EFSA, EMA and CPVO continued contributing to SANTE's specific objective 1.2 on safe and sustainable food and feed production system and general objective 2 on a deeper and fairer internal market with a strengthened industrial base. They provided independent scientific advice for products and substances subject to market authorisations and in the case of CPVO by granting Community Plant Variety Rights. The agencies work with independent experts, who often work for national public bodies, academia, or non-profit organisations. Under the specific objective 1.2 ECHA and EFSA contributed to SANTE's work on endocrine disruptors. In addition, DG SANTE worked towards an enhanced cooperation between EFSA and ECHA on the classification of chemical substances.

The **European Centre for Disease Prevention and Control** (ECDC) supported SANTE's response to serious cross-border threats to health posed by communicable diseases, notably through efforts in the areas of vaccine preventable diseases, HIV/AIDS, Tuberculosis, Hepatitis and AMR as well as public health laboratory support (see also section 1.1.1.). In 2017, ECDC continued to operate dedicated surveillance networks, provided scientific opinions, notably 41 rapid risk assessments, some of which were jointly produced with EFSA, and several surveillance reports and technical guidance documents. Through daily and weekly reports, the ECDC continued to provide the Commission with epidemiological intelligence data, situation awareness and assessment of emerging threats to human health from communicable diseases. ECDC also provided scientific advice in response to 59 requests. On major threats, the input from ECDC was essential to guide the Commission in coordinating the work of the Health Security Committee, for example the assessments of the measles outbreak in Romania (March 2017), the Ebola outbreak in the Democratic Republic of the Congo (June 2017), the outbreaks of vector-borne diseases (malaria and chikungunya) in the EU (September 2017) and the outbreak of Plague in Madagascar (October 2017).

ECDC provided training to 37 fellows graduating in the ECDC Fellowship Programme (EPIET & EUPHEM) and 238 external participants in 6 training sessions. ECDC provided essential support to SANTE's international response in support of the enlargement process and in neighbourhood countries: in 2017 it organised an assessment of Albania, provided support to Ukraine, and led the scientific coordination of the MediPIET project to train epidemiologists in 16 neighbourhood-policy countries.

In 2017, **EFSA** made an essential scientific contribution to SANTE's work by providing scientific advice in the areas of animal health and welfare, plant health, biological risks and contaminants. Its support in these areas was, in particular, key to supporting the new plant health law (first quantitative plant pest risk assessment and 42 plant pest categorisation step 1 reports), the new animal health law (30 scientific opinions and a set of 36 story maps on vector-borne diseases supporting risk managers to prioritise control measures) and the ongoing priority of AMR (annual AMR report and second Joint Interagency Antimicrobial and Resistance Analysis).

EFSA also continued to support SANTE's work on the authorisation of regulated products by processing over 400 authorisation questions in 2017. Highlights include work in the area of pesticides and endocrine disruptors particularly the guidance on the assessment of endocrine disruptors in pesticides and biocides prepared with ECHA, the re-evaluation of three neonicotinoid insecticides to bees and several activities following up the glyphosate evaluation. The annual monitoring report on pesticides residues which analyses data from all Member States was also finalised.

EFSA also provided timely scientific support to the EU and Member States regarding outbreaks of animal diseases. In particular, EFSA issued a scientific opinion on avian influenza and three overview reports on avian influenza and African swine fever. The input from EFSA was decisive and of direct use in addressing preventive and response measures in particular for biosecurity and early detection in poultry. It worked with ECDC on an increased number of rapid outbreak assessments linked to salmonella and incidents of histamine intoxication. Following DG SANTE mandates, EFSA also started projects to support EU plant health crisis preparedness.

EFSA also strengthened its scientific assistance to DG SANTE and the Member States via accessible datasheet in the area of pathogens, chemical contamination, and food consumption.

ECHA's scientific opinions supported SANTE's work on the authorisation of biocidal products, approval of active substances and classification of active substances used in biocidal products and pesticides. In 2017, DG SANTE received 39 opinions related to the approval of active substances used in biocidal products and two opinions related to Union authorisation of biocidal products. ECHA also delivered 11 opinions for a harmonised classification and labelling for active substances used in biocides and pesticides. In 2017, ECHA published two new and updated four guidance documents relating to biocides.

CPVO contributed to greater investment and innovation by the adoption of measures modernising the intellectual protection of plant varieties, and implemented the respective legislation by granting plant variety protection at EU level. Plant variety protection serves as an incentive to breed new and improved plant varieties to help meet the challenges of plant health threats and food security in the context of climate change. The CPVO also helped increase EU's influence in international fora by promoting its plant variety system outside the EU.

As for the **European Medicines Agency (EMA)**, in 2017, it produced numerous scientific opinions or recommendations related to around 2,800 EMA procedures, linked to which 1,245 Commission decisions were adopted (see sections 1.2 and 1.2.2). EMA contributed to EU authorisation of new medicinal products and to the optimal use of current authorisation procedures for a competitive pharmaceutical sector and patients' access to safe medicines. EMA recommended 92 human medicines and 17 veterinary medicines for marketing authorisation by the Commission. This includes 31 new active substances for human use and seven 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 also gives scientific advice to companies on the appropriate tests and studies in the development of innovative medicines.

EMA supported SANTE in international fora to harmonise the pharmaceutical sector and promote EU standards globally (see section 1.3.1).

DG SANTE also continued to be involved in the governance of the **European Foundation for the Improvement of Living and Working Conditions (Eurofound)**. DG SANTE's involvement is limited to Eurofound's activities on quality of life and public services. DG EMPL is the lead partner DG. DG SANTE also continued to be involved in the governance of the **European Monitoring Centre for Drugs and Drug Addiction (EMCDDA)**. The synergies with DG SANTE's work covered addictions, including the European School Survey Project on Alcohol and Other Drugs (ESPAD), and drug use associated communicable diseases. DG HOME is the lead partner 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 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 ***non-communicable diseases*** can also help reintegrate people into the labour market and reduce disease-related early retirement. DG SANTE activities in 2017 which aimed to address non-communicable 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.

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.

Given the importance of mental health at the workplace, this topic was prominently on the agenda of the Compass Forum on mental health and well-being in June 2017.

DG SANTE also supervised a pilot project, which aims to identify the health needs of population groups in vulnerable or isolated situations to increase access to preventive or curative health care. The deliverables were brought to the attention of a Member States' Joint Action on Health Inequalities, foreseen for launch under the Health Programme in June 2018.

1.1.1 Specific objective 1.1: Effective preparedness, prevention, response to 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 2017 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;
- Improving preparedness and management of foodborne crisis;
- Managing, isolating and preventing outbreaks of major animal disease;
- Managing, isolating and preventing plant disease.

1. Tackling and improving the preparedness for 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.

In 2017, SANTE advanced implementing measures to address the recommendations made by the ***European Court of Auditors***' special report on cross-border health threats published in December 2016. In reply to this report, measures taken to strengthen the implementation of Decision 1082/2013/EU include the adoption of implementing acts; the upgrade of the Early Warning and Response System (EWRS) in line with the newest IT technologies to make it more efficient for notification and crisis management; the development of an action plan on preparedness with the Health Security Committee to coordinate work in this area; and progress with the implementation of joint procurement procedures. Council conclusions in this regard were adopted. 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 considered under the Decision on serious cross-border threats to health. Its aim is to secure more equitable access to selected medical countermeasures and an improved security of supply for the participating EU countries. Work continued in 2017 on the **joint procurement of pandemic influenza vaccines**, where DG SANTE plays a key role in the tendering, negotiation and implementation of the framework contracts. The tender documents were finalised in 2017 with participation of 18 Member States and the Commission. In addition, Member States have expressed interest in joint procurement procedures of further medical countermeasures, to be pursued in 2018.

Together with the Health Security Committee, in 2017, DG SANTE contributed to the preparation of an **action plan to strengthen preparedness** and support the implementation of the International Health Regulations (IHR) in the EU in light of the developments under the World Health Organisation's (WHO) Health Emergencies Programme. 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 build upon the lessons learnt from the Ebola outbreak, the findings of the Commission report on preparedness, and the recommendations of the European Court of Auditors' report.

DG SANTE also assessed the update provided by Member States every three years on their preparedness and response planning. This will feed into the preparation of the second report on preparedness with the European Centre for Disease Prevention and Control in the first half of 2018.

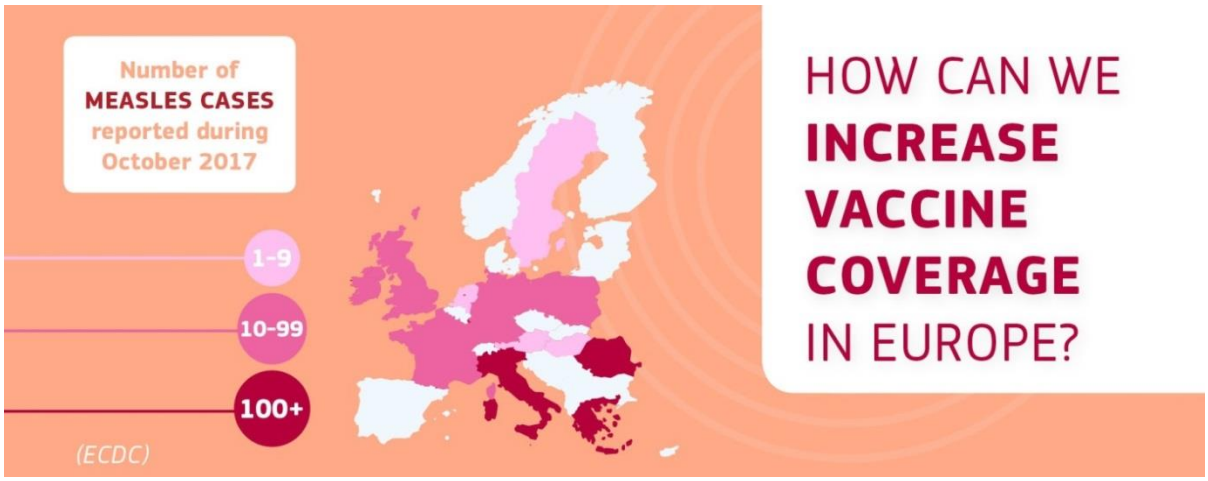
Progress under this objective is measured against the number of Member States which have improved preparedness and response planning[19] and the number of Member States with improved preparedness and response planning addressing arrangements aimed at ensuring interoperability between the health sector and other critical sectors (**result indicators 1.1A and 1.1B**). Reporting analysis of data provided by Member States will be

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

finalised in first semester of 2018 therefore no data is currently available for these two indicators.

DG SANTE also hosted the meeting of the **17th Ministerial Meeting of the Global Health Security Initiative** (GHSI) in February 2017 in Brussels. Health Ministers and delegations from the US, Canada, France, Germany, Italy, Japan, Mexico, and the UK joined leaders from the Commission and the World Health Organisation (WHO) to continue to strengthen global health security, reflect on emerging threats, and explore additional joint actions, focusing on cross-sectorial response to terror attacks and outbreak preparedness and response at global level in light of the new WHO Health Emergencies Programme.

In the context of cross-border health threats, vaccine-preventable diseases are major health scourges. Due to their cross-border nature and the challenges to national vaccination programmes, there is a clear added value of common EU action and more coordinated approaches to limit the spread of epidemics and cross-border diseases. In May 2017, DG SANTE hosted a high-level workshop on **vaccination** aimed at tackling vaccine hesitancy, promoting access to vaccines and sustainability of EU vaccine policies, and making vaccine research and development more effective.



In December 2017, DG SANTE also launched a public consultation on strengthened cooperation **against vaccine preventable diseases** with a view to the preparation, in 2018, of a Council Recommendation on vaccination.

In 2017, preparation for the **Joint Action on vaccination (2018-2021),** funded under the EU Health Programme, started, involving 20 countries, ECDC, WHO, industry and stakeholders.

FINANCIAL CONTRIBUTION TO TACKLING SERIOUS CROSS-BORDER HEALTH THREATS

In 2017, the Health Programme committed EUR 8.32 million to serious cross-border health threats. Six grants and contracts were signed, which focused on:

- Joint Action on preparedness and action at points of entry (air, maritime and ground crossing) to be launched in 2018
- Vaccination actions.

In relation to **HIV/AIDS, viral hepatitis and tuberculosis**, 2017 saw the launch of Joint Action INTEGRATE, which will run until August 2020. The budget is EUR 2.5 million with 80% funding from the EU Health Programme. Involving 15 EU Member States and other partners, its key objective is to integrate early diagnosis and link prevention and care of

HIV, hepatitis, tuberculosis and sexually transmitted infections in EU Member States by 2020. This Joint Action will reinforce another on-going Joint Action on prevention and harm reduction and the existing projects on early diagnosis and integrated care of hepatitis and tuberculosis.

The Joint Action on **Antimicrobial Resistance** and Healthcare Associated Infections (HCAI) (2017-2020) was launched in September 2017, coordinated by France. It supports the implementation of national policy on Antimicrobial Resistance and HCAI through peer reviews of Antimicrobial Resistance action, infection prevention – human/animal, and implementing research in priority areas.

Crisis management across SANTE and other Commission services and Agencies was further strengthened through exercises financed under the Health Programme. A cross-sectoral table-top exercise was organized in September 2017, to test outbreak response to zoonotic diseases with the participation of Member States, Commission services and UN organisations. An intersectoral workshop on vector-borne disease control took place in October 2017.

2. Improving preparedness and management of foodborne crisis

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 2017 (see specific objective 1.6) assessed contingency planning in Member States for food-borne emergencies and promoted the constant improvement of control systems.

In 2017, DG SANTE continued to focus on a better prevention of outbreaks and crises and improved preparedness in order to limit the extent of foodborne outbreaks (e.g. E. coli in sprouts) and their impact on public health and the economy. The revision of the Commission Decision on a general plan for crisis management in food and feed was initiated with finalisation expected mid-2018.

Following the Fipronil incident (illegal use of fipronil in poultry farms resulting in contamination of eggs and poultry meat) in 2017 and the High-level Ministerial meeting on 26 September 2017 on this issue the Member States and the Commission agreed on several measures which will reinforce the EU's action against food fraud and strengthen the efforts to ensure an EU-wide harmonised and co-ordinated risk management approach in case of a widespread contamination incidents.

In 2017, EUR 19.1 million was allocated to a total of 86 co-financed *Salmonella* control programmes in poultry populations in 24 Member States.

3. 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.

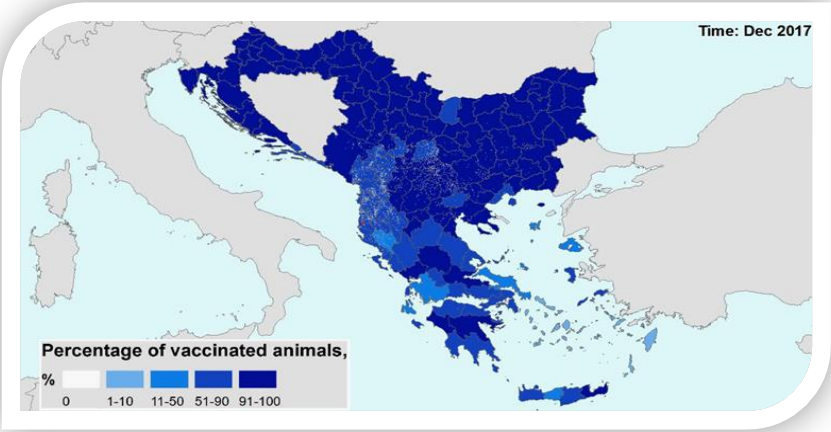
Diseases control for the major diseases is carried out under fully harmonised EU veterinary legislation based on specific disease control Directives.

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.

On **crisis management**, DG SANTE operates together with the Member States using legislative and non-legislative instruments, notably: 1) the Animal Disease Notification

System, an IT tool managed by DG SANTE; 2) Commission Decisions on the interim and definitive safeguard protective measures and on regionalisation to separate infected and disease free areas enabling safe trade; 3) the Community Veterinary Emergency Team managed by DG SANTE; 4) networks of animal disease EURLs which provide immediate technical and scientific support; 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 2017, there were outbreaks of several major epidemic animal diseases including **African swine fever** (ASF) in the Czech Republic, Estonia, Latvia, Lithuania, Poland and Romania. Outbreaks of **lumpy skin disease** (LSD) occurred in Albania, with a few sporadic outbreaks in Greece and the former Yugoslav Republic of Macedonia; other outbreaks in South East Europe were prevented thanks to systematic LSD vaccination in 2016-2017 which will continue into 2018.

Highly pathogenic **avian influenza** affected poultry in Hungary, Poland, Germany, Austria, the Netherlands, Sweden, Romania, France, Bulgaria, the United Kingdom, Slovakia, Italy, Belgium, Croatia, Spain, Czech Republic and Greece). **Bluetongue**, spreading from North Africa, affected 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.

The 4th **Ministerial Conference on African Swine Fever** was held in Riga on 2 June 2017 and the 5th Ministerial meeting in Prague on 9 November. The conclusions of the meetings focused on the need to further reinforce international cooperation (using in particular the Global Framework for the progressive control of Trans boundary Animal Diseases (GFTADs) Standing Group of Experts), stimulate additional research on ASF (focussing on the epidemiology of the virus), learn from best practices and address problems linked to the human factor (awareness campaigns, checks at entry points and review of ASF legislation).

A joint meeting of Member States' Chief Veterinary and Medical Officers was held in October in Brussels to strengthen preparedness and intersectoral collaboration between Member States authorities, EFSA, ECDC and UN under the "One Health" approach organisations for the next epidemic waves of animal and human influenza.

However, successful disease evolution depends on Member States effectively implementing EU disease control rules and operators and stakeholders properly complying with them.

The number of restrictions in the EU caused by outbreaks of major epidemic animal diseases totalled 529 in 2017. This marked an increase compared to previous years mainly

due to the unprecedented epidemic of highly pathogenic avian influenza with increased virus transmission by wild birds to poultry (**result indicator 1.1.C**).

Due to the epidemiological situation in 2017, there was a slight deterioration in the EU's containment of major epidemic animal diseases after initial outbreak (**result indicator 1.1.D**), with the indicator falling from 21/25 in 2016 to 18/25 in 2017. The situation for foot and mouth disease, Newcastle disease and classical swine fever remained excellent (scoring 5, 5 and 4 respectively) while ASF and avian influenza only scored 2.

In 2017, DG SANTE focused on the development of the delegated and implementing acts under the **Animal Health Regulation** (No. 2016/429), adoption of which is foreseen by April 2019. Several expert and working groups on listing and categorisation of animal diseases and listing of animal species, germinal products, bees and horses and entry into the EU of products of animal origin were organised.

Under the **Animal Breeding Regulation** (No. 2016/1012)four delegated and implementing acts were adopted laying down model forms for zootechnical certificates and for the presentation of information on the recognised breed societies and breeding operations. Also, an EU reference centre for zootechnics linked to purebred bovine breeding animals was appointed.

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 2017, around EUR 150 million was awarded to support the eradication, control and surveillance for 130 **national eradication programmes**, including Bovine Tuberculosis, Classical Swine Fever, Rabies, Salmonellosis, Transmissible Spongiform Encephalopathies and Bovine Brucellosis. An additional EUR 13.82 million was allocated to tackle ASF (EUR 6 million more than in 2016). The EU also provided co-funding worth around EUR 52 million for **emergency measures** to contain animal disease outbreaks quickly.

Strong financial support was also provided by the EU for the vaccination campaign against the lumpy skin disease (LSD) in affected Member States and the Balkan countries. It supported reimbursement of the vaccines purchased and used in 2017 (EUR 4,2 million committed) and through the direct shipment of vaccines from the EU vaccine bank (325 000 doses).

A vaccine bank to tackle Sheep and Goat Plague (also called "peste des petits ruminants") was also set up for the first time in 2017, to ensure the EU can react rapidly and support the Member States in case this disease enters the Union from infected neighbouring countries such as Turkey.

SANTE also advanced on implementing measures to address the recommendations made in the European Court of Auditors' special report on "Eradication, control and monitoring programmes to contain animal diseases" published in April 2016. The Court drew overall positive conclusions on DG SANTE's management of the programmes. Three of the four recommendations were implemented by the end of 2017. Please see more information on the European Court of Auditors' report under point 2.1.2.1.

4. 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.

The **Plant Health Regulation** (Regulation (EU) No 2016/2031) 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.

DG SANTE has started the process of implementing the Plant Health Regulation, including the adoption on 13 December 2017 of the harmonised format specifications of plant passports. It means that from 14 December 2019, plant passports will be required to accompany consignments of plants traded between professionals within EU territory. These labels will guarantee that the plants were grown under official supervision, in the absence of regulated pests and will ensure their traceability. The common format of plant passports will make also increase the transparency in the system and enhance stakeholders' awareness.

DG SANTE stimulated 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. In 2017, amongst the 46 pests listed for survey in the work programme adopted by the Commission, 18 of them absorbed more than 80% of the total budget allocated.

24 programmes were implemented in 2017, bringing the total percentage of EU territory covered by surveys to 85.71%, surpassing the 2017 milestone of 70% (**result indicator 1.1.E)**. In 2017, 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, in particular for *Xylella fastidiosa*, Epitrix and Pine Wood Nematode.

A high-level meeting on *Xylella fastidiosa* organised by DG SANTE and the French Ministry for Agriculture and Food took place in Paris on 30 November with affected Member States. The participants expressed their collective commitment to tackle *Xylella* by adopting an ambitious roadmap to strengthen control of this disease. The success of the roadmap depends on adequate allocation of human and budgetary resources by each delegation, at all levels.

In 2017, the import emergency measure to prevent the entry into the EU of citrus blackspot was extended to one further non-EU country (Argentina). In addition, legislative requirements were updated to account for the latest scientific knowledge, resulting in four new harmful organisms being added to the list of organisms banned in the EU. Import conditions of different commodities were also revised to ensure better protection of EU territory.

The various activities undertaken with the support of DG SANTE to address plant health risks from non-EU countries have resulted in a steady reduction in interceptions of harmful organisms in imports from these countries. According to the electronic plant health notification system, EUROPHYT, the reduction in 2017 was almost 20% compared to 2016.

On **innovative solutions in seed production**, a temporary experiment on the use true potato seed as propagating material was adopted. The harmonised certification scheme for propagating material and fruit plants was also implemented by Member States from 1 January 2017. In addition, the European Patent Office rules were aligned with the Commission Notice on the Biotechnology Directive; only plants made by technical methods are patentable.

Member States took an average of 19 days in 2017 to notify the Commission of pest outbreaks which is a significant improvement over the 49 days taken in 2016 and the 2015 baseline of 42 days meeting the 2017 milestone target of 20 days (**result indicator 1.1 G**).

The new module of EUROPHYT for reporting pest outbreaks (EUROPHYT Outbreaks) was launched at the beginning of 2017 and has significantly improved the streamlined transmission of information and ensures it is kept up-to-date. Increasingly, it will also hold pest eradication records and contribute to an increased eradication success rate (**result indicator 1.1 H**[20]).

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 of DG SANTE in the food and feed area introduced under Regulation (EU) No 652/2014. The budget for implementing plant health survey programmes in 2017 was close to EUR 14 million, supporting survey programmes for 46 plant pests in 24 Member States. The highest financial allocation was invested in fighting the *Xylella fastidiosa* pest.

In 2017 (for the year 2016), DG SANTE spent EUR 4.9 million on pest outbreaks. Amongst the outbreaks, *Anoplophora glabripennis* and *Bursaphelenchus xylophilus* 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 and feed 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 2017, 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

[20] Currently it is not possible to calculate the success rate indicator. At the time when this indicator was set, DG SANTE anticipated that the new harmonised reporting requirements introduced by a Commission implementing Decision in December 2014 would lead to the provision of all the data necessary to calculate the indicator in the short term. However, it is taking more time than expected for the Member States to adapt to the new reporting requirements. The launch of a new web-based notification system at the beginning of 2017 and the development of a common protocol for notifications are expected to facilitate timely and complete reporting by Member States. Over time, the comprehensive population of this database by the Member States will provide the necessary data to enable this indicator to be calculated. However, this is unlikely to be achieved before 2020.

framework continues to provide a high level of consumer protection whilst simultaneously encouraging growth and innovation within this very valuable economic sector.

- **Fitness Check of the General Food Law** (Regulation (EC) No 178/2002 - GFL) was positively reviewed by the Regulatory Scrutiny Board in October 2017 and formally published in January 2018. The Fitness Check concluded that the GFL was still relevant today with respect to the current trends: growth and competitiveness and increased globalisation. Nevertheless, it was less adequate to address new challenges like food sustainability in general, and more specifically, food waste. Overall, the GFL has achieved its core objectives, namely high protection of human health and consumers' interests and the smooth functioning of the internal market. No systemic failures have been identified. Nevertheless, some shortcomings were recognised:
    - National differences in the implementation and enforcement of the EU legislative framework; however, these are not systematic but occur rather on a case-by-case basis;
    - General public's perception of a certain lack of transparency and independence in risk analysis and lack of effective risk communication which have a negative impact on the acceptability of EFSA's scientific work;
    - A number of negative signals in relation to the capacity of EFSA to maintain a high level of scientific expertise and to fully engage all Member States in scientific cooperation;
    - Lengthy authorisation procedures in some sectors (e.g. feed additives, plant protection products, food improvement agents, novel foods, health claims) which slow down the market entry process.

Building on this, preparatory work began on a proposal to amend the GFL and related sectorial legislation in 2018 to increase transparency and ensure the EU's

risk assessment model in the food chain remains sustainable.[21]

In addition, on 27 November, DG SANTE organised an anniversary event celebrating 15 years of the GFL.

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https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-6265773_en.

- **Evaluations on plant protection products and pesticides residues legislation** (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005) – the study supporting the evaluation was launched in 2017 and its results are expected in mid-2018. The study will be the basis for a final report at the beginning of 2019.
- **Evaluation on nutrition and health claims legislation** (Regulation (EC) No 1924/2006 and the general regulatory framework for nutrition and health claims use in foods) – Following the completion of the study, the final report is planned for mid-2018.

DG SANTE also launched evaluations of the legislations on **feed additives** (Regulation (EC) No 1831/2003)**, on food contact materials** (Regulation (EU) No 1935/2004) and **on food irradiation** (Directives 1999/2/EC and 1999/3/EC) in 2017.

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

REDUCING INTAKES OF TRANS-FATTY ACIDS (TFAS) IN FOOD

A Commission report in 2015 concluded that setting a legal limit for industrially produced TFAs in foods would be the most effective measure to protect consumers and public health and ensure compatibility with the internal market. In 2017, DG SANTE worked on the impact assessment on TFAs which should be finalised in the first half of 2018 for submission to the Regulatory Scrutiny Board. If the impact assessment confirms the report's findings, the Commission could start work on a measure aiming to restrict the use of industrially produced TFAs in foods.

FOOD LABELLING

In 2017, DG SANTE continued to work on the implementation of the Regulation on food information to consumers (1169/2011). The Regulation, among others, reinforces the rules on voluntary origin labelling. When the origin of a product is given and the origin of its primary ingredient is different, this difference will have to be communicated. An implementing act setting the modalities for applying this rule was prepared in 2017 by DG SANTE, for which adoption is planned in the first half of 2018. In addition, the Commission adopted notices on the provision of information on substances or products causing allergies or intolerances and on the application of the principle of quantitative ingredients declaration (QUID). They will provide businesses and national authorities with clarity on the relevant requirements of the Regulation on food information to consumers.

In March 2017, the report on alcohol labelling was adopted. It concluded that the sectors concerned should develop, within a year, a self-regulatory proposal to provide a list of ingredients and nutrition information on all alcoholic beverages to help consumers to make informed choices.

NOVEL FOOD

In 2017, DG SANTE focused on the elaboration and adoption of the implementing rules for the Regulation on Novel Foods (2015/2283) which came into application on 1 January 2018. The new Regulation will improve the efficiency and transparency of the safety evaluation and authorisation procedure, promote innovation and provide for a faster and more proportionate safety assessment for traditional foods from non-EU countries which have a history of safe food use. To facilitate and simplify the submission of applications for novel foods and notifications for traditional foods from non-EU countries an e-submission system was developed in 2017 as part of the innovation portal.

The success of the Novel Foods Regulation is monitored by **result indicator 1.2.C** which measures DG SANTE's compliance rate with its legal obligation to complete delegated and implementing acts identified as a priority under the Regulation. In 2017, three implementing acts containing four out of five implementing measures were adopted. There is still one remaining implementing act which will clarify the procedures for requesting consultation process of the Member States on the novel food status of a particular food that will be adopted by the end of 2018. The adoption of the delegated act on engineered

nanomaterials will be deferred to 2019 as it depends on the Commission adopting a Recommendation to revise Commission Recommendation 2011/696/EU on a definition of nanomaterials.

PREVENTING FOOD WASTE AND PROMOTING THE CIRCULAR ECONOMY

DG SANTE continued to implement initiatives to prevent food waste as laid down in the Circular Economy Action Plan (CEAP). Actions which aim to prevent food waste bring both economic and environmental benefits and strengthen the sustainability of the food chain. The EU Platform on Food Losses and Food Waste met twice in 2017 (14 June and 7 November) and focussed on preparing methodology to measure food waste consistently across the EU, the development of EU guidelines to facilitate the donation of safe, edible food and, more generally, facilitating exchange of best practice amongst Platform members.

To support this process, a sub-group dedicated to **"action and implementation"** was established in 2017, in addition to other sub-groups addressing food donation and food waste measurement. A new digital tool was also introduced in order to help platform members and the Commission exchange information. The EU food donation guidelines, adopted on 16 October 2017 – World Food Day, aim to promote **food donation** in the EU by facilitating compliance with relevant EU regulatory requirements and promoting common interpretation of EU rules amongst Member State authorities.

DG SANTE has been actively exploring ways to improve the understanding and use of date marking by actors in the food chain including consumers. For this purpose, it launched a study to investigate date marking practices of food business operators and control authorities; key findings were presented to the Platform in November and the final report was published in January 2018[22].

DG SANTE has worked closely with DG Environment to support negotiations on the Commission proposal to revise the Waste Framework Directive. In December 2017, a political agreement was reached with co-legislators on the new legislation which, for the first time, will introduce specific obligations for Member States to reduce food waste, at each stage of the food supply chain, in line with Sustainable Development Goals. It also provides the legal basis for the Commission to adopt a methodology for the measurement and reporting on food waste levels in the EU.

In January 2017, the Court of Auditors published its Special Report 34/2016 'Combating Food Waste: an opportunity for the EU to improve the resource-efficiency of the food supply chain' in which it made three audit recommendations addressed to DG SANTE as lead DG. DG SANTE prepared an action plan with deadlines in late 2018 and 2019. Please see more information on the European Court of Auditors' report under point 2.1.2.1.

[22] https://data.europa.eu/doi/10.2875/808514

SUSTAINABLE FEED PRODUCTION SYSTEMS

In the same context, in 2017, DG SANTE worked closely with Member States to elaborate guidelines to clarify the legal status of former foodstuffs intended for feed. These aim to facilitate safe use of food resources as feed and thereby prevent food waste. Adoption is planned for the 1st half of 2018. DG SANTE also published an overview report on its project on interactions between official feed controls in the Member States and private assurance schemes.

A project on risk-based controls in the feed sector, with visits to 9 Member States in 2017, aims to support more effective and efficient controls and a higher level of safety along the feed chain through improved risk-based prioritisation of Member State controls.

FOOD CONTACT MATERIALS

Based on the EFSA opinion, DG SANTE prepared a measure on bisphenol A (BPA) in food contact materials (FCMs) lowering the migration limit for plastics, introducing the same limit for varnishes and coatings and banning BPA in FCMs containing foods for infants and young children. Following a vote in the Standing Committee in September 2017, the measure was adopted on 12 February 2018 and will apply from 6 September 2018.

In addition, six substances for use in the manufacture of plastics were authorised and five more substances were prepared for authorisation in 2018. Four more amendments were made to the plastics Regulations, including a lowered limit for nickel. The planned authorisations of plastic recycling processes were postponed to 2018 due to several constraints.

In January 2017, the Commission published a comprehensive report on the state of play concerning food contact materials for which no specific measures exist at EU level. Following on from this SANTE published a Roadmap in November on an evaluation of Regulation (EU) No 1935/2004 on food contact materials. A study will commence in 2018 to support this work and the results will be subject to a 12-week public consultation.

MARKET ACCESS FOR SAFE SUBSTANCES

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

These authorisations included new substances and new uses of substances already authorised as food additives (one new food additive and nine amendments to the use or specification), food flavourings (20 amendments to existing authorisations), and novel foods (12 authorisations by the Commission, six authorisation by Member States and 58 notifications). DG SANTE also adopted Regulation (EU) 2017/1250 withdrawing one flavouring substance on the basis of EFSA opinion in the framework of the ongoing evaluation programme of existing flavourings.

Re-evaluations of authorisations, new authorisations, modifications of authorisations and renewal of authorisations of feed additives were proposed based on the outcome of the safety evaluations (in 2017: 56 implementing regulations approving 243 feed additives, one additive authorisation denied, 385 additives withdrawn and one additive authorisation suspended).

On plant protection products, the Commission adopted 13 Regulations for approval and 12 Regulations for non-approval of new active substances (including three non-approvals after specific review) as well as 15 Regulations for renewal and four Regulations for non-renewal of approval of active substances.

In the area of biocides, 16 Regulations were adopted for approval and two Decisions for non-approval of active substances for use in biocidal products of different product-types, as well as eight Regulations renewing the approval of previously approved active

substances for use in biocidal products. Of these 26 legal acts, 22 referred to existing active substances and four to new active substances.

On pesticide residues, the Commission adopted, on DG SANTE's proposal, Regulations setting maximum residue levels (MRLs) for 80 substances following applications and/or implementing Codex MRLs as well as Regulations reviewing the full set of existing MRLs for 14 substances.

DG SANTE also set four maximum levels for contaminants in feed and food.

In 2017, the Commission adopted Regulation (EC) 2017/2158 to reduce the presence of **acrylamide in food**. Once implemented, it will require that food business operators apply mandatory measures to reduce the presence of acrylamide, proportionate to the size and nature of their establishment.

Progress on the approval of safe substances is measured by the compliance rate with legal deadlines for the presentation of a regulatory decision on the approval of pesticides (**result indicator 1.2.B**) and on the approval of food additives (**result indicator 1.2.BB**). In 2017, the compliance rate for pesticides was 83% (the milestone for 2017 was 80%) and for food additives 87.5% (almost meeting the 2017 milestone of 90%). Even though approval processes are largely dependent on DG SANTE, enforcement is down to Member States and food business operators are ultimately responsible for applying the rules at source.

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 2017, 31 new GMOs were authorised and two GMOs had their authorisation renewed. In addition, the proposals to authorise two GMOs for cultivation and renew existing authorisations for cultivation were presented for a vote to the Members States in the Standing Committee.

As regards the environmental risk assessment of genetically modified plants, DG SANTE worked on the adaptation to the 2010 EFSA guidance of the Annexes of the Directive 2001/18/EC on deliberate release of GMOs into the environment as foreseen in the cultivation Directive (EU) 2015/412. The Commission adopted the measure on 8 March 2018[23].

No progress was made on the inter-institutional negotiations on the GM food/feed proposal nor on the proposals on suspending the cloning technique on farm animals and the placing on the market of food from animal clones in the EU. The GM food/feed proposal gives the possibility to Member States to take account of their national societal concerns.

NEW BREEDING TECHNIQUES

On 28 September 2017, DG SANTE organised a high-level conference on "Safe Use of Modern Biotechnologies – Paving the way for responsible innovation". The aim of the conference was to stimulate an informed and open debate among all stakeholders on how the EU can benefit from modern biotechnologies and innovation in the food and agricultural sector while maintaining high safety standards.

SUSTAINABLE USE OF PESTICIDES

In 2017, DG SANTE continued working with Member States on the implementation of Directive 2009/128/EC on the sustainable use of pesticides (SUD). It aims to reduce the

[23] Commission Directive (EU) 2018/350 of 8 March 2018 amending Directive 2001/18/EC of the European Parliament and of the Council as regards the environmental risk assessment of genetically modified organisms (OJ L 67, 9.3.2018, p. 30–45)

risks and impacts of pesticide use on human health and the environment and promote the use of integrated pest management (IPM) and alternative approaches such as non-chemical alternatives. The Commission report on the Member States' implementation of the SUD, published in October 2017, showed that the Member States had made progress in some areas, for example, the training of professional users, a general ban on aerial spraying and the testing of spraying equipment. However, overall the implementation of the Directive should be improved, including IPM which, although compulsory for professional users, remains underused and compliance at individual grower level is not systematically checked by Member States. The Commission therefore plans to support the Member States in the development of methodologies to assess compliance with IPM principles. The report was based on a questionnaire to all Member States, followed by a series of fact-finding visits to six countries. It calls on the Member States to set up quantifiable objectives and targets in their revised National Action Plans to demonstrate the progress made.

The Commission's report was accompanied by an overview report which includes many examples of good practice being implemented by Member States. In addition, DG SANTE launched a new SUD web portal[24] which contains links to Member States' websites on **sustainable use of pesticides** with a view to **facilitating the exchange** of information between them and increasing the flow of relevant information to farmers and the general public. The Commission also published Guidance on monitoring and surveying the impacts of pesticide use on human health and the environment.

In 2017, DG SANTE continued working with the Member States on the execution of the implementation plan prepared by the Expert Group on Sustainable Plant Protection which was endorsed by the Agriculture and Fisheries Council in June 2016. The Plan identifies actions for increasing the availability of low-risk plant protection products and speeding up the application of IPM. A Regulation setting new criteria for the approval of low risk substances was adopted in 2017. A draft list of potential low risk substances has been prepared for formal adoption in 2018. DG SANTE also worked on a progress report on the implementation of actions and technical guidance to harmonise the assessment of low risk substances, including micro-organisms.

[24] https://ec.europa.eu/food/plant/pesticides/sustainable_use_pesticides_en

ENDOCRINE DISRUPTORS

On 4 September 2017, the Commission adopted the criteria to identify endocrine disruptors in the context of biocides (a delegated act). After scrutiny within the Council and European Parliament, the scientific criteria for biocides entered into force on 7 December 2017 and will become applicable on 7 June 2018.

On 4 July 2017 a draft Implementing Regulation containing the criteria to identify endocrine disruptors in the context of pesticides received a favourable opinion in the Standing Committee. However, the draft Regulation was rejected by the European Parliament on 4 October 2017 on legal grounds due to one specific provision. An amended draft Regulation received a favourable opinion from the Committee on 13 December 2017. The draft Regulation is under a three-month scrutiny period in the Council and the European Parliament until 9 April 2018.

ECHA and EFSA launched a public consultation on 7 December on the joint draft technical Guidance document to implement the criteria once they become applicable for biocides and pesticides.

GLYPHOSATE

On 27 November 2017, Member States voted in favour of the Commission's proposal for a 5 year renewal of the approval of glyphosate, which was subsequently adopted by the Commission on 12 December 2017.

Also on 12 December 2017, the Commission adopted a Communication in reply to the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides" in which it considered that the decision to renew the approval of glyphosate (for 5 years) is fully justified and committed to presenting a legislative proposal to further increase the transparency of studies used in the scientific assessment of substances in 2018.

NEONICOTINOIDS

In 2013, the Commission significantly restricted the use of plant protection products and treated seeds containing three neonicotinoids (clothianidin, imidacloprid and thiamethoxam) to protect honeybees. Based on an EFSA evaluation, the Commission proposed in 2017 to further restrict the use of these substances to permanent greenhouses only. A vote on these drafts was postponed to early 2018.

FOOD HYGIENE

In 2017, DG SANTE discussed a number of policy actions with Member States linked to the EU's food hygiene legislation with a view to adapting it to biological risks and innovation whilst remaining proportionate and maintaining a high level of food safety. More flexible temperature conditions for the transport of meat, tests for certain marine toxins in shellfish, hygiene criterion for Campylobacter in slaughterhouses, use of proteins of insects in fish feed and adaptation to the rules on export of processed ruminant proteins were authorised. DG SANTE also published a guidance on food safety management systems for small food retailers allowing them to apply a 'simplified approach'.

DG SANTE started discussions on the implementation of the new Official Controls Regulation (see section 1.1.6), in particular with regard to the revision of meat inspection rules and the setting of import conditions for food products.

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**). In 2016, there were 94 530 confirmed cases of human salmonellosis. This represents a slight increase compared to 2012 figures and remains far in excess of the 2018 target of 67000 cases. DG SANTE continues to monitor the situation closely. Though this pathogen is present in various animal species, EU legislation targeted poultry as it is this sector where the impact was assessed to be most significant. The plateau currently

reached should not hide the success of those measures as pigs are now a more common source of contamination than broilers. However eggs remain the main cause of human salmonellosis and efforts should therefore be pursued in the egg-production sector as there is still room for improvement. For instance, the 2016-2017 outbreak of Salmonellosis with its origin in Polish eggs accounted for more than 500 reported human cases alone.

FEED HYGIENE

In 2017, DG SANTE was preparing a Guidance document on the implementation of certain provisions of Regulation (EC) No 183/2005 laying down requirements for feed hygiene (the Feed Hygiene Regulation). The document aims to assist all players in the feed chain, mainly feed business operators and competent authorities, to apply correctly and in a uniform way the Regulation, mainly regarding to the registration requirement of feed establishments. Its adoption is planned for the 1st half of 2018.

ANIMAL WELFARE

Following calls from several Member States, the European Parliament and stakeholders, DG SANTE set up the **EU Platform on animal welfare** in 2017. The aim of the Platform is to increase dialogue, improve the implementation and enforcement of existing legislation and exchange information and best practices also with the view to promote EU standards domestically and globally. The first meeting of the Platform took place on 6 June 2017 and concluded that the Commission would propose initiatives on the basis of topics that attracted the most interest among Platform members and that correspond to EU priorities. At the second Platform meeting, on 10 November 2017, the Commission announced the creation of the sub-group on animal transport.

Several actions of the EU **Animal Welfare Strategy 2012-2015** were completed in 2017 namely: a pilot project on best practices in protection of animals during transport, a study on best practices on the protection of animals at the time of killing and a study on transport and killing of farmed fish. DG SANTE also worked on the remaining actions of the Animal Welfare Strategy i.e. reports on the impact of animal welfare international activities (adopted in January 2018), the application of the broilers Directive (adoption envisaged for April 2018) and protection of fish at the time of killing (adopted in March 2018).

Following the entry into force of the Official Controls Regulation (No. 2017/625), DG SANTE designated the first **EU Reference Centre for Animal Welfare** (Commission Implementing Regulation (EU) 2018/329) which will focus on pig welfare. Its designation will be reviewed every five years.

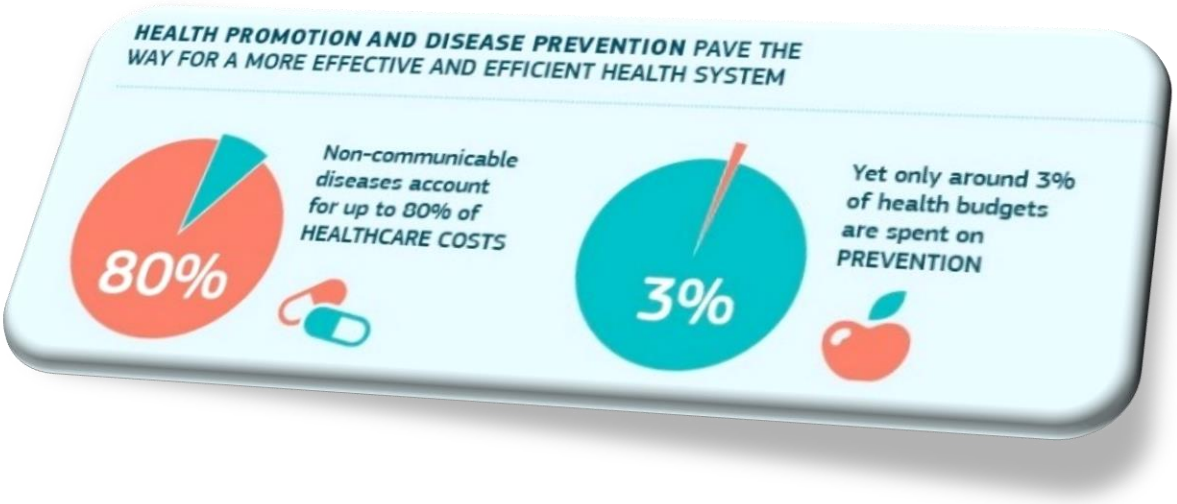
DG SANTE also continued to work on better enforcement of EU legislation with priorities including pig welfare (especially tail-docking) and the transport of animals through audits, meetings and trainings. DG SANTE prepared leaflets on animal welfare during transport for drivers transporting animals to Turkey and factsheets and videos on tail-docking in pigs. As a result, for example, the implementation of the animal transport Regulation (Regulation 1/2005) improved greatly. The non-compliance rate at the Bulgarian border with Turkey decreased from 15% at the beginning of the year to 5% at the end of 2017.

Moreover, DG SANTE continued its international activities on animal welfare in particular with the World Organisation of Animal Health as well as with its key trading partners. At the same time, it 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.

Non-communicable diseases account for the vast bulk of the pressure on health and social systems (70-80% of healthcare costs, or EUR 700 billion in the EU). Up to 7% of GDP may be lost due to the impact of non-communicable diseases. Only a small fraction of health spending goes on prevention activities. OECD countries allocate less than 3% of their health spending on average to public health and prevention activities. EU actions mainly focus on risk factors and primary prevention including legislation on tobacco products.



To address these issues under one comprehensive framework, DG SANTE continued to steer the work of the **Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases** as part of a new approach to maximise and focus joint efforts with the EU Member States on reaching the nine voluntary targets of the WHO on non-communicable diseases by 2025 and the Sustainable Development Goal target (SDG 3) by 2030. It brings together senior level health officials from the 28 Member States, EEA countries and the Commission services. The Steering Group met twice in March and October 2017 and selected the first set of best practices whose implementation will be funded under the Health Programme and other EU funding instruments.

The work of the Group will be supported by a variety of online resources, including the Promotion and Prevention Gateway being developed by the Joint Research Centre on behalf of DG SANTE, and a best practice portal developed by DG SANTE bringing together the best practices identified by different projects in a one-stop-shop.

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 non-communicable diseases and encourage best practice transfer. This promotes conditions for more cost-effective health promotion and disease prevention and in turn improves the sustainability of health systems and contributes to boosting jobs, growth and investment.

In 2017, around EUR 17.46 million were committed from the **Health Programme** to health promotion and disease prevention, financing the following major activities: the first Joint Action on Chronic Diseases (CHRODIS) was completed and a concluding conference hosted in February 2017. In September 2017, "CHRODIS Plus" was launched, a Joint Action (2017-2020) aimed at supporting EU countries in piloting the models developed by

CHRODIS and transferring best practices identified. CHRODIS Plus includes 42 partners from 18 EU countries plus Norway, Serbia and Iceland and has a budget of EUR 6.8 million, of which EUR 5 million come from the Health Programme.

Other Joint Actions launched together with Member States in 2017 addressed rare cancers, frailty, an innovative partnership on action against cancer, and health inequalities.

Projects in support of Member States and stakeholders to address the challenge posed by non-communicable diseases addressed exchanging best practice on measures reducing underage drinking and heavy episodic drinking, the European Initiative on Breast Cancer and the upgrade of the European Cancer Information System.

The expert group on cancer control met in May 2017 with support from DG SANTE to endorse the recommendations of the Joint Action on Cancer Control (CANCON) and discuss the implementation of the Council recommendation on cancer screening and Joint Actions relating to cancers.

In the area of **mental health**, DG SANTE supported the organisation of two expert group meetings in May and June and the work of the European Compass for mental-health and well-being, including a conference and a brochure with good practices which was published on the Mental Health Day in October. With financial support of the Health Programme, the WHO launched the Global Dementia Observatory which will also be beneficial for the EU Member States.

In addition, DG SANTE continued to monitor pilot projects and preparatory actions, funded by the European Parliament, covering self-care, cardiovascular, rheumatic and rare diseases, epilepsy, cancer and mental health.

In 2015, 12 Member States had an integrated national plan in place to address non-communicable diseases and implement the WHO targets. In 2017, 15 Member States had such a plan - **result indicator 1.3A** which is below the 2017 milestone of 19 Member States. Reaching this milestone is dependent upon actions taken by Member States. Concerning the number of EU countries in which a European accreditation scheme for breast cancer services is implemented - **result indicator 1.3C** - in 2017, 15 Member States have implemented the first steps of the process by preparing themselves for the pilot phase of the breast cancer accreditation scheme. The pilot phase of the accreditation scheme is part of the European Initiative on Breast Cancer, coordinated by the Joint Research Center (JRC).

HEALTH DETERMINANTS - HEALTHY DIETS, PHYSICAL ACTIVITY, ALCOHOL AND TOBACCO

In 2017, DG SANTE launched two tenders to take forward work on healthy diets. One monitors national reformulation initiatives, helping to establish a benchmark, and the other maps the exposure of children to marketing of foods high in fat, sugar or salt, helping to protect children in the context of the revision of the Audiovisual Media Services Directive. DG SANTE also supported the preparation and lauch in 2017 of a tool to help schools draft better food catering contracts; public procurement provides a EUR 80 billion/year opportunity to improve the food provided to children, the elderly, the low socio-economic groups and the workforce.

During 2017, one Member State decided to only fully subsidise milk without added sugars for distribution in primary schools under the Commission's School Fruit, Vegetables and Milk Scheme. Several industry members committed to reduce added sugars by 10% by 2020. These were direct results of processes held at the Member States' High-Level Group and stakeholders' Platform. Six Member States credited the Action Plan on Childhood Obesity (and the support of DG SANTE) with having directly sparked or facilitated the adoption of a specific national plan on nutrition. Two others further noted that it supported the allocation of financial resources and one Member State revised its public procurement procedures for food in accordance with these objectives.

DG SANTE also helped to organise 50 stakeholder meetings in the context of the EU Platform for Action on Diet, Physical Activity and Health for stakeholders to propose or revise commitments in support of the WHO targets on non-communicable diseases. This resulted, inter alia, in an improved version of an important commitment to reduce the exposure of children to food marketing.

The Action Plan on Youth Drinking and on Heavy Episodic Drinking was prolonged by the Committee on National Alcohol Policy and Action until 2020 and an evidence overview of the links between alcohol and health was prepared.

Dozens of examples of validated best practices on nutrition, physical activity and alcohol related harm have been collected from Member States to support implementation, in particular in the context of Steering Group on Prevention and Promotion.

Result indicator 1.3B measures progress on the issues of healthy diet and food reformulation. In 2017, 1) 22 Member States had national initiatives on reduction of saturated fat (+4 change from 2015), plus three in the process of adoption; 2) 26 Member States (plus Norway) had national initiatives on reduction of salt (+6 change from 2015), plus two in the process of adoption, thus meeting the milestone of 2017; 3) 24 Member States (plus Norway and Switzerland) had national initiatives on reduction of sugar (+4 change from 2015), plus 2 in the process of adoption; and 4) 22 Member States had national initiatives on reduction of alcohol-related harm (+1 from 2015); with the overall target of covering all Member States in all categories by 2020. Reaching the milestones above is dependent upon actions taken by Member States.

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. The impact assessment launched in 2017 will provide the basis for a decision on the way forward, in the interest of protecting consumers and public health and ensuring the compatibility with the internal market.

DG SANTE continued its work to discourage tobacco consumption. All Member States have notified the complete transposition of the Tobacco Products Directive (TPD) 2014/40/EU. In December 2017, DG SANTE adopted tertiary legislation outlining new measures for tobacco tracking and tracing that EU Member States and economic operators will need to enact, as planned for in the TPD. This means that unit packets of tobacco products will be marked with a unique identifier and safety feature and their movements will be recorded throughout the supply chain.

In 2017, DG SANTE also established an Independent Advisory Panel to assist Member States and the Commission in determining tobacco products with characterising flavour, as well as a technical group to assist the advisory panel with sensory and chemical analysis.

In order to facilitate submission of product data by manufacturers and importers to national regulators, DG SANTE developed the electronic reporting tool (EU Common Entry Gate). In addition, the Joint Action on Tobacco Control (JATC) was set up for the national regulators to join forces in the implementation and enforcement of the TPD. The JATC is a three year collaborative action bringing together 31 project partners and 13 collaborating partners that span 31 countries, including 25 Member States.

As to international activities to discourage tobacco consumption, please refer to specific objective 3.1.

INEQUALITIES IN HEALTH

Health is one of the priority topics in the Commission Action Plan for integration of migrants and refugees[25].

[25] Commission Communication (COM (2016) 377) on an action plan on the integration of third country nationals

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 effective, accessible and resilient 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 economic competitiveness.

Specific priorities addressed by SANTE in 2017 included:

COUNTRY KNOWLEDGE

In his mission letter to Commissioner Andriukaitis, President Juncker requested to develop expertise on health systems performance and to build country-specific and cross-country knowledge to inform policy making at EU and national level.

To implement this request, DG SANTE initiated a knowledge-brokering cycle: **State of Health in the EU**. It is a two-year cycle generating evidence-based cross-country and country-specific information on health systems as a source of mutual learning. This has been developed through a tripartite collaboration between the Commission, the OECD and the European Observatory on Health Systems and Policies.

2017 saw the presentation of the State of Health in the EU products, including 28 country health profiles and their Companion Report[26]. The profiles published in partnership with the OECD and the European Observatory on Health Systems and Policies, provide an in-depth analysis of the situation in each EU Member State, looking at the health of the population and important risk factors, as well as at the effectiveness, accessibility and resilience of health systems. The Companion Report analyses cross cutting policy levers that can improve the effectiveness, accessibility and resilience of health systems across the EU and explores the scope for mutual learning.

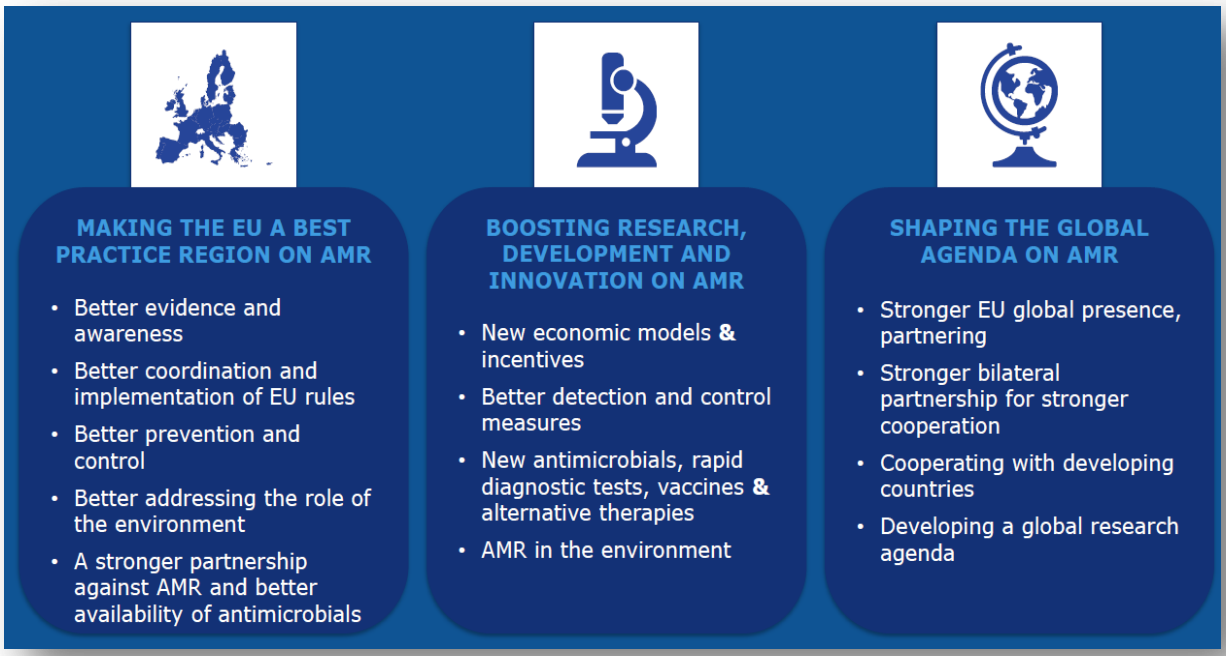
DG SANTE also hosted the annual meeting of the **EU Health Policy Platform** in November 2017. The Platform is a collaborative initiative to facilitate communication between Commission services and health stakeholders and ensure transparency in the health policy dialogue. The agenda included an overview of health policy activities, and presentations by thematic networks, e.g. on Antimicrobial Resistance, non-communicable diseases, and vaccination.

DG SANTE also continued to contribute to the **European Semester** by providing health-related expertise for the various steps of the macro-economic coordination mechanism aimed at identifying challenges in the health systems of Member States. This input was based on the processing of health indicators and on the intelligence gathered through interaction with national authorities and stakeholders, including through the State of

[26] Commission staff working document SWD (2017)400: State of Health in the EU – Companion report

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.[27] 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 Action Plan on Antimicrobial Resistance. In June 2017, SANTE presented this new **EU One Health Action Plan** against Antimicrobial Resistance which was developed by DG SANTE in cooperation with DG RTD, other Commission services and relevant stakeholders. The Action Plan is underpinned by a One Health approach that addresses resistance to antimicrobials in humans, animals and the environment. The plan foresees more than 75 actions built on three main pillars: a) making the EU a best practice; b) boosting research, development and; c) shaping the global agenda through multilateral and bilateral cooperation. The Action Plan will offer a clear EU added-value as a symbol of joint political commitment, stimulating action in Member States, and strengthening international cooperation.

In parallel, SANTE secured the adoption of the first deliverable of the Action Plan: the EU Guidelines on the prudent use of antimicrobials in human health. The Guidelines aim to reduce inappropriate use and promote prudent use of antimicrobials in humans, with a special focus on antibacterial agents.

In 2017, DG SANTE was involved in intense discussions **on veterinary medicinal products** and **medicated feed legislative proposals** in the Council. On 20 December 2017, the COREPER agreed on a mandate to start negotiations with the European Parliament on both proposals. These proposals are critically important in the fight against

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

AMR as they introduce a comprehensive set of provisions aiming to minimise the risk to public and animal health arising from the use of antimicrobials in the sector including amongst other, a ban on preventive use of antibiotics via feed, possibility to reserve certain antimicrobials for humans only, compulsory collection of data on sales and use of antimicrobials and other provisions aiming at responsible use.

In September 2017, led by France, DG SANTE and Member States launched a Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections funded by the Health Programme. The Joint Action will provide an added value at the EU level by developing and supporting best practice exchange on AMR and healthcare-associated infections in 2017-2020.

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 October 2017, the three agencies published a joint report on how to assess progress on reduction of Antimicrobial Resistance and consumption.

Moreover, in February 2017, EFSA and ECDC published their annual report on AMR in zoonotic and indicator bacteria from humans, animals and food and in October 2017 EMA published the seventh 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. EMA also continued its work to increase the availability of antimicrobials and alternatives.

DG SANTE also organised the first meeting of the One Health Network in February 2017 gathering government experts to share innovative ideas, launched a new series of Better Training for Safer Food workshops on AMR in November 2017 aiming to train Member States' authorities involved in official control activities and supported the implementation of national One Health action plans against AMR through joint visits with the ECDC.

In line with the third pillar of the Action Plan, SANTE actively participated in AMR-related international activities (please refer to specific objective 3.1).

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**. Based on the latest data available (2016), there has only been a very slight reduction (0.07 defined daily doses) since the 2013 baseline of 24.03 defined daily doeses/1000 inhabitants/day consumed in the Community and hospital sectors combined.

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[28] to ensure its correct implementation. All infringement proceedings for late or incomplete notification transposition were successfully closed in 2017. With regard to the compliance check, two out of ten EU Pilot procedures were successfully closed and one is at the Reasoned Opinion stage. A data collection exercise was launched in preparation for the 2018 report on the operation of the Directive. DG SANTE is also supporting the development of effective National Contact Points (NCPs) by organising regular meetings to encourage cooperation and exchange of good practices, notably for the provision of high-quality information to citizens, and through technical support studies.

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

INNOVATIVE HEALTH TECHNOLOGIES

As part of the Commission's Digital Single Market (DSM) Strategy, three priorities for health-related actions were identified in the DSM mid-term review issued in May 2017: a) enable citizen's secure access to and use of health data across-borders; b) support a cross-border data infrastructure to advance research and precision medicine; and c) facilitate feedback and interaction between patients and health care providers, supporting citizen empowerment. A Communication on these topics has been prepared following a public consultation between July and October and is scheduled for adoption in April 2018.

In 2017, nine Member States (one above the 2017 milestone of eight Member States) reported on their capacity for health data exchange and participated in cross-border eHealth information services by informing the Commission that they will seek to join the system when it opens for business in 2018 (**result indicator 1.4.A**).

On 9 May 2017, the eHealth Network adopted the agreement between Member State authorities on the criteria required for the participation in the Cross-Border eHealth Information Services. The building of the core services continued and the audit procedure for applicants to join the system was agreed at the end of the year. 16 Member States signed a contract in 2017 to build the eHealth National Contact Point with a view to becoming operational 2018-2020. The second round of applications closed in September, with seven Member States applying.

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.

In 2017, SANTE initiated the **evaluation of EU law on blood, tissues and cells**, including a stakeholder consultation and an external study to provide SANTE with an evidence base to finalise the evaluation towards end 2018.

In 2017, a study was finalised on the **Action Plan on organ donation and transplantation** (2009-2015). The report concluded that Member States, who managed a strong overall increase of 4600 transplants (+17%) in the EU, felt strongly supported by the EU Action Plan and by the development and exchange of knowledge through EU-funded actions in the Health Programme.

Finally, several transplant registries were supported through EU-funded actions, and DG SANTE started developing guidance the optimise their use for regulatory purposes.

FINANCIAL CONTRIBUTION FROM HEALTH PROGRAMME

In 2017, the Health Programme committed EUR 5.26 million towards 9 new grants and contracts 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 NON-COMMUNICABLE DISEASES

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

Between 6,000 and 8,000 rare diseases, for which knowledge is often scarce and unevenly distributed, affect the daily lives of around 30 million people in the EU. Freely accessible for everyone, the **Orphanet database** is co-financed by the Health Programme and 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 the number of data requests from the database (**result indicator 1.5B**). To date, the number of pages viewed per day changed from 130,000 in 2016 to 82,000 in 2017. This can be explained by Orphanet changing the structure of the website in 2017 and the decrease in pages viewed means that users had a more direct access to the information they needed. The number of sessions was stable from 2016 to 2017. The number of diseases annotated with prevalence or incidence data increased from 5,329 in 2016 to 5,822 in 2017.

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 56 in 2016 to 82 in 2017. The size of the EU population covered by surveillance networks increased from 34% of EU birth population, approximately 1.8 million people, to 43% of birth population, approximately 2.2 million people in 2017 - **result indicator 1.5C**.

DG SANTE also continued to cooperate with national and regional authorities through the **European Network of Cancer Registries**, with a view to launching the European Cancer Information System that will be run under the coordination of the Joint Research Centre (JRC) in the first quarter of 2018. As of 2017, 128 cancer registries from 29 European countries are part of the Network with more than 30 million of records in the database so far. The European Cancer Information System is expected to improve the system in terms of data upload and analysis.

EUROPEAN REFERENCE NETWORKS (ERNS)

Via the European Reference Networks (ERNs), DG SANTE promotes greater access to medical expertise for rare, low prevalence 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 with clear added value, providing important economies of scale and a more efficient use of increasingly stretched EU healthcare resources.

As noted by the Health Programme's Statement prepared for the draft budget procedure 2018, ERNs are able to maximise the speed and scale with which innovations in medical science and health technologies are developed and put into use. Economies of scale can be achieved by connecting existing reference networks found in individual Member States, and greater efficiency and coordination can be achieved by sharing resources and expertise across the EU. Reference networks are also ideal environments for research and innovation (clinical trials, patient registries, training of professionals).

On 1 March 2017, the ERNs were formally launched. **24 ERNs were established**, already surpassing the 2018 milestone of 20 (**result indicator 1.5A**), and started their activities, gathering over 900 highly specialised healthcare units located in 313 hospitals of 25 Member States (plus Norway). Throughout the year, DG SANTE provided funding, strong coordination and support to the ERN process to ensure its success. Their clinical operation started in November 2017 when the Clinical Patient Management System started functioning. This is the ERN software for data sharing and virtual panels that DG SANTE has developed for the ERNs financed from the EU's Connecting Europe Facility. By using this tool, the 24 ERNs are now fully developing their potential to offer patients and doctors access to the best expertise and timely exchange of life-saving knowledge.

MEDICINAL PRODUCTS

In March 2017, DG SANTE adopted a report on the shortcomings in the **summary of product characteristics** (SmPC) and the **package leaflet** (PIL) for medicinal products (as required under Directive 2001/83/EC), and suggested improvements to better meet the needs of patients and healthcare professionals, including by making it more readable and understandable by the elderly and those with low literacy skills. The recommendations should be implemented by improvements of the existing regulatory guidelines. DG SANTE and the European Medicines Agency (EMA) will work on this in collaboration with Member State authorities.

In September 2017, DG SANTE adopted two tertiary acts aimed at improving patient safety in the EU through Good Manufacturing Practices (GMP) that ensure the highest quality of medicines for human use. The first act sets out principles and guidelines of GMP in medicines where the manufacture or import is subject to a manufacturing authorisation and the second act sets out GMP for investigational medicinal products, as required by the Clinical Trials Regulation (see section 2.2).

In 2017, DG SANTE also discussed a revision of Commission Implementing Regulation 847/2000 on orphan medicinal products, which will be adopted early 2018. Certain definitions in the Regulation needed to be adapted to technical and scientific progress.

In October 2017, DG SANTE and the EMA launched a new joint action plan to foster the development of **advanced therapy medicinal products** (ATMPs) - innovative medicinal products based on cells or tissues and gene-therapy. The plan aims to streamline the procedures and better address the specific requirements of ATMPs developers. This was followed in November 2017 by the adoption of new Guidelines on GMP specific to ATMPs. They aim to improve the regulatory framework by reducing administrative burden and adapting manufacturing requirements to the specific characteristics of these products, thereby contributing to the emergence of new products for the benefit of patients.

FINANCIAL CONTRIBUTION FROM HEALTH PROGRAMME

In 2017, around EUR 8.45 million were committed from the Health Programme to finance five new activities under the specific objective 1.5 which includes, inter alia, the ERNs and rare diseases registries.

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 and some areas of human health. These audits – which take place in EU countries and non-EU countries exporting to the EU - are essential to ensure our high standards and safety levels are not compromised and that the industry can operate on a level playing field.

In 2017, DG SANTE carried out 199 **audits and fact-finding missions** in Member States, candidate countries and non-EU countries exporting to the EU, covering food safety, animal health, animal welfare and plant health.

In addition, in the human health area DG SANTE conducted 15 joint assessments of notified bodies in the medical devices sector in 2017. Since joint assessments in this area started back in 2013, the number of notified bodies has been reduced by approximately 25%, as poorly functioning ones have not been re-designated.

In 2017, DG SANTE carried out, together with the European Centre for Disease Prevention and Control (ECDC), three **joint country visits** to Member States to discuss policies relating to Antimicrobial Resistance in a "One Health" perspective (see section 1.1.4).

DG SANTE systematically follows up on actions taken by competent authorities in response to recommendations made in audit reports. In 2017, in relation to follow-up in Member States, five general follow-up audits were performed and three administrative (desk-based) follow-ups were initiated. From the 3-year reporting cycle 2013-2015, 74% of DG SANTE's audit recommendations were satisfactorily addressed by the Member States at the end of 2017 (**result indicator 1.6.A**) therefore the 2017 target of 70% was achieved. 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 the transparency of the state of enforcement in each and every Member State.

In addition to individual audit reports, DG SANTE produces overview, annual and survey 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. 22 of such reports (18 overview, two annual and two survey reports) were published on DG SANTE's website in 2017.

In 2017, 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 planned to be adopted in 2018. This report will provide an overview of the delivery of official controls in the Member States in the period 2014-2016 based on their annual official control reports and controls carried out by the Commission.

Other major activities in 2017 to improve the performance of control systems included: meetings of networks of Member State officials responsible for the multi-annual national control plans and for the performance of audits of official control systems; 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 Systems for Plant Health Interceptions and Outbreaks (EUROPHYT).

MODERNISING AND SIMPLIFYING EU LEGISLATION

The revised **Official Control Regulation** (OCR) No. 2017/625 was adopted on 15 March 2017 and will be fully applicable on 14 December 2019. The OCR creates a single framework for all official controls along the entire agri-food chain, including plant health and animal by-products. The OCR applies a risk-based approach to official controls and allows more harmonised and efficient controls and resulting enforcement actions. Such targeted controls will free up resources to focus on areas where enforcement needs to be prioritised. The new rules also require increased transparency and greater accountability from Member State authorities, who are obliged to publish annual reports. The OCR will be implemented through around 35 tertiary acts over the next two years and the preparatory work for the first acts began in 2017.

USE OF DIGITAL TECHNOLOGIES TO STRENGTHEN OFFICIAL CONTROLS

The OCR foresees an Integrated Management System for Official Control (IMSOC) which will integrate current EU-managed IT systems such as TRAde Control and Expert System (TRACES) and the EU's alert systems (the Rapid Alert System for Food and Feed (RASFF) and EUROPHYT). DG SANTE launched the preparatory work in 2017. This will offer additional simplification for border controls authorities.

One of the follow-up actions to the Fipronil incident (illegal use of fipronil in poultry farms resulting in contamination of eggs and poultry meat in 2017) was to explore where communication chains and the use of the alert systems, such as the Food Fraud/Administrative Assistance and Cooperation (AAC), RASFF and TRACES, can be improved to enhance detection and coordinated response to food fraud. In 2017 DG SANTE started this assessment on the need for legislative adjustments and the development of a combined platform for RASFF and the AAC systems. DG SANTE will also continue to coordinate its work on food fraud with other Commission services, EUROJUST and INTERPOL to ensure better cooperation with police and justice authorities.

Finally, in response to the increasing amount of agri-food products offered online DG SANTE has initiated a number of actions to strengthen the enforcement of EU agri-food legislation on internet sales of food chain products. In 2017, it launched a coordinated control plan with Member States on the official controls of food supplements with medicinal claims and certain unauthorised novel foods. DG SANTE also engaged in a dialogue with platforms offering food chain products for sale online.

FINANCIAL CONTRIBUTION TO OFFICIAL CONTROLS' RELATED ACTIVITIES

Official control activities carried out in 2017 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 EU Reference Laboratories (EURLs) and the Better Training for Safer Food programme (BTSF).

The **EURLs** support implementation of EU legislation in the agri-food chain with state of the art analytical and diagnostic services for national authorities and enforcers. Funding for 46 EURLs was granted in 2017. This helped to maintain the efficiency of the network, capitalise on existing knowledge and ensure the same high level of food safety in the EU. The budget for the EURLs for 2017 was around EUR 16 million.

The **BTSF** continued to play a key role in improving the efficiency and reliability of official controls in 2017 and in spreading knowledge of EU legislation. 170 training courses were carried out for Member States' authorities responsible for official controls. More than 30 training activities were held for non-EU countries' authorities to help 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 2017, managed by DG SANTE's executive agency CHAFEA, was EUR 16.5 million.

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, the GVA of the EU health sector (human health activities) in GDP remained stable since 2009 and oscillates around 4.6% (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, intra-EU trade in food (and live animals) as a % of GDP has shown a steady increase since 2008 reaching almost 1,9% in 2013 where it has remained since (Table 2 in Annex 12). This demonstrates a well-functioning internal market for food based on clear and harmonised rules that are recognised as both proportionate and efficient.

The increase in intra-EU export/import in live animals and food products is expected to continue reaching, respectively, EUR 283.6 billion and EUR 280 billion in 2016 (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 2016, both intra-EU exports/imports and extra-EU export/import in food were growing. Intra-EU exports/imports grew respectively by 3.1% and 3.2% in 2016 and extra-EU export/import respectively by 2.5% and 0.8% (Tables 3 and 4 in Annex 12). 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, such as the General Food Law and Regulations on official controls, plant health and animal health, as well as by EU authorisations for products and substances used in the food chain, such as food/feed additives, pesticides and 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.

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. For the period 2016-2020, the Health Programme has committed EUR 16 million to activities related to HTA.

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. Over the course of the year, based on the conclusions of an Impact Assessment and public consultation, a legislative proposal was developed and adopted on 31 January 2018.

The **result indicator 2.1** 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 providing data for the assessments. In 2017, EUnetHTA did not carry out the number of assessments as planned, due to a challenging start and because only a few companies volunteered to submit products for joint assessments. Fourteen HTA reports were carried out by EUnetHTA JA3 in 2017 (two up from 2016); it includes a report presenting key implementation challenges in 59 HTA bodies in 31 countries, which was published in December 2017.

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 very active, despite the cost-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 research based pharmaceutical sector in Europe (including Switzerland, Russia and Turkey) was estimated to be worth EUR 250 billion in 2016, and employed about 745,000 people. In the same year, EFPIA indicated an estimated positive trade balance of EUR 100 billion and EUR 35 billion spending on research and development.[29]

In 2017, the third Health Programme committed EUR 4.7 million to six new activities related to objective 2.2.

In 2017, SANTE focussed on the following priorities:

IMPROVING ACCESS TO INNOVATIVE MEDICINES

Patient access to affordable medicines and the balance between pharmaceutical innovation and the sustainability of health systems in the EU is one of DG SANTE's focus areas.

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

In October 2017, DG SANTE presented a report to the European Parliament and the Council on progress made in children's medicines since the Paediatric Regulation came into force 10 years ago. It concluded that positive advances in the development of medicines for children could not have been achieved without specific EU legislation, including, for example, the authorisation of 260 new medicines. However, the report acknowledged that more effort is needed to combine the effects of the Paediatric Regulation with those of the Orphan Medicines Regulation to address shortcomings in treating rare diseases in children.

The development of innovative medicines is supported by a variety of incentives, some of which are linked to Intellectual Property (IP) rights, and others linked to the marketing authorisation and the data it contains. Those incentives are seen as an important driver for research and investment. At the same time, questions have been raised regarding their impact and their ability to support patients' need-driven innovation. To further analyse the drivers around current incentive schemes, the Commission is carrying out an evaluation of the impact of the pharmaceutical incentives (including supplementary protection certificates, data protection rules and market exclusivity for orphans), on innovation, as well as on the availability and accessibility of medicinal products. DG SANTE and DG GROW are working together on this project and aim to present results in 2018.

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.

MARKETING AUTHORISATIONS OF MEDICINAL PRODUCTS

DG SANTE continued work linked to the authorisation of medicinal products, including advanced 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 2017, 87% of new medicines were authorised within the legal deadline which is a decrease compared to 89% in 2016, but very close to the 2017 milestone of 90%. For Commission Decisions for which there was an accelerated assessment (5 out of 92 Commission decisions), 100% of medicines were authorised within the legal deadline which is an increase compared to 87.5% in 2016. With regard to initial authorisations, i.e. for new products, just below 90% were within the legal deadline. For accelerated reviews of initial marketing authorizations by the European Medicines Agency (EMA), 100% were within the legal deadline (**result indicator 2.2**). The Commission works with the European Medicines Agency to optimise the processes associated with the adoption of the initial marketing authorisation within the overall timeframe foreseen in the legislation.

TERTIARY LEGISLATION TO SUPPORT THE NEW EU CLINICAL TRIALS REGULATION AND FALSIFIED MEDICINES DIRECTIVE

In 2017, DG SANTE adopted additional legislation required by the clinical trials Regulation (EU) No 536/2014, specifically a Commission delegated Regulation on good manufacturing practices (GMP) for investigational medicinal products for human use; a Commission Directive on good manufacturing practices (GMP) for finished products; a Commission implementing Regulation on the detailed arrangements for Good Clinical Practice inspection procedures; and a guideline on good manufacturing practices for investigational medicinal products. These acts ensure reliable data generation during clinical trials, high quality medicines and legal certainty for pharmaceutical companies. DG SANTE has also tracked the development of the clinical trial portal by the European Medicines Agency to facilitate the conduct of clinical trials in the EU as of 2019.

Concerning the falsified medicines Directive 2011/62/EU, DG SANTE worked with Member States and stakeholders to ensure the successful implementation of the safety features for

medicines, so that, by February 2019, the authenticity of all prescription medicines can be checked before they are dispensed to patients.

DG SANTE also made progress in improving the quality of medicines at international level (please refer to specific objective 3.1).

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 (please refer to the specific objective 1.4), DG SANTE is supporting the development of expertise on the performance of health systems at national level in the EU expert group on **Health Systems Performance Assessment** (HSPA), co-chaired by DG SANTE.

In 2017, the group continued to identify tools and methodologies that can contribute to improve national assessment schemes and projects. It focussed on measuring the performance of primary care leading to the production of a report (to be published in 2018) which can offer expertise in the context of national policy making (**result indicator 2.3A**). In 2017, four Member States referred to the findings of the expert group on Health Systems Performance Assessment (HSPA) in their national policy documents, one off from the 2017 milestone of five. Reaching this milestone is dependent upon actions taken by Member States.

1.3 General objective 3: A balanced and progressive trade policy to harness globalisation

The table with impact indicators is included in Annex 12.

In 2017, DG SANTE worked closely with other Commission departments, Member States and export industries to tackle sanitary and phytosanitary (SPS) barriers to trade and to improve market access to non-EU countries.

The Commission's contribution to the general objective on trade policy will be measures by the **impact indicator 3.1 – 'Percentage of EU trade in goods and services as well as investment covered by applied EU preferential trade and investment agreements'** (see Annex 12).

The work of DG SANTE in negotiating balanced and ambitious SPS chapters in Free Trade Agreements (FTAs), as well as working with other trading partners to remove SPS-related trade barriers is key to the continued increase in exports of agri-food products. The share of the EU-extra trade in food and live animals to the total EU-extra trade has been steadily increasing since 2010 and in 2016 it reached 5.3% (Table 5 in Annex 12).

DG SANTE's efforts to promote EU health and safety standards for pharmaceuticals globally, in particular through the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH), contribute to increase in EU-extra trade of these products. The share of the EU-extra trade of medicinal and pharmaceutical products to the total EU-extra trade has been steadily increasing since 2011 and in 2016 it reached 6.3% (Table 6 in Annex 12).

1.3.1 Specific objective 3.1: 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 the World Trade Organisation (WTO), the World Health Organisation (WHO), the Codex Alimentarius Commission, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), 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 DG SANTE's action to tackle food waste).

CONTRIBUTING TO GLOBAL HEALTH

DG SANTE's key priorities for multilateral cooperation in the health sector were AMR, health security, tobacco control and pharmaceuticals.

Historically, EU Member States have negotiated texts individually at **World Health Organisation (WHO)** governing bodies but in recent years there has been a move towards more coordinated EU action. This is associated with greater uptake of EU input into the texts of agreed resolutions. In 2017, coordinated EU inputs were reflected in 87% of WHO Executive Board's resolutions negotiated (very close to the 2017 milestone of 90%), 80% World Health Assembly's resolutions negotiated (surpassing the 2017

milestone of 75%) and 90% WHO Regional Committee for Europe's resolutions negotiated (surpassing the 2017 milestone of 70%) - **result indicator 3.1.A**. These coordinated EU inputs are provided at different stages, from the contribution to upstream technical consultations to the provision of EU amendments on draft decisions or resolutions under adoption. DG SANTE also cooperated with WHO in the framework of existing administrative arrangements.

Moreover, DG SANTE worked with OLAF to encourage ratification of the WHO's Framework Convention on **Tobacco** Control (FCTC) Illicit Trade Protocol and participated in the Panel of Experts on Illicit Trade established by the FCTC Secretariat. DG SANTE also participation in the first meeting of the Global Tobacco Regulators Forum and the WHO Study Group on Tobacco Product Regulation.

DG SANTE continued to reinforce cooperation with the **OECD** in the framework of the new cooperation arrangement from 2016 and worked closely with the **G7 and G20** with a focus on global health security issues.

In February 2017, the Commission hosted the Ministerial Meeting of the Global Health Security Initiative (GHSI) organised by DG SANTE which provided an opportunity to emphasise the role the EU plays in global health security and public health crisis management and to influence future priorities for the initiative (see section 1.1.1).

In order to contribute towards global efforts to tackle the threat of **Antimicrobial Resistance** in collaboration with international partners and help achieve objectives of the WHO Global Action Plan on Antimicrobial Resistance, in 2017 DG SANTE actively participated in AMR-related activities of Codex Alimentarius (revision of the Code of Practice to Minimize and Contain AMR; development of new Guidelines for Integrated Surveillance), OIE (revision of the Terrestrial Code, questionnaire on global action to alleviate the threat of AMR), Trans Atlantic Task Force on Antimicrobial Resistance (exchange of information/updates on action points), G7 (preparation of G7 CVO document on AMR-related definitions) and G20 (meeting of Public Health and Veterinary Public Health Institutes). DG SANTE also organised a conference entitled "EU and South-America: working together on anti-microbial resistance" on 29 March in collaboration with the EU Delegation in Brasilia, partnering with countries of the South American region. Three further seminars focusing on different AMR issues took place in the capitals of the partner countries (Argentina, Chile, Colombia), with the collaboration of DG RTD for the Chile seminar. See section 1.4 for more information on AMR.

DG SANTE continued to contribute to the negotiation and implementation of association agreements with **non-EU countries** (including Andorra, Monaco, San Marino) and provided the health input to political bilateral dialogues as appropriate (including Ukraine, Moldova, Georgia, Switzerland, Norway, China, United States, Cuba, Mexico), as well as for regional political dialogues (EFTA, Central Eastern European Countries + China ("16+1")).

DG SANTE continued to work with EU enlargement and neighbourhood countries on the health "acquis" and policy. DG SANTE contributed to the start of the EU-Montenegro negotiations of Chapter 1 (Free Movement of Goods), which include closing benchmarks in the field of medical products; and organised a peer-review mission in the field of communicable diseases in the candidate country Albania.

In 2017, DG SANTE coordinated the long-standing Inter-service Group on Global Health and the Global Health Policy Forum, exchanging information on global health governance and security issues in WHO, G7, G20, OECD, UN, among others.

CONTRIBUTING TO HARMONISATION IN THE PHARMACEUTICAL SECTOR

The EU is a global leader in the pharmaceutical industry and the world's major trader in medicinal and pharmaceutical products - amounting to extra-EU trade of EUR 220 billion in

2016[30]. Since 2002, intra-EU trade more than doubled from EUR 156 billion to EUR 327 billion, equivalent to an average annual growth of 5.4 %.

DG SANTE, supported by the European Medicines Agency (EMA), was involved in harmonising standards for pharmaceuticals internationally through the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and its activities. Harmonisation through the adoption of ICH guidelines facilitates access to multiple markets, including those of the United States, Switzerland and Japan, the three most important export markets for the EU, and plays an essential role in promoting the EU position.

In 2017, DG SANTE continued to represent the Commission in ongoing work linked to the selection of topics for harmonisation at the ICH and ICH reform. As one of the founding regulatory members of the ICH, the Commission used its experience to promote the EU views and actively contribute to the output of this body. It also actively facilitated the implementation of the new structure through its chairmanship of the ICH Assembly. The ICH reform facilitates an increased membership which in 2017 amounted to 15 members and 24 observers in total. In 2017, membership fees were agreed for all members and the necessary transfer of all ICH assets to the ICH Association (legal entity) was finalised, thus making the ICH Association fully independent.

Result indicator 3.1.B monitors the increased recognition of ICH guidelines at global level and increased global harmonisation. Since 2015, regulatory authorities from four new countries have joined ICH as members. 60% of the ICH guidelines were implemented by the four new members. In terms of new or revised ICH guidelines or Questions and Answers (Q&As) (which provide additional implementation advice on ICH guidelines), two new ICH guidelines, two revised guidelines, two new Q&As and two revised Q&As were adopted in 2017 (for a total of eight).

Moreover, DG SANTE continued to make progress in improving the quality of medicines at international level. In 2017, SANTE conducted the scientific assessment for the extension of scope of the mutual recognition of good manufacturing practices (GMP) with Japan for sterile and biological products, and the technical agreement on GMP in the context of the EU-Canada Comprehensive Economic and Trade Agreement (CETA).

CONTRIBUTING TO BALANCED AND PROGRESSIVE TRADE IN FOOD AND LIVE ANIMALS

Improving multilateral relations

The EU is the largest exporter and importer of food in the world with a well-recognised and respected framework of food safety legislation. Harmonisation is an important priority in the food sector. In 2017, DG SANTE continued to strive for alignment between international and EU standards through its representative work in international fora to reduce its exposure to dispute settlements. This particularly concerns the positions taken by the EU in the WTO's Sanitary and Phytosanitary Committee (SPS Committee) and in the international standard setting bodies, OIE, IPPC and Codex Alimentarius.

In the World Organisation for Animal Health (OIE), DG SANTE defends the EU's high animal health and welfare standards to influence the international standards. In 2017, as each year, DG SANTE led and coordinated the EU common position with regard to new OIE standards or revision of existing standards at the General Session in May.

In 2017, in order to ensure alignment between EU legislation and Codex standards, DG SANTE, in close cooperation with Member States, represented the EU in 14 **Codex** Committee and working group meetings and in the Codex Alimentarius Commission.

[30] 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

In 2017, DG SANTE, together with DG TRADE, represented the EU at three meetings of the **World Trade Organisation Sanitary and Phytosanitary Committee** to promote and defend EU interests in the SPS area. The EU position was prepared in cooperation with Member States in the SPS expert group co-chaired by DG SANTE and DG TRADE.

In 2017, DG SANTE contributed to the 13th Trade Policy Review (TPR) of the EU carried out by the WTO. Out of the 1300 questions received by the EU, 107 were related to DG SANTE's portfolio falling in the area of SPS and pharmaceuticals.

During 2017, DG SANTE initiated the organisation of a thematic session on regionalisation, which took place in Geneva in the margins of the SPS Committee meeting in July 2017. The objective of this event was to provide an opportunity for WTO Members to increase their awareness of regionalisation principles and continued with a high level international seminar in October.

DG SANTE also contributes to the work of the WTO Standards and Trade Development Facility (STDF) to ensure coherence of SPS capacity building activities and proper coordination between donors. In this regard, DG SANTE contributed to the ongoing work of the World Bank under its Global Food Safety Programme to map food safety capacity building activities in Africa. In addition, it was ensured that DG SANTE can actively contribute to the ongoing work on electronic certification in IPPC and OIE.

Last year the EU submitted seven written communications to the WTO SPS Committee, in particular concerning regionalisation and pesticides. Furthermore, the EU provided oral information to WTO Members on the new plant health law and gave update on the avian influenza situation (in March) and on the revised phytosanitary import requirements (in November).

Concerning the WTO dispute settlement case opened by the EU against Russia on its unjustified ban on EU pigs and pig products in relation to African swine fever which the EU won, DG SANTE worked with Member States and ensured a unified EU approach vis-à-vis Russia's compliance with the ruling. In a letter dated 5 December 2017 Russia informed the EU about the lifting of the SPS ban. Nevertheless, in practice, exports of the concerned products are not possible because of the political embargo that was extended in November 2017 to cover those products that would have had the possibility to be traded after the lifting of the SPS ban (e.g. offals). Currently, only the export of live breeding pigs is possible from the EU to Russia.

DG SANTE also followed other dispute settlement cases, including the ruling in a case lodged by China against the EU on measures affecting tariff concessions on certain poultry meat products.

In 2017, WTO Members raised five new Specific Trade Concerns (STCs) against the EU in the SPS Committee (**result indicator 3.1.C**). Furthermore, the STC on endocrine disruptors, first raised against the EU in March 2014, continued to be raised by the US, China and Argentina at all three Committee meetings in 2017. Therefore the 2017 milestone of seven cases (or less) was achieved.

There were two additional issues (glyphosate and novel foods), where other WTO Members raised their concerns with regard to the EU policy under another agenda item.

During last year, DG SANTE also continued to raise, at all SPS Committee meetings, two STCs against the Russian Federation complaining about the import restrictions on certain animal products from Germany and the import restrictions on processed fishery products from Estonia and Latvia.

In the International Plant Protection Convention (IPPC), there is a strong EU input, coordinated by SANTE on global plant health strategy and the development of international standards for phytosanitary measures. In 2017, DG SANTE was closely involved in the IPPC dispute settlement case on citrus black spot opened by South African against the EU on imports of citrus fruits.

The EU is the world's largest exporter of seeds. International policies on seeds play an important role for securing jobs in the EU, but also for food security, climate change adaptation and sustainability. In 2017, DG SANTE continued to work towards international harmonisation in this area by taking part in discussions with the Organisation for Economic Co-operation and Development (OECD), the United Nations Economic Commission for Europe (UNECE), the International Union for the Protection of New Varieties of Plants (UPOV) and the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) to shape the international governance of seed trade, related intellectual property rights and the access to plant genetic resources.

The work performed in the framework of the non-EU Better Training for Safer Food (BTSF) trainings contributes to establishing and improving relations with international organisations and (potential) trading partners as it promotes regulatory cooperation, exchange and efficiency. The SPS capacity building efforts, either through BTSF or through other programmes beyond DG SANTE (where proper liaison is ensured), pays off in terms of building confidence and hence helps to reinforce and improve both multilateral and bilateral relations.

In June, an international conference was organised to discuss the results of the DG DEVCO funded BTSF-WORLD programme for which 35 regional workshops were held and over 1200 days of sustained training missions were implemented all over the world. The activities covered a broad range within the fields of food safety, plant health, animal health and welfare and led to establishing new markets (sprouting seeds, aquaculture shrimps) and improving SPS conditions in non-EU countries. The conference underscored the need for continued SPS training in non-EU countries.

Improving bilateral trade relations

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's ultimate goal is to achieve better conditions for trade: greater market access for EU exports at the same time as ensuring our food safety standards are not compromised on imports.

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

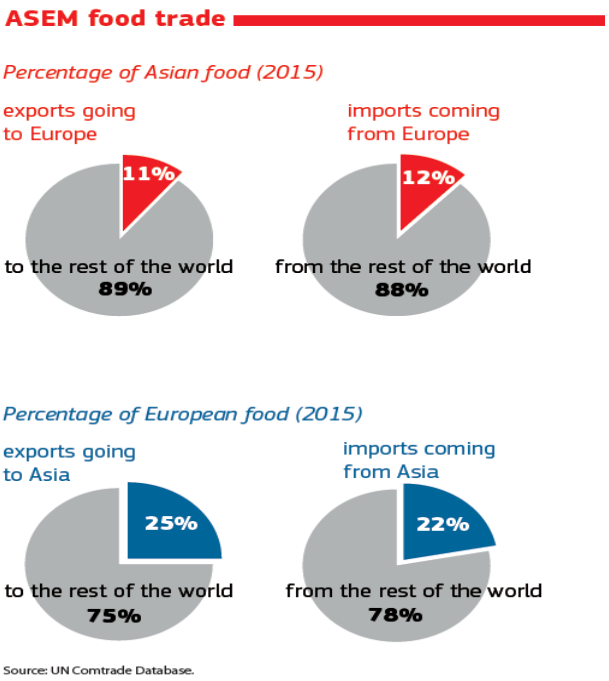
The main activities involved negotiating safe, secure and harmonised export conditions for EU products with non-EU countries and managing, monitoring and implementing existing agreements.

In 2017, DG SANTE reached a consensus on ambitious SPS chapter in the EU – Japan agreement, contributed to negotiations on Sanitary and Phytosanitary issues with MERCOSUR and worked towards finalisation of a mutual recognition agreement between Australia and the EU which would allow export of heat treated pork meat for the whole EU.

DG SANTE reacted promptly to the Brazilian meat fraud incident which was discovered in March 2017. DG SANTE asked Brazilian authorities to immediately remove the establishments implicated in the scandal from the EU-approved list, rejected and returned to Brazil all consignments from the establishments implicated in the fraud which were "en route" to the EU, monitored closely imports of animal products from Brazil including the reinforced checks at Border Inspection Posts and performed audits to Brazil to follow up on the measures introduced by the Brazilian authorities.

DG SANTE organised on 5-6 December 2017 an international conference on food safety where more than 50 of Asia–Europe Meeting (ASEM) country members shared common

conclusions on animal health, food safety, AMR, fraud and e-certification which play a pivot role for improving bilateral trade relations.



DG SANTE supervised technical assistance provided to the countries applying for EU membership to progressively adopt the EU SPS standards. Technical assistance was also provided to numerous European neighbourhood countries to develop and enhance their standards in the SPS area and to access the EU agricultural market for their agricultural goods.

Close co-operation took place in the framework of the EU Association Agreements in Deep and Comprehensive Free Trade Areas with Ukraine, Moldova and Georgia aiming at to implement bilateral commitments in the SPS area.

The signature of the Administrative Arrangement on Animal Welfare with Argentina was an important step to consolidate our good relationships with this country in the SPS field.

1.3.2 Specific objective 3.2: 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.

PHARMACEUTICAL PRODUCTS

In 2017, the Commission and the United States Food and Drug Administration (USFDA) successfully concluded the Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP) inspections. The MRA allows 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 will entail significant cost savings for industry and lead to a better use of respective inspection resources by avoiding the current overlap of inspections. Resources freed can be redeployed to other inspection priority areas in non-EU countries. This strengthened bilateral collaboration will provide greater capacity to control the safety of products irrespective of origin. It will lead to reduced risk and promote the global adoption of high quality standards for the production of medicinal products.

DG SANTE has also made major progress, with DG TRADE, to adopt the legal act setting the basis for the MRA. To this end, DG SANTE set up the EU-US joint sectoral Committee and confirmed that the USFDA has the capability, capacity and procedures in place to carry out GMP inspections at a level equivalent to the EU. For its part, the USFDA completed the capability assessments of drug manufacturing regulatory authorities. November 1, 2017 marked the beginning of mutual recognition of inspections of manufacturing sites for human medicines between the US and eight EU countries (Austria,

Croatia, France, Italy, Malta, Spain, Sweden, and United Kingdom). The remaining EU countries will be assessed by the FDA on a rolling basis, to be completed by 15 July 2019.

ANIMAL HEALTH, PLANT HEALTH AND FOOD SAFETY

Despite the suspension of free trade agreement (TTIP) negotiations with the US, in 2017 DG SANTE maintained extensive contacts at technical and political level with the US, our most important global agri-food trading partner.

This collaboration remained focussed on attaining a fair and balanced trading relationship based on reciprocity. DG SANTE conducted these negotiations on the basis of the pragmatic 'EU as Single Entity' concept. Currently, the EU is excluded either wholly or partially from many important US agri-food markets due to SPS barriers. A number of key EU agricultural products are affected including beef, sheep and goat meat, pasteurised dairy products, egg products, apples and pears.

Concerning the **result indicator 3.2.A**, in 2017, four Member States were listed to export beef to the US, up from three in 2016. Progress on market access indicators has been slower than hoped, primarily due to lack of action by the US on our applications. Whilst some of this is typical of US response to EU requests, some is also due to a more protectionist US administration. 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 due to changes in the US administration, the necessary legislation has still not been published. It is the same situation for market access for Grade A (pasteurised) dairy products and sheep/goat meat.

One of the upsides of the pause in TTIP negotiations has been the possibility to focus more resources on technical issues of interest. In 2017, DG SANTE engaged at technical level in two working groups on Animal Health (July) and Plant Health (April and October). Progress was made in a number of areas, notably the recognition of the animal health status of the EU by the US for the main pig and poultry diseases.

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

DG SANTE 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 2017, approximately the same number of barriers overall were in place as for 2016 (**result indicator 3.2.B**). This falls short of the projected interim milestone and is again symptomatic of a climate in which there is decreased cooperation on trade issues.

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, including hand-over reports of outgoing 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 firstly, on the annual assessment of the implementation of the internal control standards applicable in 2017, and secondly, on the actions taken to manage the transition towards the new corporate internal control framework applicable as from January 2018;
- 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-subdelegation;
- Reports on control results from the Consumers, Health, Agriculture and Food Executive Agency (CHAF-EA);
- Reports on control results from EU decentralised agencies to which DG SANTE is partner.

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[31]. 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 2017, 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.

The objectives, indicators and assessments in this section cover all expenditure and other significant non-expenditure items[32]

Table 2.1 DG SANTE's budget of 2017[33]

Type of expenditure	Operational budget, implemented by (M€)				Total (M€)
Policy area	**CHAF-EA** ("entrusted entity")	**Other DGs** (cross-sub-delegation)	**DG SANTE** Operational credits	Admin. credits	
Food and Feed	16,3	0,2	241,3	1,3	**259,1**
Public Health	46,8	0,5	9,4	1,4	**58,1**
Sub-total programmes	***63,1***	***0,7***	***253,4***		***317,2***
Subsidy to CHAF-EA's operating budget				5,5	**5,5**
Subsidies to EU agencies operating budgets			170,4		**170,4**
Sub-total agencies			***175,9***		
Global envelope for administration				7,4	**7,4**
Building expenditure Ireland, et al.				5,2	**5,2**
Sub-total admin.			***12,6***		
Total SANTE policy areas	***63,1***	***0,7***	***421,1***	***20,8***	***505,7***

[31] 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).

[32] These include only the significant amounts, i.e. assets (inventories exceeding EUR 5 million); no other items were significant, for example, revenue operations did not account for more than 5% of the total budget allocation in 2017.

[33] 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 166,5 million under "Public Health" and EUR 3,9 million under "Food and Feed"; (b) Annex 3 includes in "administrative expenditure of Title 17, the subsidies to CHAF-EA of EUR 5,5 million; the administrative support credits on operational budget lines of EUR 2,7 million; the part of the expenditure for the building in Ireland on budget line 17.01 of EUR 4,6 million.

Type of expenditure	Operational budget, implemented by (M€)				Total (M€)
Policy area	**CHAF-EA** ("entrusted entity")	**Other DGs** (cross-sub-delegation)	**DG SANTE** Operational credits	Admin. credits	
Other policy areas			3,2	4,3	**7,5**
TOTAL including CHAF-EA					**513,2**
TOTAL excluding CHAF-EA (commitments made as per Annex 3)					**450,1**

EC balance sheet category	DG SANTE (M€)
Assets – inventories of vaccines and antigen stocks for animal diseases	*9,7*

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. Commitment and payment credits were almost fully consumed. 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. Commitment and payment credits were almost fully consumed (see section 2.1.1.2 below for more detail and Annex 5.1.2 for the internal control template).
- DG SANTE implemented about 20% of its 2017 credits related to EU funding programmes (EUR 63,1 million out of EUR 317,2 million) through the Consumers, Health, Agriculture and Food Executive Agency (CHAF-EA). Only EUR 0,7 million of DG SANTE's commitment appropriations were implemented by authorising officers of other Directorates General (see section 2.1.1.3 below).
- The credits listed under "other" include EUR 2,7 million co-delegated to DG SANTE by DG Connect and EUR 0,5 million by DG ENV on operational budget lines mainly for IT services as well as EUR 2,5 million co-delegated by DG AGRI and EUR 1,7 million by DG JUST on administrative budget lines to pay their respective shares of the subsidy to CHAF-EA's running costs. Commitment and payment credits were fully consumed.
- DG SANTE paid subsidies to finance – partially or in full – the operating budgets of the executive agency, CHAF-EA, and four 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 7,4 million) includes missions, meetings, committees, studies, IT (administrative tools only), training and credits for external staff. The administrative expenditure for Grange, Ireland, (EUR 5,2 million) relates to the office building in Grange which is managed directly by DG SANTE (not by OIB or OIL). The commitment credits were almost fully consumed; the payment budget was only implemented to 75% in 2017, but as payments can still be made in 2018, the credits are expected to be used almost fully.
- In its balance sheet, DG SANTE identifies current assets (inventories) of a total value of EUR 9,7 million pertaining to vaccines/antigen stocks for animal diseases: food and mouth disease (EUR 9,0 million), lumpy skin disease (EUR 0,5 million) and classical swine fever (EUR 0,2 million) (see section 2.1.1.4 below).

– DG SANTE's best estimate of the detected error rate during ex-post controls is between 0,8% and 2,7% in the Food and Feed policy area and between 1,3% and 1,6% in DG SANTE as a whole[34].

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 2017.

DG SANTE reported reasonable assurance to the DGs which cross-subdelegated credits to DG SANTE.

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.

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. The grants refer mainly to DG SANTE's specific objective 1.1, point 3 "managing and isolating outbreaks of major animal diseases" and point 4 "preventing plant diseases".

[34] 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 0,5% and the worst case error rate of just under 2%.

Table 2.2 Food and Feed Safety

Commitment credits implemented by DG SANTE *(without CHAF-EA)*	**2017** **M€**	**2016** **M€**	**2015** **M€**
Animal disease eradication programmes (grants to Member States)	**148,6**	156,9	165,3
Veterinary emergency fund (grants to Member States)	**51,9**	20,0	16,4
Phytosanitary expenditure (grants to Member States)	**0,5**	17,1	7,6
Other veterinary, plant health and food safety expenditure (grants to Member States, EURL, etc)	**17,3**	19,1	28,2
Sub-total grants	**218,3**	**213,1**	**217,5**
Procurement DG SANTE[35]	**23,0**	22,6	19,3
Administrative support credits	**1,3**	1,3	1,5
Total budget implemented	**242,6**	**237,0**	**238,3**

Provisions for the management of expenditure for the policy area Food and Feed are set out in the Common Financial Framework (CFF)[36]. Direct financial contributions to Member States is by far (more than 80%) the most important budget implementation instrument:

- In 2017, a total of 128 animal disease eradication and control programmes were approved for implementation by 28 Member States.
- In addition, a total of 30 files for cost reimbursements were handled in relation to the veterinary emergency fund, to combat, first and foremost, Avian Influenza (EUR 46,9 million mostly paid through advances) but also African Swine Fever and Lumpy Skin Disease (EUR 4,9 million). The advance payments to the Member States for their high expenses caused by the Avian Influenza crisis could be realised thanks to the EUR 10,0 million DG SANTE received during the budget transfer.
- Addressing the combat of organisms harmful to plants, 24 Member States submitted their 2017 "pest survey programmes" of a total amount of EUR 13,8 million and 8 Member States submitted emergency plant health measures accounting for EUR 0,5 million. Other grants to Member States also included EUR 1,6 million financial aid towards a coordinated control plan for antimicrobial resistance in zoonotic agents[37].

Other measures to contain animal disease outbreaks are the purchase of vaccines. In 2017, DG SANTE spent around EUR 8,1 million on vaccines and antigens through public procurement (see sections 2.1.1.2 and 2.1.1.4 below).

The 2017 commitment appropriations at the end of the year of EUR 242,8 million, and the 2017 payment credits of EUR 224,6 million, were each almost fully implemented (99,4% and 98,6% respectively)[38].

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 70% of the grants in the Food and Feed policy area (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.

[35] Without credits cross-subdelegated to other DGs: EUR 0,2 million in 2017 (EUR 0,0 in 2016).

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

[37] Commission Decision C(2017)245

[38] See Annex 3.

Stage 1: Programming and evaluating the 2018 national programmes

In 2017, DG SANTE paved the way for the award of the 2018 animal disease eradication programmes of the Member States. In compliance with the Commission work programme[39] to implement the Common Financial Framework (CFF)[40] for the Food Chain, Member States submitted their 2018 disease eradication and control programmes by 31 May 2017. 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 138 programmes submitted, 4 were rejected as they did not meet 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 the 2018 national programmes and Grant Decisions

On 17 January 2018, DG SANTE communicated the list of the 2018 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 23 January 2018 the authorising officer by sub-delegation took the award decision. The corresponding grant decisions were signed by 31 January 2018. 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 2017 the deadlines fixed in the legislation were respected allowing a timely launch of the 2018 programmes in the Member States.

Table 2.3a) Indicators for grants	***Targets***	**2017**	**2016**	**2015**
Stage 1: Programming and evaluation				
Ratio of rejected national programmes to total programmes submitted: 4 out of 138 programmes for 2018 submitted in 2017 (5 out of 133 in 2016; 11 out of 141 in 2015)	*n/a*	**3%**	4%	8%
Ratio of modified programmes to total programmes retained after evaluation: 89 out of 134 programmes evaluated in 2017 (92 out of 130 in 2016; 46 out of 130 in 2015)	*n/a*	**66%**	70%	35%
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%

[39] Commission Implementing Decision C(2017)2841 of 2 May 2017 on the adoption of the multiannual programme for 2018, 2019 and 2020 for the implementation of veterinary programmes for animal diseases and zoonoses, and the related financing decision Commission Implementing Decision C(2017)3524 of 31 May 2017

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

Stage 3: Monitoring national programmes and managing financial transactions

Throughout the year, DG SANTE monitored the implementation of the national programmes. Firstly, the progress made by the Member States was assessed on the basis of interim technical and financial reports pertaining to the 2017 programmes. 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 on their 2016 programmes 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)[41]. The aim was to detect and correct errors before authorisation of a financial operation.

Thirdly, on the basis of a risk analysis, a number 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 2017, this ex-ante "on-the-spot" control focused on the high risk areas as follows: veterinary emergency fund and plant health measures for which the request for funding exceeded EUR 2 million or other exceptionally high amounts. In 2017, all errors 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***	**2017**	**2016**	**2015**
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[42]	*99%*	**99,5%**	99,6%	100%
Percentage of implemented **payment** credits after global transfers[43]	*100%*	**98,7%**	99,3%	100%
Desk ex-ante 2nd-level verification coverage: % of transactions % of total amounts	*10%* *50%*	**19%** **75%**	17% 70%	14% 75%
Desk ex-ante 2nd-level verification: rejection rate % of amounts with financial errors	*< 2% in value*	**0,2%**	0,5%	0,0%
On-the-spot ex-ante controls: **correction rate** *(average of all corrections)* - Eradication programmes - Veterinary emergency fund - Phytosanitary measures		 **-** **11,2%** **-**	 27,0% 20,1% 1,9%	 0,6% 27,8% 23,5%

[41] The selection of operations for the second-level verification is supported by the IT application "MUS-DICE", based on a risk analysis with a set of risk criteria.

[42] Annex 3 in 2017 shows a commitment implementation rate of 99,4% in the Food and Feed Safety policy area as it includes the subsidies to ECHA (European Chemicals Agency) of EUR 3,9 million; see section 2.1.1.1.3.

[43] Annex 3 in 2017 shows a payment implementation rate of 98,6% in the Food and Feed Safety policy area as it includes the subsidies to ECHA (European Chemicals Agency) of EUR 3,9 million; see section 2.1.1.1.3.

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

There is a risk that not all errors in the Member States' cost claims are detected and corrected during ex-ante controls at the desk; thus, DG SANTE complements its desk checks by ex-post controls in the Member States. The aim of ex-post controls is to provide reasonable assurance on the legality and regularity of expenditure on an annual basis.

Ex-post controls are carried out on a sample of payments DG SANTE made based on Member States' cost declarations. The audit samples are taken on the basis of a risk analysis rather than following a statistical random selection. The risk based approach is considered more cost-effective given the heterogeneity and relatively small size of DG SANTE's audit population. A key indicator is the estimated residual error rate, calculated as an average error rate from the audited sample and complemented with a qualitative analysis of the errors found before comparing it to the materiality threshold set at 2% (for more information on materiality see Annex 4).

The 2017 audit work plan was adopted by the Directors' Steering Committee of DG SANTE in January 2017. 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 2017 audit work plan included 20 audit missions of which 18 were carried out as planned. In October, the audit plan was adapted to include one additional ex-ante audit on Avian Influenza as a reaction to the Avian Influenza crisis. To free the necessary resources, two audits on Salmonella were postponed to 2018. The changes did not impact significantly on the assurance building capacity of the ex-post control function in 2017 as the planned audit coverage was almost fully achieved.

The residual error rate for 2017 was between 1,0% and 2,5%. No reservation to be made to the declaration of assurance.

The errors detected during the ex-post controls finalised in 2017 resulted in an error rate of 2,7% (EUR 2,4 million) for the audited national programmes for animal disease eradication and monitoring. The relatively high error rate is due to one particular audit on a national programme for which the Member State submitted cost claims for the years 2014 and 2015 overstating the eligible costs by about 37%. The error happened in the context of changes this Member State made to its management and controls of the cost claims in the audited period – and is not applicable to other cost claims or other Member States. Apart from the unique circumstances in this exceptional file, the situation in the other files giving rise to corrections were common to a number of audited cost claims of Member States, and were due mainly to the inclusion of ineligible costs. Other corrections were made for ineligible animals, payments delays, errors in the calculation of staff costs, incorrect value of animals.

About 11% of the errors detected in audits finalised in 2017 were corrected by March 2018 (EUR 0,3 million) by issuing recovery orders. The low recovery rate is due to the fact that several audit reports were finalised only recently, including the exceptional file. After correction, the 2017 residual error rate amounted to 2,5% for the overall ABB activity Food and Feed Safety. This is above the materiality threshold of 2%. However, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance as the relatively high error rate is due to an isolated error in one Member State's cost claim which cannot be extrapolated as being 'representative' to other animal disease eradication and monitoring programmes (see explanation above). The overpayment will be corrected through the recovery procedure to be launched in the first half of 2018. If this isolated error is excluded from the calculation, the residual error rate drops to just under 1%. This is in line with the rate since 2014 (when the reservation made in the Annual Activity Reports of 2011, 2012 and 2013 was lifted). DG SANTE is confident that the mitigating actions taken in the past are still effective to keep the residual error rate in the national programmes for animal disease eradication and monitoring below the materiality threshold under the Common Financial Framework 2014-2020 (CFF, Regulation (EU) No 652/2014).

Ex-post control in the Food and Feed policy area	2017	2016	2015	2014	2013	2012	2011
Residual error rate	**2,5% (1%)**	1,1%	1,2%	0,8%	2,3%	3,4%	4,3%
Reservation	**No**	No	No	No	Yes	Yes	Yes

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 actions have been implemented, except for one: the planned merge of two IT systems, of which one is from the Commission (ADNS[44]) and one from the OIE (WAHIS)[45], is technically much more complex than initially planned and will thus not be finalised before 2020.

Table 2.3c) Indicators for grants	*Target*	2017	2016	2015
Stage 4: Ex-post controls				
Ex-post control **detected error rate** (ABB activity: Food and Feed Safety)	*n/a*	**2,7%**	1,3%	1,7%
Ex-post control **residual error rate** (policy area Food and Feed) (Without one exceptional file)	***< 2,0%***	**2,5%** (1%)	1,1%	1,2%
Amount of net financial corrections identified in year N compared with amount of transactions audited	*n/a*	**2,6 M€ 97,0 M€**	0,5 M€ 37,1 M€	0,8 M€ 47,1 M€
Financial corrections in year N linked to audits finalised in year N (until March N+1)	*n/a*	**0,2 M€ 8%**	0,4 M€ 72%	0,72 M€ 91%
Total financial correction of detected errors	*100%*	**0,3 M€ 11%**	0,4 M€ 72%[46]	0,75 M€ 97%[47]

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 2,5% for the ABB activity "Food and Feed Safety" as a whole. The relatively high average error rate is due to an isolated error in one Member State's cost claim which cannot be extrapolated to the whole policy area Food and Feed (see explanations above). The error was not detected by the ex-ante desk controls but does not indicate a significant deficiency in the internal control system. It will be corrected through the recovery procedure to be launched in the first half of 2018. If the isolated error is excluded from the calculation, the residual error rate drops to just under 1% which was the rate in previous years.

Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance. Nevertheless, DG SANTE

[44] Animal Disease Notification System

[45] OIE: World Organisation for Animal Health, operating the World Animal Health Information System (WAHIS)

[46] With regard to 2016, a total of EUR 0,4 million was corrected by late 2016; the recovery procedure for the remaining amount of EUR 0,1 was on-going in late March 2018.

[47] With regard to 2015, a total of EUR 0,74 million was corrected by late 2016; an additional correction of EUR 0,02 million was made in November 2016; the recovery procedure for the remaining amount of EUR 0,04 was on-going in late March 2018.

will pay special attention to similar circumstances in other Member States' cost claims related to the same type of programme.

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 seven 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 DG SANTE

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

Table 2.4 Procurement in the two policy areas

Commitment credits implemented by DG SANTE *(without CHAF-EA)*	**2017** **M€**	**2016** **M€**	**2015** **M€**
Health Programme implemented directly by DG SANTE[48]	**8,9**	7,1	7,2
Administrative budget of the Health programme implemented by DG SANTE	**1,4**	1,4	1,6
Pilot projects/preparatory actions implemented by DG SANTE through procurement	**0,5**	0,9	3,1
Public Health total	**10,8**	**9,4**	**11,9**
Food and Feed Safety: DG SANTE procurement expenditure	**23,0**	22,6	19,3
Administrative budget Food and Feed implemented by DG SANTE	**1,3**	1,3	1,5
Food and Feed Safety total	**24,3**	**23,9**	**20,8**
Other procurement	**3,2**	0,3	-
Building expenditure Ireland (administrative credits)	**5,2**	5,3	5,4
Total budget implemented	**43,5**	**38,9**	**38,1**

- The third **Programme of the Union's action in the field of health (2014-2020)** was adopted in March 2014[49]. It 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[50]. The Commission decided on the specific Public Health work programme for 2017 on 26 January 2017[51] with a total programme budget of EUR 60,3 million. DG SANTE implemented 20% (EUR 9,4 million)[52] under direct management, almost exclusively through public procurement[53], 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.

[48] Without credits cross-subdelegated to other DGs: EUR 0,5 million in 2017 (EUR 0,0 in 2016).

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

[50] The Health Programme contributes to several specific objectives under the first and second general objective described in section 1.

[51] C(2017) 316 final

[52] The remaining 80% of the 2017 work programme for Public Health is implemented by the executive agency

In addition to the funds for the Public Health programme, DG SANTE received EUR 0,5 million in 2017 for one pilot project which will be implemented under public procurement.

The 2017 DG SANTE's commitment credits of the Public Health policy area (EUR 11,3 million) and payment credits (EUR 14,0 million) were almost fully consumed (99,8% and 93,8% respectively)[54].

- The 2016 to 2017 financing decision in the **Food and Feed Safety** policy area for animal and plant health programmes was adopted on 29 May 2015[55]. In addition, the 2017 work programmes for other measures in the Food and Feed Safety policy area was adopted on 24 January 2017[56] and for IT tools in the food and feed area on 30 March 2017[57]. 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 Food and Mouth Disease (FMD) virus antigens for EUR 5,6 million, Lumpy Skin Disease (LSD) vaccines for EUR 2,0 million, and Sheep Pox and Goat Pox vaccines, for EUR 0,5 million (other expenditure in the Food and Feed policy area is described in section 2.1.1.1 on grants).

- The credits listed under "other procurement" encompass EUR 2,7 million co-delegated funds from DG CNECT for IT services related to the eHealth cross border patient information exchange (eHealth DSI) in the framework of the Connecting Europe Facility. In addition, EUR 0,5 million were co-delegated to DG SANTE by DG ENV for a pilot project in the area of animal health. Both the commitment and payment credits were fully consumed (100%).

- The administrative expenditure for Grange, Ireland, (EUR 5,2 million) relates to the office building in Grange which is managed directly by DG SANTE (not by OIB or OIL).

The control process for public procurement 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 2017, a few exceptions to the centralisation still existed for organisational/technical or geographical reasons; these concerned mainly communication, and local calls for tender managed by and for DG SANTE's site in Grange, Ireland.

CHAF-EA (see section 2.1.1.3 below as well as CHAF-EA's 2016 AAR).

[53] A direct grant is given to an international organisation (WHO) amounting to EUR 0,1 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

[54] In the Public Health policy area, Annex 3 shows implementation rates of 92,9% for EUR 176,5 million of commitment and 92,6% for EUR 179,1 million of payment credits. The difference to the figures above is the subsidy payments to EU decentralised agencies which are included in Annex 3 under "Public Health": EUR 166,5 million commitments and EUR 167,0 payments with an implementation rate of around 92%.

[55] C(2015) 360 final

[56] C(2017) 245 final

[57] C(2017)2005 final

Striving to reduce administrative burden, DG SANTE published all 2017 calls above the threshold of EUR 135.000 through the e-tendering platform of the Commission. Preparations to also use e-submission have advanced well although some adjustments to the security systems of DG DIGIT still have to be made to better fit DG SANTE's control environment.

In 2017, several types of procurement procedures have been applied as shown in table 2.5 below.

Table 2.5 Procurement contracts above EUR 60.000[58]

Type of procedure	2017		2016		2015	
	N° of contracts	**Amount M€**	***N° of contracts***	**Amount M€**	***N° of contracts***	**Amount M€**
Open (Art. 104(1a) FR 2012)	***4***	**24,8**	*2*	0,9	*3*	1,3
Open (Art. 127.2 RAP, FR 2012)	***2***	**0,6**	*3*	2,6	*7*	6,3
Negotiated (Art. 134 RAP)	***3***	**9,3**	*3*	1,1	*1*	3,3
Restricted (Art. 104(1) (b) FR 2012)	***3***	**1,2**	*2*	2,4	-	-
Restricted (Art. 127.2 RAP, FR 2012)	**-**	**-**	*1*	0,3	-	-
Restricted (Art. 136.1(a))	**-**	**-**	-	-	*2*	3,1
Competitive dialogue Art. 104(1) (e) FR)	**-**	**-**	*1*	5,0	-	-
TOTAL	***12***	**35,9**	***12***	**12,3**	***13***	**14,0**

Following the open procedure, two framework contracts were awarded for (i) evaluation and impact assessment services (EUR 20,0 million) and (ii) electronic signature for TRACES (EUR 2,0 million). In addition, two direct contracts were awarded in the policy area Public Health for (i) the Pilot Project on access to health care (EUR 0,25 million) and (ii) monitoring services to support the "EU Platform for Action on Diet, Physical Activity and Health" and the European Health and Alcohol Forum (EUR 0,35 million).

In 2017, DG SANTE bought vaccines for lumpy skin disease (EUR 2,5 million) and for "Peste des Petits Ruminants" (EUR 0,3 million) following two open calls for tender. In addition, DG SANTE awarded two contracts for the purchase and storage of vaccines for food and mouth disease with a total contract value of about EUR 9,2 million. In both cases the negotiated procedure was applied. At the end of 2017, the total value of stocks amounted to EUR 9,7 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: three contracts of a total amount of EUR 1,2 million for audit services, technical consultancy and joinery works for the building in Grange.

In 2017, 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). The share of different procedures thus fluctuates significantly from year to year: while in 2017 and

[58] Annex 3 table 12

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). Expressed in amounts, in 2017, 26% of the contract value was awarded through the negotiated procedure; in 2016, the rate was 9% and in 2015, 24%. 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 2017, preparatory work for the joint procurement of pandemic influenza vaccines with 18 Member States was completed and Invitations to Tender were sent to the manufacturers in January 2018. Member States have expressed interest for joint procurement procedures of further medical products, all of which are currently in early preparatory phase.

Procurement procedures (open calls for tender and negotiated procedures) for contracts above EUR 135.000 are examined by DG SANTE's "Public Procurement Committee". It 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 Committee may be asked to review the draft tender documents before the publication of the contract notice in the Official Journal. In 2017, this voluntary additional check was used in three cases.

Table 2.6a) Indicators for procurement	***Targets***	**2017**	**2016**	**2015**
Stage 1: Assessing procurement needs and selecting the offer				
Rate of open calls for tenders for which - No offer was received (in 2017: 1 out of 6) - The procedure had to be cancelled *(3 in 2017; 2 in 2016; 0 in 2015)*	*0%* *0%*	**16,7%** **50%**	0,0% 25%	0,0% 0,0%
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%**	0,0% 0,0%	66% 66%
Positive/negative opinions of the Public Procurement Committee (2017: 10 opinions; 2016: 15 opinions; 2015: 12 opinions)	*n/a*	**100%**	93% (1 negative)	92% (1 negative)
Public Procurement Committee opinions followed by the authorising officers responsible	*100%*	**100%**	100%	100%

In 2017, three open calls for tender procedures had to be cancelled: in one case, no offer was submitted; in another case no admissible bid was received and in the last case the procedure was cancelled for administrative reasons.

In 2017, the Public Procurement Committee provided 10 opinions on procurement contracts with a total maximum value of EUR 36,7 million. All opinions were positive. There was thus no situation of the authorising officer overruling an opinion of the Public Procurement Committee.

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 thus 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 for the second-level verification is supported by the IT application "MUS-DICE", based on a risk analysis with a set of risk criteria. As no file was rejected for financial corrections, there was thus no situation of the authorising officer overruling a blockage by the second-level verifying officer.

Table 2.6b) Indicators for procurement	***Targets***	**2017**	**2016**	**2015**
Stage 2: Monitoring of contract implementatio and financial management				
Ex-ante 2nd-level verifications coverage: % of transactions % of amounts	*10%* *50%*	9% 44%	8% 52%	8% 52%
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 2017: no cases; *in 2016: 2 cases of a total of €459,25; in 2015: no cases)*	*0%*	0,0%	0,0%	0,0%
Percentage of implemented final commitment appropriations	*99%*	**99%**	100%	100%
Percentage of implemented payment credits after global transfers	*100%*	**96%**	100%	100%

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 2017, no such audit was conducted. 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***	**2017**	**2016**	**2015**
Stage 3: Supervisory measures				
Number of registered **"exception reports"** relative to procurement procedures	*n/a*	**6**	7	8
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	*< 2%*	**n/a**	n/a	n/a
Recovery orders of year N: (in number) in amount	*n/a*	**(1)** **0,04 M€**	(0) n/a	(0) n/a
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 22 February 2018. Of the six "exception reports" in 2017, five pertain to non-compliance events (for example, à posteriori commitments). 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; nevertheless, some additional mitigating actions were agreed with the authorising officers concerned to avoid similar situations in the future.

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

Table 2.7 Cross-subdelegations

DG	2017 Appropriations		2016 Appropriations	
	Commitments M€	Payments M€	Commitments M€	Payments M€
ESTAT	**0,34**	**0,20**	1,47	-
OLAF	**0,15**	**-**	-	-
AGRI	**0,20**	**-**	-	-
TOTAL	**0,69**	**0,20**	**1,47**	**-**

DG SANTE has entrusted parts of its budget for indirect management implementation by a number of cross-subdelegations 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 5.2 (internal control template).

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

In 2017, DG SANTE cross-subdelegated a total of EUR 0,5 million of commitment credits to DGs ESTAT and OLAF in the Public Health area and EUR 0,2 million to DG AGRI in the Food Safety area. No other amounts were cross-subdelegated due to the fact that previous years' cross-subdelegations 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-subdelegation 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 2017, the authorising officers of AGRI, ESTAT and OLAF 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*	*2017*	*2016*	*2015*
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-subdelegated 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[59]) 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. Other parent DGs are AGRI, GROW and JUST. 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. Other parent DGs also pay their share of the total costs to implement the transferred tasks related to their programmes.

Table 2.9 Subsidies paid by DG SANTE to CHAF-EA

CHAF-EA (former EAHC)	2017 M€	2016 M€	2015 M€
Subsidy for administrative budget	**5,5**	5,5	5,5
Operational budget transferred from SANTE	**63,1**	65,1	63,2

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.

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 bilateral 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 the new situation in which the CHAF-EA became a multi-parent agency. The general guidelines are

[59] 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, as amended by Commission Decision C(2015)2856 of 4 May 2015.

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.

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 2017 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).

No serious control issue came to the attention of DG SANTE that would warrant a financial or reputational reservation in DG SANTE's 2017 Annual Activity Report. However, the following issues requested special attention:

(a) CHAF-EA's budget implementation related to the Health programme showed a high number of payment delays. CHAF-EA kept the Steering Committee informed on the main factors causing the payment delays and the measures taken to improve the situation.

(b) In its implementation of the 2017 Health Work Programme, CHAF-EA awarded Framework Partnership Agreements and received complaints from unsuccessful candidates. In one case, the third party addressed DG SANTE directly. All cases are handled within the agreed working relations between CHAF-EA and DG SANTE and in close co-operation with the Commission Legal Service and DG BUDG.

Table 2.10 Indicators of control effectiveness as regards legality and regularity

Executive agency CHAF-EA	***Targets***	***2017***	***2016***	***2015***
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*	**6,4%**	4,7%	8,5%

EU decentralised agencies

In 2017, DG SANTE was responsible for four EU decentralised agencies, of which three received an annual subsidy from the EU budget. In addition, DG SANTE contributes to the running costs of ECHA for its biocides activities (the responsible DG for ECHA is DG GROW).

- European Centre for Disease Prevention and Control (ECDC) located in Stockholm, Sweden[60].
  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[61].
  EFSA provides independent scientific opinions and scientific and technical advice on food and feed safety.
- European Medicines Agency (EMA) located in London, UK[62].
  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[63].
  CPVO supports innovation through the protection of new plant varieties throughout the EU; CPVO is fully fee-financed.
- European Chemicals Agency (ECHA) located in Helsinki[64].
  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.

In addition, DG SANTE is involved in the governance of Eurofound[65] (lead partner DG is EMPL) and EMCDDA[66] (DG HOME is the lead partner DG), but does not contribute to their running costs.

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[60] 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

[61] 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

[62] 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)

[63] 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

[64] 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.

[65] European Foundation for the Improvement of Living and Working Conditions; DG SANTE's involvement is limited to Eurofound's activities on quality of life and public services.

[66] European Monitoring Centre for Drugs and Drug Addiction; DG SANTE is involved in the governance of the EMCDDA, the synergies with DG SANTE's work cover addictions and comorbidity with communicable diseases.

Table 2.11 EU decentralised agencies – subsidies

EU decentralised agencies	*Number of staff* *			EU contribution		
	2017	***2016***	***2015***	**2017 M€**	**2016 M€**	**2015 M€**
ECDC	***287***	*291*	*295*	**58,0**	58,2	58,4
EFSA	***463***	*470*	*477*	**79,2**	79,4	79,6
EMA[67]	***799***	*787*	*779*	**29,3**	17,2	33,9
CPVO[68]	***49***	*46*	*46*	**n/a**	n/a	n/a
ECHA[69] (biocides)	***59***	*55*	*60*	**3,9**	0,9	6,0
Total	***1.658***	***1.673***	***1.681***	**170,4**	**155,7**	**177,9**

* Total number of human resources as authorised under the budget for officials and temporary agents and as estimated for contract agents and seconded national experts

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)[70]. The EU contribution to the ECHA budget fluctuates over the years due to the variations in fee income. In 2016 it was exceptionally high 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-2017, the Court gave all EU agencies for which DG SANTE is responsible (including CPVO and ECHA) a positive declaration of assurance for the reliability of their 2016 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 declarations into question. The agencies draft action plans to implement the Court's audit recommendations and report on the progress made[71]. Further to the Court's assurance received in mid-2017, DG SANTE cleared all pre-financing payments made to the agencies in 2016 and made the final payments of the 2016 subsidies. Thus no reservation to DG SANTE's declaration is warranted.

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67 EMA's total 2017 budget amounted to EUR 322,1 million (in 2016: EUR 324,7 million; in 2015: EUR 308,1 million), mainly financed by fees. The EU contribution is a balancing grant (in 2017: 9%; in 2016: 5%; in 2015: 11%).

68 CPVO does not receive any EU subsidies; its 2017 budget amounted to EUR 18,8 million (2016: EUR 18,8 million; 2015: EUR 15,1 million).

69 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 2017 amounted to EUR 10,4 million (in 2016: EUR 7,9 million; in 2015: EUR 9,1 million). The EU contribution is a balancing grant (in 2017: 37,5%; in 2016: 11%; in 2015: 66%).

70 COM(2013) 519 final of 10/07/2013

71 EFSA: in its 2016 annual report, the Court pointed to an audit of the Commission's Internal Audit Service (IAS) which concluded that the controls in place for IT project management are adequate, but referred to significant weaknesses in relation to IT governance. EFSA agreed with the IAS on a plan to take corrective actions and reported to the Management Board that all actions have been implemented in 2017.

ECDC: in its 2016 annual report, the Court highlighted weaknesses in ECDC's procurement procedures which were also found in an audit of the Commission's Internal Audit Service (IAS). ECDC made considerable efforts to improve its internal control procedures and reported to the Management Board that all audit recommendations were implemented by late 2017.

EMA: in its 2016 annual report, the Court pointed to weaknesses related EMA's procurement procedures, including IT project development and implementation. The measures EMA started to put in place are expected to be effective in 2018.

DG SANTE, within the limits of its role on the EU agencies' Management Boards and Audit Committees, if applicable[72], 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 three very important recommendations were implemented by the end of 2017 as follows (see also section 2.1.2.2 below): (1) the Commission's leverage effect on the agencies' programming was reinforced through the Commission Opinions on the agencies' Strategic Programming Documents for 2017 to 2019 and 2018 to 2020; (2) DG SANTE adopted an internal guidance paper setting out common principles and objectives for the supervision and monitoring of its decentralised partner agencies; (3) to strengthen the control approach towards its agencies, DG SANTE updated and improved its control strategy.

Table 2.12 Indicators of control effectiveness as regards legality and regularity

EU agencies	***Targets***	***2017***	***2016***	***2015***
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 5 out of 5
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 (€13,7/€170,4 million in 2017)	*n/a*	**8,0%**	13,9%	3,6%

[72] DG SANTE has two nominated members in ECDC's and one member in EFSA's Audit Committee; EMA and CPVO do not have an Audit Committee and all audit related issues are brought directly to the Management Board and the Administrative Council respectively.

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.

For DG SANTE, the estimated overall amount at risk *at payment*[73] (for the 2017 payments of EUR 425,3 million is between EUR 5,0 and 6,2 million. This is the AOD's best, conservative estimate of the amount of *relevant expenditure*[74] 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[75] for those 2017 payments made are EUR 1,8 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* between EUR 3,2 and 4,4 million.

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	201,3 M€	47,6 M€	176,4 M€	**425,3** M€
(3) Minus new prefinancing	-10,9 M€	1,2 M€	180,6 M€	**192,8** M€
(4) Plus cleared prefinancing	1,8 M€	0,1 M€	142,5 M€	**144,4** M€
(5) Relevant expenditure = (2) – (3) + (4)	**192,2** M€	**46,5** M€	**138,2** M€	**377,0** M€
(6a) Weighted average error rate (detected; lower limit) in %	2,7%	0,5%	0,5%	**1,3%**
(6b) Weighted average error rate in % (detected; upper limit)	2,7%	2,0%	0,5%	**1,6%**
(7a) Estimated overall amount at risk at payment (lower limit) = (5) * (6)	5,2 M€	0,2 M€	0,7 M€	**5,0** M€
(7b) Estimated overall amount at risk (upper limit) = (5) * (6)	5,2 M€	0,9 M€	0,7 M€	**6,2** M€
(8) 7-year average recovery/corrections as % of relevant payments[76]	1,1%	0,5%	0,5%	**0,5%**

[73] 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.

[74] 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.

[75] 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.

[76] The "corrective capacity" (7-year average) included in DG BUDG's reports amounts to 2,3% for

(1) Type of expenditure	Grants - relevant expenditure (Food and Feed)	Procurement and other expenditure (Public health/ Food and Feed)	Agencies	Overall/ Total
(9) Estimated future corrections = (5) x (8)	2,1 M€	0,2 M€	0,7 M€	**1,8** M€
(10a) Estimated overall amount at risk at closure = (7) – (9)	3,2 M€	0,0 M€	0,0 M€	**3,2** M€
(10b) Estimated overall amount at risk at closure = (7) – (9)	3,2 M€	0,7 M€	0,0 M€	**4,4** 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 2017 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 2017 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.

Table 2.14 Indicators of control efficiency – timeliness in grant management

Indicators per stage of the grant procedure	*Targets*	*2017*	*2016*	*2015*
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 (in number) in amount	*95%*	**(97%)** **95%**	(97%) 99%	(97%) 99%
Average payment time[77]	*90 days*	**48 days**	52 days	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 2017; 19 in 2016; 13 in 2015)	*100%*	**95%**	95%	83%
Percentage of financial audit recommendations accepted by the beneficiaries/Member States	*100%*	**99%**	100%	86%
"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*	**58 days**	64 days	60 days

DG SANTE; it includes not only ex-post controls but also other differences between the registered cost-claim/invoice and the actual payments made.

[77] 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. While in 2016, still some payments were made based on the previous legislation, this was much less the case in 2017.

In 2017, 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; they are mainly based on estimates made in the annual Unit Management Plans which were discussed within the Directorates and approved at the level of the Directorate-General.

Table 2.15 Indicators of cost effectiveness in grants - resources[78]

Indicators per stage of the grant procedure (average FTE times standard annual costs) [79]		**2017 M€**	**2016 M€**	**2015 M€**
Stages 1 and 2: Programming, evaluation and operational monitoring				
Cost of operational staff in the policy Units concerned	2017: FTE: 7,5	**1,0**	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	2017: FTE: 8,3	**1,0**	1,0	1,0
Cost of staff involved in second-level ex-ante and other internal controls of the central financial Unit	2017: FTE: 2,0	**0,3**	0,1	0,1
Stage 4: On-the-spot controls (ex-ante and ex-post)				
Cost of DG's internal staff dealing with on-the-spot controls	2017: FTE: 3,7	**0,5**	0,6	0,6
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)		**3,0**	**2,8**	**2,8**
Budget spent on "grants" ("benefit" of the controls)		**218,3**	**213,1**	**217,5**
Total cost as % of total annual budget (commitment appropriations)		**1%**	**1%**	**1%**

Conclusion on control efficiency and cost effectiveness 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, especially thanks to the management recommendations made in the control reports. 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.

[78] 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.

[79] FTE = full time equivalent; standard annual costs 2017: EUR 143.000 (in 2016: EUR 138.000) for officials and temporary agents; EUR 74.000 (in 2016: EUR 70.000) for contractual staff according to DG BUDG circular note to the RUF of December 2017.

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[80]; 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.

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 reached a positive conclusion on the control efficiency in its procurement procedures.

Table 2.16 Indicators of control efficiency in procurement - timeliness

Indicators on control efficiency in procurem	*Targets*	2017	2016	2015
Stage 1: Rate of timely launched procurement procedures as specified in the annual work programmes	*100%*	**61%**	85%	61%
Stage 2: Average payment times	*30 days*	**18 days**	24 days	21 days
Ratio of payments made on time (in number)	*95%*	**(95%)**	(87%)	(91%)
Ratio of payments made on time in amount		**(99%)**	(98%)	(99%)
Stage 3: "Time to recover": average days from information/confirmation date to issuing the debit note (in 20147: 1 case; in 2016 and 2015, no cases related to procurement)	*n/a*	**27**	n/a	n/a

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; they are mainly based on estimates made in the annual Unit Management Plans which were discussed within the Directorates and approved at the level of the Directorate-General.

[80] Commission Decision C(2014)1035 of 24 February 2014

Table 2.17 Indicators of cost effectiveness in procurement - resources[81]

Indicators for procurement (average FTE times standard annual costs) [82]		**2017 M€**	**2016 M€**	**2015 M€**
Cost of operational staff in the policy Units concerned	2017: FTE: 3,3	**0,5**	0,5	0,6
Cost of staff involved in the CMP activities	2017: FTE: 0,2	**0,03**	0,03	0,03
Cost of staff involved in 2nd-level ex-ante and other internal controls of the central financial Unit	2017: FTE: 2,0	**0,3**	0,2	0,05
Cost of central staff involved in procurement and financial procedures	2017: FTE: 10,4	**1,4**	1,1	1,1
Cost of DG's internal staff dealing with on-the-spot controls	2017: FTE 0,0	**0,0**	0,0	0,0
Total annual cost (without overhead rate)		**2,2**	**1,8**	**1,8**
Budget spent on "procurement" ("benefit" of the controls)		**43,5**	**38,9**	**38,1**
Total cost as % of total annual budget spent through procurement (commitment appropriations)		**5%**	**5%**	**5%**

Conclusion on control efficiency and cost effectiveness 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 to reach a conclusion as of the relative efficiency of the controls. The centralisation of the administrative management of procurement procedures has been implemented since May 2014; in 2015 and 2016, time and experience was needed to establish mature procedures and guidance, mainly to improve the quality of the procedures and their documentation. Therefore, DG SANTE expects its cost of control to remain at around 5% of the budget spent through procurement procedures, if the number and size of contracts remain relatively stable as was the case in the past few years.

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.

The table below shows the costs of control. They cover the annual costs of DG SANTE staff carrying out the control tasks in the different stages of the control procedure and are calculated on an all-cost basis without including an overhead rate; they are mainly based on estimates made in the annual Unit Management Plans which were discussed within the

[81] 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.

[82] FTE = full time equivalent; standard annual costs 2017: EUR 143.000 (in 2016: EUR 138.000) for officials and temporary agents; EUR 74.000 (in 2016: EUR 70.000) for contractual staff according to DG BUDG circular note to the RUF of December 2017.f

Directorates and approved at the level of the Directorate-General.

Table 2.18 Indicators of cost effectiveness with regard to entrusted entities – resources employed[83]

DG SANTE's cost of monitoring the agencies in relation to the subsidies paid (average FTE times standard annual costs)[84]		**2017 M€**	**2016 M€**	**2015 M€**
Cost of staff in the central Unit ensuring co-ordination within DG SANTE and with the agencies	2017: FTE 1,2	**0,1**	0,2	0,1
Cost of operational staff involved in monitoring the operations of the agencies	2017: FTE 4,5	**0,7**	0,7	0,6
Cost of staff involved in budgetary, financial, audit matters, evaluation of the agencies and other internal controls	2017: FTE 2,4	**0,3**	0,2	0,1
Total annual cost (without overhead rate)		**1,1**	**1,1**	**0,8**
Subsidies paid to the agencies		**175,9**	**161,2**	**183,4**
Total cost as % of total annual subsidies paid		**0,6%**	**0,7%**	**0,5%**

Overall, the costs of monitoring and supervision represent less than 1% 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.

Conclusion on "entrusted entities"

For the 2017 reporting year, the cross-subdelegated 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 2017, the Court of Auditors gave a positive declaration of assurance for the year 2016. 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 its own monitoring and supervision work as a responsible DG, DG SANTE did not become aware of anything that would indicate that the reporting from the agencies would not be reliable. In 2016, 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 did not call the Director-General's assurance into question. They were mitigated by actions taken in 2016 and 2017.

Consequently, in view of DG SANTE's residual responsibility for the management of the

[83] 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.

[84] FTE = full time equivalent; standard annual costs 2017: EUR 143.000 (in 2016: EUR 138.000) for officials and temporary agents; EUR 74.000 (in 2016: EUR 70.000) for contractual staff according to DG BUDG circular note to the RUF of December 2017.

parts of the budget cross-subdelegated 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 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 was updated in July 2017.

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 2017, DG SANTE looked into the risk of fraud in the context of its update of the anti-fraud strategy adopted in July 2017 and as part of the annual risk management exercise finalised in November. The fraud risks are addressed by specific controls designed and implemented to mitigate the risks.

Table 2.19 Indicators for fraud prevention and detection

Indicators for fraud prevention and detection	*Targets*	2017	*2016*	*2015*
Updated anti-fraud strategy of January 2014	*October 2016*	**Adopted in July 2017**	Not yet done	n/a
% of actions listed in SANTE's anti-fraud action plan without delays in the implementation phase (milestones in 2017: 13 actions; 2016: 5 actions, in 2015: 15 actions)	*100%*	**77%**	40%	73%
% of payments subject to close monitoring or additional controls due to relatively high risk of fraud	*100%*	**96%** (3,1 M€ paid)	93% (3,4 M€ paid)	81% (3,5 M€ paid)
% of financial officers reached in financial cell network meetings	*100%*	**100%**	100%	100%
% of new-comers reached in training on ethics	*100%*	**n/a**	n/a	100%
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 July 2017, DG SANTE finalised the update of its first anti-fraud strategy of January 2014, mainly to include the substantial organisational changes that affected the DG throughout the whole year 2016. Therefore, management conducted a comprehensive analysis of real residual risks of fraud in the DG's diverse financial and non-financial functions in mid-2016 and adopted the results in October 2016. In addition, the annual risk assessment exercise, finalised in November 2016, fed into the update of the anti-fraud strategy and its action plan.

The updated action plan covers the years 2017 to 2020 and includes the actions from the previous action plan that need to be finalised or continued as well as new actions. Relevant for the monitoring in 2017 were 13 actions of which 77% were implemented on time and three were delayed. They mainly address non-spending legislative initiatives of DG SANTE, for example, legislative fraud proofing in non-financial contexts, which are much more complex than expected; DG SANTE is in contact with other DGs and OLAF on these issues.

Main actions implemented in 2017 were:

- Update of DG SANTE's Intranet to publish the anti-fraud strategy, the main procedural steps in the Standard Operational Procedures for handling allegations of fraud, other irregularities and OLAF cases as well as other information related to ethics and anti-fraud issues;
- Participation in OLAF's workshop to share experience and best practices on common issues, fraud risks and anti-fraud measures;
- Contact with other DGs and OLAF on the topic of fraud proofing in legislation not linked to EU spending programmes; the action is in its second phase with the aim to develop guidelines in 2018;
- Actions linked to handling "conflict of interest" in agencies, scientific committees and expert groups.

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 2017.

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 9,7 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 9,0 million, lumpy skin disease vaccines accounting for EUR 0,5 million, and classical swine fever vaccines with a value of EUR 0,2 million.

The Common Financial Framework[85] 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[86].

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)[87]. The contractors'

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

[86] 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)

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

reports on 2017 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 2017 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 inventories, EUR 9,7 million vaccines stocks, was ensured throughout the year as stated in the reports received by the contractors.

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 2017

(1) 2016 DAS – compliance audit

In 2017, the Court finalised its annual report (2016 DAS) on the implementation of the 2016 budget. The structure of the Court's 2016 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 finding related to DG SANTE, DG SANTE is not mentioned in any policy chapter nor in the horizontal chapters on budgetary and financial management.

(2) Court's special reports

The Court of Auditors launched three performance audits in 2017, on animal welfare, on cross-border health care access and on food safety. In addition DG SANTE was involved in the follow-up audit on organic products.

All audits were still on-going at the end of March 2018. First results are expected in the second quarter of 2018.

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 of audits finalised before 2016, DG SANTE is the lead DG for a total of 19 recommendations issued by the Court of Auditors in 2016 and 2017 as follows:

(i) EU implementation of animal disease eradication and monitoring programmes

The Court published its Special Report 06/2016 in April 2016. The audit covered Member States' 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.

The Court addressed four audit recommendations to DG SANTE as lead DG on the following topics: (a) improved exchange of epidemiological information between Member States; (b) analysis of the existing set of indicators to provide better information on veterinary control activities and the cost-effectiveness of programmes; (c) inclusion of the wildlife aspect in the veterinary programmes more systematically, when relevant; (d) support to Member States in acquiring vaccines, when this is epidemiologically justified.

DG SANTE prepared an action plan with deadlines, mostly in 2017. Three of the four recommendations have been implemented. The planned merge of two IT systems, of which one is from the Commission (ADNS) and one from OIE (WAHIS), is technically much more complex than initially planned and will not be finalised before 2020[88].

(ii) Implementation of the EU framework for protecting citizens from serious cross-border threats to health

The Court published its Special Report 28/2016 in December 2016. The Court recognised 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's conclusions did not point to any critical issue neither for the Commission nor for the Member States. Twelve audit recommendations were addressed to DG SANTE on the following main topics to improve the implementation of the 2013 Decision: (a) develop a strategic roadmap for the Health Security Committee; (b) upgrade the Early Warning Response System; (c) improve the sustainability of the results from co-funded actions for health threat protection and the related performance measurement methodology; (d) establish a more structured coordination between different Commission services for health security activities.

DG SANTE prepared an action plan with deadlines mostly in 2017 and 2018. Good progress was made in 2017 on all topics, for example, a roadmap is under preparation to help the work of the Health Security Committee (HSC) become more strategic and structured towards a better and more effective coordination of preparedness and response to cross-border health threats in Europe. The roadmap is planned to be adopted at the HSC plenary in June 2018. Subsequently, the roadmaps for the specific working groups will be finalised. Furthermore, DG SANTE contributed to an action plan for the HSC on preparedness and the implementation of the International Health Regulations.

[88] Since 2012, a joint project between the Commission and OIE has worked on linking the ADNS and WAHIS systems with a common interface called Animal Disease Information System (ADIS). OIE is the World Organisation for Animal Health, operating the World Animal Health Information System (WAHIS).

The modernisation of the Early Warning Response System is well advanced in full co-operation with the ECDC and the Member States: the first module of the new IT platform is expected to go live in the summer of 2018.

A good structured coordination between different Commission services for health security activities is already in place, in particular through DG SANTE's active contribution to the Security Union Task Force. A cross-DG policy initiative – the DGs RTD and SANTE Communication on protecting citizens against health threats from infectious diseases – is being prepared.

(iii) Combating Food Waste: an opportunity for the EU to improve the resource-efficiency of the food supply chain

The Court published its Special Report 34/2016 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 either for the Commission or for the Member States. However, the Court concluded that currently the EU does not contribute to a resource-efficient food supply chain by combating food waste effectively. It issued the following three audit recommendations addressed to DG SANTE as lead DG with several other DGs associated: (a) strengthen and better coordinate the EU strategy to combat food waste; (b) consider food waste in future impact assessments and better aligning the different EU policies which can combat food waste including assessment of the need to intervene in order to prevent labelling practices that generate food waste; (c) promote the option of donating food that is safe for consumption and that would otherwise be wasted, in particular by clarifying relevant EU legal provisions.

DG SANTE prepared an action plan with deadlines in late 2018 and 2019. All actions refer to long-term measures and their implementation started already in 2016. For example,

- The EU Platform on Food Losses and Food Waste, established in 2016, met twice in 2017 and focussed on preparing methodology to measure food waste consistently across the EU, the development of EU guidelines to facilitate the donation of safe, edible food (adopted by the Commission in October 2017) as well as guidelines on the safe use of former foodstuffs in feed and, more generally, to share best practice amongst members facilitated by Platform meetings, sub-groups dedicated to specific themes (food waste measurement, food donation, action and implementation) and the implementation of a digital network.
- The Commission's study on date marking practices was concluded in 2017, key highlights presented to the Platform and a specific sub-group will be established in 2018 in order to discuss policy options (legislative, non-legislative) and help guide coordinated action by all players.
- Furthermore, DG SANTE has worked closely with DG Environment to support negotiations on the Commission proposal to revise the Waste Framework Directive. A political agreement was reached with co-legislators in December 2017. On the basis of the revised Directive, the Commission will adopt a methodology to measure food waste along the different stages of the food supply chain; preparatory work for this methodology has already started in 2017 together with the dedicated sub-group of the EU Platform.

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 2017 by submitting a "conclusion on the state of internal control" in mid-February 2018. Based on the audit work performed in the period 2015 to 2017, the IAS points to two open recommendations rated "very important", and as a result concludes that the internal control systems audited are partially effective. The two open recommendations were made in late 2017 on certain aspects of DG SANTE's activities related to food safety crisis preparedness. DG SANTE is confident that the identified weaknesses are not likely to have a bearing on the content of the annual declaration of the Director-General of DG SANTE. Both the very important recommendations and DG SANTE's on-going actions are explained under point (1) below.

IAS audits of 2017 on DG SANTE

(1) IAS audit on "DG SANTE's food safety crisis preparedness"

In 2017, the IAS started and finalised a performance audit on certain aspects of DG SANTE's activities related to food safety crisis preparedness. The overall objective of the audit was to assess whether DG SANTE has put in place adequate processes for its preparedness to react to food safety crises. The IAS issued its final audit report in December 2017 and made no critical recommendation. Two recommendations were rated "very important". DG SANTE accepted all recommendations and produced an action plan in January 2018. Most of the actions are already on-going and are expected to be completed in 2018.

(a) The IAS found that the general plan for crisis management in the field of the safety of food and feed as well as the related procedures and arrangements have not been updated on a regular basis. Furthermore, the IAS identified weaknesses in relation to business continuity in the event of prolonged and/or simultaneous crises situations, communication and information sharing.

The IAS recommended reviewing the existing "general plan" and validating the related procedures regularly, including communication aspects, redeployment arrangements and aspects of business continuity management as well as roles and responsibilities of all relevant stakeholders. In addition, the IAS recommended encouraging Member States to share information on their national contingency plans, and that DG SANTE design internal working arrangements to ensure that DG SANTE's food safety crisis management team is able to make use of the information regarding those plans and to follow up instances of non-compliance.

DG SANTE is in the process of preparing a Commission Decision on a general plan for crisis management in the field of the safety of food and feed. The external consultation with Member States and EFSA on the draft Commission Decision is expected to be launched in the first half of 2018. Subsequently, the existing Standard Operating Procedures will be adapted to experience learnt. In addition, the next meeting of crisis coordinators will address the role of Member States crisis coordinators.

(b) The IAS acknowledged that DG SANTE gained experience in managing serious food safety incidents since the establishment of the "general plan" in 2004, but pointed to insufficient testing of the arrangements for crisis management and lack of concrete plans to exercise the "general plan". Therefore, the auditors recommended developing a multi annual plan for exercising the "general plan", based on identified needs, involving key stakeholders as appropriate and conducting adequate exercises in practice.

DG SANTE plans to conduct an exercise in late 2018, will identify the needs on the basis of lessons learned and discussions with the Member States crisis coordinators. The needs analysis will feed into the design of subsequent exercises to address emerging issues as well as the timing and frequency of such exercises.

(2) 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 19 recommendations in previous years, two are still to be implemented in 2018. They pertain to an IT solution of one element in the management of veterinary programmes. In light of the progress made, the IAS downgraded the two recommendations to "important".

DG SANTE's follow-up on IAS audit recommendations

DG SANTE organises its follow-up work using the corporate IT tool 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 before the deadlines. No undue delays of audit recommendations rated "very important" occurred.

(i) DG SANTE's working arrangements with EU decentralised agencies

The IAS submitted its final audit report in May 2016 and made three recommendations rated "very important". DG SANTE implemented all planned actions as follows:

(a) To reinforce DG SANTE's leverage effect on the agencies' programming: the most important action addressing this recommendation was the preparation of the Commission Opinions on the Single Programming Document (SPD) of each agency to which DG SANTE is partner. This new tool was applicable for the first time in 2016 and was again applied in 2017 for the agencies' SPDs 2018-2020.

(b) To strengthen DG SANTE's monitoring and control approach, DG SANTE updated its guidance paper on its relations with the decentralised agencies. The paper was built on a template developed by the Secretariat General and central services in July 2017 and was adopted by DG SANTE's Management Board in November 2017. In addition, 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 monitoring and reporting which shows in Section 1 of this document.

(c) To strengthen DG SANTE's control approach towards the agencies, DG SANTE updated its control strategy document which was adopted by DG SANTE's Management Board in December 2017.

(ii) DG SANTE's management of Pilot Projects and Preparatory Actions

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 implemented all actions by the end of 2017. Actions included the 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.

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 2017, the Commission's Internal Audit Service (IAS) points to two open recommendations rated "very important". They stem from an IAS audit finalised in December 2017 on certain aspects of DG SANTE's food safety crisis preparedness. DG SANTE management assesses that the on-going mitigating actions have already 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 food safety crisis preparedness or issues addressed by the Court of Auditors do not point to significant quantifiable errors. Furthermore, DG SANTE is confident that the elements identified could not seriously damage the reputation of the Commission. 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 an Internal Control Framework based on international good practice, aimed to ensure the achievement of policy and operational objectives. In addition, as regards financial management, compliance with the internal control framework 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 Changes in DG SANTE's control environment

In 2017, the following major changes to DG SANTE's control environment took place:

- DG SANTE was affected by the Commission's centralisation of Human Resources as well as building and logistic services. In addition, the new corporate middle management policy resulted in the replacement of three middle managers with more than 10 years of management seniority in DG SANTE at the beginning of 2017, and a further three during 2017. The combined impact of these events was significant, but it was managed in a way to ensure business continuity in important files throughout the year.

- In mid-December, the Deputy Director-General for Food Safety left DG SANTE. He was also the authorising officer by sub-delegation for the entire policy area food safety. He handed over his tasks as authorising officer by sub-delegation to the Director of Directorate D "food chain stakeholder and international relations" with a dedicated financial team in the Unit D4 "food safety programme emergency funding".

  In his handover note the outgoing Deputy Director-General provided reasonable assurance that the resources assigned to the activities of the DG have been used for their intended purpose, in accordance with the principles of sound financial management, and under the control procedures put in place to offer the necessary guarantees concerning the legality and regularity of the underlying transactions.

The Director-General ensured continuity of operations as Deputy Director-General for the policy area Food and Feed Safety; the new authorising officer by delegation took over the same day.

2.1.3.2 Annual assessment of internal control by management

In its internal control system, DG SANTE embedded continuous 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 the fourth quarter of 2017 and finished in the first quarter 2018 with the endorsement of a summary note by the Directors' Steering Committee on 22 February 2018 and the adoption by the Management Board on 27 February 2018. 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 2017 management reports received from the authorising officers by sub-delegation, DG BUDG's validation of local systems, as well as the audit observations of both the IAS and the Court of Auditors in the period 2015 to 2017;

  (c) Contributions of key staff supporting important elements of the set up and functioning of internal controls.

- Throughout the year, the functioning of the internal control system 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 22 February 2018. Although some issues were recurrent, management assessed that, overall, the existing controls are sufficient and that the procedures in place function well; nevertheless, some additional mitigating actions were agreed with the authorising officers concerned to avoid similar situations in the future. 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.

- 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. Since 2016, DG SANTE is engaged in the 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).

- With regard to budget implementation in 2017, 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.

- In July 2017, DG BUDG submitted its final report on the validation of local systems in DG SANTE. DG BUDG concludes that it has not identified any weaknesses in the design or implementation of the local systems in place in DG SANTE which would indicate that they do not meet the validation criteria laid down by the Accounting Officer of the Commission. DG BUDG also made three recommendations which were accepted by DG SANTE and already partially implemented in 2017.

- 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" and open at the beginning of 2017 were related to DG SANTE's planning and monitoring of its EU decentralised agencies; however, the weaknesses have been addressed by the end of 2017 through actions that mitigate the risks identified by the auditors.

  In December 2017, the IAS made two recommendations rated "very important" on certain aspects of DG SANTE's food safety crisis preparedness. They have no impact on the implementation of the budget, and have no bearing on the Director-General's declaration of assurance. Actions to address the identified weaknesses are on-going.

2.1.3.3 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 2018 Management Plan started in September 2017. 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 2018 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 2017 report was discussed with the Commissioner in a meeting on 26 September 2017.

In 2017, no major event impacting the Director-General's declaration of assurance occurred. However, the following issues are worth mentioning:

- **The Friponil crisis could have a negative effect on the Commission's reputation with regard to food safety[89].**

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

  The Member States and the Commission agreed on 19 actions which will reinforce the EU's action against food fraud. Moreover, DG SANTE will continue to coordinate its work on food fraud with other DGs, EUROJUST and INTERPOL to ensure better cooperation with police and justice authorities.

- **Glyphosate[90]**

  On 12 December 2017, in agreement with Member States, the Commission renewed for 5 years the approval of glyphosate (a herbicide). In reply to the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", the Commission adopted a Communication in which it committed to presenting a legislative proposal in 2018, to further increase the transparency and quality of studies used in the scientific assessment of substances.

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89 More information is available in Section 1 under specific objective 1.6.

90 More information is available in Section 1 under specific objective 1.2.

- **Update on Endocrine disruptors reported in previous years reputational events** [91]

  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). On 4 September 2017, the Commission adopted the criteria to identify endocrine disruptors in the context of biocides (a delegated act). After scrutiny within the Council and European Parliament, the scientific criteria for biocides entered into force on 7 December 2017 and will become applicable on 7 June 2018.

  The European Chemicals Agency (ECHA) and the European Food Safety Authority (EFSA) launched a public consultation on 7 December 2017 on the joint draft technical Guidance document to implement the criteria once they become applicable for biocides and pesticides.

2.1.3.4 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 residual error rate found in DG SANTE's ex-post controls or 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. Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance.

2.1.3.5 Progress towards the transition to the new corporate internal control framework

The revised Commission internal control framework was adopted by the Commission with Communication C(2017)2373 of 19 April 2017 and constitutes the minimum standards referred to in Article 66(2) of the Financial Regulation. It is based on the same five internal control components (control environment, risk assessment, control activities, information and communication, monitoring activities). The aim of the revision is to ensure robust internal control while enabling a more flexible and less burdensome framework, responsibilities are clarified and reinforced and departments are given more flexibility in implementing the control principles as deemed adequate considering their specific characteristics and circumstances.

As a first step to implement the new framework, DG SANTE carried out a "gap analysis" and presented a comparative table between old and new internal control framework to the Management Board on 10 July 2017. The gap analysis was a good opportunity to raise awareness of the existing internal control framework in DG SANTE and of the actions needed to adapt and improve it. The following actions were already taken in 2017:

- In November 2017, the Director-General nominated the Director "Resource Management and Better Regulation" as the Director in charge of risk management and internal control (RMIC) clarifying his roles and responsibilities.
- In the framework of the 2018 Management Plan, DG SANTE Management Board adopted in November 2017 a list of internal control monitoring indicators to define its own baseline for each principle, as best adapted to its specificities and risks.

[91] More information is available in Section 1 under specific objective 1.2.

- In December 2017, DG SANTE finalised the update of its internal control strategy for budget implementation referring to the new internal control framework.
- Already in July 2017, DG SANTE's Management Board decided that, in line with DG SANTE's organisational structure, from the 2017 AAR the Deputy Director General for Health and the Deputy Director General for Food Safety would each sign a declaration of assurance covering their respective policy parts in section 1 of the AAR and thus assume responsibility for the robust reporting on the achievement of the operational objectives in their respective fields according to a standard text drafted by the central services (Communication C(2017)2373).

  In March 2018, the Deputy Director-General for Health signed the declaration without making a reservation. The Deputy Director-General for Food Safety left DG SANTE in mid-December 2017 and his role was taken over by the Director-General. As the Director-General signs the declaration of assurance for the AAR as a whole, no separate declaration for the policy area Food Safety was prepared.

2.1.4 Conclusions as regards assurance

This section reviews the assessment of the elements reported above (in Sections 2.1.1, 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.

In 2017, DG SANTE's average residual error rate of 2,5% exceeded the materiality threshold of 2% after it was down to around 1% in the last three consecutive years. The relatively high average error rate is due to one particular audit in the context of the animal disease eradication programmes in the food and feed policy area. An exceptionally high amount will be recovered as one Member State submitted cost claims for 2014 and 2015 programmes which were overstated by about 37%. The error happened in the context of structural changes this Member State made to its management and controls of the cost claims in the audited period and is not applicable to other cost claims or Member States. As it is an isolated error, it cannot be extrapolated to other animal disease eradication and monitoring programmes. If it is excluded from the calculation, the residual error rate of 2,5% drops to just under 1%, the rate in previous years. Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance.

In particular, DG SANTE's best estimate of the risks relating to the legality and regularity of the expenditure authorised during the reporting year[92] is between 1,3% and 1,6%. This is the weighted average detected error rate which implies an overall amount at risk at payment between EUR 5,0 and 6,2 million. This is the best, conservative estimate 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[93] are EUR 1,8 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 between EUR 3,2 and 4,4 million.

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

[93] The "corrective capacity" included in DG BUDG's reports amounts to 1,9% for DG SANTE; it includes not only

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

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 Health and Food Safety (SANTE)

In my capacity as authorising officer by delegation

Declare that the information contained in this report gives a true and fair view[94].

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 Auditor 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 Commission.

Brussels, 23 March 2018

Xavier Prats Monné

Authorising Officer by Delegation

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

2.2 Other organisational management dimensions

In 2017 DG SANTE continued to develop initiatives to improve efficiency and economy.

- As indicated in the 2017 Management Plan, DG SANTE plans to use IT solutions to better organise meetings in the framework of its stakeholder relations. The aim is to manage the entire process from planning a meeting to inviting and reimbursing experts using one single electronic tool. In late 2017, DG SANTE started to use the new IT tool AGM, a standard solution in the Commission with PMO as system owner and DIGIT as system provider. The AGM solution is expected to reduce DG SANTE's administrative burden considerably especially by significantly reducing the number of manual interventions. However, it is expected to become fully operational in DG SANTE only towards the end of 2018.

- In the 2017 Management Plan DG SANTE already announced the intention to use existing IT applications to realise efficiency gains in its procurement procedures. After having subscribed to the DG DIGIT e-submission module, in 2017, DG SANTE has made the necessary preparations to be able to use the tool to full capacity in the course of 2018. DG SANTE staff involved in procurement attended the training courses offered by DG DIGIT as from September 2017.

2.2.1 Human resource management

Tables with result indicators and outputs are included in Annex 2.1.

2017 was an important year for the Commission's HR community. On 16 February the new three tiered model was introduced as a pilot project. It impacted seriously on the local HR function, and in particular on SANTE's HR Unit. Although business continuity was ensured during the year, the installation and operation of the new HR service model required and continues to require an important investment of SANTE's local HR-BC which consists only of 3,5 FTEs.

Despite the above restrictions SANTE was able to implement successfully the major HR actions foreseen in its 2017 Management Plan.

The 360° senior management feedback exercise was launched in January 2017 and finalised in October 2017. Each senior manager discussed their individual reports with the external consultant and with their staff. The objective of the exercise was to foster leadership development and not to measure performance. The exercise gave participants the opportunity to interpret the feedback coming from different perspectives with the help of an experienced external coach, and to develop an individual leadership development Overall the exercise showed that the assessments of senior management was positive, with high average scores on the different competencies assessed.

With the recruitment in 2017 of four new female Heads of Unit, DG SANTE reached the Equal Opportunities quantitative target for female middle managers as set for the DG in College decision SEC(2017)359 two years in advance. The efforts invested in the past years to prepare and develop female colleagues has thus paid off.

DG SANTE has continued, although at a slower pace as initially planned for the reasons explained above, to engage in action under the umbrella of the 'Culture and Engagement' and 'Prioritisation and simplification' pillars of its 'Towards excellent SANTE' programme. Several dedicated team events were organised during 2017 aiming at increasing efficiency, performance and staff engagement, encourage collaboration and break silos, enhance knowledge sharing, communication, innovation. Attention was also given to work on improving assertiveness of colleagues, helping them to find ways to take a more active role in improving their working conditions and environment and thus be less reliant on the work of others (the organisation, management, and colleagues).

In line with this "focus on staff members" approach, work is engaged with the European School of Administration to roll out a series of 'Pillars of Mental Wellbeing' events. The above actions have and will significantly contribute to 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 2.2.

THE BETTER REGULATION ACTIVITIES IN DG SANTE IN 2017

DG SANTE updated the results of the mapping exercise carried out in 2016 and continued to evaluate the acquis under its remit, collecting evidence for better policy-making and assessing the impacts of future legislation.

Four evaluations intended to be finalised[95] in 2017 were completed as follows: (i) the results of two mid-term evaluations, on the Health Programme[96] and on the Common Financial Framework (CFF)[97], fed into the preparation of the next Multiannual Financial Framework (MFF post 2020); (ii) the Fitness Check analysed the legislative framework on general food law and included the evaluation of the Rapid Alert System for Food and Feed and of crisis management procedures.

Thirteen studies were successfully completed with the support of external contractors. The results of the study on the economic incentive to paediatric medicines[98] identified the need of an evaluation in the area of medicines for children and rare diseases, which will start in 2018. Two other ongoing studies, started in late 2017, aim to fill data and information gaps and to support the preparation of the next MFF programme. The studies will also support the design of a monitoring system, with appropriate indicators for the future programmes in the areas of public health and food safety.

On-going field work or pending publication of the final reports postponed the publication of nine other studies, initially planned to be finalised in 2017. Within the public health domain, two studies planned to begin in 2017 were transferred to 2018[99]. One follow-up study in relation to HTA was also shifted to 2018[100]. After careful consideration and prioritisation, taking into account available resources, DG SANTE decided to cancel, for the time being, 5 studies and 8 evaluations which were included in the 2017 MP. The changes do not affect the short term planning of evaluations, as the cancelled evaluations were all expected to start after 2019.

Better regulation guidelines and tools are being applied to preparatory work for the vast number of implementing and delegated acts produced by DG SANTE.

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95 See Annex 9 to this report for details

96 Mid-term Evaluation of the Health Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020 (http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3527)

97 Mid-term evaluation report on the achievement of the objectives set out in the frame of the Common Financial Framework (CFF) for food and feed (http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3548)

98 http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3556

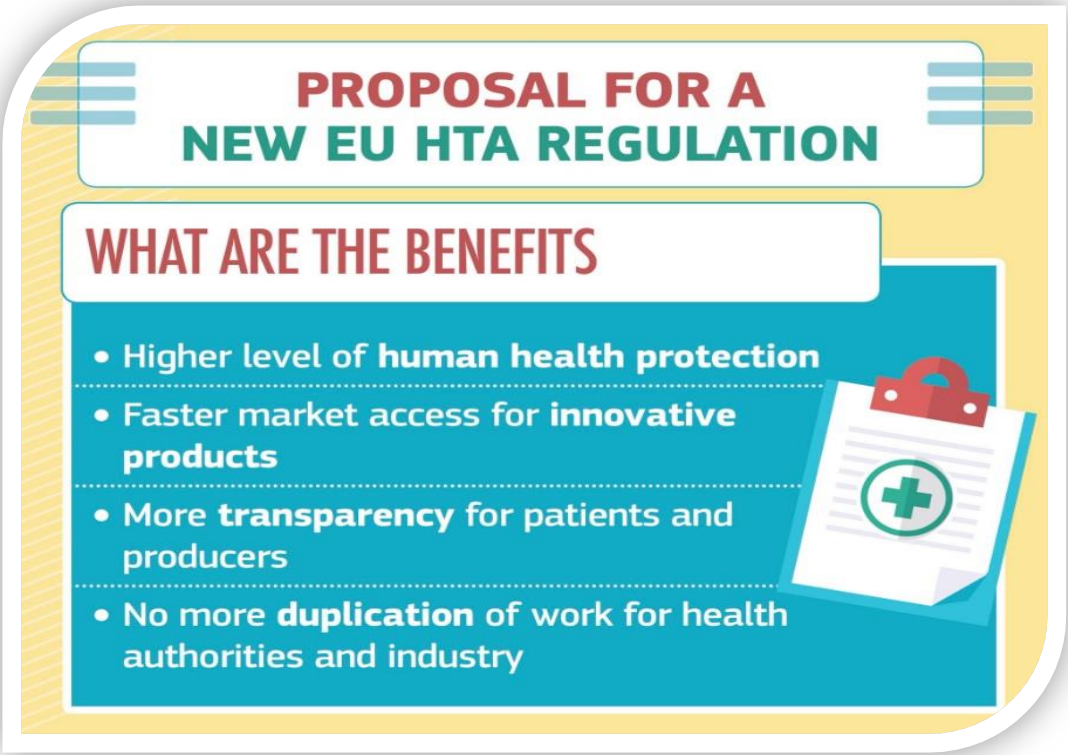
99 1. A study on the added value of the strategic and life-course approach to vaccination and on shortcomings related to low vaccination coverage in health care workers; 2. Economic burden of AMR in OECD countries (OECD study); 3. Feasibility study: analysis of skills for doctors and nurses. Health Workforce. OECD; 4. Study assessing the application of the broilers Directive and the implementation of the welfare indicators; 5. Study of Action Plan on organ donation & transplantation (2009-2015); 6. Conformity assessment of the transposition of Directive 2014/40/EU (Tobacco Products Directive); 8. Study on Cross-border healthcare cooperation; 9. Comparative assessment of the accessibility of healthcare service.

100 Mapping of EU market access paths for medical technologies with a focus on Health Technology Assessment

BETTER REGULATION ITEMS IN 2017 - ON-GOING ITEMS FROM PREVIOUS YEARS

All items listed below were finalised as planned in the 2017 MP.

Impact Assessment on Health Technology Assessment (HTA)



The DG finalised an Impact Assessment analysis aimed to assess the added value on an EU initiative in this area on the public health policies and the industry. This is supported by three studies to establish a robust baseline scenario and to gather data on alternative policy options. Following an Impact Assessment and public consultation, a legislative proposal was developed and adopted on 31 January 2018.

General Food Law Fitness Check[101]

This evaluation assessed the synergies of the General Food Law requirements/mechanisms as such, the implementation of the general principles and requirements in other EU secondary legislation and national law, the cumulate effects of the General Food Law and other EU secondary legislation. The aim was to identify any potential overlaps/duplications/inconsistencies, and to explore whether there is a need for simplification.

[101] https://ec.europa.eu/food/safety/general_food_law/fitness_check_en

Evaluation of the Rapid Alert System for Food and Feed (RASFF) and of crisis management procedures
The evaluation assessed whether the regulatory framework established by Articles 50 to 57 of Regulation (EC) No 178/2002[102] is effective, working efficiently and providing added value to its stakeholders. The assessment reveals that while the RASFF has functioned effectively throughout the reference period (2002-2013), there is scope for enhancing its role as a cornerstone of the EU system for food/feed safety. The findings also point to a need to review Commission Decision 2004/478/EC[103].

Mid-term Evaluation on the achievement of the objectives set out in the frame of the Common Financial Framework (CFF) for food and feed[104]
Regulation (EU) No 652/2014[105] covers the spending for animal health measures, plant health measures and official control activities. The evaluation assessed 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. The evaluation findings fed into the preparations of the next Multiannual Financial Framework (MFF post 2020).

Mid-term Evaluation of the Health Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020[106]
The purpose was primarily to assess the implementation of the Programme at mid-term with a special focus on the state of implementation of the 23 thematic priorities and their relevance in relation to the Programme's objectives and their contribution to the Commission's priorities. The evaluation also aimed to assess if the objectives of (EU) Regulation No 282/2014 and corresponding actions remain valid. The evaluation findings fed into the preparatory work for the next Multiannual Financial Framework.

Better Regulation items in 2017 - to be continued in 2018[107]

DG SANTE will continue its work on the following on-going 2017 projects.

- ***Evaluation of the Union policy framework for blood and tissues & cells***[108]
- ***Evaluation of the fee system of the European Medicines Agency (EMA)***[109]
- ***REFIT Evaluation on MRL legislation pesticides (regulation 396/2005) and Regulation 1107/2009 concerning the placing on the market of plant protection products***[110]
- ***REFIT 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***[111]

102 http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32002R0178

103 http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX:32004D0478

104 http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3548

105 http://eur-lex.europa.eu/legal-content/en/TXT/?uri=CELEX%3A32014R0652

106 http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3527

107 More information on the most recent status of the ongoing evaluations is to be found on the Interinstitutional Database: http://studiesdb.opoce.cec.eu.int/studiesdb/Home.xhtml

108 http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3550

109 http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3546

110 http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3547

111 http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3526

New Items which started in 2017 with foreseen completion date in 2018

Impact Assessment of Trans fatty acids (TFA)[112]
The Impact Assessment responds to the needs highlighted by the Commission report of 3 December 2015, to further consolidate the evidence base for setting legal limits for industrial TFA presence in foods.

Evaluation of the European Food Safety Authority (EFSA)[113]
The overall objective of the external evaluation is to assess EFSA and its core activities in terms of their relevance, effectiveness, efficiency, coherence, complementarity and EU added value. The evaluation assesses the working practices and the impact of the Authority and takes into account the views of the stakeholders, at both community and national level.

Evaluation of the Consumers Health Agriculture and Food Executive Agency (CHAF-EA)[114]
The purpose of this evaluation is the periodical (tri-annual) evaluation of the operation of the Consumers, Health, Agriculture and Food Executive Agency (CHAF-EA). CHAF-EA is governed by its Establishing Act, which sets out the tasks to be performed by the Agency and the Act of Delegation which delegates powers to the agency to perform its tasks. These tasks relate to the implementation of dedicated parts of certain EU financial programmes. The evaluation addresses and covers the whole scope of CHAF-EA's mission and tasks as well as its functioning as provided for in its Establishing Act.

Evaluation of the food contact materials (FCM) legislation[115]
The purpose of this evaluation is to assess whether the current EU legislative framework for food contact materials is fit for purpose and delivers as expected. The overall effectiveness, efficiency, relevance, coherence will be assessed, including coherence with other chemicals and food legislation, and EU added value of the food contact materials Regulation. The evaluation covers the functioning of the Regulation in its entirety and the rules and tools provided for by this legislation applicable in the European Union

Evaluation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council of 22 September 2003 on additives for use in animal nutrition[116]
The aim of the evaluation is to assess whether the objectives of the Regulation have been achieved properly and, more importantly, whether it is fit for purpose (as regards both safety and innovation) and in tune with the priorities of the Commission. In particular the evaluation addresses the issue of the development of new feed additives as this is one element in the fight against antimicrobial resistance (AMR).

Evaluation of legislation related to the irradiation of food and food ingredients [117]
Directives 1999/2/EC (framework Directive) and 1999/3/EC (implementing Directive) set out the legal framework to improve the free movement of irradiated foodstuffs within the single market. The purpose of this evaluation is to assess, in the light of the experience gained and technical progress made during their implementation, whether they are still fit for purpose. The evaluation will consider past and current performance and provide an assessment through five different criteria: relevance, effectiveness, efficiency, EU-added value and coherence. The evaluation is expected to provide a sound evidence base which will be used to identify the need for possible changes to the legislation.

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112 http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_143_trans_fats_en.pdf

113 http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3549

114 https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4843509_en

115 https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-5809429_en

116 https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4196253_en

117 https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4196327_en

2.2.3 Information management aspects

Tables with result indicators and outputs are included in Annex 2.3.

The Commission relies on information for every aspect of its work. Therefore, the adoption of specific policies at DG level is essential to enable the effective implementation of the corporate strategy on management of data, information and knowledge.

DG SANTE's collaboration platform policy provides the standard framework and tools for the management of key horizontal Units' activities including coordinating work with operational Units and projects within DG SANTE. In 2017, further steps have been taken to integrate existing IT systems with ARES, allowing long term preservation and a more efficient retrieval of the information.

A series of Knowledge Hours have been organised on topics such as personal data protection, approval and validation processes for Better Regulation deliverables, DG SANTE standard operating procedures on studies, and the novelties of the updated Better Regulation Guidelines. Training courses have been given aiming at disseminating among colleagues horizontal specialised knowledge through ad hoc presentations of specific subjects and "questions & answers" sessions mainly in the areas document management, personal data protection and access to documents.

In the framework of broader simplification exercises, DG SANTE assessed alternatives related to the handling of requests for access to documents to reduce administrative burden, especially in operational services. With the aim of increasing transparency and efficiency at the same time, DG SANTE examined the feasibility of publishing documents released on the basis of access to documents requests. A Pilot is planned for the first half of 2018, which will contribute to the assessment of the technical and administrative implications.

Finally, following extensive preparatory work the Management Board decided to adopt a web based application, KOEL (Knowledge Online on European Legislation) to support the management of the large DG SANTE acquis, and replace the current local excel based tables. This new tool will allow mapping and managing more effectively, efficiently and transparently the entire acquis of the Directorate General while maintaining an overview on the entire policy cycle, thanks also to the interoperability with other existing IT applications, such as DECIDE (managing the decision making process) and ARES (document management tool). KOEL is expected to be implemented in DG SANTE in the first half of 2018.

DG SANTE eGovernment policy is to work open and digital toward full e-government. For some systems, DG SANTE has reached the highest level of eGovernment maturity level, namely Transformed Government, with fully automated activities, full electronic case handling and electronic signatures for the processes implemented for interaction with Member States, business and citizens. The policy aims towards the digital economy by raising the maturity level for as many applications as possible, using standards and providing high value e-services, and reducing bureaucracy where possible. DG SANTE actively promotes and publishes all available information in the European Union Open Data Portal (ODP) in human and machine readable formats.

The eGovernment actions are covering all of DG SANTE's policy areas and are a subject of continuous evolution for all processes, systems and interactions with Member States, businesses and citizens. In particular during 2017, DG SANTE developed pilot versions with full electronic signatures for sanitary and phytosanitary certificates for the food safety pillar, implemented new e-services and workflow systems for the authorisation of novel foods applications and continues to pursue this evolution for all authorisation procedures. The publication of available information in the European Union Open Data Portal (ODP) has been revised and more information is now made available in a periodic manner.

2.2.4 External communication activities

Tables with result indicators and outputs are included in Annex 2.4.

DG SANTE's communication activities for 2017 contributed to the Commission's political priorities, and the general and specific objectives described in the DG SANTE Strategic Plan and the Commission work programme. Communication focused on the main policy deliverables and had a direct impact on the Institution's credibility, in particular in areas with a clear European added value. These include: the *State of Health in the EU* cycle which provides country-specific and cross-country knowledge as a support for national policies; the European Reference Networks (ERN), a collaboration model between healthcare providers across the EU that have a direct impact on the life of citizens with rare diseases (30 000 million in Europe); and specific deliverables in the area of Food Waste. Our communication activities during 2017 also stressed the importance and economic relevance of fighting Antimicrobial Resistance (AMR) through a new Action Plan, and of having a strong and efficient EU preparedness, prevention and response to crises in the health and food sector. Messaging also contributed to broader corporate communication, notably by underlining the importance of health investments which helps to create a Europe that protects, empowers and delivers.

DG SANTE's communication activities contributed to managing the Commission's reputational risks on sensitive health and food safety issues by monitoring traditional and social media and preparing solid press material to help inform public opinion. To integrate communication priorities upstream in the policy making process, a separate detailed communication work plan for 2017 was prepared. For each priority in this work plan, separate communication plans were developed, implemented, monitored and evaluated in close coordination with policy units.

In 2017, communication activities focused on the following areas:

a) Launch of the **European Reference Networks**: Around 900 health care providers and researchers joined forces to establish the first 24 ERNs for rare and complex diseases to deliver faster, better and more innovative diagnosis and treatment. The initiative is a successful example of how EU action responds to the needs of patients and stakeholders, especially in areas such as rare disease where knowledge and expertise is scarce and scattered. Communication efforts focused on informing and involving the medical community and on raising media attention through the organisation of a media seminar for national and EU-level journalists, audio-visual productions, social media promotion campaigns and a communication toolkit for partners and multipliers.

b) The new **EU Action Plan to combat Antimicrobial Resistance** (AMR) and the subsequent discussions with stakeholders. Communication activities included an animated clip that was disseminated through "Euronews" as well as press material, press briefings, social media, web and graphic material around the main AMR events such as the European Antibiotic Awareness Day.

c) Publication of the first series of Country Health profiles within the first complete **"*State of Health in the EU*" cycle**, which delivered 28 profiles and an EU-wide Companion Report. The initiative, carried out in close partnership with the OECD and the European Observatory on Health Systems, provided country-specific and cross-country knowledge necessary to render European health systems more effective, accessible and resilient. The related communication activities (press conferences, publications, social media promotion) raised the visibility and promoted the use of the cycle deliverables among Member State authorities and other stakeholders.

d) **Food Waste**: This area is a key contribution to the Circular Economy Package in an area of significant public concern. Communication activities gave visibility to the Food Waste Platform, the study on date marking, the adoption of food donation guidelines and our input to the Waste Framework Directive.

A large part of DG SANTE's communication activities are dedicated to reacting quickly and robustly to critical issues, **incidents and crises**, both in the health area (e.g. mandatory vaccinations in Italy, pharmaceuticals, preparation for Brexit - new location and EMA's contingency planning) and the food safety area (e.g. fipronil). This involves careful monitoring and excellent planning in cooperation with agencies such as the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC) or the European Medicines Agency (EMA).

A series of four videos on the role of audits in the food safety area, and one on EU import conditions, were also published to increase confidence in the EU control systems and recognition of the EU added value in this area, which is key for trade and entails a significant economic impact.

The strong handling of media-related issues (from monitoring to proactive press and social media actions) contributed to the successful conclusion of some sensitive files such as the renewal of glyphosate or the adoption the endocrine disruptors criteria.

In 2017, DG SANTE contributed to Commission **corporate communication** campaign *InvestEU* by providing DG COMM with relevant health-related content, and by reviewing and disseminating specific campaign material. DG SANTE also gave visibility to the Investment Plan for Europe and the (extended) European Fund for Strategic Investment (EFSI) through its own communication channels. DG SANTE organised the conference "Strategic investments for the future of healthcare" in February 2017 to promote the EFSI among relevant stakeholders. DG SANTE was also involved in the preparation of two other corporate campaigns, which are expected to be launched in 2018: *EU Empowers* and *EU Protects*, by contributing to the preparation of the Terms of Reference of the EU Protects campaign, with tangible examples in the areas of food safety, health (in particular vaccination) and emergency responses in crisis, which are key concerns for EU citizens.

In regard to communication infrastructure, work continued on the **Digital Transformation** front. The DG's old departmental page was replaced by a new one at the corporate level. SANTE contributed to the work on three content classes: Food, Farming, Fisheries; Live, Travel, Work in the EU; and Research and Innovation. SANTE web content has been further optimised in line with user test data and has gradually been integrated within a common Commission structure.

DG SANTE made increasingly strategic use of its **social media** accounts (@EU_Health and @Food_EU) to give visibility to the political priorities and to the Commissioner's role, including through cooperation with strategic partners and stakeholders and, where appropriate, with social media buying.

External communication overall spending

Annual communication spending (based on estimated commitments):			
Baseline (2016):	Target (2017):	Total amount spent	Total FTEs working on external communication
€1 683 887	**€2 2 402 092**	**€1 705 261**[118]	**8.5**[119] **FTE**

[118] The total amount spent in 2017 corresponds to activities for external communication, including SANTE's contribution to a joint stand with DG AGRI on international events as the International Green Week (IGW) and the Salon International de l'Agriculture (SIA), following a request by the Commissioner (total € 200.000). Some of the activities initially included in the MP estimates have been carried out in-house, resulting in some savings. One activity has not been implemented (animated clips on Food Safety, Plant Health and Animal Health).

[119] The figure includes tasks not only related with external communication activities strictly speaking but also related to policy advice/development and coordination. Other FTEs within the communication unit in charge of management and administrative support are excluded.