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European Commission

2018

Annual Activity Report

DG Health and Food Safety (SANTE)

FOREWORD

DG Health and Food Safety (DG SANTE) works intensively to provide an efficient policy framework to protect human, animal and plant health and promote a high level of food and animal feed safety.

Its day-to-day work supports stability, growth and innovation in two of the EU's most important economic sectors: public health, and food and drink. This makes an essential contribution to the EU's broader agenda and the priorities identified by President Juncker.

I took over as Director-General in October 2018 and have been impressed by the expertise and dedication of colleagues in their respective policy areas. Together, we support EU countries to tackle key challenges such as antimicrobial resistance, health system reform and food safety as well as preparedness and crisis management to handle and contain disease outbreaks. In 2018, we coordinated the EU's response to two highly contagious and potentially catastrophic plant and animal diseases – *Xylella* and African swine fever.

Significant resources are devoted to the implementation and enforcement of our legislative *acquis* which involves a high number of decisions on, notably, market authorisations for food and medicinal products. At the same time, we work hard to ensure the legislative framework remains fit-for-purpose in an ever-changing environment. The agreement of new EU rules on veterinary medicines and medicated feed prompted a major step forward on antimicrobial resistance, promoting a more prudent use of antimicrobials in animals and reducing the knock-on risk to human health.

DG SANTE also developed a proposal to improve transparency and sustainability of risk assessment in the food chain, based on a prior "fitness check", and responding to a European Citizens' Initiative on glyphosate. Intense discussions with co-legislators were very fruitful enabling a political agreement between the co-legislators in February 2019.

On the health side, the Commission adopted a proposal to improve EU cooperation on Health Technology Assessment aimed at delivering innovative health tools to patients and reducing fragmentation and duplication in the internal market. Discussions on this file are ongoing and it will remain an important priority into 2019.

We also followed-up on implementation of the Cross-border Healthcare Directive and continued to support the 24 European Reference Networks in their work on rare and low prevalence diseases. Alongside, we prepared a Council Recommendation on vaccination and continued to support EU countries in their efforts to promote effective action to tackle and prevent non-communicable disease. Other initiatives contributed to the digital transformation of health and care, including a Recommendation on a common exchange format for Electronic Health Records which paves the way for people to access their full health records across EU borders.

In a broader global context, DG SANTE continued to promote EU standards in various international fora to ensure they are respected by trading partners. We also monitored progress towards the global Sustainable Development Goals to ensure these objectives are fully integrated into our policy work.

Other important work included preparations for the new multiannual financial framework and the United Kingdom's withdrawal from the EU. Within this report you will find more detailed analysis of our work, measured against our multiannual strategic objectives and indicators. Bonne lecture!

Anne Bucher, Director-General of DG SANTE

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THE DG IN BRIEF

DG Health and Food Safety's mission (DG SANTE) is to promote and protect public health, food safety and the environment and a well-functioning and fair internal market in food, feed, agricultural and medicinal products. The food manufacturing and health sectors make an important contribution to employment and economic growth in the EU: food production and processing accounts for 7.5% of employment and 3.7% of total value added in the EU[1]. Health spending has now reached 9.9%[2] of GDP and the health sector accounts for 11% of employment[3]. Both sectors require a solid policy framework built on science and protecting a high level of human, 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. Our 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 168 (public health), 43 (agricultural policy), 114 (internal market), and 13 (animal welfare).

Article 168 stipulates that a high level of human health protection is ensured in all Union policies and activities. EU action in health is mainly linked to incentive and support for **disease prevention** and **health promotion**, and improving cooperation between Member State health systems. There is also binding legislation in areas such as serious cross border health threats, medicinal products and substances of human origin.

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. It provides 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. Its effectiveness depends on the will and commitment of Member States 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 and 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 the **Better Training for Safer Food initiative**. DG SANTE is a partner DG to the following EU decentralised agencies: the European Medicines Agency (EMA), the European Food Safety Authority (EFSA), the European Centre for Disease Prevention and Control (ECDC), the Community Plant Variety Office (CPVO) and the European Chemicals Agency (ECHA).

[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.

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, and weekly management meetings involving the Director-General and Management Team.

DG SANTE delivered its objectives in 2018 using a total of 778 staff.

DG SANTE Human Resources[6]	**Staff of DG SANTE** **Establishment plan posts**	
	At 31/12/2018	**At 31/12/2017**
Administrators	**431**	426
Assistants and secretaries	**212**	213
Contractual agents	**92**	97
National experts	**43**	44
Total	**778**	**780**

DG SANTE focusses on prudent management and protection of 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 implemented through indirect management consists of subsidies paid to EU decentralised agencies for running costs. Risk management helps establish specific internal control strategies focussing on activities and domains representing the highest risks.

DG SANTE 2018 budget[7] **in EUR million**	**Operational Expenditure**	**Administrative expenditure (DG managed)**	**Total Financial Resources**
Food and Feed Safety	260,7	1,2	261,9
Public Health	12,7	1,3	14,0
Other policy areas	3,8	4,9	8,7
Horizontal Administration[8]	-	12,1	12,1
Consumers, Health, Agriculture and Food Executive Agency (CHAF-EA)	-	5,7	5,7
European Centre for Disease Prevention and Control (ECDC)	58,1	-	58,1
European Chemicals Agency (ECHA) biocides[9]	4,9	-	4,9
European Food Safety Authority (EFSA)	79,1	-	79,1
European Medicines Agency (EMA) [10]	32,6	-	32,6
Total	**451,9**	**25,2**	**477,1**

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.

In 2018, DG SANTE's average residual error rate of 1.9% did not exceed the materiality threshold of 2%. Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's declaration of assurance.

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[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, including credits cross-subdelegated to other DG but without credits implemented by CHAFEA, according to Annex 3.

[8] The horizontal credits include EUR 7.2 million for the Global Envelope and EUR 4.9 million related to the building in Grange, Ireland.

[9] The EU contribution to ECHA-biocides activities is a balancing grant; 58,6% of ECHA's budget for biocides in 2018 (EUR 11,1 million) is financed by fees from industry

[10] The EU contribution to EMA is a balancing grant; about 90% of EMA's total 2018 budget of EUR 337.7 million is financed by fees from industry.

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 constitute 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 2018, DG SANTE actively contributed to 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.

Its work helps to promote good health in the EU population, a high level of food safety, animal and plant health and a well-functioning internal market in food and feed. This is essential to deliver key competitiveness and economic growth priorities, facilitate research and investment and reduce pressure on national health systems and budgets.

1. Promoting sustainable growth, competitiveness and job creation

Supporting the EU's capacity to deal with crisis situations

Disease outbreaks require a collective cross-border response, where EU actions offer a clear added-value. It is essential that Member States respond quickly to disease outbreaks and contain them to protect human, animal and plant health. DG SANTE continued to support Member States to achieve this in 2018.

On **animal disease**, the Commission signed 19 emergency grant decisions for Member States, and six grant agreements for third countries to help control outbreaks of major animal diseases, including avian influenza, Newcastle disease, African swine fever and lumpy skin disease. It provided EUR **137.6** million to support **134** national eradication programmes targeting, *inter alia*, rabies, African swine fever, salmonella and bovine tuberculosis. Emergency measures were also adopted or updated to control outbreaks of organisms threatening **plant health**, notably *Xylella fastidiosa*. Ultimately, the successful control of these diseases also depends on effective implementation by the Member States.

On **infectious diseases**, DG SANTE contributed to national response and international control efforts for coronavirus (MERS-CoV), Zika, Ebola, measles and seasonal flu.

To tackle **vaccine-preventable diseases**, DG SANTE prepared a Commission Communication, as well as a Council Recommendation on vaccination, which was adopted by the Council in December 2018. It aims to strengthen EU cooperation to counter vaccine hesitancy, improve vaccination coverage and ensure sustainability of vaccination programmes. 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.

> *"As a doctor I can honestly say that vaccination is truly one of the greatest successes of public health of our time and most cost effective tool in our hands."*
>
> Commissioner Andriukaitis

Tackling increased pressure on health services

Non-communicable diseases place enormous pressure on the EU's health and social systems (70-80% of healthcare costs, or EUR 700 billion). DG SANTE supports Member States to improve the sustainability of their health systems by promoting effective action.

[11] Article 17(1) of the Treaty on European Union.

In 2018, it formalised 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 to reach the Sustainable Development Goals in health and World Health Organisation targets. Member States were asked to consider priority areas for action to reduce the impact of non-communicable diseases (nutrition, physical activity and mental health were chosen as the first areas). Validated best practices were collected and support made available for countries to adapt and roll out more widely.

Antimicrobial resistance is a major global challenge with serious implications for human health and the economy. DG SANTE, with DG RTD and seven other DGs, is implementing the European One Health Action Plan against antimicrobial resistance (adopted in 2017). It includes over 75 actions across three main pillars:

- making the EU a best-practice region
- boosting research, development and innovation,
- shaping the global agenda through multilateral and bilateral collaboration.

In 2018, a major step forward was the agreement on the new EU legislation on veterinary medicines and medicated feed that contain a comprehensive set of provisions to minimise the risk to human and animal health from the use of antimicrobials and promote prudent use.

DG SANTE continued work on the two-year cycle, **State of Health in the EU.** This responds to President Juncker's mission letter to Commissioner Andriukaitis to develop expertise on the performance of health systems and country-specific and cross-country knowledge. DG SANTE completed the first cycle by delivering voluntary exchanges in seven Member States. The second cycle was launched with the publication of the 2018 "Health at a Glance: Europe report".

DG SANTE continued its work to discourage **tobacco** consumption by promoting the transposition and implementation of the Tobacco Products Directive. This caps a multi-year effort by the Commission to tackle illicit tobacco trade and decrease consumption of 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, it adopted a Communication on enabling the digital transformation of health and care in April 2018.

European Reference Networks continued to bring together highly specialised medical expertise on rare and low prevalence complex diseases affecting EU citizens. They ensure new technologies are applied to urgent patient needs and help patients across the EU receive faster, more accurate diagnosis and better treatment.

Safe and sustainable food and feed systems

DG SANTE proposed targeted revisions to the **EU's General Food Law** in April to increase transparency and ensure the EU's risk assessment model remains sustainable. This responds to the European Citizens' Initiative on glyphosate. Intensive efforts in the fourth quarter enabled trilogue discussions to begin at the start of 2019. The Commission has called on the co-legislators to adopt the proposals in the current legislative period, i.e. by mid-2019.

"The EU's science-based risk assessment for food safety is one of the most stringent in the world. We are now making it even stronger through clearer transparency rules and more effective risk communication throughout the process."

Commissioner Andriukaitis

In 2018, DG SANTE completed its work on **Bisphenol A,** adopting a Regulation that significantly tightens the restrictions on its use in food contact materials. It also launched a proposal to set a maximum limit on the use of industrially produced **trans-fat** in foods in the EU to protect consumers' health and promote healthier food options.

Continued progress was made in implementing the new **Novel Food Regulation** (applicable from 1 January 2018), and the **Animal Health**, **Official Controls** and the **Plant Health Regulations**.

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, supported by the EU Platform on Food Losses and **Food Waste** which met twice in 2018. DG SANTE also published a study on date marking and guidelines to facilitate the valorisation of food no longer intended for human consumption as animal feed.

On **pesticides**, following a comprehensive scientific review, three Regulations were adopted prohibiting all outdoor uses of three **neonicotinoids** to help protect bees.

The Commission continued to support Member State efforts to implement the Directive on sustainable use of pesticides, including the preparation of the first two harmonised **risk indicators** for estimating trends in risk from pesticide use.

The Commission concluded the adoption process for the scientific criteria to identify **endocrine disruptors**. These became applicable to biocidal products and plant protection products in June and November 2018 respectively. Scientific guidance to accompany these criteria was finalised by the European Food Safety Authority and European Chemicals Agency, with the support of DG JRC and DG SANTE. Specific implementing rules and guidance were developed to enable them to be applied to ongoing evaluations of substances used in biocides and pesticides. DG SANTE also contributed to the Commission Communication "Towards a comprehensive EU framework on endocrine disruptors" which updates the 1999 Commission strategy on endocrine disruptors.

The Platform for **Animal Welfare** promoted dialogue on animal welfare, EU rules and standards and better legislative implementation and enforcement. Two Platform meetings were organised in 2018. The Commission also designated the first EU Reference Centre for Animal Welfare, focussing on pig welfare. The Centre began work in October 2018.

DG SANTE carried out **220 audits** and on-the-spot visits in 2018 in EU and non-EU countries. 178 covered food safety and quality, animal health, animal welfare and plant health. 42 covered human health protection: antimicrobial resistance, medical devices, active pharmaceutical ingredients for human medicines and eHealth. This work is essential to ensure correct implementation and enforcement of EU legislation, maintain high standards and safety levels, and ensure a level playing field for business operators. The results feed into evidence-based policy development. The ultimate effectiveness of these audits also depends on follow-up implementation of recommendations by the Member States.

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 innovation is encouraged. It is worth noting that the EU's food and drink sector is largest manufacturing sector in the EU in terms of employment and second largest in value added[12].

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**. This framework ensures a high level of health and environmental protection, gives consumers access to safe, high quality food and feed products and helps the internal market to run smoothly. In 2018, DG SANTE continued to assess and, where appropriate, authorise substances used in food and feed production.

The Commission granted the first Union authorisations for biocidal products in 2018. These allow companies access to the entire EU market for the products concerned and replace the need for multiple national authorisations.

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.

[12] Eurostat Statistics Explained, Manufacturing statistics – NACE Rev. 2

In January 2018, the Commission put forward a proposal developed by DG SANTE to boost cooperation amongst EU Member States for assessing health technology. The proposal is expected to deliver greater transparency and innovative health tools and approaches. Throughout 2018, SANTE worked with the co-legislators and other stakeholders to highlight the potential within the 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.

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 and medicines for children. This contributes to a stable legal environment and optimal use of current authorisation procedures.

3. *A balanced and progressive trade policy to harness globalisation*

2018 is expected to be the **best EU agri-food export performance** ever according to the latest available data (October 2018). Between November 2017 and October 2018, EU agri-food exports increased to EUR 137.6 billion, corresponding to a slight improvement of 0.3% in value terms compared to the same period the previous year[13].

In 2018, DG SANTE advanced the EU's broader trade agenda, leading negotiations on the Sanitary and Phytosanitary (SPS) Chapters of the Free Trade Agreements (FTA) under negotiation: Japan, Mercosur, Indonesia, Philippines, New Zealand, Australia, Chile. It also ensured the implementation of the SPS Chapters of Agreements recently concluded and the management of those in force.

In addition, through bilateral and multilateral contacts with main trading partners, huge efforts were made on the recognition of the EU's animal health regionalisation policy to ensure safe trade while respecting animal health, plant health and food safety.

Also, on the pharmaceutical front, six additional Member States joined the list of recognised EU countries under the Mutual Recognition Agreement on Good Manufacturing Practices agreed between the EU and the US. This agreement will lead to a better use of respective inspection resources and entail significant cost savings for industry.

DG SANTE also continued to work closely with its global partners in the World Trade Organisation, the World Health Organisation, the Codex Alimentarius Commission, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use, the Food and Agriculture Organization, the World Organisation for Animal Health, the International Plant Protection Convention and the Convention on Biological Diversity (CBD) to ensure its standards were recognised, accepted and promoted at bilateral and multilateral level. This contributes to a high level of health protection and growth and employment opportunities in the EU's food and pharmaceutical sectors.

Through many of the activities in 2018, DG SANTE contributed to broader Commission-wide efforts to achieve the Sustainable Development Goals (SDG), in particular SDG 3 (health), SDG 12 (halving food waste by 2030) and SDG 15 (sustainable use of pesticides).

4. *Planning for the future EU budget*

In 2018, the preparation of the next **Multiannual Financial Framework** for 2021-2027 required the investment of extensive resources. On the health side, DG SANTE worked on the Health strand of the proposed European Social Fund Plus Programme (ESF+). As regards food safety, DG SANTE worked on Food Chain strand of the proposed Single Market Programme (SMP). DG SANTE also worked on other programmes where synergies can be envisaged, including the Horizon Europe Research Programme, the new Common Agriculture Programme, the Digital Europe Programme and InvestEU.

[13] Source: European Commission, DG Agriculture and Rural Development, https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/trade/documents/monitoring-agri-food-trade_oct2018_en.pdf.

5. ***Preparing for the United Kingdom's withdrawal from the EU***

DG SANTE has worked hard to prepare for the United Kingdom's withdrawal from the EU at the end of March 2019. More than 20 notices to stakeholders and Q&As have been prepared. These documents have covered many areas: medicinal products for human and veterinary use, Plant protection products, biocidal products, EU food law, Animal feed, GMOs Natural mineral waters. Plant reproductive material, Animal breeding, Movements of live animals, Plant health, Plant Variety rights, Slaughterhouse operators, Animal transport, Substances of human origin, Clinical trials and Travelling.

In addition, DG SANTE has worked closely with the Commission's Task Force Article 50 and the Secretariat General Brexit Preparedness Group to raise awareness among Member States and stakeholders on the consequences of Brexit. Specific meetings have been organised on: biocides, animal nutrition, pesticides, food safety, plant reproductive material, medicinal products and clinical trials. A number of legal measures for preparedness and contingency have been prepared to minimise disruptions for EU-27.

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	**The latest data**	**Interim Milestone**	**Target**
2014	2018	2018	2020
19/25[14]	19/25	19/25	Increasing (internal target)

This indicator remained stable in 2018 despite changes in the EU's epidemiological situation. DG SANTE coordinated and managed preparedness and control systems through dozens of implementing decisions as well as through 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 as a slow spread occur partly due to the human factor, while the situation of avian influenza improved to 3/5 when compared to previous years.

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**
	2018	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

24 ERNs were established in 2017 (exceeding interim milestones for 2016 and 2018), and no additional ERNs were added in 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 reinforce their capacities, improve the diagnosis and clinical outcomes of patients and contribute to the efficiency of the national healthcare systems.

[14] 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.

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)	2018: 1.9% (policy area Food and Feed Safety) 2018: around 0% (policy area Public Health)

In the policy area "Food and Feed Safety", DG SANTE's residual error rate amounts to 1.9%. Thus, it does not exceed the materiality threshold of 2%. In the past few years, DG SANTE has taken a series of mitigating actions which reduced the error rate to an acceptable level.

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 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 principles. DG SANTE has assessed the internal control systems during the reporting year and has concluded that the internal control principles are implemented and function as intended. Please refer to AAR section 2.1.3 for further details.

In addition, DG SANTE has systematically examined the available control results and indicators, including those aimed to supervise entities to which it has entrusted budget implementation tasks, as well as the observations and recommendations issued by 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 her 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 the EU Health Programme and the EU's Common Financial Framework 2014-2020 in the food chain area.

EU'S 3RD HEALTH PROGRAMME 2014-2020

The EU's Third Health Programme 2014-2020 has a total budget of EUR 449.4 million. It is implemented via annual work plans which identify priority areas and criteria for funding and supports actions where there is evidence of high **EU added-value**. It is managed by the Commission with support from the Consumers, Health Agriculture and Food Executive Agency (CHAFEA) and national contact points in EU and other participating countries.

In 2018, work focused on the following areas:

- Developing country-specific and cross-country knowledge,
- Multiannual grants to European Reference Networks,
- Strengthening EU preparedness for serious cross-border health threats,
- Implementing International Health Regulations
- Prevention and management of non-communicable diseases, including tobacco control
- eHealth, and
- Health inequalities.

The Health Programme produces **tangible results.** The programme statements prepared for the draft budget procedure in 2017[15], 2018[16] and 2019[17] confirmed:

- it contributes to the evidence base to support informed policy making, in particular by collecting comparable health-related data and best practices from across the EU;

- it supports[18] actions to implement the EU's political commitments and legal obligations in health and work towards Sustainable Development Goal 3 on health;

- it helps Member States to address cross-border challenges and health threats such as antimicrobial resistance (AMR), by defining common approaches in line with EU and international policies;

- it supports capacity building and resource efficiency in Member State health systems through joint actions, training and knowledge/best practice exchange;

- it supports innovation and economies of scale in health and healthcare through e.g. Health Technology Assessment (HTA) and European Reference Networks (ERNs);

- it helps identify best practice, tools and methodologies, and financing sources to support sustainable health systems.

[15] http://ec.europa.eu/budget/library/biblio/documents/2017/DB2017_WD01_en.pdf
[16] http://ec.europa.eu/budget/library/biblio/documents/2018/DB2018_WD01_en.pdf
http://ec.europa.eu/budget/library/biblio/documents/2018/DB2018_WD01_en.pdf
[17] http://ec.europa.eu/budget/library/biblio/documents/2019/WD%20I%20with%20covers.pdf

[18] Examples of such support includes funding for operating grants to NGOs (Framework Partnership Agreements were signed with 17 NGOs in 2018) and grant agreements with the WHO and OECD to enable international cooperation on AMR and other issues of mutual interest.

- It supports awareness and sustained networking activities e.g. co-funding conferences and networks in public health and health promotion;

- It helps produce training, educational and guidance materials (e.g. to train health professionals on migrant and ethnic minority health).

The work of 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 contribute to policy decisions in 2018.

They published 19 final and five preliminary scientific opinions in 2018, including the potential human health risks of Light Emitting Diodes (LEDs), and the health risks from onshore oil and gas exploitations.

Despite the high level of engagement and clear added value, there are some challenges in the implementation of the Health Programme. For example, the current funding mechanism of the Programme only allows for project-oriented funding, which can have a negative impact on longer-term sustainability of the actions undertaken. Furthermore, some mechanisms in the programme, such as Joint Actions implemented with Member States, are quite complex in their set-up. This in turn means that timelines from the initial planning of the activity to its actual launch can be rather lengthy.

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, and ensures consistently high and uniform levels of safety are applied across the EU. This contributes to the stability of the EU's internal and export markets and supports more effective disease prevention and crisis management.

Actions in this area are governed by Regulation (EU) No 652/2014. Expenditure covers animal and plant health measures, emergency measures for animal and plant disease outbreaks, official control activities and relations with relevant international organisations. The total budget of the CFF 2014–2020 is EUR 1.892 billion.

The CFF finances actions under specific objectives 1.1.1 (preparedness, prevention and eradication of animal, foodborne and plant diseases) and 1.1.6 (official controls).

The CFF's Programme Statement for the draft budget procedure 2018[19] confirmed there is a clear **EU added value** within the Programme: a safe and well-functioning food chain is a key public health and economic priority. Outbreaks of serious animal and plant diseases can spread between Member States and affect the whole EU market.

In 2018[20], the CFF co-financed a number of measures with tangible results:

- significant progress eradicating diseases such as bovine spongiform encephalopathy (BSE), rabies, and brucellosis by implementing national programmes;

- containment and management of animal disease outbreaks, e.g. lumpy skin disease (through vaccination) and avian influenza and African swine fever (by implementing tailor-made emergency measures);

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

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

- better implementation of EU legislation thanks to funding for EU Reference Laboratories (EURLs) and training activities under "Better Training for Safer Food" (BTSF).

The implementation of the CFF has faced some challenges over the past year. Notably, the lack of access to a crisis reserve facility has represented a hurdle. Emergency situations are unpredictable in terms of their timing and impact. Without a crisis reserve, this has required re-allocations of funds from other important activities co-financed by the CFF. A further challenge has been the absence of an established method of valuation for animals, plants and products which need to be destroyed in the course of disease containment measures. It is important for all stakeholders involved that valuation and compensation is as transparent and comprehensive as possible.

The effectiveness of regional eradication programmes also depend on full and effective cooperation and collaboration between neighbouring Member States, which was not always the case. On a related note, Member States could not always count on full cooperation to be extended by neighbouring third countries in order to implement specific veterinary measures (such as wildlife rabies vaccination).

PLANNING FOR THE FUTURE EU BUDGET (2021-2027)

DG SANTE contributed substantially towards planning for the future Multiannual Financial Framework (MFF) for 2021-2027, notably the legislative proposals for a new European Social Fund Plus (ESF+) Programme and Single Market Programme, adopted in May 2018.

The health strand of the ESF+ Programme will support a continued high level of health protection in the Union and access to healthcare and services. This will help reduce health inequalities and complement other ESF+ actions and health challenges identified in the European Semester.

The focus will be on key areas and priorities where Europe can deliver added value and make a real difference to the life of citizens. It will build on actions and achievements under the current EU Health Programme.

Food safety programmes will be integrated in the Single Market Programme (SMP). This new programme includes a food safety strand with a total budget of EUR 1.68 billion for the MFF period. It aims to improve the functioning of the internal market, protect and empower citizens, consumers and businesses, promote human, animal and plant health and animal welfare, and provide high-quality, comparable, timely and reliable European statistics.

WORKING IN PARTNERSHIP WITH THE EU'S EXECUTIVE AND DECENTRALISED AGENCIES

The **Consumers, Health Agriculture and Food Executive Agency (CHAFEA)** helps deliver the EU Health Programme and manages the Better Training for Safer Food (BTSF) initiative under the financial framework for food safety, animal and plant health. In 2018, it organised cluster meetings and conferences in both policy areas.

In 2018, under the Health Programme, CHAFEA launched 20 procurement procedures; 20 service contracts were signed and three tenders published (to be awarded in the first quarter of 2019). It also signed six direct grants with international organisations, including work with the OECD on patient reported measures; 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 Framework Convention on Tobacco Control (FCTC).

Under BTSF, CHAFEA launched 14 procurement procedures and signed 12 service contracts. CHAFEA and DG SANTE worked closely to develop the BTSF Academy, which currently includes 10 e-learning modules in 5 languages.

Overall, CHAFEA's expertise in the implementation of projects is a valuable contribution to the work of DG SANTE. Its advice helps orient projects towards results which reflect the original intent of the policy-making. Nevertheless, DG SANTE constantly reviews its performance and identified that CHAFEA's budget implementation related to the Health Programme has included a number of payment delays during the year. CHAFEA kept the Steering Committee informed on the main factors causing the payment delays and the measures taken improved the situation by the end of the year.

DG SANTE's work was also supported in 2018 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, independent expertise and network opportunities that support evidence-based policy making and effective disease prevention and crisis management.

The **European Centre for Disease Prevention and Control** (ECDC) helps the EU respond to serious cross-border health threats posed by communicable diseases, notably on vaccine preventable diseases, HIV/AIDS, Tuberculosis, Hepatitis and antimicrobial resistance and its public health laboratory support. It provides scientific advice, technical guidance and epidemiological surveillance data on an ongoing basis that feeds into EU policy making and the work of the EU's Health Security Committee.

In 2018, other important work included assessments on several vector-borne diseases (yellow fever, West-Nile virus infections, dengue, chikungunya, Zika and yellow fever) and the threat of Ebola spreading in the Democratic Republic of the Congo. ECDC also contributed to improving the EU's Early Warning and Response System.

In 2018, the **European Food Safety Authority (EFSA)** provided essential scientific advice on animal health and welfare, plant health, biological risks and contaminants. It provided 140 scientific opinions and technical reports which supported *i.a.* the new plant health law (48 pest categorisations, horizon scanning for new plant health threats, guidance on quantitative pest risk assessment and a risk assessment on *spodoptera frugiperda*), the new animal health law and EU work on antimicrobial resistance.

EFSA also continued to support SANTE's work to authorise regulated products, handling over 500 authorisation questions in 2018, including pesticides and Maximum Residue Levels reviews and an increasing number of novel food applications and notifications of traditional food.

EFSA provided scientific support to the EU and Member States on outbreaks of animal diseases, issuing scientific opinions and conducting surveillance notably on avian influenza. It worked with ECDC on a number of rapid outbreak assessments on Lysteria monocitogenes and salmonella. It also started projects on EU plant health crisis preparedness and developed a multi-annual crisis preparedness training programme.

The **European Chemical Agency's (ECHA)** supports the EU's work to authorise biocidal products, approve active substances and classify active substances used in biocidal products and pesticides. In 2018, work included 25 opinions on active substances used in biocidal products and seven opinions on biocidal products. It also delivered 33 opinions on classification and labelling for active substances used in biocides and pesticides and published one new and six updated guidance documents on biocides.

ECHA and EFSA made an important contribution to SANTE's work on endocrine disruptors by developing, with the support of DG JRC, joint scientific guidance for implementing the new criteria to identify endocrine disruptors under the Regulations for biocidal products and plant protection products. In addition, DG SANTE worked towards an enhanced cooperation between EFSA and ECHA on classification of chemical substances.

The **Community Plant Variety Office (CPVO)** contributed to greater investment and innovation, adopting measures to modernise the intellectual protection of plant varieties, and granting plant variety protection at EU level. This is an important incentive to breed new and improved plant varieties to counter plant health threats, climate change and food security challenges. The CPVO also promoted the EU's plant variety system at global level.

The **European Medicines Agency (EMA)** produced numerous scientific opinions and recommendations in 2018, linked to which 1783 Commission decisions were adopted (see sections 1.2.2). EMA contributed to EU authorisations of new medicinal products, supporting a competitive pharmaceutical sector and patients' access to safe medicines. It recommended 92 human medicines and nine veterinary medicines for marketing authorisation, many of which are therapeutic innovations. EMA also supported SANTE in international fora to harmonise the pharmaceutical sector and promote EU standards globally (see section 1.3.1).

In 2018, the EMA fee system was the subject of a formal evaluation by DG SANTE to help assess the extent to which the current fee and remuneration system is cost-based, fair, proportionate and not unduly complex. As part of this evaluation, an external support study was finalised in 2018, and a Staff Working Document will be published in 2019. These will feed into an impact assessment in 2019 to assess possible future policy options.

DG SANTE also continued to be involved in the governance of the **European Foundation for the Improvement of Living and Working Conditions (Eurofound)** on quality of life and public services. DG EMPL is the lead partner DG. It also continued to be involved in the governance of the **European Monitoring Centre for Drugs and Drug Addiction**, which ties in with our work on addictions, including the European School Survey Project on Alcohol and Other Drugs, and drug use associated communicable diseases. DG HOME is the lead partner DG.

PERFORMANCE INFORMATION AND DECISION-MAKING

DG SANTE uses a Unit Management Plan (UMP) process to set objectives and assess performance information to guide the internal decision-making and priority-setting process. Within the UMP, each Unit's general objective, impact indicators, specific policy objectives and result indicators are all derived from the DG SANTE Strategic Plan 2016-2020. Each Unit then updates its objectives with specific goals it seeks to attain by the end of the year. These may include the adoption of specific initiatives, major conferences or events, or the submission of evaluations. The UMP also includes identified challenges and potential mitigation measures. The UMP is reviewed in person with the Director-General, and performance is assessed regularly, including through a mid-term update, to guide internal decision-making related to resources, activities and their overall timing.

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 prevention of social exclusion.

DG SANTE contributes to the achievement on General Objective 1 in several ways: by promoting effective, accessible and resilient health systems; by encouraging disease prevention and health promotion; and by fostering health coverage as a way of reducing inequalities and tackling social exclusion. DG SANTE's health-in-all-policies approach represents a means of achieving smart, sustainable and inclusive growth.

For example, 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 2018 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.

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.

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, tuberculosis, or with mental health illnesses and dementia, and to fight health inequalities. DG SANTE also contributes to facilitate food donation by clarifying the legal framework in Member States for donors and receivers.

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 impact significantly on economic growth, consumer confidence and international market access if they are not contained or well-managed. While preparedness, response planning and implementation are the responsibility of individual Member States, the EU plays an essential role in coordinating cross-border action, preparation and response mechanisms to tackle disease and food safety crises effectively. Crisis preparedness, disease prevention and response is a critical part of DG SANTE's work.

In 2018, SANTE's work ensured the EU's framework remained robust in an ever-evolving context and that our emergency measures could support rapid and effective management of any disease outbreaks.

The following priorities were addressed:

- Improving preparedness for and tackling serious cross-border health threats;
- Improving preparedness and management of foodborne crises;
- 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

The Joint Procurement Agreement enables participating Member States to jointly purchase medical countermeasures for serious cross-border health threats. It aims to improve Member States' preparedness, ensure more equitable access to specific medical countermeasures; and ensure more balanced prices. In 2018, work continued on the agreement, focussing on the joint procurement of pandemic influenza vaccines.

A large number of Member States have joined forces with the Commission to improve preparedness and secure access to pandemic influenza vaccines. The calls for tender for production and supply of pandemic influenza vaccines were launched in early 2018.

Negotiations with the main producers of these vaccines were either concluded in 2018 or at the final stage. Signature of the contracts is foreseen in the first months of 2019.

In June 2018 the Commission adopted Implementing Decision 2018/945/EU on communicable diseases and related special health issues to be covered by epidemiological surveillance as well as relevant case definitions.

Together with the Health Security Committee, in 2018, DG SANTE continued to implement activities under the technical action plan to support preparedness and implementation of the International Health Regulations (IHR). This included capacity building activities, preparedness for terrorist attacks, exchanging medical countermeasures, and sharing passenger personal data for contact tracing purposes.

A new version of the Early Warning and Response System (EWRS) was launched in October 2018. It includes a structured notification template, search function, built-in workflow for alert notifications, and a new tool to notify and monitor public health measures responding to serious cross-border threats to health.

The second reporting exercise on preparedness and response planning at national level took place in 2017-2018 (Decision 1082/2013/EU). It was followed by a progress report prepared by the ECDC which found most Member States reported strengthened preparedness and response planning compared to 2014 (first reporting cycle).

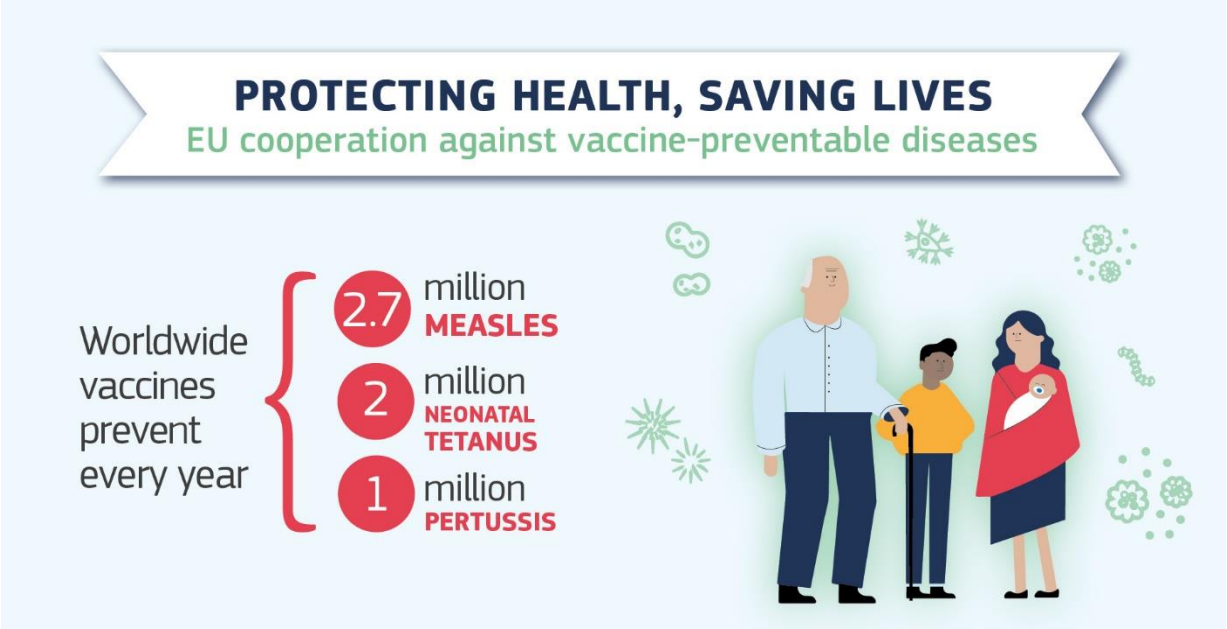
Under the Global Health Security Initiative, the Commission contributed to the work of G7 countries, Mexico and the WHO to improve preparedness for chemical, biological, radio nuclear terrorism and pandemic influenza. It included the network of rapid communication in crises to share surveillance data and information on control measures; sample sharing and laboratory collaboration; exchange of medical countermeasures; security threats including chemical events, and the Epidemic Intelligence from Open Sources system for threat detection and assessment under the WHO Health Emergencies Programme.

Vaccine-preventable diseases are a major health problem, complicated by their cross-border nature, differences in national vaccination programmes and increasing vaccine hesitancy. EU action offers clear added value and a coordinated approach to limit the spread of vaccine preventable diseases and epidemic.

In 2018, DG SANTE prepared a Council Recommendation on Vaccine Preventable Diseases, adopted by EU Health Ministers in December 2018, and a Commission Communication. The Recommendation focuses on tackling vaccine hesitancy and improving vaccination coverage, sustainable vaccination policies in the EU and EU coordination and contribution to global health. It reflects a targeted outreach towards vulnerable groups, calls to strengthen vaccination training in medical curricula and exploits the synergies with eHealth and digital technologies to establish electronic vaccination records for all EU citizens.

In October 2018, DG SANTE published two reports on vaccination and an expert panel opinion on *Vaccination programmes and health systems in the European Union*. The first report ("State of Vaccine Confidence in the EU 2018") showed that confidence in vaccination is declining overall in the EU, while the second report ("The organisation and delivery of vaccination services in the EU") indicated significant differences in national vaccination strategies and approaches. Both studies confirmed the need for EU action.

In 2018, the Joint Action on Vaccination (2018-2021) began, funded under the EU Health Programme, involving 20 countries, ECDC, WHO, industry and stakeholders. It is coordinated by France's National Institute of Health and Medical Research. By sharing tools for stronger national responses to vaccination challenges, the Joint Action aims to support long-lasting European cooperation against vaccine-preventable diseases.



FINANCIAL CONTRIBUTION TO TACKLING SERIOUS CROSS-BORDER HEALTH THREATS

In 2018, the Health Programme committed EUR 6.9 million to serious cross-border health threats, which is one of the four specific objectives outlined in the Health Programme Statement. Six grants and contracts were signed, focussing on:

1. Joint Action on preparedness and action at points of entry (air, maritime and ground crossing) (EUR 3 million co-funding)

2. Joint Action on vaccination (EUR 3.5 million co-funding)

3. Organising an inter-sectorial table top exercise on business continuity planning during a pandemic (EUR 229 209).

4. Organising a training on entry and exist screening (EUR 229 900).

In relation to HIV/AIDS, viral hepatitis and tuberculosis, work continued in 2018 on:

- The Joint Action INTEGRATE, which will run until August 2020 (budget: 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. It reinforces another on-going Joint Action on prevention and harm reduction and existing projects on early diagnosis and integrated care of hepatitis and tuberculosis.
- The project HepCARE, which will run until April 2019 (EUR 1 million funding from the EU Health Programme). It involves six partners in four Member States and aims to optimise Hepatitis C diagnosis; link primary, secondary and outreach community care and access to treatment for at-risk populations in the EU; and introduce a new model of care.
- The project e-DETECT TB will run until May 2019 (EUR 1.8 million from the EU Health Programme). It involves 11 partners in six Member States. Its overall aim is to help reduce, and eventually eliminate tuberculosis in the EU, in line with the ECDC and the WHO Europe Action Plans.
- The study ESTICOM, which will hold its final workshop in June 2019 (EUR 2 million from the Health Programme). Eight partners from five countries aim to provide sound evidence on the sexual health of men who have sex with men in Europe. It seeks to assess and define the knowledge, attitudes and practices to ensure effective implementation of targeted prevention strategies by community-based health workers providing health services for men who have sex with men.

In July 2018, DG SANTE published a Staff Working Document on combatting HIV/AIDS, viral hepatitis B and C and tuberculosis in the EU and neighbouring countries. It takes stock of EU support to Member States across multiple policy areas and presents EU-funded good practices on early diagnosis, testing, outreach to vulnerable groups, integrated care, rapid linkage to care, treatment and prevention, health promotion and support to networks and civil society organisations.

In 2018, DG SANTE held two EU HIV/AIDS, viral hepatitis and tuberculosis Think Tank and the Civil Society Forum meetings. In addition, a first-ever joint meeting with the EU Civil Society Forum on Drugs was co-organised with DG HOME.

Work continued on the Joint Action on Antimicrobial Resistance and Healthcare Associated Infections (2017-2020), funded under the Health Programme. It supports the implementation of national policy on antimicrobial resistance and healthcare associated infections through peer reviews of 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 EU-wide exercises with Member States, EEA and neighbouring countries financed under the Health Programme, including a hybrid threats exercise involving public health, civil protection and security authorities, with NATO as observer; an intersectoral table-top exercise focusing on business continuity planning and strengthening capacity to respond to a series of disruptive events during an ongoing influenza pandemic; and a workshop aiming to support strengthening preparedness and the implementation of International Health Regulations under Decision 1082/2013/EU.

2. Improving preparedness and management of foodborne crisis

DG SANTE plays a key role helping the EU respond effectively and rapidly to high-profile, multinational outbreaks of food-borne pathogens. In 2018 it conducted audits (see specific objective 1.6) to assess contingency planning in Member States for food-borne emergencies and to promote constant improvement of control systems.

The revision of the Commission Decision on a general plan for crisis management in food and feed was finalised in 2018 and its adoption foreseen for early 2019. This will support better prevention and preparedness and limit the impact of foodborne outbreaks.

In 2018, EUR 21.3 million was allocated to 87 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 ensuring 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.

In 2018, there were outbreaks of several major epidemic animal diseases, including African swine fever, lumpy skin disease, avian influenza and bluetongue.

DG SANTE continued to fight **African swine fever** (ASF), applying prevention and control measures whenever the virus was suspected or confirmed in holdings or wild boars. It closely monitored the epidemiologic situation (which saw significant outbreaks in Romania and Bulgaria, and an outbreak in Belgium) and responded with constant updates of the Commission Implementing Decision on **regionalisation**[21].

DG SANTE also organised **two ASF Better Training for Safer Food initiatives** in 2018, as well as a Ministerial conference in December on the eradication of ASF in the EU and long-term management of wild boar populations. DG SANTE has been involved in ASF

[21] 2014/709/EU

cooperation activities with neighbouring countries via EU Veterinary Emergency Teams, BTSF initiatives and the OIE/FAO Global Framework for Transboundary Diseases Eradication (GF-TADS), though which DG SANTE provided leadership and support. This cooperation enhanced coordination and cooperation on surveillance and control of ASF and helped contain ASF in affected regions. That being said, the disease continued to spread despite actions taken at EU level and in affected Member States.

WHAT IS ASF?

African swine fever (ASF) is an exotic and usually deadly infectious disease of pigs and wild boar that started occurring in certain eastern areas of the EU in 2014.

The ASF virus can be transmitted either via direct animal contact or via dissemination of contaminated food. It does not affect humans nor other animal species. No vaccine exists to combat this virus.

During the period 2014-2018, ASF has been reported in Lithuania, Poland, Latvia, Estonia, the Czech Republic, Hungary, Romania, Bulgaria and Belgium.

WHAT IS THE EU DOING TO FIGHT AGAINST ASF?

The persistence of the ASF virus, and its spread in affected area, presents a serious threat to the EU pig farming sector due to direct (culling of pigs) and indirect (trade restrictions by third countries, preventive slaughter etc.) losses.

Since the early stages of ASF in the EU and at its borders, several initiatives were taken at EU level to prevent the spread of the disease. These include:

- regionalisation measures to contain the spread of the virus whilst ensuring continued safe trade from unaffected areas
- immediate assistance and best expertise provided on the spot for affected Member States by the experts of EU Veterinary Emergency Team;
- financial support to prevent, control and eradicate ASF. Since 2013, grants for a total amount of almost EUR 100 million have been awarded for programmes and emergency measures implemented by Member States in the fight against ASF.
- scientific opinions and reports by European Food Safety Authority (EFSA), the World Organisation for Animal Health (OIE) and the Food and Agriculture Organization (FAO) as well as support for research on ASF, including funding for research and development of effective vaccine;
- international activities, including participation and promotion of GF-TADs (Global framework for transboundary diseases) under OIE and FAO.
- enhancing public awareness and cooperation with stakeholders at EU and national level (farmers, hunters, veterinary services, travellers, forestry bodies and etc.).

Success depends on effective implementation of EU rules and in Member States and operators and stakeholders complying.

411 restrictions were imposed in the EU as a result of major outbreaks of epidemic animal diseases in 2018. This figure was down from previous years mainly due to a better epidemiological situation for avian influenza (**result indicator 1.1.C**).

There was also a slight improvement in the EU's containment of major epidemic animal diseases after an initial outbreak (**result indicator 1.1.D**), with the indicator rising from 18/25 in 2017 to 19/25 in 2018.

Major progress on the **Animal Health Regulation** was achieved in 2018. Two Commission Regulations were adopted, the first providing a list of animal diseases for the EU intervention, and the second on the categorisation and listing of animal species relevant for these diseases. These two Regulations were crucial to develop further animal health requirements in subsequent delegated and implementing acts.

Nine additional delegated acts were also developed in 2018 covering animal disease prevention, surveillance, eradication and control, safe and smooth movements of animals and their products in the EU, approval and registration of establishments, traceability

rules, and rules for entry into the EU of animals and animal products. Although these acts were not adopted in 2018, the work is well advanced and broadly supported by Member States.

The **Animal Breeding Regulation** (Regulation (EU) 2016/1012) has been applied in all Member States since 1 November 2018. It aims to ensure a harmonised approach to trade in breeding animals and their germinal products, including their entry into the EU. To make the Regulation operational, Member States may lay down national measures and several Member States have notified draft national implementing provisions to the Commission. The Commission started to assess these in 2018. It also hosted meetings with Member States to exchange experiences on the implementation of the Regulation and help find solutions to any challenges.

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 2018, EUR 137.6 million was awarded to support the eradication, control and surveillance for **134 national eradication programmes**, including bovine tuberculosis, classical swine fever, rabies, salmonella infection of certain poultry populations, transmissible spongiform encephalopathies and bovine brucellosis. EUR **13.8** million was allocated to tackle African swine fever.

The EU also provided co-funding through the signature of grant decisions and grant agreements of EUR 73,9 million for **emergency measures** to contain animal disease outbreaks quickly (avian influenza, Newcastle disease, African swine fever, etc.). Of this, EUR 2.7 million was allocated to grants for emergency measures for exotic diseases – including lumpy skin disease, peste des petit ruminants, sheep pox and goat pox.

For the control of lumpy skin disease, 876,000 doses of vaccines were donated in 2018 to six countries from the EU LSD vaccine bank. EUR 1.8 million was awarded for LSD vaccines purchased nationally. In December 2018, a new contract was awarded for EUR 1.7 million for LSD vaccines for the EU LSD vaccine bank.

4. Preventing plant diseases

Globalisation of 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, as also stated in the CFF Programme Statement.

DG SANTE has continued implementing the **Plant Health Directive** 2000/29/EC, including updating the list of regulated harmful organisms, plant commodities for import control and specific import requirements. Existing emergency measures have been revised e.g. for *Xylella fastidiosa* and wood packaging material from China and Belarus. Two new measures were adopted to protect the rest of the EU territory for the spread of the redneck longhorned beetle (*Aromia bungii*), and preventive measures to protect the Union territory against the introduction of the fall armyworm (*Spodoptera frugiperda*), a devastating insect that is quickly spreading in Africa.

DG SANTE stimulated Member States to improve surveillance and surveillance activities by co-financing **national survey programmes** which are designed to detect and eradicate priority plant pests on EU territory. In 2018, **46** pests were listed for survey in the work programme adopted by the Commission.

24 EU co-financed programmes were implemented in 2018, bringing the total percentage of EU territory covered by surveys to **90**%, exceeding the 2017 milestone of 70% (**result indicator 1.1.E).** In 2018, 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.

Import conditions of different commodities were also revised to ensure better protection of the EU territory. Import requirements for citrus fruits in particular were strengthened.

The increased focus on plant health risks from non-EU countries have resulted in a steady increase in interceptions of harmful organisms in imports, preventing their entry into EU territory. According to the electronic plant health notification system, EUROPHYT, the increase in 2018 was almost **15**% compared to 2017.

In 2018, DG SANTE prepared tertiary legislation under the new **Plant Health Regulation** (Regulation (EU) No 2016/2031) which will apply from December 2019 - it introduces a more pro-active approach to detecting and eradicating plant pests in the EU territory and strengthens rules on imports to prevent pests entering from non-EU countries.

Proposed tertiary legislation includes:

- a list of 38 high-risk plants to ensure their introduction into the EU is provisionally prohibited until a full risk assessment is completed.
- a Regulation specifying the information required from third countries and procedures for risk assessment on high risk material before getting possible access to the EU market.
- enlarging the scope of regulated plant material that needs to be accompanied by a phytosanitary certificate at import, with the exemption of five fruits.
- a harmonised minimum level for import inspections of newly regulated plant material.

Emergency measures were also updated to control outbreaks of harmful organisms within the EU, in particular for *Xylella fastidiosa*. EFSA was mandated to update the Pest Risk Assessment in view of the next revision of Decision (EU) 2015/789 on prevention and containment of *Xylella* and the EU Guidelines for surveillance.

Survey activities and emergency measures in Member States were eligible for EU co-financing to support early detection and response. Enforcement of EU rules was closely monitored through Commission's audits and follow-up actions and referred to the EU Court of Justice where necessary (e.g. case vs. Italy).

Regular exchanges of views were organised at different levels with Member States and national stakeholders. DG SANTE participated at EU and international conferences to improve dialogue with relevant parties and trading partners. An **Expert Group on Awareness Raising for Plant Health** was created and material on *Xylella* to promote awareness of the risks it poses were shared amongst different target groups.

WHAT IS IT?

The bacterium is spread by insects such as spittlebugs, cicadas and sharpshooters feeding on the plant xylem. Over longer distances, X. fastidiosa can also spread through human activity, such as the transport of infected planting material.

WHAT IS THE EU DOING TO FIGHT AGAINST XYLELLA?

The EU has taken strict control measures to prevent the further spread of Xylella in the EU territory, including by making it a regulated quarantine organism subject to protective measures against its introduction and spread in the EU territory.

EU plant health co-financing may be granted for the implementation of surveillance programmes and eradication/containment campaigns. EU financial contribution for compensation to the owners (farmers/ nurseries) for the value of the destroyed plants is also possible since 2017.

Additionally, in the framework of the EU Common Agricultural Policy, the European Agricultural Fund for Rural Development (EAFRD) supports knowledge transfer activities and the use of advisory services which can help farmers to identify, prevent and combat Xylella.

Pilot projects testing new ways to fight and prevent the disease can also be supported by the EAFRD, as well as the restoring of the agricultural production damaged by the disease.

Finally, two research projects are funded on Xylella fastidiosa within the HORIZON 2020 EU Framework:

- POnTE - Pest Organisms Threatening Europe, which aims to increase knowledge on Xylella fastidiosa and its vectors in olive, grapevine, citrus, stone fruit, ornamentals and landscape trees of high socio-economic importance.
- XF-ACTORS - Xylella Fastidiosa Active Containment Through a multidisciplinary Oriented Research Strategy. The project aims to promote a comprehensive package of activities to increase the knowledge of the bacterium and develop options for its prevention and control along with tools for risk assessment and plant health policies.

On **innovative solutions in seed production**, the possibility for Member States to take part in a temporary experiment for marketing cereal populations was extended by the Commission. Member States agreed on measures to protect young palm trees (propagating material) from the red palm weevil. DG SANTE continues to support the application of harmonised international standards in seed production to facilitate international trade. The Commission adopted a proposal to grant equivalence to seed produced in Moldova and Brazil to Parliament and Council in October 2018.

Member States took an average of 23 days in 2018 to notify the Commission of **pest outbreaks** regulated as "not known to occur in the EU". The average number of days has slightly increased since 2017 due to three exceptional cases where there was over three months before the outbreak was notified. Without these exceptional cases the average would be 14 days which is a significant improvement on 2017, and significantly better than the 49 days in 2016 and the 2015 baseline of 42 days. Moreover, the proportion of notifications sent within eight working days, the target for 2020, has increased from 31% in 2017 to 39% in 2018 (**result indicator 1.1 G**).

DG SANTE continued using the new module of EUROPHYT for reporting pest outbreaks (EUROPHYT Outbreaks). This has significantly improved the 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**[22]).

[22] 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 monthly outbreaks report is presented by the Commission to the Standing Committee on Plants, Animals, Food and Feed (PAFF). Emphasis is given to outbreaks of non-regulated organisms as part of the crisis preparedness for emerging risks e.g. the adoption of an emergency measure for *Aromia bungii* in 2018.

These activities are complemented by EFSA's monthly media scanning for outbreaks on regulated and non-regulated harmful organisms. An emergency measure on *Spodoptera frugiperda* was adopted as a result of this monitoring in 2018.

Preventing the introduction of new pests, as well as containing and eradicating them once they entered the EU, remain daunting challenges as epitomised by the outbreaks of *Xylella Fastidiosa* still occurring in certain Member States. Eradication in particular can only be achieved by introducing strict measures and through the provision of appropriate financial resources and personnel. Moreover, when it comes to implementing plant health measures, the competent authorities in the Member States play a major role.

FINANCIAL CONTRIBUTION FOR PLANT HEALTH MEASURES

National survey programmes ensure early detection and eradication of pest outbreaks. This is a new funding activity of DG SANTE in the food and feed area. The budget for implementing plant health survey programmes in 2018 was EUR 11.5 million, supporting surveys for 46 plant pests in 24 Member States. The highest financial allocation was invested in fighting *Xylella fastidiosa*.

In 2018, DG SANTE spent EUR 4.9 million on pest outbreaks. Amongst these, *Xylella fastidiosa* and *Anoplophora glabripennis* were received the most EU co-financing.

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.

Food and animal feed is subject to a well-developed legal framework that, consistently with the CFF Programme Statement, protects and promotes a high level of safety and quality, supports sustainable food and feed production and encourages free trade, investment and innovation.

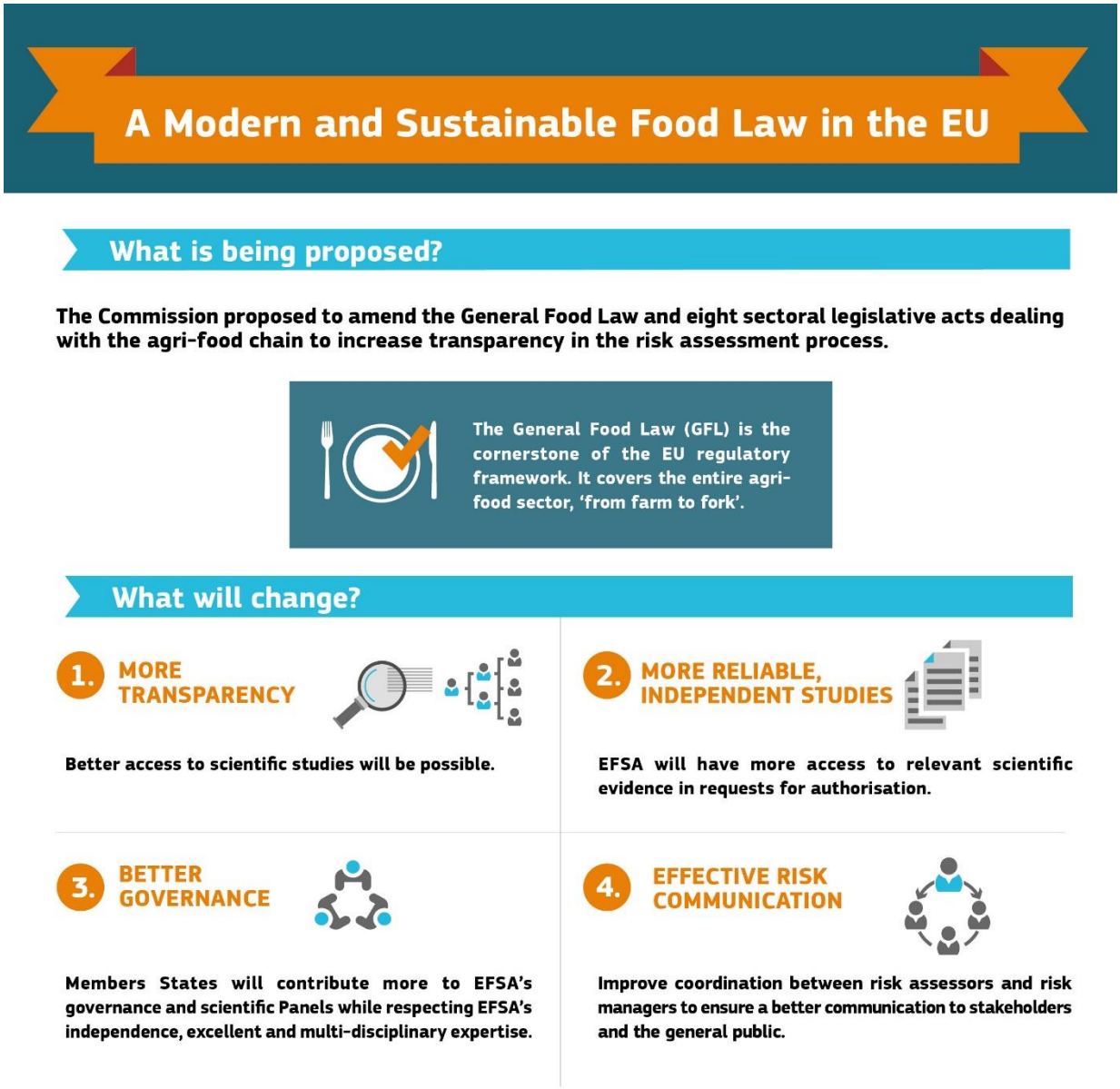
MODERNISING AND SIMPLIFYING EU LEGISLATION

"Better regulation" is an important part of DG SANTE's work. Regular evaluation and update of the EU's rules for food and feed production is essential to ensure a continued high level of consumer protection at the same time as growth and innovation in this very valuable economic sector. DG SANTE's activities on Better Regulation are described in more details in point 2.2.2.

- **Fitness Check of the General Food Law (GFL)** (Regulation (EC) No 178/2002 – GFL) – the final report (a Commission Staff Working Document) was published in January 2018. It concluded the GFL was still relevant and achieves its core objectives: a high protection of human health and consumer interests and smooth functioning of the internal market. However, the Fitness Check report highlighted that national differences still exist in the implementation and enforcement of the GFL. Moreover, despite overall considerable progress, transparency of risk analysis remains an issue 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.

terms of perception. In addition, a number of negative signals were identified on the capacity of EFSA to maintain a high level of scientific expertise and to engage all Member States in scientific cooperation. In addition, lengthy authorisation procedures in some sectors slowed down the market entry process. These shortcomings have been addressed by the GFL reform proposal. Finally, the GFL was found not to adequately address new challenges like food sustainability in general, and more specifically, food waste.



In April 2018, following the Fitness Check of the GFL and in response to the European Citizens' Initiative "Ban glyphosate and protect people and the environment from toxic pesticides", DG SANTE proposed a targeted revision of the GFL, coupled with the revision of eight pieces of sectoral legislation. The proposals is designed to increase the transparency of scientific studies and risk assessment done by EFSA, strengthen EFSA's governance and scientific sustainability and improve risk communication to further strengthen the EU food system.

The revision of sectoral legislation will align them with general rules, and strengthen transparency on GMOs, feed additives, smoke flavourings, food contact materials, food additives, food enzymes and flavourings, plant protection products and novel foods.

The European Parliament adopted its position on 11 December and the Council reached a General Approach on 17 December enabling inter-institutional negotiations to begin in early 2019.

- **Evaluations on plant protection products and pesticides residues legislation** (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005) progressed and the external study collecting all relevant evidence was completed and published in 2018. The draft staff working document was submitted to the Regulatory Scrutiny Board. Finalisation of the evaluation is expected in the first half 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): the external study supporting the evaluation was concluded in June 2018. The drafting of the staff working document has been launched on the basis of the study.
- **Evaluation on Food Contact Materials** (Regulation (EC) No 1935/2004) was launched in 2018 and is due to be completed in early 2020 with a staff working document.

DG SANTE also **continued** evaluations on the rules for **feed additives** (Regulation (EC) No 1831/2003), and **food irradiation** (Directives 1999/2/EC and 1999/3/EC).

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

In 2018, DG SANTE concluded the impact assessment on TFAs and submitted it to the Regulatory Scrutiny Board. It confirmed the Commission's previous report (2015) which 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.

DG SANTE thus launched a proposal to set a **maximum limit on the use of industrially produced trans-fat in foods in the EU**. It aims to protect consumers' health and promote healthier food options. DG SANTE's proposal was endorsed by Member States at the Standing Committee in December 2018.

FOOD LABELLING

DG SANTE continued to implement the Regulation on food information to consumers (1169/2011) which reinforces i.a. the rules on voluntary origin labelling. In May 2018, DG SANTE adopted an Implementing **Regulation on primary ingredient origin labelling** which will apply from 1 April 2020. This Regulation clarifies how information on the origin of the primary ingredient in foods should be displayed on labels.

Following the Commission report on alcohol labelling adopted in 2017, DG SANTE assessed the **self-regulatory proposal submitted by the alcoholic beverage industry** in March 2018. It then launched bilateral discussions with the different sub-sectors of the industry to improve their commitments.

The Commission also 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 legal requirements for food information to consumers.

Finally, DG SANTE worked on Phase 1 of a **Food Labelling Information System**, i.e. a database on EU and national requirements on food labelling. The project planning for delivery has been established in 2018 and a public site for the EU labelling requirements should be available at the end of 2019, account being taken of different approaches to data collection and update, difficulties to appoint competent external resources for the project and the approach to the technical delivery of the public interface adopted by DG DIGIT.

NOVEL FOODS

DG SANTE finalised the remaining implementing rules for the Regulation on Novel Foods (2015/2283) which entered into force on 1 January 2018. It also focused on its application, with a number of authorisations for novel foods and traditional foods from third countries which have a history of safe food use. The new Regulation improves the

efficiency and transparency of the safety evaluation and authorisation procedure, promotes innovation and provides a faster and more proportionate safety assessment for traditional foods.

The success of the Novel Foods Regulation is monitored by **result indicator 1.2.C.** This measures DG SANTE's compliance rate with its legal obligation to complete delegated and implementing acts identified as a priority under the Regulation.

In 2018, **two** implementing acts were adopted, one clarifying the procedures for settling the novel food status of a particular food, the other amending Commission Implementing Regulation (EU) 2017/2470 establishing the Union list of novel foods. The adoption of the delegated act on engineered nanomaterials has been deferred - it requires the Commission to adopt a Recommendation to revise the definition of nanomaterials.

PREVENTING FOOD WASTE AND PROMOTING THE CIRCULAR ECONOMY

DG SANTE continued to implement initiatives to prevent food waste in line with the Circular Economy Action Plan. Actions which aim to prevent food waste strengthen the sustainability of the food chain and bring both economic and environmental benefits.

The **EU Platform on Food Losses and Food Waste** - a forum to facilitate best practice exchange - met twice in 2018. During the first meeting, in May, the Platform took stock of the progress made in implementing the Circular Economy Action Plan. Members also discussed future challenges, including strategies to influence consumer behaviour.

A High Level Political Forum on food losses and food waste also took place, with representatives from EU institutions and Member States, the UN, China, and the United States acknowledging the importance of tackling this issue across the whole food supply chain, to contribute to food security, resource efficiency and environmental protection. During the second meeting, in December, Platform members discussed key deliverables of the Circular Economy Action Plan and the work of Platform sub-groups.

In February 2018, DG SANTE published a **study on date marking** which estimated that up to 10% of EU food waste is linked to this. To follow up, DG SANTE established a dedicated EU Platform sub-group. One of its immediate priorities is to develop technical guidance to foster more consistent date marking practices.

In April, DG SANTE also published **guidelines on using food no longer intended for human consumption as animal feed**. They were developed in close cooperation with Member State authorities, the EU Platform and other stakeholders and aim to provide legal clarity to valorise an avoidable source of food waste.

In January 2018, a 3-year **EU Pilot Project on food redistribution** was launched by DG SANTE to investigate existing regulatory, policy and operational frameworks for food redistribution in the EU, promote stakeholder engagement and facilitate the dissemination of EU guidelines on food donation.

Following adoption of the **revised waste legislation package** on 30 May 2018, which introduced new obligations for Member States to monitor and report food waste levels annually, DG SANTE worked on harmonised methodology to quantify food waste levels across the EU.

In November 2018, the Commission hosted a webinar to showcase EU actions carried out in support of Sustainable Development Goal 12.3 as part of the G7 Alliance on Resource Efficiency. It aimed to facilitate exchange of best practices and lessons learned to reduce food loss and waste among G7 members. It was followed by over 450 people, with over 250 stakeholders connecting from countries outside the EU.

DG SANTE also promoted more efficient use of feed resources in the EU livestock sector and enabled increased, safe use of emerging feed materials e.g. by-products from food production or insects to improve sustainability of livestock farming in the EU.

FOOD CONTACT MATERIALS

In 2018, an **evaluation** of the food contact materials legislation was launched**,** supported by a study and consultation exercise. The evaluation will examine the functioning of the current legislation and provide a basis on which the Commission can consider what, if any, steps need to be taken for future EU regulation in this field.

On **plastic food contact materials**, SANTE prepared two amendments to Regulation (EU) No 10/2011 to add or update 11 substances, based on EFSA opinions following applications from business operators. DG SANTE also prepared six mandates for EFSA to re-evaluate authorised substances.

The ongoing activities to prepare **authorisation Decisions of plastic recycling processes** continued in 2018. In this context SANTE contributed to the Commission's policies for the plastic strategy and on single use plastics.

DG SANTE also explored how to best address the limits for the release of **heavy metals from ceramic food contact materials**, following finalisation of a JRC study in 2017 and its conclusions on the analytical approach. Because of the chemical similarity of the materials, glass and enamels were added to the scope of this project. Given the potential impacts of a measure, in particular for manufacturers of artisanal and traditional products, an impact assessment has been planned for 2019.

In February 2018, DG SANTE completed its work on **Bisphenol A** - the Commission adopted a Regulation that significantly tightens the restrictions on use of this substance in food contact materials. The Regulation lowers the legal limit, which is the amount allowed to safely migrate from the plastic material into food, and extends this restriction to coating materials, used to line food and drink cans. It also extends the 2011 ban on BPA in baby bottles, to include infant 'sippy' cups and BPA from coated materials containing food intended for infants and children 0–3 year olds. The new Regulation entered into application on 6 September 2018.

Despite the above, and pending the outcome of the ongoing evaluation, experience suggests that the current approach to regulating food contact materials is complex and expensive for the Member States to enforce and is burdensome to industry. Moreover, it requires a lengthy assessment of substances used to manufacture food contact materials. Finally, the safety of the final article falls outside the scope of this assessment.

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** (uses of 16 and specifications of six food additives were amended), **food flavourings** (one new authorisation and 14 amendments to existing authorisations, three withdrawals), and **novel foods** (11 authorisations of new novel foods, seven amendments to existing authorisations and three authorisations for traditional foods from third countries).

Re-evaluations of authorisations, new authorisations, modifications of authorisations and renewal of authorisations of **feed additives** were proposed based on the outcome of safety evaluations (in 2018: 45 implementing regulations approving 135 feed additives and denying four additive authorisations).

The Commission adopted three Regulations for approval and one for non-approval of new active substances used in **plant protection products**, two Regulations for approval and one for non-approval of basic substances, 11 Regulations for renewal and nine for non-renewal of approval of active substances. However, the citizens' trust in the science-based approach that underpins pesticides' authorisations seem to be currently compromised (e.g. glyphosate). Shortcomings exist in relation to the efficiency of the processes for, on the one hand, approval of active substances and, on the other hand, authorisation of plant protection products by Member States.

In **biocides,** ten regulations were adopted for approval and one decision for non-approval of 47 active substances for use in biocidal products of different product-types no longer supported by applicants, and four Union authorisations of biocidal products.

On **pesticide residues**, the Commission adopted Regulations setting maximum residue levels (MRLs) for 55 substances following applications and/or implementing Codex MRLs as well as Regulations reviewing the full set of existing MRLs for 11 substances.

On **residues of veterinary medicinal products** in foodstuffs of animal origin, the Commission adopted Regulations to set maximum residue levels (MRLs) for six substances. DG SANTE also set maximum levels for one **contaminant** in food.

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 2018, the compliance rate for pesticides was **94**% (the milestone for 2017 was 80%) and for food additives **90**% (the milestone for 2017 was 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 pending GM food and feed and cultivation applications. In 2018, 23 new GMOs were authorised for food and feed use and four GMOs had their authorisation renewed. All went through a comprehensive authorisation procedure, including a favourable scientific assessment by the European Food Safety Authority. The authorisations are valid for 10 years and any related products will be subject to the EU's strict labelling and traceability rules.

The Commission adopted also a Directive on environmental risk assessment of genetically modified plants on 8 March 2018 (Directive (EU) 2018/350).

The existing GMO legal framework, including the authorisation procedure, is no longer effective. However, no progress was made in inter-institutional negotiations on the **GM food/feed proposal** nor on the proposals suspending the **cloning** technique on farm animals and placing food from animal clones on the EU market. The GM food/feed proposal gives the possibility to Member States to take account of their national societal concerns.

NEW BREEDING TECHNIQUES

DG SANTE considered policy options to implement the EU Court of Justice ruling on targeted mutagenesis techniques[23], issued in July 2018. It discussed the judgement with Member States in the meetings of the Standing Committee on Plants, Animals, Food and Feed on 11 September and 3 December and the Regulatory Committee on 18 October 2018. DG SANTE recalled it is a national responsibility to enforce GMO legislation in accordance with the Court's judgement, including control of products to be placed on the EU market and compliance with GMO legislation of ongoing and future field trials.

DG SANTE also requested the EU Reference Laboratory for GM Food and Feed and the European Network of GMO laboratories assess current and future possibilities and limitations to detect food or feed obtained by new mutagenesis techniques. This work is expected to be finalised in March 2019.

DG SANTE mandated EFSA for two opinions on subjects linked to new scientific developments in biotechnologies. These concern engineered gene drives and synthetic biology. ESFA was asked to identify new developments, potential risks and determine whether existing guidance for risk assessment is adequate or needs to be updated.

SUSTAINABLE USE OF PESTICIDES

In 2018, DG SANTE continued working with Member States to implement Directive 2009/128/EC on the sustainable use of pesticides (SUD). It aims to reduce the risks and impacts of pesticide use on human health and the environment and promote integrated pest management (IPM) and alternative approaches such as non-chemical alternatives. A training course to assess IPM at farm level was developed and initiated for Member States.

In November 2018, DG SANTE launched the feedback mechanism on a draft Commission Implementing Directive to establish the first two **harmonised risk indicators** to estimate trends in risks from pesticide use. These are intended to ease progress in measuring the reduction of risks from pesticide use for human health and the environment.

DG SANTE maintains a SUD web portal with links to Member States' websites on sustainable use of pesticides to facilitate information exchange and increase the flow of relevant information to farmers and the general public.

ENDOCRINE DISRUPTORS

The Regulations setting the criteria to identify endocrine disruptors for biocidal products ((EU) 2017/2100) and plant protection products ((EU) 2018/605) entered into force in 2018, ensuring a harmonised approach in both areas.

Since the criteria also apply to ongoing evaluations of active substances and products, specific procedural guidance was also adopted.

In order to effectively apply the criteria to identify endocrine disruptors, a scientific guidance document was published on 7 June 2018. This was developed jointly by EFSA, ECHA and DG JRC with close involvement of DG SANTE.

Finally, DG SANTE contributed to the Commission's Communication "Towards a comprehensive EU framework on endocrine disruptors". This paper was developed under

[23] Case C-528/16, Confédération paysanne and Others, Judgement of 25 July 2018.

the lead of the Secretariat-General and updated the 1999 Commission strategy on endocrine disruptors. It was adopted on 7 November 2018.

NEONICOTINOIDS

The protection of bees is an environmental priority. On 29 May 2018, the Commission adopted three **Regulations banning the outdoor use of three neonicotinoid active substances** (imidacloprid, clothianidin and thiamethoxam). The new restrictions only allow use of these products inside permanent greenhouses following a comprehensive scientific review that concluded their outdoor use harms bees. Despite this significant achievement, the overuse of temporary emergency authorisations by certain Member States risks to prevent bee-protection goals. The EFSA conducted an evaluation on emergency authorisations in 2018 which concluded that only in some cases were those authorisations in line with the provisions set out in the legislation.

In 2018, DG SANTE began implementing a 2-year pilot project from the European Parliament on environmental monitoring of pesticide use through honeybees.

FOOD HYGIENE

In 2018, DG SANTE discussed a number of policy actions with Member States to adapt the EU's food hygiene legislation to biological risks and innovation whilst maintaining a high level of food safety and remaining proportionate. An Implementing Regulation was voted in 2018 making *Salmonella* control a mandatory part of meat inspection in all species (so far it only was in pigs).

DG SANTE measures success in this area by a reduction in the number of human cases in the EU of diseases linked to food safety or zoonoses (**result indicator 1.2.A**).

In 2017, there were **91,662** confirmed cases of human salmonellosis[24]. This is well above the 2018 target of 67,000 cases and DG SANTE continues to monitor the situation closely. Though this pathogen is present in various animal species, EU legislation targets poultry as it is this sector where the impact was assessed to be most significant. These efforts have paid off since the levels of contamination in broilers has decreased. 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.

FEED HYGIENE

In 2018, DG SANTE continued discussions on a Guidance document on implementing certain provisions of Regulation (EC) No 183/2005 on feed hygiene. It would help all players apply the Regulation uniformly, notably the requirement to register feed establishments.

In addition the Commission audited Member States' controls on feed business operators involved in (a) production and use of feed additives, (b) production, use and trade of processed animal proteins, and (c) production and marketing of insects and insect protein for feed.

ANIMAL WELFARE

In 2018 DG SANTE adopted three reports that completed the actions listed in the **EU Animal Welfare Strategy 2012-2015**. One report touched on the Commission international activities on animal welfare; two technical reports covered the slaughter of farmed fish and welfare of chickens kept for meat production.

In 2018, DG SANTE organised two meetings of the **EU Platform on Animal Welfare**. It also created two Platform subgroups, one on welfare during transport, which met twice

[24] Latest figures available from EFSA are for 2017.

during 2018, and another to deal with pig welfare, which met once. The Platform helps the Commission to improve animal welfare through better implementation of EU rules, voluntary commitments and by promoting EU welfare standards at global level. DG SANTE also launched a **digital tool** to enable Platform members to exchange information on a permanent basis.

The Commission also designated the **first EU Reference Centre for Animal Welfare** following a public selection process. It consists of a consortium of the Wageningen Livestock Research (the Netherlands), the Friedrich Loeffler Institute (Germany) and the Department of Animal Science at Aarhus University (Denmark). It focuses on pig welfare and started became operational in October 2018.

Following a European Parliament report on "Minimum standards for the protection of farmed rabbits", DG SANTE published a **report on rabbit farming** in May 2018. It gives a better understanding of the EU commercial rabbit farming sector and outlines factors that contribute to rabbit welfare and the impact of different production systems.

Other significant work included 11 factsheets on the **protection of animals at the time of killing**, to help farmers and small slaughterhouses understand and apply EU legislation and a study on best practices to promote meat from uncastrated or immunocastrated pigs.

The Commission also adopted a recommendation on a coordinated control plan for the official controls of online sales of dogs and cats and a Regulation for a new stunning method for poultry (low atmospheric pressure stunning).

Enforcement of animal welfare legislation remained a priority. Particular focus was given to **tail docking in pigs** (including various information material and a two-day expert meeting on rearing pigs with intact tails) and welfare of animals during **transport.** This included information for drivers transporting animals to Turkey and three meetings with the network of National Contact Points.

These awareness raising activities have improved compliance with the animal transport Regulation: non-compliance at the Bulgarian border with Turkey decreased from 7% at the end of 2017 to an average of 2.2% throughout 2018 and exports during the July-August decreased from 1015 consignments in 2017 to 533 in 2018.

At the same time, DG SANTE continued to promote its animal welfare standards on the world stage, at the World Organisation of Animal Health and with key trading partners via the EU's free trade agreements.

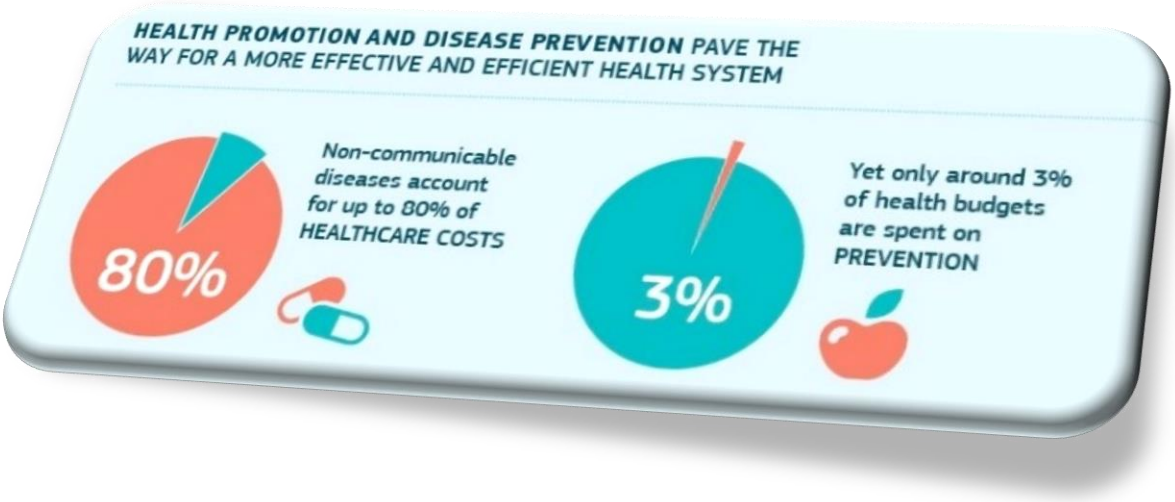
Whereas the EU has some of the world's highest regulatory animal welfare standards and actions to improve animal welfare are successful in some areas, there are still some **weaknesses in compliance with minimum standards**, as outlined by the European Court of Auditors in a report from 2018. Weaknesses persist in some areas related to welfare issues on the farm, during transport, and at slaughter. Finally, the standard **enforcement** ultimately depends on the Member States' official control systems.

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 - namely cardiovascular diseases, cancer and mental health illnesses - place huge pressure on health and social systems in the EU. They account for 70-80% of healthcare costs (EUR 700 billion) and a loss of up to 7% of GDP. Although many of these diseases can be cost-effectively prevented, EU member states allocate less than 3% of their health spending to health promotion and disease prevention. EU action

focusses mainly on key health determinants (unhealthy diet, smoking, inactivity, harmful alcohol use) and legislation on tobacco products and support for wide scale implementation of validated best practices.

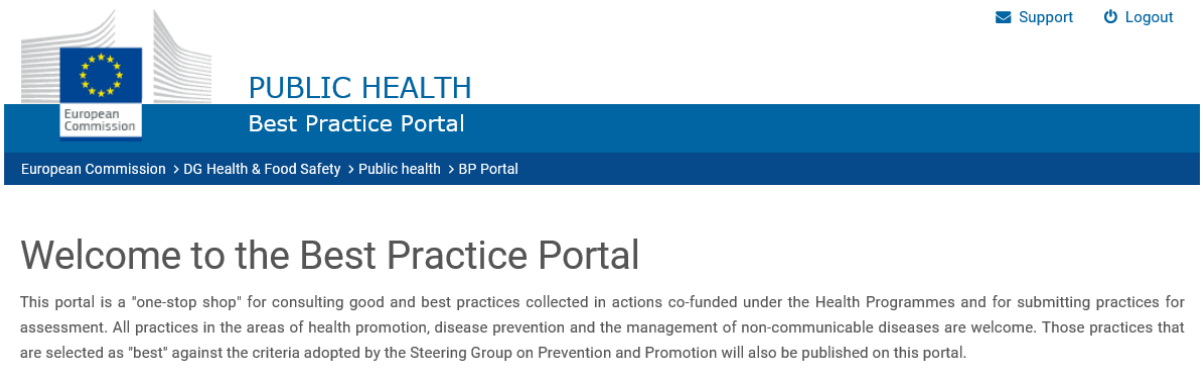


As part of a new approach to maximise collective EU work towards the WHO's nine voluntary targets on non-communicable disease and the UN Sustainable Development Goals for health and well-being, DG SANTE formalised the **Steering Group on Health Promotion, Disease Prevention and Management of Non-Communicable Diseases** in July 2018.

The Steering Group establishes a single framework and brings together senior health officials from EU Member States, EEA countries and Commission services for a broad overview of public health policy. It is chaired by SANTE and may set up subgroups to work on specific issues for limited time periods. To avoid duplication and unnecessary burden on Member States, existing Commission expert groups on particular diseases, e.g. cancer control and rare diseases, will now be replaced by the Steering Group.

In practice, the Steering Group provides expert advice on developing and implementing activities on health promotion, disease prevention and management of non-communicable diseases. It advises the Commission on selecting and using best practices for transfer and scaling up at national and European level using funds from the EU Health Programme or other EU financial instruments. Importantly, the process focuses on validated "best in class" approaches, not the minimum common denominator. In the spirit of the new EU budget proposals, all relevant EU financial envelopes are scanned to find possible support for implementation of the best practices. This is a major step towards working across silos.

The Steering Group is supported by a variety of online resources, including the Promotion and Prevention Gateway developed by the Joint Research Centre on behalf of DG SANTE, and a best practice portal developed by DG SANTE to bring together identified best practices in a one-stop-shop.



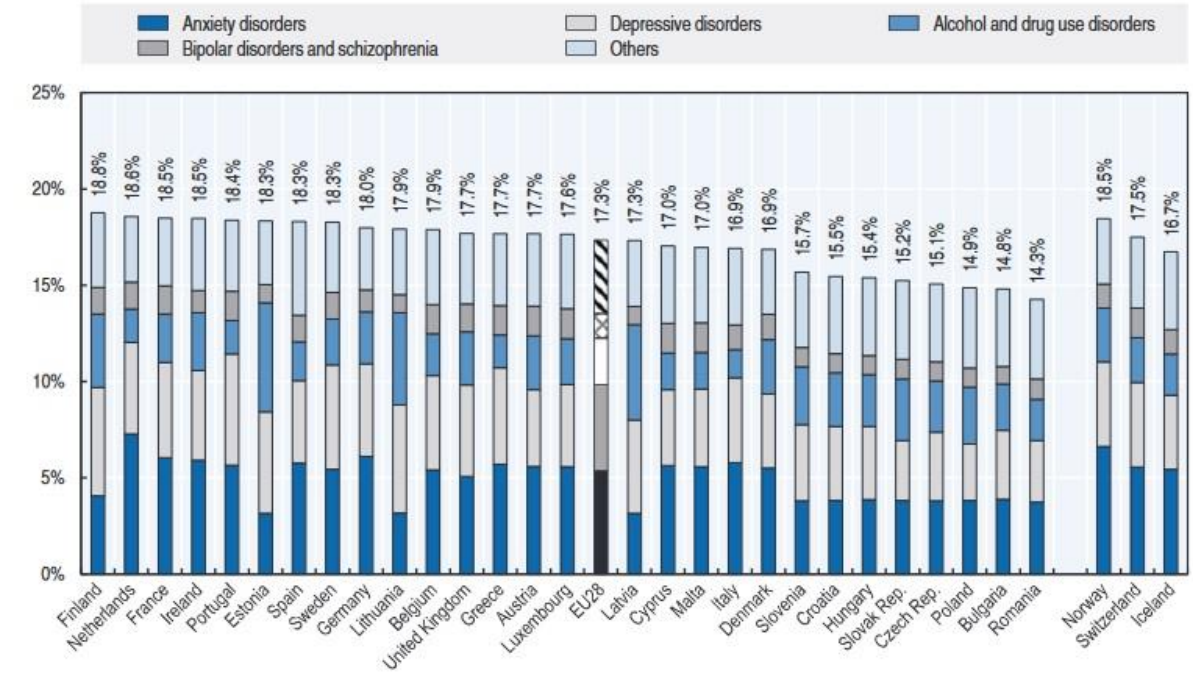
In 2018, three good practices identified by the Steering Group were selected for scale-up and transfer and implementation has started. These were:

- Piloting the implementation of Orphacodes (the rare diseases specific codification system developed through earlier Health Programme-funded efforts) into the clinical health information systems and/or national registries in the Czech Republic, Malta, Romania and Spain;
- Transferring the Swedish "Physical Activity on Prescription" initiative to Belgium, Germany, Denmark, Spain, Italy, Lithuania, Malta, Portugal and Romania;
- Transferring the Italian "CARDIO 50 – screening for a healthy heart" programme to France, Lithuania, Luxembourg, Romania and Spain.

A temporary Subgroup on Proton Therapy Centres was also set up under the Steering Group, following a request from the European Investment Bank to better understand the demand for innovative particle therapy centres in Europe.

At the Steering Group's first formal meeting in November 2018, mental health was identified as a priority area for best practices and screening of implementable research results in 2019.

Figure 1.1. **More than one in six people in EU countries have a mental health problem**



Source: IHME, 2018 (these estimates refer to 2016).

Other projects on health promotion and disease prevention launched in 2018 included Joint Actions with Member States on health inequalities ("Health Equity in Europe", June 2018) and cancer ("Innovative Partnership for Action Against Cancer", April 2018).

DG SANTE hosted the third Annual EU Compass Forum on Mental Health and Well-being in February. This event brought together policy makers and Member State representatives, non-governmental stakeholders from advocacy groups and care organisations, and mental health care providers, professionals, and service users. It focussed on community-based mental health services and mental health in all policies.

In addition, DG SANTE continued to monitor pilot projects and preparatory actions, funded by the European Parliament, covering issues such as health inequalities in alcohol related harm, nutrition, diets, obesity and physical activity.

In 2015, 12 Member States had an integrated national plan in place to address non-communicable diseases and implement the WHO targets, rising to 15 in 2018 - **result indicator 1.3A (**below the 2017 milestone of 19 Member States). This indicator depends on actions taken by Member States.

In 2018, 15 EU countries had implemented the first steps for a European accreditation scheme for breast cancer services and prepared themselves for a pilot phase (**result indicator 1.3C)**. The pilot phase is part of the European Initiative on Breast Cancer, coordinated by the Joint Research Center (JRC).

The work outlined above also contributes to the achievement of the goals set out in the Health Programme Statement, where disease prevention is one of the four specific objectives.

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

The High Level Group on Nutrition and Physical Activity met twice in 2018 and continued its work on the reformulation of food products, mainly focussing on sugar reduction, marketing of foods high in fat salt and sugar, particularly to children; preparation of public procurement guidelines for healthy food in schools; better implementation of the EU School Fruit Vegetables and Milk Scheme; and ongoing implementation of the Action Plan on Childhood Obesity 2014-2020. A monitoring report on the Action Plan was finalised.

Transfats are an important risk factor in the development of heart disease yet are consumed at unhealthy levels in certain population groups. An initiative to protect consumers and public health whilst ensuring compatibility with the internal market was adopted in 2018 (see section 1.1.2).

Collaboration with DG AGRI continued on the EU School Fruit Vegetables and Milk Scheme, and with DG AGRI and DG EAC to follow-up the Tartu Call for Healthy Lifestyles. Three calls for tender (on food reformulation, marketing of high-fat-salt-sugar, food to children (joint project by SANTE and CNECT) and lifestyle medicine) were launched.

DG SANTE also organised two stakeholder meetings of the EU Platform for Action on Diet, Physical Activity and Health to propose or revise commitments supporting WHO targets on non-communicable diseases. This led to commitments to reduce, by 5-10%, sugar content in processed foods and non-alcoholic beverages (by UNESDA, Nestle, Danone) and in an improved EU Pledge (a voluntary initiative) to change the way leading food and beverage companies advertise to children.

Interservice work with other DGs continued. Our work with DG CNECT focused on the revised Audiovisual Media Services Directive (AVMSD) published on 28 November 2018. Most important for DG SANTE are new provisions on the voluntary code of conduct for marketing foods high in fat salt and sugar, non-alcoholic and alcoholic drinks, using public health as a basis for derogation from the rules of the AVMSD.

With DG AGRI, it focussed on the impact of wine promotion measures and the Common Agricultural Policy post-2020, and with DG TAXUD on excise duties for alcoholic beverages and cross-border acquisition of alcoholic beverages by private individuals. Two calls for tender have been launched to help Member States reduce alcohol related harm. A third was launched on cross-border acquisition of alcoholic beverages by private individuals (TAXUD lead).

The Committee on National Alcohol Policy and Action met twice in 2018 and continued its work to reduce youth and underage drinking, heavy episodic drinking, drinking during pregnancy and implementation of the Action Plan on Youth Drinking and Heavy Episodic Drinking 2014-2020. A monitoring report on the Action Plan was finalised.

Result indicator 1.3B measures progress on the issues of healthy diet and food reformulation, starting in 2015. In 2018,

1) **20** Member States had national initiatives on reduction of saturated fat (+**2** from 2015), plus **3** in the process of adoption;

2) **23** Member States (plus Norway) had national initiatives on reduction of salt (+**6** from 2015), plus **3** under adoption;

3) **21** Member States (plus Norway and Switzerland) had national initiatives on reduction of sugar (+**4** from 2015), plus **3** under adoption;

4) **26** Member States had national initiatives on reducing alcohol-related harm (+**5** from 2015)

The overall target is to cover all Member States in all categories by 2020. This depends on actions taken by Member States.

DG SANTE continued its work to discourage **tobacco** consumption. Transposition checks in 2018 targeted effective implementation of the Tobacco Products Directive (2014/40/EU).

We also managed a Joint Action, co-funded by the Health Programme, to help Member States implement the Tobacco Products Directive in a range of areas including ingredient regulation, priority additives, and e-cigarettes. It includes analysing the significant data generated by the reporting obligations for tobacco products, e-cigarette ingredients and emissions, and comprehensive studies on priority additives carried out by manufacturers.

In parallel, SANTE managed and improved the electronic reporting tool for tobacco and e-cigarettes and further developed the mechanism to determine whether tobacco products have a characterising flavour.

In September 2018, the WHO's international Framework Convention on Tobacco Control (FCTC) Protocol to Eliminate Illicit Trade in Tobacco Products entered into force. Following adoption of three implementing and delegated acts on tobacco traceability and security features, the technical roll-out work continued towards the Tobacco Products Directive operational deadline of May 2019. Around 30 economic operators notified DG SANTE on contracts for storing data. We worked to approve each contract after verifying the suitability of a data storage provider, notably its independence and technical capacities.

International activities to discourage tobacco consumption continued, including DG SANTE's participation at the 8th session of the Conference of the Parties to FCTC in October 2018 (see also specific objective 3.1).

INEQUALITIES IN HEALTH

Health is a priority in the Commission Action Plan for integration of migrants and refugees[25]. Activities to support Member States have focused on training professionals (health, law enforcement officials, social workers) working with this vulnerable population. Training modules on communicable diseases and mental health have been developed and delivered and will continue in 2019 in all Member States. Joint activities the World Health Organisation and International Organisation for Migration have supported health assessments of migrants and guidance for health professionals. A Joint Action on health inequalities, co-funded by the Health Programme, focuses on improving the health status of migrants and other vulnerable populations.

[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.

Health systems must become more sustainable, effective and accessible; they must adapt to specific challenges and embrace cost-effective solutions. DG SANTE supports growth-enhancing investment in health and care at EU level, along with necessary health system reforms, which adds value by improving outcomes for individuals and contributing to economic prosperity and social cohesion. Contributing to "innovative, efficient and sustainable health systems" is also one of the four specific objectives outlined in the Health Programme Statement.

COUNTRY KNOWLEDGE

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

In response, DG SANTE initiated a two-year knowledge-brokering cycle: **State of Health in the EU**, which generates evidence-based information on health systems in EU countries. It has been developed collectively by the Commission, the OECD and the European Observatory on Health Systems and Policies.

In 2018, the three parties delivered **seven "Voluntary Exchanges"**. These meetings completed the first State of Health in the EU cycle and allowed national authorities and other stakeholders to explore issues arising in the 2017 Country Health Profiles, the Commission's Companion Report, and the 2016 "Health at a Glance: Europe" report.

In November 2018, DG SANTE launched the second State of Health in the EU cycle, and published the 2018 Health at a Glance joint report with the OECD. The themes of this report were wasteful spending and mental health. This report was based on comparative analyses of the health status of EU citizens and the performance of the health systems in the 28 Member States, 5 candidate countries and 3 EFTA countries. It showed that the steady increase of life expectancy has slowed down and that large health inequalities persist, notably leaving people with a low level of education behind.

The next step in the cycle is the publication of Country Health Profiles for all EU countries, and a Companion report due in 2019.

HEALTH SYSTEM TRANSFORMATIONS

DG SANTE continued to provide cross country data, analysis and concrete tools to support the transformation of health systems and better access to medicines and healthcare. An Expert Panel on "effective ways of investing in health" produced five opinions on "Benchmarking access to healthcare in the EU", "Tools and methodologies for assessing the performance of primary care", "Innovative payment models for high-cost innovative medicines", "Vaccination programs and health systems in the European Union", and "Application of the ERN model in European Cross-border healthcare cooperation outside the rare diseases area".

SANTE also continued to contribute to the **European Semester,** providing health-related expertise for the various steps of the macro-economic coordination mechanism to help identify challenges in Member State health systems. This input was based on the health indicators and intelligence gathered from national authorities, stakeholders, and through the State of Health in the EU cycle.

DG SANTE also encouraged Member States to use structural funds and technical assistance to accompany health systems reforms and capacity building (e.g. ESIF for Health project).

ANTIMICROBIAL RESISTANCE (AMR)

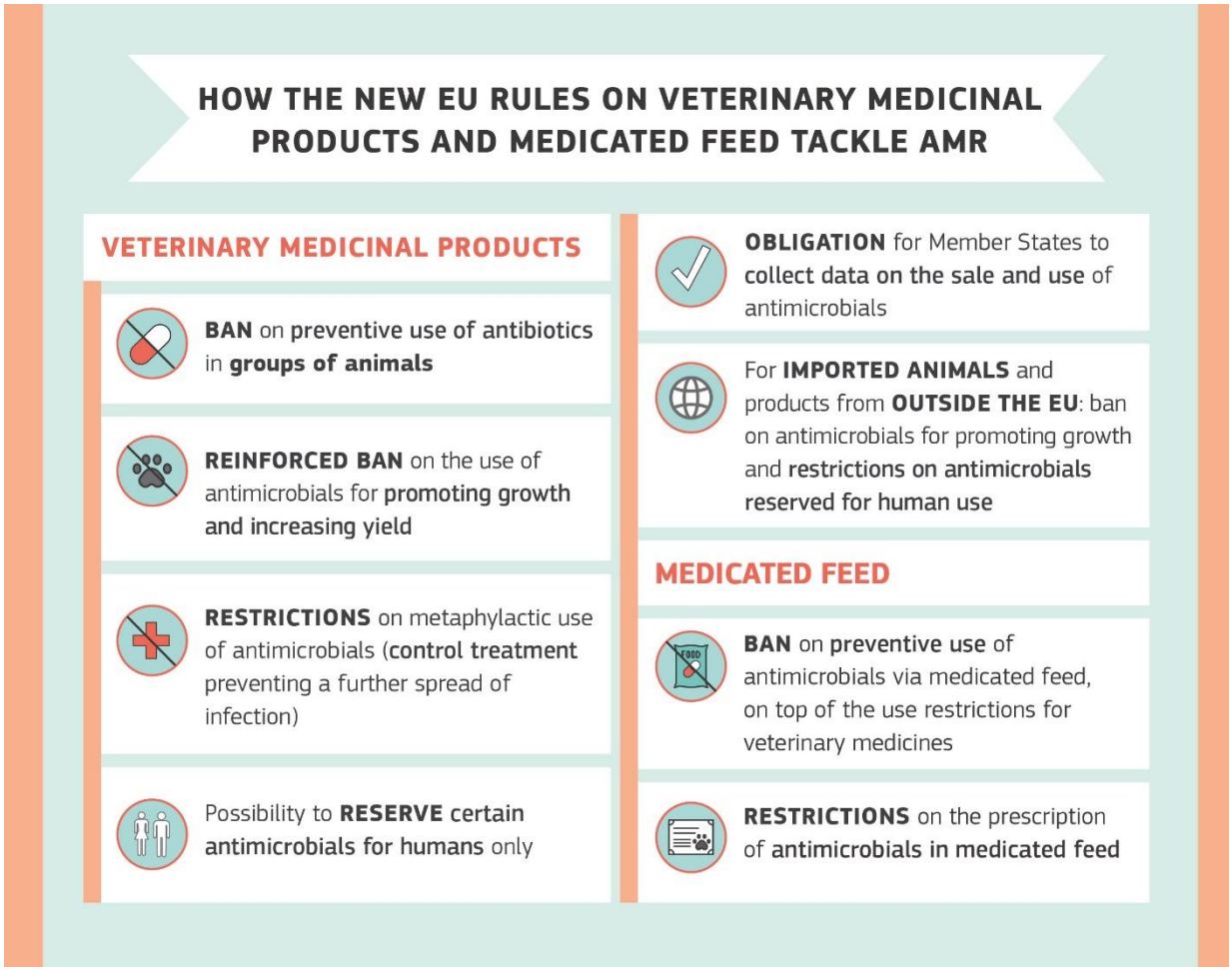
AMR is a major global challenge with serious implications for the economy and human health. Each year, drug resistant infections cause at least 33,000 deaths in the EU and an estimated EUR 1.5 billion worth of healthcare and productivity losses. Without tough action, it will have a significant negative impact on health, jobs, growth and investments.

The **EU One Health Action Plan** against Antimicrobial Resistance, adopted in 2017, is underpinned by a "One Health" approach that addresses antimicrobial resistance in humans, animals and the environment. The plan has over 75 actions built on three main pillars: a) making the EU a best practice region; b) boosting research and development and; c) shaping the global agenda through multilateral and bilateral cooperation. It offers clear EU added-value and a joint political commitment, stimulating action in and across Member States, and strengthening international cooperation.

In 2018, the EU took an important step forward in its work to tackle AMR, adopting DG SANTE's 2014 proposal for a new Veterinary Medicines Package.

The package consists of three Regulations, on Veterinary Medicinal Products (VMP), Medicated Feed (MF), and the European Medicines Agency (EMA). It introduces comprehensive rules to minimise the risk to public and animal health from antimicrobial use.

The new rules entered into force on 28 January 2019 and will apply from 28 January 2022.



EFSA, ECDC and EMA make an important contribution to SANTE's in this area, collecting, analysing and reporting key data on AMR and antimicrobial consumption. The monitoring and reporting by Member States of antimicrobial resistance in zoonotic and commensal bacteria[26] continued in 2018.

In February 2018, EFSA and ECDC published their annual report on AMR in zoonotic and indicator bacteria from humans, animals and food and, in October 2018, EMA published the eighth annual report on sales of veterinary antimicrobials in EU/EEA countries. These reports inform antimicrobial policy and support responsible use of antimicrobials. EMA also continued its work to increase the availability of antimicrobials and alternatives.

DG SANTE also hosted two meetings of the **EU AMR One Health Network** in 2018, bringing together government experts from human and animal health, the EU scientific agencies (ECDC, EMA, and EFSA) and Commission experts. The network provides a platform to present national action plans and strategies, progress updates, best practices, and discuss policy options and cooperation. In the October meeting, Network members discussed the European Parliament's Resolution on AMR, and the outcome of the latest survey conducted by WHO, FAO and OIE in the context of the Global Action Plan on AMR.

DG SANTE also supported the implementation of national One Health action plans through joint visits to Member States with the ECDC (two country visits in 2018).

Training is a key component to strengthen prevention and control of AMR across the human, veterinary and food sector. Training activities for EU countries continued in 2018 within the 'Better Training for Safer Food' programme. Please see section 3.1 for details.

[26] in the framework of Commission implementing Decision 2013/652/EU

For actions on AMR at international level, please see section 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 (2017), there has only been a slight reduction (to 23.4 defined daily doses) since the 2013 baseline of 24.03 defined daily doses/1000 inhabitants/day consumed in the Community and hospital sectors combined.

IMPLEMENTATION OF THE DIRECTIVE ON PATIENTS' RIGHTS IN CROSS-BORDER HEALTHCARE

Cross-border healthcare is an important right for EU citizens that can only be achieved if EU legislation is properly implemented and recognised in all EU countries.

DG SANTE continued to monitor transposition of the Directive on patients' rights in cross-border healthcare[27] to ensure its correct implementation. In September 2018, it adopted an Implementation Report which found that the Directive has helped clarify and guarantee patients' rights to receive cross-border healthcare and, since its adoption, no further European court rulings have been needed to ensure this. It also found that while patients are increasingly aware of their rights, patient mobility in the EU remains relatively low and the Directive has not had a major budgetary impact on the sustainability of national health systems.

Following the adoption of the Commission Communication "Boosting Growth and Cohesion in EU Border Regions", DG SANTE, with DG REGIO, continued to encourage cooperation between EU countries to improve the complementarity of health services in border areas. A DG SANTE study on "Cross-border cooperation: Capitalising on existing initiatives" included a toolkit for stakeholders and authorities wishing to set up a cooperation partnership.

DG SANTE also supported the work of National Contact Points (NCPs), organising regular meetings to encourage cooperation and exchange of good practices.

INNOVATIVE HEALTH TECHNOLOGIES

In April 2018, as part of the EU's Digital Single Market Strategy, the Commission adopted a "Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society", which DG SANTE developed jointly with DG CNECT. It identified three priorities:

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

- Citizens' secure access to their health data - enabling them to access their health data across the EU;
- Personalised medicine through shared European data infrastructure - allowing researchers and other professionals to pool resources across the EU (data, expertise, computing processing and storage capacities);
- Citizen empowerment - using digital tools to empower people to look after their health, stimulate prevention and enable interaction between users and healthcare providers.

The Communication identifies concrete actions under each priority.

In 2018, 22 Member States were building the necessary national infrastructure to join the Cross-Border eHealth Information Services and exchange electronic health data across borders (**result indicator 1.4.A**). Four countries (Finland, Estonia, Czech Republic, Luxembourg) finalised their national infrastructure and were authorised by the eHealth Network to start exchanging ePrescriptions and Patient Summaries.

In parallel, DG SANTE worked together with Member States to implement a new multi-annual Work Plan for the eHealth Network. The new Joint Action supporting the eHealth Network took up its work on 1 June 2018.

BLOOD, TISSUES, CELLS AND ORGANS

The supply of blood, tissues, cells and organs is crucial in EU healthcare systems. It supports essential and often life-saving treatments and allows many patients to regain or retain an active and productive life.

As part of an evaluation of EU law on blood, tissues and cells, an external support study was finalised in 2018, with a Staff Working Document to be published in 2019. The overall evaluation, following the Better Regulation approach, will consider whether the legislation has achieved its original objectives and remains fit-for-purpose.

SANTE also managed EU-funded projects on organ donation and transplantation - the EU Joint Action EDITH and the pilot project EUDONORGAN.

FINANCIAL CONTRIBUTION FROM HEALTH PROGRAMME

In 2018, the Health Programme committed EUR 7.4 million towards 16 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

Dedicated databases and registries at EU level are an efficient and cost-effective way to ensure healthcare professionals, patients and researchers have access to reliable, up-to-date information in highly specialised areas, across the EU.

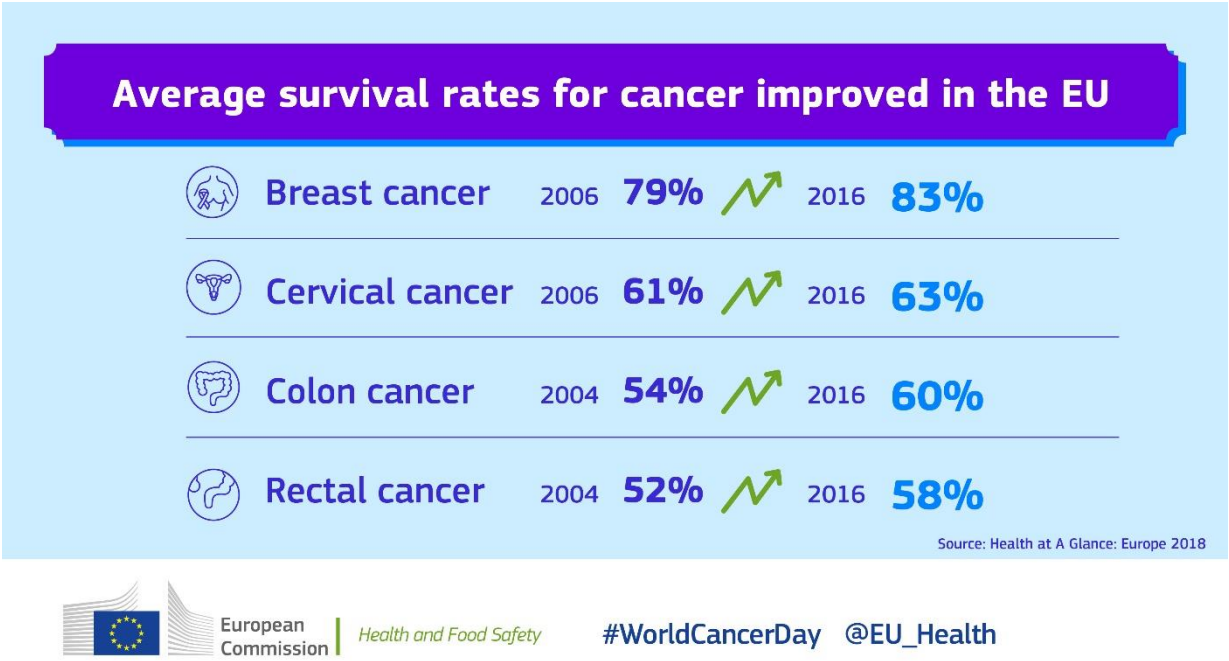
Between 6,000 and 8,000 rare diseases affect the daily lives of around 30 million people in the EU for which knowledge is scarce and unevenly distributed. The EU's **Orphanet database** – which is publicly accessible and co-financed by the Health Programme - provides information and guidance on diagnosis and care for about 6,000 rare diseases that have been identified in the EU.

Support for developing and maintaining the Orphanet database is measured by the number of data requests from the database (**result indicator 1.5B**). To date, the average number of pages viewed per day changed from 82 000 in 2017 to 87 700 in 2018. The number of diseases annotated with prevalence or incidence data increased slightly from 5 822 in 2017 to 5 926 in 2018. This represents 96% coverage of the rare disorders annotated with at least one epidemiological indicator.

DG SANTE continued to manage the **European Platform on Rare Diseases Registration**. It helps address fragmentation and sustainability of data on rare diseases. The number of stakeholders included in the Platform increased from 82 in 2017 to 84 in 2018. The size of the EU population covered by surveillance networks increased from 34% of EU birth population, approximately 1.8 million people, to 38% of birth population, approximately 2 million people in 2018 - **result indicator 1.5C**.

DG SANTE also continued to work with national and regional authorities through the **European Network of Cancer Registries,** which provide data directly to the European Cancer Information System (ECIS). They were launched in February and are run by the Joint Research Centre in Ispra.

178 cancer registries from 38 European countries are now part of the Network. 149 registries from 34 European countries (25 EU Member States plus Switzerland, Norway, Iceland, Serbia, Bosnia and Herzegovina, Montenegro, Ukraine, Belarus, Russia) have contributed to the ECIS database so far – which now includes over 34.5 million records. The European Cancer Information System provides the latest indicators to quantify the cancer burden across Europe, including geographical patterns and temporal trends of incidence, mortality and survival data across Europe for major cancers.



EUROPEAN REFERENCE NETWORKS (ERNS)

DG SANTE promotes greater access to medical expertise for rare and low prevalence complex medical conditions via the European Reference Networks. These networks bring together highly specialised healthcare providers, knowledge and resources from across the EU. ERNs represent one of the most important and innovative cross-European cooperation initiatives in healthcare, providing clear EU added value, important economies of scale and a more efficient use of increasingly stretched EU healthcare resources.

24 ERNs were established in 2017, four more than the 2018 milestone of 20 (**result indicator 1.5A**). They include over 900 highly specialised healthcare units in 313 hospitals of 25 Member States (plus Norway). Throughout 2018, DG SANTE provided support, funding and coordination to the ERNs to ensure their success, and support their integration into national healthcare systems.

DG SANTE developed the Clinical Patient Management System with financial support from the EU's Connecting Europe Facility. This software allows ERNs to share data and hold virtual panels, helping them develop their potential to offer patients and doctors access to the best expertise and timely exchange of life-saving knowledge. Since its launch, 250 virtual panels have taken place.

In November 2018, DG SANTE organised the 4th conference of the ERNs, gathering over 400 participants from national authorities, healthcare providers, members of the ERNs, health professionals, hospital managers, patients' representatives, EU Institutions. It presented the main clinical and organisational outcomes of the networks, and identified the challenges and margins for future improvements.

FINANCIAL CONTRIBUTION FROM HEALTH PROGRAMME

In 2018, EUR 21.9 million was committed from the Health Programme to finance new activities under specific objective 1.5.

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 correct implementation and enforcement of EU legislation on food safety and quality, animal health, animal welfare, plant health and some areas of human health, consistent with the CCF Programme Statement. 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 met and industry can operate on a level playing field.

In 2018, DG SANTE carried out **220 audits** and on-the-spot visits in EU and non-EU countries, including **178** on food safety and quality, animal health, animal welfare and plant health and **42** linked to human health.

In human health, DG SANTE conducted 27 joint assessments of notified bodies, with Member States' designating authorities, in the **medical devices** sector. DG SANTE also performed two audits of non-EU countries exporting **active substances** of medicinal products for human use to the EU and - with the ECDC - two country visits to Member States to discuss policies on **antimicrobial resistance** (see section 1.1.4). 11 National Contact Points for **eHealth** were also audited.

DG SANTE systematically follows up on actions taken by competent authorities to respond to recommendations made in audit reports. In 2018, six general follow-up audits were performed and two administrative follow-ups initiated. From the 3-year reporting cycle 2014-2016, 71% of DG SANTE's audit recommendations were satisfactorily addressed by the Member States at the end of 2018 (**result indicator 1.6.A**) therefore the 2018 target of 71% was met. 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 helps to update Member State "country profiles" which provide country-specific knowledge and summarise their performance in official controls. It also ensures transparency on the state of enforcement all Member States.

In addition to individual audit reports, DG SANTE published six overview and annual reports in 2018, summarising the outcome of its audits and analysis work. These reports help identify common problems and best practices to share.

In 2018, DG SANTE adopted a **report on official controls** in Member States on food safety, animal health and animal welfare and plant health. It gives an overview of the delivery of official controls in Member States in 2014-2016, based on their annual reports and controls carried out by DG SANTE.

Other major activities in 2018 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).

In 2018, DG SANTE published the 2017 "EUROPHYT - Interceptions Annual Report". It gives an overview of interception notifications in 2017 and evaluates the main trends between 2013-2017. In 2017 there were 1,484 interceptions due to the presence of harmful organisms, down 18% from the previous year.

The Commission's work with countries whose exports to the EU are intercepted frequently have also helped reduce the number of interceptions by 40% since 2013. The main non-EU commodities intercepted in 2017 were fruit and vegetables, wood packaging material and cut flowers.

MODERNISING AND SIMPLIFYING EU LEGISLATION

The **Official Control Regulation** (OCR) creates a single framework for official controls along the entire agri-food chain, including plant health and animal by-products, ensuring a harmonised, risk-based approach to official controls and efficient enforcement actions. This helps free up resources to focus on areas where enforcement needs to be prioritised.

The new rules require increased transparency and greater accountability from Member State authorities, who are obliged to publish annual reports. In 2018, DG SANTE continued to consult Member States and stakeholders on the relevant supporting legislation (delegated and implementing acts).

USE OF DIGITAL TECHNOLOGIES TO STRENGTHEN OFFICIAL CONTROLS

In 2018, DG SANTE continued to prepare for merging the current EU information systems on official controls under the umbrella of the **Information Management System for Official Controls (IMSOC)**. This will integrate: TRACES (migration has begun), the Rapid Alert System for Food and Feed (RASFF), Administrative Assistance and Cooperation System (AAC) and EUROPHYT.

In parallel, DG SANTE has advanced work on the implementing act to support IMSOC, and continued implementing the Plant Health Directive[28], setting standards for electronic certification of plants imported from third countries.

2018 was a very active year for **RASFF**, with the same level of "original" (new) notifications as in 2017, but no major incidents. 3986 original notifications were received (of which 206 were rejected). There were also 10 484 follow-up notifications on traceability of lots, analyses and measures taken. In total, 14 471 notifications were received, which is the highest number in RASFF's 40 year history. On top of that, 81 non-compliance notifications were transmitted. Non-compliance notifications are a new category of notifications, supporting the requirements of Commission Regulation (EC) No 669/2009 on reinforced checks at the border for products of non-animal origin.

The 2018 Annual Report on the **Administrative Assistance and Cooperation System** shows a steady increase in cases exchanged: 239 suspicions of fraud (compared to 178 in 2017), 1153 on non-compliances (597 in 2017). DG SANTE coordinated actions on 5 EU-wide suspicions of fraud and strengthened its cooperation with EUROPOL and EUROJUST, notably during a coordinated action on tuna in the framework of operation OPSON VI

The 2018 **TRACES** annual report shows TRACES has continued to intensify its activities with over 35 000 active users and more than 2 million certificates, entry documents and commercial documents managed in the system. TRACES is used by operators and competent authorities worldwide, for intra-Union trade in or imports of animals and products of animal origin, plants and food of non-animal origin.

DG SANTE began implementing an e-signature system in TRACES, enabling paperless workflow for certain commodities in line with the Digital Single Market Strategy.

FINANCIAL CONTRIBUTION TO OFFICIAL CONTROLS' RELATED ACTIVITIES

Official control activities aim 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. In order to support this network, funding for 45 EURLs and 2 EU Reference Centres was granted in 2018 with a budget of around EUR 17 million.

The BTSF plays a key role in efficiency and reliability of official controls and spreading knowledge of EU legislation. Over 160 training courses were carried out for Member States' authorities and over 20 in non-EU countries to help create a level-playing field and build confidence in the EU regulatory model (see specific objective 3.1). The budget for BTSF for 2018, managed by DG SANTE's executive agency CHAFEA, was EUR 17.5 million.

[28] 2000/29/EC

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 by the contribution the health sector makes to the Commission's **impact indicator 2.1** on **the Gross Value Added (GVA) of EU industry in GDP**. The GVA of the EU health sector (human health activities) in GDP has remained stable since 2009 and oscillates around 4.6% (Table 1 in Annex 12).

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

Intra-EU trade in food and live animals has steadily increased since 2008 to almost 1.9% of GDP in 2013 where it has remained since (Table 2 in Annex 12). This demonstrates a well-functioning internal market for food, based on clear, harmonised rules that are recognised as both proportionate and efficient.

The increase in intra-EU trade in live animals and food products reached, respectively, EUR 300.7 billion and EUR 298.8 billion in 2017[29] (Table 4 in Annex 12). This trend is supported by ongoing efforts to reduce administrative burden in the sector.

The added value of harmonised EU-wide legislation on food safety extends well beyond EU borders, building trust and reputation that supports increasing and free-flowing trade and full citizen engagement in the Single Market. The EU "brand" is known for its quality, especially on food, helping to win markets outside the EU despite higher production costs in Europe.

In 2017, both intra-EU exports/imports and extra-EU export/import in food were growing. Intra-EU exports/imports grew by 6.1% and 6.7% respectively and extra-EU export/import by 4.2% and 2.6% respectively (Tables 3 and 4 in Annex 12). Between November 2017 and October 2018, EU agri-food exports increased to EUR 137.6 billion, an increase of 0.3% in value terms compared to the same period the previous year. At the same time, the EU imported EUR 115.2 billion of agri-food, down 2.5 % compared to the same period the year before[30]. The increase in trade shows the internal market works well and the EU's high standards are recognised.

DG SANTE contributes to General Objective 2 by ensuring trade – in particular in food and pharmaceutical products – can take place freely and that innovation is encouraged. As regards the regulatory framework for pharmaceuticals, to take one example, there is a clear EU added-value. Challenges such as access and shortages are often common to all Member States and require a harmonised response. Within the limits of its competences, the EU can address these challenges. Measures by DG SANTE and other Commission bodies encourage innovation, competition, trade, research and the economic and budgetary governance to complement this framework.

However, there are also clear challenges to how far DG SANTE, and the Commission as a whole, can act to address system limitations. The organisation of health systems, including decisions on pricing and reimbursement is a national competence and the EU only has a complementary role.

Food and feed safety is ensured in the EU by a wide range of harmonised rules, including 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 (see

[29] Latest figures available from Eurostat are for 2017

[30] Source: European Commission, DG Agriculture and Rural Development, https://ec.europa.eu/info/sites/info/files/food-farming-fisheries/trade/documents/monitoring-agri-food-trade_oct2018_en.pdf.

objective 1.2). This framework helps the internal market run smoothly, providing a level playing field and legal certainty for business operators, supporting free circulation of food/feed products and giving consumers across the EU access to safe and quality food products.

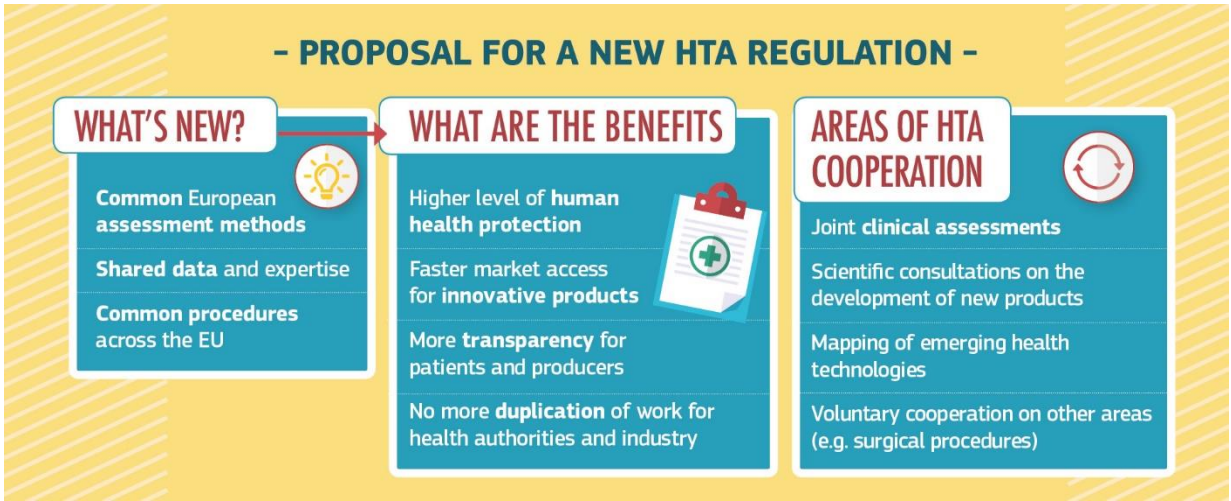
A political agreement on the new Regulation on medicated feed was reached between the co-legislators in June 2018. The Regulation addresses the public health risk of antimicrobial resistance, creates a level playing field throughout the EU for an economically viable production of safe medicated feed and paves the way for innovative applications of medicated feed, in particularly for chronically diseased pets.

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 (i.e. pharmaceutical product, medical device or health intervention) in a systematic manner to inform decision-makers on its relative effectiveness compared to other technologies. It helps to achieve the best outcome and value for money for patients, 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 2016-2020, the Health Programme has committed EUR 16 million to HTA activities.

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 Member State HTA procedures. In January 2018, following an Impact Assessment and public consultation, the Commission put forward a proposal developed by DG SANTE to boost cooperation between EU countries for assessing health technology. The proposal is expected to deliver greater transparency and innovative health tools and approaches.



Throughout 2018, SANTE worked with the Parliament and Council and other stakeholders to highlight the potential of stronger HTA cooperation and try and find an agreement.

In July 2018, DG SANTE organised a conference bringing together over 300 policy makers, healthcare providers, patient representatives and experts to share views on future HTA cooperation. The discussions indicated that, after 20 years of joint work, HTA cooperation should be given a fair chance to become more structured, sustainable and efficient, to support optimal use of resources and share expertise across the EU.

The **result indicator 2.1** shows the number of joint HTA reports 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 the individual companies providing data for assessments. In 2018, EUnetHTA Joint Action carried out 22 joint reports (eight assessments and 14 early dialogues). This increased from 14 Joint Reports in 2017, and the baseline of two in 2012.

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 consistently high safety and quality standards for medicinal products across Europe and promotes measures which encourage innovation and competiveness.

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 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 258 billion in 2017, and employed about 750,000 people. In the same year, EFPIA indicated an estimated positive trade balance of EUR 98 billion and EUR 35 billion spending on research and development.[31]

In 2018, the third Health Programme committed EUR 650,000 to three new activities related to objective 2.2.

IMPROVING ACCESS TO INNOVATIVE MEDICINES AND OPTIMISING THE USE OF CURRENT LEGISLATION

Patient access to affordable medicines and the balance between pharmaceutical innovation and sustainability of EU health systems remained a focus area in 2018.

The development of innovative medicines is supported by a variety of **incentives**, some of which are linked to Intellectual Property (IP) rights, and others to the marketing authorisation and data it contains ('regulatory' incentives). 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.

In 2018, DG SANTE (with DG GROW) finalised a study on the drivers around current incentive schemes and the impact of the pharmaceutical incentives (including supplementary protection certificates, data protection rules and market exclusivity for orphans), on innovation, and availability and accessibility of medicinal products. The results were published in May 2018[32].

[31] Source: https://efpia.eu/media/361960/efpia-pharmafigures2018_v07-hq.pdf

[32] Further info on the Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe https://ec.europa.eu/docsroom/documents/29521

DG SANTE also requested and funded an additional study on the functioning of the EU Regulation on orphan (rare diseases) medicinal products (EC) No 141/2000. The results of this study will feed into the ongoing evaluation of the EU Regulations on orphan medicinal products and medicines for children, foreseen in the second half of 2019.

In parallel, DG SANTE adopted a revision of a Commission Implementing Regulation[33] on orphan medicinal products, which adapted definitions of "similar medicinal product" to technical and scientific progress.

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 timely access to innovative medicines and improve application of the legal framework.

SUPPORTING THE DEVELOPMENT OF ADVANCED THERAPY MEDICINAL PRODUCTS AND IMPROVING PRODUCT INFORMATION

DG SANTE continued work to support development of advanced therapy medicinal products (ATMPs). The Guidelines on Good Manufacturing Practice specific for ATMPs entered into force in May 2018 and Commission services have been discussing specific aspects related to implementation with Member States.

Commission services have agreed a number of initiatives with national competent authorities to support clinical trials in gene therapy medicinal products. They include: (1) creating a repository of national regulatory requirements for medicinal products containing GMOs, (2) developing a Q&A document on questions related to the interplay between the GMO and the pharmaceutical framework, and (3) developing an adapted approach to assess genetically-modified cells via retro/lentiviral vectors (including the development of a common application form which has been endorsed by 18 Member States plus Norway). All initiatives have been published on SANTE's website.

In addition, a document has been developed by the Commission – with the European Medicines Agency – addressing questions on the application of "similar active substance" in an ATMP setting. Finally, a public consultation on development of Good Clinical Practices specific to ATMPs was launched in 2018.

Following 2017's work on product information and package leaflets for medicinal products, DG SANTE worked with EMA and the Heads of the Medicines Agencies in 2018 to identify stakeholder needs and map ongoing activities on electronic product information (ePI). A workshop was held on 28 November 2018 to discuss stakeholder needs and concerns and decide on a future common approach. The outcome of the workshop was a proposal for "key principles" on ePI to be released for public consultation in early 2019.

MARKETING AUTHORISATIONS OF MEDICINAL PRODUCTS

In 2018, 92.4% (85 out of 92 Commission decisions) of new medicines were authorised within the legal deadline (the indicator is 90%). This is an increase from 87% in 2017. For Commission Decisions for which there was an accelerated assessment, 83.3% of medicines were authorised within the legal deadline (down from 100% in 2017) (**result indicator 2.2**). The Commission works with EMA to optimise the adoption process for initial marketing authorisation within the overall timeframe foreseen in the legislation.

In 2018, DG SANTE requested and funded a study on the procedures for authorising and monitoring medicinal products for human use. The purpose is to gather evidence for a Commission report to the co-legislators. The scope of the study comprises centralised, decentralised and mutual recognition procedures (except for subjects falling exclusively within the competence of the Member States).

[33] Commission Regulation (EU) 2018/781

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

Under the falsified medicines Directive 2011/62/EU, DG SANTE worked with Member States and stakeholders to ensure successful implementation of the safety features for medicines, so that by February 2019, the authenticity of all prescription medicines can be checked before reaching patients. DG SANTE published a report in January 2018 which highlighted the requirement for all EU countries to put in place proportionate, effective and dissuasive penalties for falsified medicines. DG SANTE also updated a guidance document to industry, distributors and pharmacies.

DG SANTE worked with the European Medicines Agency and national authorities to prepare implementation of the new rules on clinical trials in the EU including the IT portal and interpretation of the EU's General Data Protection Regulation (2016/679).

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 (see specific objective 1.4), DG SANTE supports the development of expertise on health systems performance via the EU expert group on **Health Systems Performance Assessment** (HSPA), which it co-chairs.

In 2018, the group continued to identify tools and methodologies to improve national assessment schemes and projects and define ways to measure the efficiency of health systems. In March 2018, it published a report on primary care in Europe, intended to help policy makers and health practitioners set objectives and measure progress towards improved primary care services. It examines core aspects of well-performing primary care systems, focusing on their key functions e.g. access, coordination of care and continuity of care.

In 2018, seven Member States referred to the findings of the expert group on Health Systems Performance Assessment (HSPA) in their national policy making **(result indicator 2.3A)**, up from the baseline of zero in 2015 and the interim milestone of five in 2017. The results of this indicator 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 2018, DG SANTE worked closely with other Commission departments, Member States and industry to tackle sanitary and phytosanitary (SPS) barriers to trade and improve market access to non-EU countries.

The Commission's contribution to the general objective on trade policy is measured by 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).

DG SANTE contributes by negotiating balanced and ambitious SPS chapters in Free Trade Agreements (FTAs), and by working with other trading partners to remove SPS-related trade barriers. Success here is essential to continue increasing exports of agri-food products. The share of the EU-extra trade in food and live animals to total EU-extra trade has been steadily increasing since 2010. In 2018 it reached 10% (Table 5 in Annex 12).

This work makes an essential contribution to the cohesion of the EU internal market and represents clear added value. It helps avoid situations where non-EU countries impose different SPS requirements on EU countries or EU countries accept different export conditions that may jeopardize the internal market. It also ensures fair competition between Member States and gives the EU a strong and effective mandate to promote its standards internationally.

DG SANTE promotes EU health and safety standards for pharmaceuticals at global level through the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) which helps increase EU-extra trade. The share of EU-extra trade of medicinal and pharmaceutical products to total EU-extra trade has been steadily increasing since 2011. In 2017 it reached 6.3%% (Table 6 in Annex 12).

SANTE continues to work closely with the US to implement the Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP), which was concluded in 2017. (See 1.3.2)

1.3.1 Specific objective 3.1: Increased EU influence in international fora

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

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 and greater recognition of EU standards. By promoting a single, common position for all Member States, the EU gives individual Member States a stronger voice on the world stage.

DG SANTE worked closely with third countries and 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), Food and Agriculture Organisation (FAO) and the International Plant Protection Convention (IPPC) and the Convention on Biological Diversity (CBD) and its protocols (e.g. Cartagena Protocol on Biosafety) to ensure its standards were recognised, accepted and promoted at bilateral and multilateral level.

This EU-level work contributes to a high level of health protection and important growth and employment opportunities in the EU's food and pharmaceutical sectors.

DG SANTE contributed to EU efforts to achieve the **Sustainable Development Goals** (SDG), in particular: health (SDG3) and halving food waste by 2030 (SDG 12) (see specific objective 1.2).

DG SANTE also coordinated the Commission's health input for G20 and G7 ministerial meetings and summits and the OECD health ministers' meeting.

CONTRIBUTING TO GLOBAL HEALTH

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

At the **World Health Organization (WHO)** governing body meetings in 2018, EU inputs (e.g. technical consultations of EU amendments) were reflected in **90**% of WHO Executive Board's resolutions (equalling the 2017 milestone of 90%), **80**% World Health Assembly's resolutions (surpassing the 2017 milestone of 75%) and **75**% of WHO Regional Committee for Europe's resolutions (surpassing the 2017 milestone of 70%) - **result indicator 3.1.A**. DG SANTE also cooperated with WHO on the Vilnius Declaration which outlines the objectives, principles and modalities for cooperation between the Commission and the WHO Europe office. DG SANTE co-organised the Commission-WHO Senior Level Officials meeting with involvement of DG DEVCO, ECHO, ENV, RTS, CLIM on 29 June 2018 in Geneva, where the close partnership between the Commission and WHO was underlined in key areas, such as crisis preparedness, antimicrobial resistance and vaccination.

DG SANTE contributed to the United Nations General Assembly High level meetings on Tuberculosis and Non-communicable diseases in September 2018 with Commissioner Andriukaitis participating on behalf of EU and its Member States in both events.

In 2018, DG SANTE ensured strong and coordinated EU participation at the 8th session of the Conference of the Parties (COP8) to the WHO Framework Convention on **Tobacco Control** (FCTC). COP8 achieved important advances in tobacco control with the adoption of key decisions on novel and emerging tobacco products, and cross-border advertising. The Commission highlighted the EU's comprehensive and cross-sectorial policy approach to tobacco control. DG SANTE also acted as Key Facilitator in the Working Group on Regulation of Tobacco Products Contents and Disclosures. It 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. The COP8 meeting was followed by an historic First Meeting of the Parties (MOP) to the Protocol to Eliminate the Illicit Trade in Tobacco Products, which will become the central forum to discuss illicit tobacco trade at multilateral level.

DG SANTE continued to reinforce cooperation with the **OECD** in the framework of the Strategic Medium-term cooperation arrangement", focusing on successful implementation of the State of Health in the EU cycle, antimicrobial resistance, support for Member States to make their health systems more patient-centred and improving access to innovative medicines. DG SANTE was present during the two meetings of the OECD Health Committee.

Work in **G7** and **G20** focused on global health security, strengthening health systems and universal health coverage, and malnutrition, in particular childhood obesity, which was a priority for the Argentinian G20 Presidency. This was reflected in a dedicated G20 Health Ministerial meeting in October which Commissioner Andriukaitis joined.

In line with the third pillar of the EU Action Plan, SANTE participated in a number of international AMR activities, complementing its domestic agenda and supporting broader global efforts under WHO Global Action Plan on Antimicrobial Resistance.

Notable examples include its participation at **Codex Alimentarius** (e.g. drafting new Guidelines for integrated monitoring and surveillance of foodborne AMR), **OIE** (e.g. 2018 OIE Global conference on AMR and revision of the OIE Code chapter on prudent use of antimicrobials), **Trans Atlantic Task Force on Antimicrobial Resistance** (annual meeting and video/teleconferences with TATFAR Working Groups), **G7** (G7 leaders' communiqué mentioning AMR and the One Health approach) and **G20** (various G20 Declarations incorporating AMR).

In June 2018, DG SANTE published a **report on national policies and measures on antimicrobial resistance in non-EU countries**. The report analyses national policies and measures to address the important challenge posed by AMR in human and veterinary medicine. It found significant international variation in AMR policies.

In early 2018, DG SANTE also completed a series of seminars focusing on different AMR issues at technical level in Argentina, Brazil, Chile, Colombia, Peru, and Uruguay supported by the Foreign Partnership Instrument (FPI). DG SANTE also prepared multi-country regional workshops on **AMR in Enlargement and European Neighbourhood Policy** countries with ECDC support, to be held in 2019.

In parallel, it continued to contribute to the negotiation and implementation of association agreements with third countries and provide health input to political bilateral dialogues. Prior to political developments, the draft agreement on public health between EU and **Swiss Confederation** was updated and ready for conclusion.

As part of capacity building towards the health acquis, DG SANTE carried out a communicable disease assessments in Bosnia and Herzegovina, an assessment on substances of human origin in Serbia, a workshop in Moldova to support its participation in the Health Programme, and targeted support to Ukraine for public health and blood system reform implementation. DG SANTE continued to contribute to the negotiation and implementation of association agreements with third countries and provide the health input to political bilateral dialogues as appropriate.

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[34]. Since 2002, intra-EU trade more than doubled from EUR 156 billion to EUR 347 billion in 2017.

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 the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH). Harmonisation by adopting ICH and VICH guidelines facilitates access to multiple markets, including 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 2018, DG SANTE, as one of the founding regulatory members of the ICH, used its experience to promote common EU views and actively contribute to the output of this body. It actively facilitated the implementation of the new structure through its chairmanship of the ICH Assembly. The ICH reform facilitates an increased membership which in 2018 amounted to 16 members and 28 observers in total.

[34] 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

Result indicator 3.1.B monitors the increased recognition of ICH guidelines at global level and increased global harmonisation. Since 2015, regulatory authorities from five new countries have joined ICH as members. Approximately 50% of the ICH guidelines have been implemented by these five new members. No new ICH guidelines or revised guidelines were adopted in 2018.

Bilateral relations with key strategic partners on pharmaceuticals

Bilateral activities are generally carried out through regulatory dialogues with our key strategic partners, such as the US, Japan, China and India.

The following three Regulatory Dialogues took place in 2018:

- DG SANTE/EMA – United States (June 2018), agreed a number of actions, reaffirming the mutual willingness of the EU and the US to continue their already close cooperation at both strategic policy and technical level (see also 1.3.2);

- The EU-India Joint Working Group on Pharmaceutical, Biotechnology and Medical Devices (September 2018);

- The China-EU Regulatory Dialogue on Pharmaceuticals (October 2018) where both parties stressed the importance of further strengthening collaboration.

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 a key priority. In 2018, DG SANTE continued to promote the EU's common position in international fora to encourage alignment of international standards and reduce its exposure to dispute settlements. This includes in the World Organisation for Animal health (OIE), Codex Alimentarius and the International Plant Protection Convention (IPPC).

In 2018, 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 (**result indicator 3.1.C**). 2018 has been a year of intense EU pre-regulatory activity by DG SANTE. Given the importance of the EU market and the high level of its sanitary and phytosanitary standards, WTO Members heavily scrutinised EU measures in the SPS Committee by raising several Specific Trade Concerns. Whilst resorting to this instrument requires little effort form the complainant and provides in turn high visibility, the rising number of Trade Concerns against the EU caused the relevant indicator to worsen.

Last year the EU submitted one written communication to the WTO SPS Committee, on the EU Plant Health Import Regime.

Where non-EU country SPS trade restrictions violating WTO rules and having major impact cannot be resolved by other means, DG SANTE in cooperation with the Commission Legal Service and DG TRADE works to build solid dispute settlement cases on behalf of the EU before the WTO bodies e.g. the 2014 Russian EU-wide ban on pigs an pig products. In 2017 the WTO concluded Russia had broken the rules and in 2018, DG SANTE monitored Russia's compliance with the ruling and helped prepare the EU's appeal to a compliance panel procedure, to run in 2019.

In 2018, WTO Members raised **five** new Specific Trade Concerns (STCs) against the EU in the SPS Committee. Several Members also raised concerns on the EU's policy for agricultural application of precision biotechnology.

Following the signing of the 2017 Letter of Intents by Commissioner Andriukaitis and FAO Director General Jose Graziano da Silva, in 2018 the EU and **FAO** intensified cooperation on two EU and global priorities: AMR and food loss and waste.

In the **International Plant Protection Convention** (IPPC), there is a strong EU input, coordinated by SANTE, on global plant health strategy and international standards for phytosanitary measures (ISPMs). In 2018, DG SANTE was closely involved in the preparations of the IPPC Strategic Framework for 2020-2030 and the International Year of Plant Health 2020, and the initial discussion for the future development of commodity or pest specific ISPMs. DG SANTE also provided technical input into DG TRADE programmes for financial support to the IPPC, and to DG DEVCO on the future sustainable funding of the FAO regulatory bodies (IPPC and Codex Alimentarius). At the end of 2018, DG SANTE became directly involved in the IPPC flagship initiative for electronic certification 'ePhyto'.

The EU is the world's largest exporter of seeds. In 2018, DG SANTE continued to promote international harmonisation in this area and to help shape the international governance of seed trade, related intellectual property rights and the access to plant genetic resources.

In 2018, DG SANTE participated in the Conference of the Parties to the Convention on Biological Diversity (CBD), contributing to a decision on synthetic biology and to adoption of 16 decisions under the Cartagena Protocol on Biosafety. The negotiations on synthetic biology were challenging, however the adopted decisions are in line with the EU position.

Capacity building in third countries

In 2018, DG SANTE implemented several capacity building activities under its BTSF programme. More than 20 training activities were held for non-EU countries' authorities to build confidence in the EU regulatory model. They included seven workshops and training missions on a wide range of SPS issues including food testing, risk analysis, AMR and alert systems such as TRACES and RASFF. These trainings help build institutional capacity in the beneficiary countries to allow them to face future food safety challenges.

DG SANTE also worked with other DGs to ensure the uptake of SPS-related issues in development cooperation programmes e.g. Fit for Market programme to address plant health and pesticide residue related issues; SYMST programme in Lao PDR and Thailand to address pesticide residues related issues in fruits and vegetables). DG SANTE was also involved in the Task Force on Rural Africa, set up by President Juncker, to boost African agriculture and agribusiness.

Improving bilateral trade relations

2018 is expected to be the best **EU agri-food export performance** ever according to the latest available data (October 2018). Between November 2017 and October 2018, EU agri-food exports increased to EUR 137.6 billion, up 0.3% in value terms compared to the same period the previous year. Major gains in annual values (EUR million) have been achieved in agri-food exports to Ukraine (+272; +16%), Japan (+269; +4%), Singapore (+227; +10%) and Algeria (+142; +6%). Annual export values reflect a downward trend for China (-622; -4%), which nevertheless remains the EU's second most important export market, and destinations in the Middle East, in particular the United Arab Emirates (-451; -15%) and Saudi Arabia (-391; -9%).

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.

SANTE's 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 summary, in 2018, negotiation on the SPS chapters for the **EU-Indonesia, EU-Australia and EU New Zealand** all continued with varying degrees of progress. In the **Western Balkan** countries, the negotiations of accession for the SPS chapter have started with Montenegro and Serbia though all countries have signed stabilisation and association agreements with the EU.

Prior to political developments, substantial progress was made in 2018 in the food chapter of the **EU**-**Swiss Confederation** agreement to harmonise Swiss legislation for the sectors not yet covered by the 2002 agreement.

On **Canada**, the first meeting of the SPS Joint Management Committee meeting took place in March 2018. Discussions between the Parties aim to increase bilateral trade in animals, plants and their products. The follow-up of the agreed action items and work plan remain the key priority. In addition cooperation on AMR and animal welfare is pursued.

Concerning the longstanding **Mercosur**'s negotiation, the EU has agreed to establish, in addition to the SPS Chapter, a separate Chapter on Dialogues that will include cooperation on biotechnology; food safety, animal and plant health science; animal welfare; and the fight against antimicrobial resistance. The technical work of the two Chapters was concluded in June 2018. Two outstanding issues remain to be discussed at political level, the so-called "Peace clause" and the Private standards.

With **Chile**, EU has already a SPS agreement but the negotiation re-started for a comprehensive text. Progress is likely to be easy.

Discussions have also started with **India**.

The EU-**Japan** Economic Partnership agreement successfully concluded in July 2018 and **Vietnam** agreed a final text for the EU-Vietnam Free Trade Agreement. In 2018, DG SANTE also contributed to modernisation of the 2000 EU-**Mexico** Global Agreement's trade pillar. The new Agreement contains a fully-fledged SPS Chapter which is intended to address the some long standing SPS issues and provide specific trade facilitation measures. It also embeds progress on the recognition of the EU as a single entity.

With **China**, the second export market for EU agro-food products, negotiations remain intense. Although an overall agreement is not foreseen in the short term, gradually the Chinese door is opening slowly and allowing an exponential growth of EU agri-food products.

Close co-operation took place in under the EU Association Agreements in Deep and Comprehensive Free Trade Areas with **Ukraine**, **Moldova** and **Georgia** aiming to implement bilateral commitments in the SPS area. It is worth highlighting for Ukraine that mutual recognition of regionalisation decisions on avian influenza was achieved, as well as a technical agreement on SPS chapter meaning Ukraine will align its legislation on EU SPS acts.

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

Following positive assessments in March and June 2018, by the US Food and Drug Administration (FDA), a six additional Member States (Czech Republic, Greece, Hungary, Romania, Lithuania, Ireland) joined the list of EU countries recognised as capable to carry out good manufacturing practice (GMP) in inspections of sites that produce human medicines. This brings the total number of Member States accepted to fourteen. The

remaining Member States will be assessed by the FDA on a rolling basis, to be completed by 15 July 2019.

This recognition is possible under the Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP), which was concluded in 2017. It 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.

Mutual Recognition Agreements carry significant added value for EU countries. They will lead to significant cost savings for industry and a better use of inspection resources by avoiding the current overlap 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, meaning reduced risk. It also helps to promote high quality standards globally for medicinal products.

ANIMAL HEALTH, PLANT HEALTH AND FOOD SAFETY

The USA remains by far the largest market for EU agri-food exports, although a slight decrease was recorded between November 2017 and October 2018 (-116; -0.5%).

Despite the suspension of free trade agreement (TTIP) negotiations with the US, in 2018 DG SANTE maintained extensive contacts at technical and political level.

This collaboration remained focussed on 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 2018, four Member States were listed to export beef to the US, same as 2017. 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 is the same situation for market access for Grade A (pasteurised) dairy products and sheep/goat meat.

In 2018, DG SANTE engaged at technical level in **three** working groups, one on animal health and two on plant health.

DG SANTE was actively engaged in a Food Safety Systems Recognition exercise with the USFDA which comprised audits of each party's food safety control systems. This project has the potential to significantly reduce the burden on food business operators in the EU when exporting to US. In July 2018, within the framework of this exercise, SANTE visited the US Food and Drug Administration (FDA) to evaluate the implementation of its food safety control system and FDA visited Ireland (the fourth Member State evaluated after Denmark, Hungary and Italy). 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. However, no progress has been made on the number of barriers overall in place (**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 explains how the DG delivered the achievements described in the previous section. It is divided into 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[35]. 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, on the recorded exceptions/non-compliance events or "confirmation of instructions" according to Article 92(3) of the Financial Regulation;
- Report 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 Director in charge of Risk Management and Internal Control (RMIC) on the annual assessment of the implementation of the internal control principles applicable since 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.

[35] Art 36.2 FR: a) effectiveness, efficiency and economy of operations; b) reliability of reporting; c) safeguarding of assets and information; d) prevention, detection, correction and follow-up of fraud and irregularities; and e) adequate management of risks relating to the legality and regularity of underlying transactions.

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[36]. 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 relevant control systems.

In 2018, 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[37]

Table 2.1 DG SANTE's budget of 2018[38]

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	17,5	0,4	260,4	1,1	**279,3**
Public Health	46,6	1,0	11,7	1,3	**60,6**
Sub-total programmes	***64,1***	***1,4***	***274,4***		***339,9***
Subsidy to CHAF-EA's operating budget				5,7	**5,7**
Subsidies to EU agencies operating budgets			174,7		**174,7**
Sub-total agencies			***180,4***		
Global envelope for administration				7,2	**7,2**
Building expenditure Ireland, et al.				4,9	**4,9**
Sub-total admin.			***12,1***		

[36] 1) Effectiveness, efficiency and economy of operations; 2) reliability of reporting; 3) safeguarding of assets and information; 4) prevention, detection, correction and follow-up of fraud and irregularities; and 5) 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 Article 36.2).

[37] 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 2018.

[38] Commitments made on the basis of the final available credits taking into account EFTA credits, budget amendments and/or budget transfers without credits co-delegated to other DGs. Comparison to Annex 3:

(a) Annex 3 shows the subsidies to EU agencies of EUR 169,8 million under "Public Health" and EUR 4,9 million under "Food and Feed";

(b) Annex 3 includes in administrative expenditure of Title 17 (EUR 19,8 million): the global envelope of EUR 7,2 million, subsidies to CHAF-EA of EUR 5,7 million, the part of the expenditure for the building in Ireland on budget line 17.01 of EUR 4,4 million (an additional EUR 0,5 million are on budget line 26.01) and the administrative support credits on operational budget lines of EUR 2,5 million (EUR 0,5 million of support credits are not included in Annex 3 as they were co-delegated, mainly to DG DIGIT.

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	
Total SANTE policy areas	***64,1***	***1,4***	***467,0***	***17,9***	***532,5***
Other policy areas			3,8	4,9	**8,7**
TOTAL including CHAF-EA					**541,2**
TOTAL excluding CHAF-EA (commitments made as per Annex 3)					**477,1**

EC balance sheet category	DG SANTE (M€)
Assets – inventories of vaccines and antigen stocks for animal diseases	***10,4***

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 (99,0% and 98,6% respectively[39]). The main features of this management mode are explained in section 2.1.1.1.1 below, and Annex 5.1.1 shows the corresponding internal control system.
- In the policy area Public Health, public procurement is the most important financial management instrument. Commitment and payment credits were fully consumed (100%; see section 2.1.1.1.2 below for more detail and Annex 5.1.2 for the relevant internal control system).
- DG SANTE implemented almost 20% of its 2018 credits related to EU funding programmes (EUR 64,1 million out of EUR 339,9 million) through the Consumers, Health, Agriculture and Food Executive Agency (CHAF-EA). Only EUR 1,4 million of DG SANTE's commitment appropriations were cross-subdelegated to authorising officers of other Directorates General (see section 2.1.1.1.3 below).
- The credits listed under "other policy areas" include EUR 2,7 million co-delegated to DG SANTE by DG CNECT related to CEF[40] and EUR 1,1 million by DGs AGRI, ENV, MARE and TAXUD on operational budget lines for IT services mainly related to the IT system TRACES. In addition, EUR 3,1 million were co-delegated by DG AGRI and EUR 1,8 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 2.1.1.1.3 below; Annex 5.2 shows the relevant internal control system).
- The administrative support credits (EUR 2,4 million) on the operational budget lines are used mainly for meetings, conferences, IT and communication services. The global envelope (EUR 7,2 million) includes missions, meetings, committees, studies, IT (administrative tools only), training and credits for external staff. The administrative expenditure for Grange, Ireland, (EUR 4,9 million) relates to the office building in

[39] The commitment and payment credits voted by the budgetary authority for the 2018 budget were implemented at 100%; the credits not fully implemented are the revenues (mainly from recovery orders) which will be spent in 2019.

[40] Connecting Europe Facility (CEF) programme

Grange which is managed directly by DG SANTE (not by OIB or OIL). The commitment credits were almost fully consumed (98%); the payment budget was only implemented to 71% in 2018, but as payments can still be made in 2019, 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 10,4 million pertaining to stocks of antigens for food and mouth disease (see section 2.1.1.4 below).
- DG SANTE's best estimate of the detected error rate during ex-post controls is 2,0% in the Food and Feed policy area and between 1,1% and 1,4% in DG SANTE as a whole[41].

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 2018.

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 as well as 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 paragraphs.

2.1.1.1 Effectiveness = the control results and benefits

2.1.1.1.1 Legality and regularity of the transactions

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 2.1.1.1.4 "Conclusion on legality and regularity").

[41] The range is to be understood as DG SANTE's best estimate calculated as the weighted average error rate between the detected error rate 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%.

2.1.1.1.1.1 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".

Table 2.2 Food and Feed Safety

Commitment credits implemented by DG SANTE *(without CHAF-EA)*[42]	**2018** **M€**	**2017** **M€**	**2016** **M€**
Animal disease eradication programmes (grants to Member States)	**137,6**	148,6	156,9
Veterinary emergency fund (grants to Member States)	**49,9**	51,9	20,0
Phytosanitary expenditure (grants to Member States)	**15,9**	0,5	17,1
Other veterinary, plant health and food safety expenditure (grants to Member States, EURL, etc.)[43]	**41,6**	17,3	19,1
Sub-total grants	**245,0**	218,3	**213,1**
Procurement DG SANTE[44]	**15,4**	23,0	22,6
Administrative support credits[45]	**1,1**	1,3	1,3
Total budget implemented	**261,5**	242,6	**237,0**

Provisions for the management of expenditure for the policy area Food and Feed are set out in the Common Financial Framework (CFF)[46]. Direct financial contributions to Member States is by far (more than 80%) the most important budget implementation instrument:

- In 2018, 28 Member States implemented a total of 134 animal disease eradication and control programmes.
- In addition, a total of 25 files for cost reimbursements were handled in relation to the veterinary emergency fund, to combat, first and foremost, Avian Influenza (EUR 29,4 million) but also African Swine Fever (EUR 16,4 million), Lumpy Skin Disease (EUR 3,5 million) and Newcastle Disease (EUR 0,6 million).
- Addressing the combat of organisms harmful to plants, 24 Member States submitted their 2018 "pest survey programmes" of a total amount of EUR 11,9 million and 9 Member States submitted emergency plant health measures accounting for EUR 3,9 million. Other grants to Member States included EUR 2,0 million financial aid towards a coordinated control plan for antimicrobial resistance in zoonotic agents[47].
- Other non-typical grants concern mostly the funding of the 46 European Reference Laboratories (EURLs) with EUR 16,9 million for their 2018 activities. In addition,

[42] Without credits co-delegated to other DGs.

[43] See for example, the work programme of 2018 to 2020 for the Union contribution to the EU reference laboratories and the EU reference centres adopted on 17 October 2017 (C(2017) 6889 final); work programme and the financing for the year 2018 of activities in the food and feed area to ensure the application of the food and feed legislation was adopted on 25 January 2018 (C(2018) 296 final).

[44] Without credits cross-subdelegated to other DGs: EUR 0,3 million in 2018 (EUR 0,2 million in 2017; EUR 0,0 in 2016).

[45] Without credits cross-subdelegated to other DGs: EUR 0,15 million in 2018 (EUR 0,0 million in 2017 and 2016).

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

[47] Commission Decision C(2017)245

EUR 20,3 million were earmarked for the 2019 activities of the EURLs and the European Reference Centres for Animal Welfare.

- Other measures to contain animal disease outbreaks are the purchase of vaccines. In 2018, DG SANTE committed EUR 0,5 million on vaccines and antigens through public procurement (see sections 2.1.1.1.2 below).

The 2018 commitment appropriations at the end of the year of EUR 263,4 million, and the 2018 payment credits of EUR 238,6 million, were each almost fully implemented (99,0% and 98,6% respectively)[48].

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 almost 60% 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.

Stage 1: Programming and evaluating the 2019 national programmes

In 2018, DG SANTE paved the way for the award of the 2019 animal disease eradication programmes of the Member States. In compliance with the Commission work programme[49] to implement the Common Financial Framework (CFF)[50] for the Food Chain, Member States submitted their 2019 disease eradication and control programmes by 31 May 2018. 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 147 programmes submitted, five 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 for animal disease eradication and monitoring 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 in previous years, in 2018 the deadlines fixed in the legislation were respected allowing a timely launch of the 2018 programmes in the Member States.

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[48] In the Food and Feed Safety policy area, Annex 3 shows implementation rates of 98,6% for EUR 269,4 million of commitment credits and 98,1% for EUR 244,6 million of payment credits. The difference to the figures above is the subsidy payment to the EU decentralised agency ECHA-biocides which is included in Annex 3 under "Food and Feed Safety": EUR 6,0 million commitments and payments of which EUR 4,9 million were implemented in 2018 (81,8%).

[49] 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

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

As a simplification measure, introduced in 2014, only one grant decision per Member State was taken, covering the eradication and control programmes for all diseases for each Member State. In 2018, DG SANTE reviewed the unit costs for several elements in the Member States' animal disease eradication programmes – a concept which was introduced in 2014[51]. The purpose of the review was to revise the methodology for the calculation of unit costs based on the experience gained form the application of the system of units costs over a three-year period[52].

Table 2.3a) Indicators for grants	***Targets***	**2018**	**2017**	**2016**
Stage 1: Programming and evaluation				
Ratio of rejected national programmes to total programmes submitted: 5 out of 147 programmes for 2019 submitted in 2018 (4 out of 138 in 2017; 5 out of 133 in 2016)	*n/a*	**3%**	3%	4%
Ratio of modified programmes to total programmes retained after evaluation: 98 out of 142 programmes evaluated in 2018 (89 out of 134 in 2017; 92 out of 130 in 2016)	*n/a*	**69%**	66%	70%
Stage 2: Grant Decision on the national programmes and EU funding				
Communication of the list of programmes to be funded by 30/11 in year N for programmes of year N+1 (Art. 13 of the CFF)	*100%*	**100%**	100%	100%
Grant decisions taken on-time by end of January year N+1 for programmes of year N+1 (Art. 13 of the CFF)	*100%*	**100%**	100%	100%

Stage 3: Monitoring national programmes and managing financial transactions

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 2018 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 2017 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)[53]. 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 2018, 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.

[51] Commission Decision C(2014)1035 of 24 February 2014 authorising the use of unit costs under the annual and multiannual programmes for the eradication, control and surveillance of animal diseases and zoonoses

[52] Commission Decision C(2018)2315 of 23 April 2018 authorising the use of unit costs under the annual and multiannual programmes for the eradication, control and surveillance of animal diseases and zoonoses and under the veterinary emergency measures repealing Commission Decision C(2014)1035.

[53] 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.

In 2017/2018, the audit plan had to account for the specific situation arising from the Avian Influenza crisis which occurred in the EU in 2016-2017. Eight Member States submitted cost claims exceeding EUR 2 million and were selected for ex-ante on-the-spot controls. In the six missions already carried out, DG SANTE made the following main observations: the Member States faced difficulties to understand some of the eligibility criteria or did not apply them correctly or lacked sufficiently detailed data to evidence the costs in their claim. Although DG SANTE could not finalise the results of these audits by the end of March 2019, it already took first steps to address the issues found through further clarification and simplification of the eligibility criteria.

Table 2.3b) Indicators for grants	***Targets***	**2018**	**2017**	**2016**
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*	**3**	0	0
Instances of Article 93 FR[54]	*n/a*	**0**	0	0
Percentage of implemented final **commitment** appropriations after global transfers[55]	*99%*	**99,0%**	99,5%	99,6%
Percentage of implemented **payment** credits after global transfers[56]	*100%*	**98,6%**	98,7%	99,3%
Desk ex-ante 2nd-level verification coverage: % of transactions % of total amounts	*10%* *50%*	**20%** **72%**	19% 75%	17% 70%
Desk ex-ante 2nd-level verification: rejection rate % of amounts with financial errors *	*< 2% in value*	**0,0%**	0,2%	0,5%
Late interest payments relative to total value of grants (in 2018: 2 cases of EUR 631,32; in previous years: no cases)	*0%*	**0,0%**	0,0%	0,0%
On-the-spot ex-ante controls: **correction rate** *(average of all corrections)* - Eradication programmes - Veterinary emergency fund - Phytosanitary measures - Other grants	*n/a*	 **-** **-** **-** **0,3%**	 - 11,2% **-**	 27,0% 20,1% 1,9%

* In 2018, one financial error with an impact lower than EUR 500.

The "exception reports" pertain to three cases of non-compliance with a Commission decision[57] or grant decision. In each case, DG SANTE judged that the non-compliance with a legal provision was justified by special circumstances and unforeseen events in the EU Reference Laboratory and the two Member States concerned. The strict application of the grant decision would have put a disproportionately high burden on the beneficiaries. The "exception reports" do not have any bearing on the Director-General's declaration of assurance.

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 21 March 2019.

[54] Article 93 of the FR(2018) on the financial irregularities panel

[55] Annex 3 in 2018 shows a commitment 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 4,9 million with an implementation rate of 81,8%; see section 2.1.1.1.3.

[56] Annex 3 in 2018 shows a payment implementation rate of 98,1% in the Food and Feed Safety policy area as it includes the subsidies to ECHA-biocides (European Chemicals Agency) of EUR 4,9 million with an implementation rate of 81,8%; see section 2.1.1.1.3.

[57] Implementing Decision 2013/722/EU of 29 November 2013

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).

In January 2018, the Directors' Steering Committee of DG SANTE adopted the 2018 audit work plan. 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. However, in 2017/2018, priority had to be given to ex-ante controls on Avian Influenza cost claims. Therefore, the 2018 audit plan included an additional seven ex-ante audits on Avian Influenza files and nine ex-post audits on veterinary programmes.

While ex-ante "on-the-spot" controls were carried out exclusively by DG SANTE's own competent staff, ex-post audits were carried out by both DG SANTE staff (three audits) and by an external audit service provider (six audits).

Of the 16 planned audit missions, 14 were carried out as planned. Two ex-ante audits had to be postponed to 2019 as the files were not ready for audit on time. The changes did not impact on the assurance building capacity of the ex-post control function in 2018 as the planned audit coverage was almost fully achieved. However, due to the priority given to ex-ante controls on Avian Influenza, only seven ex-post audits were finalised in 2018 (for comparison, in the past three years, DG SANTE closed on average 18 ex-post audits per year).

Residual error rate for 2018: 1,9%. No reservation to be made to the declaration of assurance.

The errors detected during the ex-post controls finalised in 2018 resulted in a detected error rate of 2,0% (EUR 0,9 million) for the audited national programmes for animal disease eradication and monitoring of the years 2013 to 2015. The situation in the 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.

Ex-post control in the Food and Feed policy area	2018	2017	2016	2015	2014	2013	2012
Residual error rate	**1,9%**	2,5% (1%)	1,1%	1,2%	0,8%	2,3%	3,4%
Reservation	**No**	No	No	No	No	Yes	Yes

About 5% of the errors detected in audits finalised in 2018 were corrected by mid-March 2019 by issuing recovery orders (EUR 0,05 million). The low recovery rate is due to the fact that several audit reports were finalised only recently.

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[58] below the materiality threshold.

[58] Common Financial Framework 2014-2020 (CFF, Regulation (EU) No 652/2014)

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[59]) and one from the OIE (WAHIS)[60], is technically much more complex than initially planned and will thus not be finalised before 2020.

Table 2.3c) Indicators for grants	***Target***	**2018**	**2017**	**2016**
Stage 4: Ex-post controls				
Ex-post control **detected error rate** (ABB activity: Food and Feed Safety)	*n/a*	**2,0%**	2,7%	1,3%
Ex-post control **residual error rate** (policy area Food and Feed) (Without one exceptional file)	***< 2,0%***	**1,9%**	2,5% (1%)	1,1%
Amount of net financial corrections identified in year N compared with amount of transactions audited	*n/a*	**0,9 M€ 45,3 M€**	2,6 M€ 97,0 M€	0,5 M€ 37,1 M€
Financial corrections in year N linked to audits finalised in year N (until 31/12/2018)	*n/a*	**0,05 M€ 5%**	0,2 M€ 8%	0,4 M€ 72%
Total financial correction of detected errors by 28/03/2019	*100%*	**0,05 M€ 5%**	2,5 M€ 100%[61]	0,5 M€ 100%[62]

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 issues, 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 2018 residual error rate amounts to 1,9% in the policy area "Food and Feed Safety" as a whole. Thus, it does not exceed the materiality threshold of 2%. It has to be noted that the 2018 error rate is based on a relatively low number of audits closed in 2018. As the audit findings are in line with previous years' observations on the same kind of cost claims, DG SANTE believes that it is still possible to conclude on the residual error rate in 2018. For comparison, the relatively high average error rate of 2017 was due to an isolated error in one Member State's cost claim which could not be extrapolated as being 'representative' to the whole policy area Food and Feed.

Against this background, DG SANTE does not consider it appropriate to make a reservation in the Director-General's 2018 declaration of assurance. To reduce the error rate, in the past few years, DG SANTE has taken a series of mitigating actions; their cumulative effect is expected to keep the error rate at an acceptable level.

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

[59] Animal Disease Notification System

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

[61] With regard to 2017, a total of EUR 0,2 million was corrected by late 2017; the remaining amount of EUR 2,3 million was corrected by recovery orders introduced in 2018; EUR 0,1 million were corrected in different ways.

[62] With regard to 2016, a total of EUR 0,4 million was corrected by late 2016; the remaining amount of EUR 0,1 was corrected by a recovery order in June 2018.

controls, and most of the findings were systemic.

The benefits of the controls are mostly unquantifiable in monetary terms. 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. The number and amount of errors detected in ex ante controls and financial corrections and recoveries are only a very small part of the "benefits" of controls.

2.1.1.1.1.2 Public procurement in DG SANTE

The following paragraphs describe the provisions for the management of public procurement in the policy areas Public Health and Food and Feed Safety.

Table 2.4 Procurement in the two policy areas

Commitment credits implemented by DG SANTE *(without CHAF-EA)* [63]	**2018** **M€**	**2017** **M€**	**2016** **M€**
Health Programme implemented directly by DG SANTE[64]	**10,9**	8,9	7,1
Administrative budget of the Health programme implemented by DG SANTE	**1,3**	1,4	1,4
Pilot projects/preparatory actions implemented by DG SANTE through procurement[65]	**0,8**	0,5	0,9
Public Health total	**13,0**	10,8	9,4
Food and Feed Safety: DG SANTE procurement expenditure	**15,4**	23,0	22,6
Administrative budget Food and Feed implemented by DG SANTE	**1,1**	1,3	1,3
Food and Feed Safety total	**16,5**	24,3	23,9
Procurement other policy areas (operational credits mainly)	**3,8**	3,2	0,3
Building expenditure Ireland (administrative credits)	**4,9**	5,2	5,3
Total budget implemented	**38,2**	43,5	38,9

- The third **Programme of the Union's action in the field of health (2014-2020)** was adopted in March 2014[66]. 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[67]. The Commission decided on the specific Public Health work programme for 2018 on 13 December 2017[68] with a total programme budget of

[63] Without credits co-delegated to other DGs.

[64] Without credits cross-subdelegated to other DGs: EUR 1,0 million in 2018 (EUR 0,5 million in 2017; EUR 0,0 in 2016).

[65] In 2018, the preparatory action in the policy area Health (EUR 0,8 million) is implemented by means of a grant agreement rather than procurement. The grant procedure was supported by DG SANTE's central administration of public procurement procedures.

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

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

[68] C(2017) 8350 final

EUR 60,7 million. DG SANTE implemented 20% (EUR 12,2 million)[69] under direct management, almost exclusively through public procurement[70], 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.

In addition to the funds for the Health programme, DG SANTE received in 2018 EUR 0,8 million for one preparatory action which will be implemented under grant management. The procedures for pilot projects and preparatory actions, be it procurement or grant, are supported by DG SANTE's central administration of public procurement procedures (see below).

DG SANTE's commitment credits of the Public Health policy area of 2018 (EUR 12,7 million) and payment credits (EUR 10,2 million) were fully consumed (100%)[71].

- The work programme and the financing for the year 2018 of activities in the food and feed area to ensure the application of the food and feed legislation was adopted on 25 January 2018 (C(2018)296). It foresees EUR 8,8 million for procurement and other expenditure, first and foremost for the purchase of vaccines (if required by the evolution of the epidemiological situation), and also communication activities, evaluations, studies and the reimbursement of experts. The financing decision for IT expenditure in the Food and Feed Safety policy area (C(2018)2829) earmarked EUR 13,8 million for IT services (other expenditure in the Food and Feed policy area is described in section 2.1.1.1 on grants).

- The credits listed under "procurement other policy areas" 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 1,1 million were co-delegated to DG SANTE by DGs AGRI, ENV, MARE and TAXUD mainly for IT services related to the IT system TRACES. Both the commitment and the payment credits were fully consumed (100%).

- The administrative expenditure for Grange, Ireland, (EUR 4,9 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

[69] The remaining 80% of the 2018 work programme for Public Health is implemented by the executive agency CHAF-EA (see section 2.1.1.3 below as well as CHAF-EA's 2018 AAR).

[70] 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.

[71] In the Public Health policy area, Annex 3 shows implementation rates of 91,8% for EUR 198,7 million of commitment credits and 91,7% for EUR 196,9 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 186,0 million commitment credits and EUR 186,7 payment credits with an implementation rate of around 91,5%.

competition. The central team also gives support to all procedures involving pilot projects and preparatory actions, be it through public procurement or through grants. In 2018, 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.

Striving to reduce administrative burden, DG SANTE published all 2018 calls above the Directive threshold (currently EUR 144.000) through the e-tendering platform of the Commission. Preparations to also use e-submission were finalised in mid-2018 after adjustments to the security systems of DG DIGIT were made to better fit DG SANTE's control environment. The tool has been used already for three open calls for tender since October 2018.

Table 2.5 below shows the different types of procurement procedures applied in 2018.

Table 2.5 Procurement contracts above EUR 60.000[72]

Type of procedure	2018		2017		2016	
	N° of contracts	**Amount M€**	***N° of contracts***	**Amount M€**	***N° of contracts***	**Amount M€**
Open (Art. 104(1a) FR 2012)	***2***	**0,7**	*4*	24,8	*2*	0,9
Open (Art. 127.2 RAP, FR 2012)	***2***	**1,1**	*2*	0,6	*3*	2,6
Open (FR 164 (1)(a))	***2***	**1,8**				
Negotiated (Art. 134 RAP)			*3*	9,3	*3*	1,1
Restricted (Art. 104(1) (b) FR 2012)	***1***	**0,3**	*3*	1,2	*2*	2,4
Restricted (Art. 127.2 RAP, FR 2012)	**-**	**-**	-	-	*1*	0,3
Competitive dialogue Art. 104(1) (e) FR)	**-**		-	-	*1*	5,0
TOTAL	***7***	**3,9**	***12***	**35,9**	***12***	**12,3**

Following the open procedure, two direct contracts were awarded in the health policy area (i) a study on exposure of children to marketing of foods high in fat, salt and sugar (EUR 0,8 million); (ii) secretariat to support coordinators European Reference Networks (EUR 0,4 million).

In the policy area Food and Feed Safety a food crisis simulation exercise with Member States was organised under a contract with an external service provider (open call for tender; EUR 0,3 million). In addition, 2018, DG SANTE bought vaccines for lumpy skin disease (EUR 1,7 million) following an open call for tender.

The restricted procedures are typically used for DG SANTE's site management in Grange, Ireland: in 2018, one contract of a total amount of EUR 0,3 million for catering services was awarded. Using an open call for tender, the Grange site also concluded a framework contract for language training services In Grange covering a period from 2018 to 2022 (EUR 0,4 million).

In 2018, as in previous years, DG SANTE made extensive use of framework contracts concluded by itself or other DGs (for example DGs DIGIT and COMM). 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

[72] Annex 3 table 12

2018 the negotiated procedure was not used, in 2017 and 2016 it was applied in 25% of the limited number of cases included in the table above (3 out of 12 in both years). Expressed in amounts, in 2017, 26% of the contract value was awarded through the negotiated procedure; in 2016, the rate was 9% in comparison to 0% in 2018. 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 2018, DG SANTE needed to purchase only one vaccine (lumpy skin disease) for which the open procedure was found adequate.

In 2018, DG SANTE completed its work on the joint procurement of pandemic influenza vaccines. A voluntary cooperation was established[73] enabling participating Member States to purchase jointly medical countermeasures for serious cross-border health threats. Its aim is to improve Member States' preparedness to mitigate serious cross-border threats to health; ensure more equitable access to specific medical countermeasures; and ensure more balanced prices. Work on joint procurement continued in 2018 with a particular focus on the joint procurement of pandemic influenza vaccines, where DG SANTE plays a key role in the tendering and negotiation of the framework contracts. Eighteen (18) Member States and the Commission have joined forces with a view to secure access to pandemic influenza vaccines and improve preparedness for the next pandemic. The calls for tender for the production and supply of pandemic influenza vaccines to 18 participating Member States and the Commission were launched early 2018. Negotiations with the main producers of pandemic influenza vaccines have been concluded or are at the final stage. Signature of the contracts is foreseen to take place in the first months of 2019.

Procurement procedures (open calls for tender and negotiated procedures) for contracts above the Directive threshold (currently EUR 144.000), 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 2018, this voluntary additional check was used in one case (three cases in 2017).

Table 2.6a) Indicators for procurement	***Targets***	**2018**	**2017**	**2016**
Stage 1: Assessing procurement needs and selecting the offer				
Rate of open calls for tenders for which - No offer was received (in 2018: 4 out of 10; in 2017: 1 out of 6) - The procedure had to be cancelled *(1 in 2018; 3 in 2017; 2 in 2016)*	*0%* *0%*	**40%** **10%**	16,7% 50%	0,0% 25%
Rate of negotiated procedures for which - No offer was received - The procedure had to be cancelled	*0%* *0%*	**0,0%** **0,0%**	0,0% 0,0%	0,0% 0,0%
Positive/negative opinions of the Public Procurement Committee (2018: 5 opinions; 2017: 10 opinions; 2016: 15 opinions)	*n/a*	**100%**	100%	93% (1 negative)
Public Procurement Committee opinions followed by the authorising officers responsible	*100%*	**100%**	100%	100%

[73] See the Joint Procurement Agreement to procure medical countermeasures adopted in 2014 pursuant to Article 5 of Decision 1082/2013/EU on serious cross-border threats to health

In 2018, five open calls for tender procedures had to be cancelled: in four cases, no offer was submitted; in another case, DG SANTE did not receive an admissible bid.

In 2018, the Public Procurement Committee provided five opinions on procurement contracts with a total maximum value of EUR 3,7 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 of control procedures for procurement 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***	**2018**	**2017**	**2016**
Stage 2: Monitoring of contract implementat and financial management				
Ex-ante 2nd-level verifications coverage: % of transactions % of amounts	*10%* *50%*	**8%** **44%**	9% 44%	8% 52%
Ex-ante rejection rate of 2nd-level verifications: % of amounts with financial errors (no cases)	*< 2% in value*	**0,0%**	0,0%	0,0%
Late interest payments relative to total value of contracts (in 2018: no cases; *in 2017: no cases; in 2016: 2 cases of a total of €459,25)*	*0%*	**0,0%**	0,0%	0,0%
Percentage of implemented final commitment appropriations	*99%*	**100%**	99%	100%
Percentage of implemented payment credits after global transfers	*100%*	**100%**	96%	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 (latest audit of the IAS dates back to 2016).

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 2018, 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***	**2018**	**2017**	**2016**
Stage 3: Supervisory measures				
Number of registered **"exception reports"** relative to procurement procedures	*n/a*	**2**	6	7
Instances of Article 93 FR[74]	*n/a*	**0**	0	0
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*	**(0)** **n/a**	(1) 0,04 M€	(0) n/a
For procurement: **Ombudsman** cases or legal proceedings open in year N	*n/a*	**0**	0	0

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 21 March 2019. The two "exception reports" of 2018 pertain to non-compliance events (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.

The benefits of the controls are mostly unquantified such as the reduced risk of fraud and prevention of conflict of interests as well as other deterrent effects through a high degree of segregation of duties and independent oversight. The centralisation of the administrative management of public procurement procedures is a control to ensure compliance with rules and regulations as well as good quality of all steps in the procurement procedures.

2.1.1.1.1.3 Budget implementation tasks entrusted to other services and entities

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

[74] Article 93 of the FR(2018) on the financial irregularities panel

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

In 2018, DG SANTE cross-subdelegated a total of EUR 1,0 million of commitment credits to DG ESTAT in the Public Health area and EUR 0,3 million to DG AGRI in the Food Safety area. In addition, DG FISMA received EUR 0,15 million on administrative support credits for IT services related to the IT tool KOEL[75]. No other amounts were cross-subdelegated due to the fact that previous years' cross-subdelegations were replaced by co-delegations.

Table 2.7 Cross-subdelegations

DG	2018 Appropriations		2017 Appropriations		2016 Appropriations	
	Commitments M€	Payments M€	Commitments M€	Payments M€	Commitments M€	Payments M€
ESTAT	**1,00**	**0,13**	0,34	0,20	1,47	-
AGRI	**0,31**	**0,29**	0,20	-	-	-
FISMA	**0,15**	**0,00**				
OLAF	**-**	**-**	0,15	-	-	-
TOTAL	**1,46**	**0,42**	**0,69**	**0,20**	**1,47**	**-**

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 2018, the authorising officers of AGRI, ESTAT and FISMA 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***	***2018***	***2017***	***2016***
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

B) 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[76]) 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.

[75] KOEL: Knowledge Online on European Legislation"

[76] 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 Decisions C(2015)2856 of 4 May 2015 and C(2015)8752 of 11 December 2015.

CHAF-EA is subject to an individual discharge procedure by the European Parliament for the implementation of its own budget (administrative expenditure). The operational budget implemented by the agency stems from the Commission budget and is part of the general discharge given to the Commission.

Table 2.9 Subsidies paid by DG SANTE to CHAF-EA

CHAF-EA (former EAHC)	2018 M€	2017 M€	2016 M€
Subsidy for administrative budget	**5,7**	5,5	5,5
Operational budget transferred from SANTE	**64,1**	63,1	65,1

The control process is divided into three distinct stages, each with specific control objectives (for more detail see Annex 5.2).

Stages 1 and 2: Mandate of CHAF-EA and readiness assessment of the executive agency's control framework towards autonomy

The agency gained full autonomy in 2007. Since then, no re-assessment of the agency's autonomy was necessary. The latest changes of the mandate (delegation act) took place in 2015. Thus, the control stages 1 and 2 were not applicable in 2018.

Stage 3: DG SANTE's monitoring and supervision ("control with the executive agency")

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, in 2018, two persons had 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. The Steering Committee adopted general guidelines for the day-to-day co-ordination between DG SANTE and the agency in February 2013 and revised them in 2016 to accommodate the new situation in which the CHAF-EA became a multi-parent agency. More specific guidelines for certain tasks transferred to the agency complement the general guidelines.

DG SANTE follows up on the agency's consumption of both the administrative and the operational budget. In 2018, no serious control issue came to the attention of DG SANTE that would warrant a financial or reputational reservation in DG SANTE's 2018 Annual Activity Report. However, the following issues requested special attention:

- Although CHAF-EA shows an implementation rate of the 2018 operational budget of the Health Programme of almost 100%, the actual implementation is relatively low: by the end of 2018, only about 35% of the budget delegated to the agency (EUR 46,6 million) represented individual commitments related to grant agreements or procurement contracts. A special monitoring was installed to ensure the full budget will be implemented in a timely manner in 2019.

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. The following observations do not call the Court's opinion into question:

- In its annual report on 2017, the Court of Auditors highlighted as an "emphasis of matter" the agency's lack of an independent accounting officer as a consequence of CHAF-EA's accountant being on long term leave from 1 December 2017 to 20 May 2018. On 13 December 2017, the agency's Steering Committee appointed an administrator as temporary accounting officer, though, this administrator was at the same time deputising the authorising officer by delegation. This contradicted Article 28 of the agency's Financial Regulation, which states that the duties of the authorising officer and the accounting officer shall be segregated and mutually incompatible. As soon as the issue was detected, CHAF-EA withdrew the appointment of the temporary accounting officer. In May 2018, CHAF-EA's accountant resumed her duties and finalised and signed the 2017 accounts. In order to ensure continuity of its accounting services at all times, by late 2018, the agency found a temporary solution by co-operating with another executive agency: in a Memorandum of Understanding, EASME agreed to share the services of accounting officer with CHAF-EA. In addition, CHAF-EA is discussing with DG BUDG to transfer accounting responsibilities related to CHAF-EA's administrative budget to DG BUDG services. DG SANTE has followed the matter closely since late 2017.
- The Court also pointed to the agency's difficulty to attract sufficient competition for low and medium value procurement procedures. In 2017, CHAF-EA did not receive more than one offer in several cases. Following the Court's observation, CHAF-EA has taken measures to ensure more competition by better specifying services, criteria and adequate timing for the submission of offers. As a result, the agency reports having received more than one offer for all procedures launched in 2018.
- The Court observed that in 2017, the agency inadequately documented recruitment procedures. The procedures lacked anonymity and did not respect the set deadlines. CHAF-EA clarified that the observation concerned one recruitment procedure of 2017, and that in 2018, it improved the documentation of its recruitment procedures to the effect that all recruitment procedures managed during 2018 were adequately managed as concerns documentation, transparency and equal treatment of candidates.

In the CHAF-EA's 2018 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 2018 Annual Activity Report: as in previous years, CHAF-EA reported a residual error rate of ex-post controls below the threshold of 2% pertaining to the funds DG SANTE transferred to the agency).

Table 2.10 Indicators of control effectiveness as regards legality and regularity

Executive agency CHAF-EA	***Targets***	***2018***	***2017***	***2016***
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

Executive agency CHAF-EA	*Targets*	*2018*	*2017*	*2016*
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 (€0,89/€5,7 million)	*n/a*	**15,6%**	6,4%	4,7%

In October 2018, DG SANTE finalised the mid-term evaluation of CHAF-EA carried out by an external service provider. The evaluation covered CHAF-EA's operations in the period 2014 to 2016. The main conclusion states that the delegation of the programmes to the Agency was justified in terms of cost-savings and value added. The evaluators pointed to positive results in terms of effectiveness and efficiency of CHAF-EA's operations and an overall coherence in the approach for managing its diverse portfolio of programmes. However, the agency faces some difficulties regarding efficiency due to its small size, its location in Luxembourg and its variated portfolio of programmes. The actual savings of the agency scenario from 2014 to 2016 were only EUR 0,4 million.

The evaluators made five recommendations mainly addressed to CHAF-EA but also to the Commission. Actions are on-going to address them by reviewing the Memorandum of Understanding, adopting the annual work programmes of the EU funding delegated to the agency on a timely basis, further simplifying the administrative arrangements of the delegated programmes, enhancing CHAF-EA's human resources management and improving the information and transfer of knowledge from CHAF-EA to the Commission through better standardised/harmonized reporting, better quality reports/data, more regularly scheduled meetings.

C) EU decentralised agencies

In 2018, 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[77].
  ECDC works to prevent threats to human health from 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[78].
  EFSA provides independent scientific opinions and scientific and technical advice on food and feed safety. EFSA's outputs build the scientific basis for the Commission's decision-making as regards the authorisation of regulated products in the food and feed sectors; and for EU initiatives in all fields which have a direct or indirect impact on food and feed safety, including animal health and welfare, and plant health
- European Medicines Agency (EMA) located in London, UK[79].
  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's scientific opinions are the basis for the Commission's decision-making on the authorisation of medicines. EMA is to a large extent fee-financed.

[77] ECDC was established by Regulation (EC) No 851/2004 of the European Parliament and of the Council

[78] EFSA was established by Regulation (EC) No 178/2002 of the European Parliament and of the Council

[79] 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.

- Community Plant Variety Office (CPVO) located in Angers, France[80].
  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[81].
  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 activities which provide the scientific basis for the Commission's decision-making on the authorisation of biocidal products and approval of active substances. ECHA's biocides activities are partially fee-financed.

In addition, DG SANTE is involved in the governance of Eurofound[82] (lead partner DG is EMPL) and EMCDDA[83] (DG HOME is the lead partner DG), but does not contribute to their running costs.

Table 2.11 EU decentralised agencies – subsidies

EU decentralised agencies	*Number of staff* *			EU contribution		
	2018	***2017***	***2016***	**2018 M€**	**2017 M€**	**2016 M€**
ECDC	***285***	*287*	*291*	**58,1**	58,0	58,2
EFSA	***459***	*463*	*470*	**79,1**	79,2	79,4
EMA[84]	***810***	*799*	*787*	**32,6**	29,3	17,2
CPVO[85]	***51***	*49*	*46*	**n/a**	n/a	n/a
ECHA-biocides[86]	***64***	*59*	*55*	**4,9**	3,9	0,9
Total	***1.669***	***1.658***	***1.673***	**174,7**	**170,4**	**155,7**

* 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 establishment plan posts of agencies have been decreasing slightly over the years 2013 to 2017[87], as foreseen in the Commission's communication on the programming of human and financial resources for decentralised agencies (2014-2020)[88]. 2018 is the first year of an overall increase, mainly due to the workload in EMA and CPVO and the reinforcement of their workforce by additional contract agents in 2017 and 2018.

[80] The CPVO was created by Council Regulation (EC) No 2100/94.

[81] ECHA was set up by Regulation (EC) No 1907/2006 of the European Parliament and of the Council.

[82] 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.

[83] European Monitoring Centre for Drugs and Drug Addiction; the synergies with DG SANTE's work cover addictions and drug use associated communicable diseases.

[84] EMA's total 2018 budget amounted to EUR 337,7 million (in 2017: 322,1 EUR million; in 2016: EUR 324,7 million), mainly financed by fees. The EU contribution is a balancing grant (in 2018: 9,6%; in 2017: 9%; in 2016: 5%).

[85] CPVO does not receive any EU subsidies; its 2018 budget amounted to EUR 16,9 million (2017: EUR 18,8 million; 2016: EUR 18,8 million).

[86] 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 2018 amounted to EUR 10,9 million (in 2017: EUR 11,1 million; in 2016: EUR 7,9 million). The EU contribution is a balancing grant (in 2018: 45%; in 2017: 35%; in 2016: 11%).

[87] The CPVO Administrative Council as the Budgetary Authority of the agency authorized 45 establishment plan posts for 2017 and 2018. This is not in line with the Commission communication COM(2013) 519 final of 10/07/2013 which provides for 44 establishment plan posts in 2017 and 43 in 2018. The Commission had agreed on the postponement of the reduction of one temporary agent post (which means 45 posts in 2017 and 44 in 2018).

[88] COM(2013) 519 final of 10/07/2013. ECHA's biocides establishment plan was not subject to the staff reduction target over 2013-2018 as the biocides activities were in start-up phase during 2014 and 2015 and additional tasks were assigned in 2017 (three more product types becoming eligible).

Compared to 2017, the EU contribution to the agencies' budgets remained relatively stable. The EU contribution to the ECHA-biocides budget fluctuates over the years due to the variations in fee income. In 2016, ECHA's fee income was exceptionally high in response of the market to the Biocidal Products Regulation deadline of 1 September 2016.

The control process is divided into five distinct stages, each with specific control objectives (for more detail see Annex 5.2).

Stage 1: Ensuring the founding Regulation of the agency is free of legal issues

This control applies whenever an agencies' founding Regulation is amended. In April 2018, the Commission adopted a proposal to amend EFSA's founding Regulation.[89] The proposal provides for a targeted revision on the basis of the Commission's Fitness Check of the General Food Law[90] and a successful European Citizens' Initiative[91]. EFSA is assigned new tasks to improve the transparency and increase guarantees for the reliability of scientific studies in the food safety area. The composition of EFSA's Management Board is aligned with the Common Approach on decentralised agencies by including a member from each Member State. At the end of 2018, negotiations of the co-legislators on the proposal are ongoing.

In addition, in November 2018, new legislation on veterinary medicinal products and medicated feed was adopted, which included a Regulation[92] amending EMA's founding act in a targeted way.

Stage 2: Assessing the agency's control framework and financial rules

In December 2018, the Commission adopted a revised Framework Financial Regulation (FFR)[93] for decentralised agencies. DG SANTE commented on the draft FFR and will monitor, in co-operation with DG BUDG, the alignment of agencies' rules to the new FFR in 2019.

Through the Commission representative on the agencies' Management Boards and the Commission Opinions agencies' Single Programming Documents, DG SANTE also monitors the alignment of the agencies' Internal Control Frameworks with the Commission's updated Internal Control Framework adopted in April 2017.[94] Each of the agencies for which DG SANTE is responsible has developed an anti-fraud strategy adopted by the respective Management Boards.

Stage 3: DG SANTE's monitoring and supervision ("control with the agency")

DG SANTE is a member of each agencies' Management Board and participates to the meetings throughout the year (2 two 4 meetings depending on the agency). The role of the Management Boards includes the approval of the agencies' annual budgets as well as the adoption of both the multiannual and annual work programmes and the annual activity reports. They are regularly informed on the achievements of the agencies' objectives as

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89 Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002; COM/2018/0179 final.

90 Commission Staff Working Document – Executive summary of the REFIT evaluation of the General Food Law (Regulation (EC) No 178/2002), SWD(2018) 37 final of 15.1.2018.

91 Ban glyphosate and protect people and the environment from toxic pesticides, ECI(2017)000002, registered on 25.01.2017.

92 Regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, Regulation (EC) No 1901/2006 on medicinal products for paediatric use and Directive 2001/83/EC on the Community code relating to medicinal products for human use, adopted on 26.11.2018.

93 Commission Delegated Regulation of 18.12.2018 on the framework financial regulation for the bodies set up under the TFEU and Euratom Treaty and referred to in Article 70 of Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council, C(2018) 8599 final.

94 Communication to the Commission from Commissioner Oettinger, Revision of the Internal Control Framework, C(2017) 2373 final of 19.4.2017.

well as on all other important issues relating to operational and financial management, internal control, evaluations and audits.

The relevant operational Units in DG SANTE are the primary interlocutors with the agencies. Bilateral meetings take place both at senior management and technical level. A horizontal Unit takes on a coordination role to promote a coherent approach towards all agencies and to exchange good practices, for example, as regards the agencies' rules of "independence" and "conflict of interest". DG SANTE monitored actively compliance with the Commission's guidelines on independence in DG SANTE's task force with the agencies and through bilateral contacts. The annual task force meeting took place on 28 September 2018. In addition to monitoring compliance, DG SANTE identifies and disseminates good practices in collaboration with the agencies.

In June 2018 the IAS closed its 2016 audit on DG SANTE's coordination and working arrangements with EU agencies. No critical issue was raised. In June 2018, the IAS concluded that DG SANTE had adequately and effectively implemented all recommendations, most importantly (1) the Commission's leverage effect on the agencies' programming was reinforced through the annual Commission Opinions on the agencies' Strategic Programming Documents; (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.

Stage 4: Audit and evaluation, discharge

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.

Agencies are subject to periodical external evaluations[95].

- In 2018, the report of the third external evaluation of EFSA for the years 2011-2016 was finalised with the overall conclusion that EFSA had made significant progress in addressing weaknesses identified previously. Nevertheless, the evaluators also found the following main challenge: EFSA's long-term ability to continue to produce scientific advice at the current level and to the same level of quality was found to be threatened by its ability to continue to engage the best possible external expertise. EFSA faces challenges in terms of resource allocation and competing demands for resources. There is limited flexibility in the internal allocation of work and human resources, creating a need to streamline processes and introduce better mechanisms for prioritisation. EFSA's Management Board adopted its analysis of the evaluation and ensuing recommendations in October 2018[96].

- At the end of 2018, external evaluations are ongoing on EMA[97] and ECDC[98].

European Court of Auditors

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 October 2018, 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 2017 accounts as well as for the legality and the regularity of the

[95] According to their Founding Regulations, external evaluations are to be commissioned for ECDC every five years, for EFSA every six years, for EMA every 10 years.

[96] 3rd external evaluation of EFSA – Recommendations from the Management Board, mb181010-a6 https://www.efsa.europa.eu/sites/default/files/MB_Recommendations.pdf .

[97] Study on the operation of centralised procedure and decentralised and mutual recognition procedures for the authorisation and monitoring of medicinal products for human use during the period 2009-2017, final report expected mid-2019.

[98] 3rd external evaluation of ECDC, final report expected in mid-2019.

underlying transactions. The comments made by the Court on weaknesses in grant procedures of CPVO, procurement procedures of CPVO and EFSA and the independence of the accounting officer of EFSA and EMA did not call the positive declarations into question. The agencies drafted action plans to implement the Court's audit recommendations and reported on the progress made[99].

In its annual report on EMA, the Court pointed to the change of the agency's seat from London to Amsterdam[100]. EMA included provisions of EUR 18,6 million into its 2017 accounts for the move to temporary premises. The lease agreement for EMA's premises in London sets a rental period until 2039 with no exit clause. The notes to the accounts disclose a contingent liability of EUR 465 million corresponding to the remaining rent during the lease period after the Agency's move to Amsterdam.

Discharge

In April 2018, taking into account the Court of Auditors reports on the agencies annual accounts 2016, the European Parliament granted the four agencies which receive a subsidy from the EU budget discharge in respect of the 2016 budget implementation.

DG SANTE, within the limits of its role on the EU agencies' Management Boards and Audit Committees, if applicable[101], follows up closely the improvements to be made by the agencies in follow-up to audits, evaluations and discharge recommendations.

Stage 5: DG SANTE's payments of the subsidy

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).

Further to the Court of Auditors assurance received in October 2018, DG SANTE cleared all pre-financing payments made to the agencies in 2017 and made the final payments of the 2017 subsidies. Thus, no reservation to DG SANTE's declaration of assurance is warranted.

[99] In 2018, the Court of Auditors made the following observations in its report on the agencies' 2017 accounts:

EFSA: The Court asked to strengthen the accounting officer's independence, to favour framework contracts with reopening of competition where appropriate, and pointed to the Internal Audit Service's (IAS) 2017 audit report on "The process for Evaluation of Regulated Products: Assessment Phase in Pesticides Authorisation." At the end of 2018, all recommendations were implemented, except for two recommendations with target dates in June 2019.

ECDC: For the first time in several years, the Court made no comment on ECDC's financial statements and internal control. All corrective actions to follow up on previous years' comments were completed.

EMA: In the report on EMA's 2017 annual accounts, the Court noted that EMA implemented measures to improve the procurement procedures, including IT project development and implementation. Their impact is to be seen over the years. EMA had not yet introduced e-invoicing and e-submission. The Court also pointed to the Internal Audit Service's 2017 report on "Implementation of the pharmacovigilance fees Regulation". EMA has prepared an action plan to follow-up to this IAS audit.

ECHA: The Court made no observations related to ECHA's biocides activities.

CPVO: The Court pointed to weaknesses in the documentation of procurement and grant award procedures and noted that CPVO had not introduced any e-procurement tools. CPVO agreed to improve documentation and entered a contractual arrangement with the Commission for the provision of e-submission.

[100] On 20 November 2017, the General Affairs Council of the European Union agreed to move the seat of EMA to Amsterdam, The Netherlands.

[101] 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.

Table 2.12 Indicators of control effectiveness as regards legality and regularity

EU decentralised agencies	*Targets*	2018	2017	2016
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 (€17,0/€175,6 million in 2018)	*n/a*	**9,7%**	8,0%	13,9%

Conclusion on legality and regularity of subsidy payments to agencies

For the 2018 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 2018, the Court of Auditors gave a positive declaration of assurance for the year 2017. 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. Consequently, in view of DG SANTE's residual responsibility for the management of the 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 objective as regards legality and regularity.

The benefits resulting from the controls are not quantifiable. Examples of unquantified benefits are the reduced risk of fraud and deterrent effects of the audits by the Court of Auditors and the Commission's Internal Audit Service (IAS) as well as DG SANTE's following-up on the agencies' Internal Control Frameworks, including the agencies' anti-fraud strategies and policies to prevent "conflicts of interest".

2.1.1.1.1.4 Conclusion on legality and regularity in transactions

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*[102] for the 2018 payments (EUR 441,3 million) is between EUR 4,6 and 5,9 million. This is the authorising officer's best, conservative estimate of the amount of *relevant expenditure*[103] during the year not in conformity with the applicable contractual and regulatory provisions at the time the payment is made[104].

[102] In order to calculate the weighted average error rate (AER), the detected or equivalent error rates have been used; see note (6) to table 2.13.

[103] "*relevant expenditure*" during the year; see note (5) to table 2.13.

[104] "*payments made*" or equivalent, see note (2) to table 2.13.

This expenditure will 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[105] for those 2018 payments made are EUR 1,5 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*[106] for the 2018 payments between EUR 3,1 and 4,4 million.

Table 2.13 – Estimated overall amount at risk at closure

(1) Type of expenditure[107]	**Grants - relevant expenditure (Food and Feed)**	**Procurement and other expenditure (Public health/ Food and Feed)**	**Subsidy payments to Agencies**	**Overall/ Total**
(2) Total payments made as per AAR annex 3, table 2[108]	216,9 M€	43,1 M€	181,3 M€	**441,3** M€
(3) Minus new prefinancing[109]	-10,6 M€	-0,1 M€	-186,1 M€	**-196,8** M€
(4) Plus cleared prefinancing[110]	17,9 M€	0,1 M€	162,8 M€	**180,7** M€
(5) Relevant expenditure = (2) – (3) + (4)[111]	**224,2** M€	**43,1** M€	**157,9** M€	**425,1** M€
(6a) Weighted average error rate (detected; lower limit) in %[112]	2,0%	0,5%	0,5%	**1,1%**
(6b) Weighted average error rate in % (detected; upper limit)	2,0%	2,0%	0,5%	**1,4%**
(7a) Estimated overall amount at risk at payment (lower limit) = (5) * (6)	4,5 M€	0,2 M€	1,0 M€	**4,6** M€
(7b) Estimated overall amount at risk (upper limit) = (5) * (6)	4,5 M€	0,9 M€	1,0 M€	**5,9** M€
(8) 7-year average recovery/corrections as % of relevant payments[113]	0,8%	0,5%	0,5%	**0,3%**

[105] "*estimated future corrections*" see note (8) to table 2.13.

[106] "*estimated overall amount at risk at closure"* see note (10) to table 2.13.

[107] (1) Type of expenditure differentiated for DG SANTE's relevant portfolio segments, i.e. grants, procurement and subsidy payments

[108] (2) Payments made, such as after the expenditure is registered in the Commission's accounting system, after the expenditure is accepted or after the pre-financing is cleared. In any case, this means after the preventive (ex-ante) control measures have already been implemented earlier in the cycle. In all cases of co-delegations (Internal Rules Article 3), the "payments made" are covered by the delegated DGs. In the case of cross-subdelegations (Internal Rules Article 12), they remain with the delegating DGs.

[109] (3) New pre-financing actually paid out by the department itself during the financial year (i.e. excluding any pre-financing received as transfer from another department). The "pre-financing" is covered as in the context of note 2.5.1 to the Commission (provisional) annual accounts (i.e. excluding the "other advances to Member States" (note 2.5.2) which is covered on a pure payment-made basis). "Pre-financings paid/cleared" are always covered by the delegated DGs, even in the case of cross-subdelegations.

[110] (4) Pre-financing actually having been cleared during the financial year (i.e. their 'delta' in FY 'actuals', not their 'cut-off' based estimated 'consumption').

[111] (5) For the purpose of equivalence with the Court of Auditors' scope of the EC funds with potential exposure to Legality and Regularity errors (see the Court's 2017 Annual Report methodological Annex 1.1 point 15), also the Commission's concept of "relevant expenditure" includes the payments made, subtracts the new pre-financing paid out, and adds the previous pre-financing actually cleared during the financial year. This is a separate and 'hybrid' concept, intentionally combining elements from the budgetary accounting and from the general ledger accounting.

[112] (6) In order to calculate the weighted Average Error Rate (AER) for the total relevant expenditure in the reporting year, the detected error rates were used – or equivalent. For types of low-risk expenditure with indications that the equivalent error rate might be close to 'zero' (e.g. administrative expenditure, operating subsidies to agencies), an error rate of 0,5% was used as a conservative estimate.

(1) Type of expenditure[107]	Grants - relevant expenditure (Food and Feed)	Procurement and other expenditure (Public health/ Food and Feed)	Subsidy payments to Agencies	Overall/ Total
(9) Estimated future corrections = (5) x (8)	1,8 M€	0,2 M€	1,0 M€	**1,5** M€
(10a) Estimated overall amount at risk at closure = (7) – (9)[114]	2,7 M€	0,0 M€	0,0 M€	**3,1** M€
(10b) Estimated overall amount at risk at closure = (7) – (9)	2,7 M€	0,6 M€	0,0 M€	**4,4** M€

2.1.1.1.2 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 last updated in July 2017.

The internal control officer monitored the implementation of the associated action plan (2017-2020) and reported the results to DG SANTE management twice a year, at mid-term and at year-end.

Especially important to DG SANTE are the following permanent tasks well embedded in existing procedures:

- Continued awareness raising in DG SANTE's decentralised financial cell network and through promoting ethics training, in particular on how to deal with lobbyists;
- Actions linked to handling "conflict of interest" in agencies, scientific committees and expert groups;
- Active participation in the network "Fraud Prevention and Detection" (FPD) chaired by OLAF and systematic feedback given to DG SANTE staff concerned;
- Standing operating procedures for the handling of allegations of fraud, other irregularities and OLAF cases.

The controls to prevent and detect fraud are basically the same as those intended to ensure the legality and regularity of the transactions. In 2018, DG SANTE looked into the risk of fraud in the context of its update of the comprehensive sensitive post analysis carried out in July/August and adopted by the Management Board in October 2018. Risk of fraud is also included in the annual risk management exercise finalised in November 2018. The fraud risks are addressed by specific controls designed and implemented to mitigate the risks.

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113 (8) Even though to some extent 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 DG SANTE over the past years, the DG adjusted this historic average from 2,8% to 0,35%. The figure 0,35% only includes recoveries and corrections based on ex-post controls while the historic average also includes differences between the registered cost-claim/invoice and the actual payments made that are not corrections stemming from ex-post controls.

Any ex-ante elements, one-off events, (partially) cancelled or waived Recovery Orders, and other factors from the past years that would no longer be relevant for current programmes (e.g. higher ex-post corrections of previously higher errors in earlier generations of grant programmes, current programmes with entirely ex-ante control systems) were adjusted in order to come to the best but conservative estimate of the ex-post future corrections to be applied to the reporting year's relevant expenditure for the current programmes.

114 (10) For some programmes with no set closure point (e.g. EAGF) and for some multiannual programmes for which corrections are still possible afterwards (e.g. EAFRD and ESIF), all corrections that remain possible are considered for this estimate.

Table 2.19 Indicators for fraud prevention and detection

Indicators for fraud prevention and detection	*Targets*	*2018*	2017	*2016*
Update of the current anti-fraud strategy	*2020*	**n/a**	Adopted in July 2017	-
% of actions listed in SANTE's anti-fraud action plan (2017-2020) without delays in the implementation phase Milestones in 2018: 31 actions (of which 30 permanent and 1 new task) Milestones in 2017: 13 actions; Milestones in 2016: 5 actions	*100%*	**90%**	77%	40%
% of financial officers reached in financial cell network meetings	*100%*	**100%**	100%	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

The updated action plan covers the years 2017 to 2020 and includes the actions from the previous action plan that needed to be finalised or continued as well as new actions. Relevant for the monitoring in 2018 were 30 permanent tasks and one new action. The new action was the update of the sensitive post analyses which was carried out as planned in mid-2018. Three actions had to be postponed to 2019 due to other priorities. As they pertain to updates or renewals of existing arrangements, the delay did not have an important impact on the anti-fraud strategy as a whole. The action on legislative fraud proofing in non-financial contexts had to be suspended as it became much more complex than expected. DG SANTE remains in contact with other DGs and OLAF on these issues.

During the reporting year, DG SANTE transmitted one file with suspicions of fraud to OLAF that implied potential effects on DG SANTE's budget. OLAF assessed the information provided by DG SANTE and dismissed the case on the grounds that there is not sufficient suspicion to justify the opening of an OLAF investigation.

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 2018.

2.1.1.1.3 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 10,4 million at 31 December 2018. The assets pertain to antigen stocks for food and mouth disease in order to carry out emergency vaccination. No other vaccines or antigens were in stock at the end of 2018.

The Common Financial Framework[115] 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[116].

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

[116] 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)

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)[117]. The contractors' 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 2018 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 10,4 million vaccines stocks, was ensured throughout the year as stated in the reports received by the contractors.

2.1.1.2 Efficiency = the Time-to-indicators and other efficiency indicators Economy = the cost of controls Conclusions on cost-effectiveness of controls

This section outlines the indicators used to monitor the efficiency and economy of the control systems. The main indicators monitored in 2018 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 2018 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 effectiveness, efficiency and economy of the control system and reached a positive conclusion on the control efficiency in its grant management.

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

Table 2.14 Efficiency = the Time-to-indicators and other efficiency indicators related to grant management

Indicators per stage of the grant procedure	*Targets*	2018	2017	2016
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%*	**(83%) 84%**	(97%) 95%	(97%) 99%
Average payment time[118]	*90 days*	**60 days**	48 days	52 days
Stage 4: Ex-post controls and error corrections				
Timely implementation of the annual ex-post control work programme (14 audit visits carried out in 2018; 19 audits in 2017; 19 in 2016)	*100%*	**88%**	95%	95%
"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*	**55 days**	58 days	64 days

In 2018, DG SANTE's payments made on time for grants were below the target. The relatively high number of late payments was due to a combination of factors amongst which a significant shortage of human resources (4 out 20 posts could not be filled) coupled with a high work load due to the Avian Influenza crises. Thanks to corrective measures taken, the situation has improved since early 2019.

Other than the payment delays, 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.

Table 2.15 Economy = the cost of controls related to grant management

Indicators per stage of the grant procedure (average FTE times standard annual costs) [119]		**2018 M€**	**2017 M€**	**2016 M€**
Stages 1 and 2: Programming, evaluation and operational monitoring				
Cost of operational staff in the policy Units concerned	2018: FTE: 7,1	**1,0**	1,0	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	2018: FTE: 9,2	**1,0**	1,0	1,0
Cost of staff involved in second-level ex-ante and other internal controls of the central financial Unit	2018: FTE: 1,8	**0,2**	0,3	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	2018: FTE: 3,9	**0,6**	0,5	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**	3,0	2,8

[118] 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.

[119] FTE = full time equivalent; standard annual costs 2018: EUR 143.000 for officials and temporary agents; EUR 74.000 for contractual staff according to DG BUDG circular note to the RUF of December 2017.

Indicators per stage of the grant procedure (average FTE times standard annual costs) [119]	2018 M€	2017 M€	2016 M€
Budget spent on "grants" ("benefit" of the controls)	**245,0**	218,3	213,1
Total cost as % of total annual budget (commitment appropriations)	**1%**	**1%**	**1%**

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 2018 Unit Management Plans which were discussed within the Directorates and approved at the level of the Directorate-General.

Main cost-drivers are the relatively high amount of annual national programmes (around 145) to evaluate and monitor every year. In addition, more than 30 emergency files for veterinary and plant emergency measures of the Member States had to be treated. Both the programmes and the emergency files are quite diverse and complex from a technical and financial point of view entailing a high workload for operational and financial staff in the policy Unit.

Several simplification measures apply since 2013, for example, the introduction of unit costs for several elements in the Member States' animal disease eradication programmes[120]; 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.

Conclusion on cost effectiveness of controls related to grants

The control strategy for grants in direct management is considered cost-efficient overall.

DG SANTE quantifies the costs of the resources and inputs required for carrying out the controls described in Annex 5.1. 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.

Analysing the evolution of the efficiency and timeliness indicators over time and taking the simplification measures of the past few years into consideration, DG SANTE believes that the cost of control cannot be reduced below 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 and will maintain the control strategy in this regard.

2.1.1.2.2 Public procurement in DG SANTE

Based on an assessment of the most relevant key indicators and control results, DG SANTE has assessed the effectiveness, efficiency and economy of the control system and reached a positive conclusion on the control efficiency of its public procurement procedures.

[120] Commission Decisions C(2014)1035 of 24 February 2014 repealed by C(2018)2315 of 23 April 2018

Table 2.16 Efficiency = the Time-to-indicators and other efficiency indicators related to procurement

Indicators on control efficiency in procurem	*Targets*	2018	2017	2016
Stage 1: Rate of timely launched procurement procedures as specified in the annual work programmes	*100%*	**72%**	61%	85%
Stage 2: Average payment times	*30 days*	**16 days**	18 days	24 days
Ratio of payments made on time (in number) in amount	*95%*	**(99%) (99%)**	(95%) (99%)	(87%) (98%)
Stage 3: "Time to recover": average days from information/confirmation date to issuing the debit note (in 2018: 1 case; in 2017: 1 case; in 2016 no case related to procurement)	*n/a*	**29**	27	n/a

DG SANTE did not face any undue delays in its procedures related to public procurement in all policy areas including the administrative budget.

Table 2.17 Economy = the cost of controls related to procurement

Indicators for procurement (average FTE times standard annual costs) [121]		**2018 M€**	**2017 M€**	**2016 M€**
Stages 1 and 2: ex-ante controls				
Cost of operational staff in the policy Units concerned	2018: FTE: 5,2	**0,7**	0,5	0,5
Cost of staff involved in the CMP activities	2018: FTE: 0,1	**0,01**	0,03	0,03
Cost of staff involved in 2nd-level ex-ante and other internal controls of the central financial Unit	2018: FTE: 1,8	**0,2**	0,3	0,2
Cost of central staff involved in procurement and financial procedures	2018: FTE: 10,9	**1,5**	1,4	1,1
Stage 3: ex-post controls				
Cost of DG's internal staff dealing with on-the-spot controls	2018: FTE 0,0	**0,0**	0,0	0,0
Total annual cost (without overhead rate)		**2,4**	2,2	1,8
Budget spent on "procurement" ("benefit" of the controls)		**38,2**	43,5	38,9
Total cost as % of total annual budget spent through procurement (commitment appropriations)		**6%**	**5%**	**5%**

The table above 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 2018 Unit Management Plans which were discussed within the Directorates and approved at the level of the Directorate-General.

Main cost-drivers are firstly, the highly regulated public procurement procedures requiring in-depth knowledge and experience of staff to ensure compliance and good quality of each process; secondly, open calls for tender for new tasks and actions in technically complex environments entailing a relatively high workload for drafting tender specifications; thirdly, the high number of relatively small-value contracts increasing the work load indicator "cost over budget spent".

[121] 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

Conclusion on cost effectiveness of controls related to procurement

The control strategy for public procurement in direct management is considered cost-effective overall.

DG SANTE quantifies the costs of the resources and inputs required for carrying out the controls described in Annex 5.1. DG SANTE analyses the evolution of the efficiency and timeliness indicators over time to reach a conclusion as of the relative efficiency of the controls.

Through the centralisation of the administrative management of procurement procedures DG SANTE improved the quality of its procedures and their documentation. Common guidelines and the use of e-tender and e-submission streamlined some important elements. Therefore, DG SANTE believes that the cost of control cannot be reduced below 6% of the annual budget spent through procurement, if the number and size of contracts remain relatively stable over time. Therefore, DG SANTE reached a positive conclusion as to the relative efficiency of the controls of the procurement procedures and will maintain the control strategy in this regard.

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 effectiveness, efficiency and economy 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 Directorates and approved at the level of the Directorate-General.

Table 2.18 Economy = the cost of controls related to entrusted entities

DG SANTE's cost of monitoring the agencies in relation to the subsidies paid (average FTE times standard annual costs)[122]		**2018 M€**	**2017 M€**	**2016 M€**
Cost of staff in the central Unit ensuring co-ordination within DG SANTE and with the agencies	2018: FTE 2,5	**0,3**	0,1	0,2
Cost of operational staff involved in monitoring the operations of the agencies	2018: FTE 3,7	**0,5**	0,7	0,7
Cost of staff involved in budgetary, financial, audit matters, evaluation of the agencies and other internal controls	2018: FTE 1,8	**0,2**	0,3	0,2
Total annual cost (without overhead rate)		**1,0**	1,1	1,1
Subsidies paid to the agencies		**180,4**	175,9	161,2
Total cost as % of total annual subsidies paid		**0,6%**	**0,6%**	**0,7%**

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

[122] 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.

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.

Main cost-drivers are the work intense yearly exercises of drafting the Commission opinions on the agencies' Strategic Programming Documents (SPDs), DG SANTE's preparations and attendance of Management Boards and, where applicable, Audit Committees, and the follow-up of the regular external evaluations of the agencies.

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 the cost-effectiveness of controls related to "entrusted entities"

The control strategy for entrusted entities in indirect management is considered cost-efficient overall.

DG SANTE quantifies the costs of the resources and inputs required for carrying out the controls described in Annex 5.2. Analysing the evolution over time of DG SANTE's supervisory role and related monitoring costs, DG SANTE believes that its cost of control cannot be reduced below 1% of the annual budget spent on the subsidies to agencies.

Therefore, DG SANTE reached a positive conclusion as to the relative efficiency of the controls and will maintain the control strategy in this regard.

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

2.1.2.1.1 Court's audits of 2018

(1) 2017 DAS – compliance audit

In 2018, the Court finalised its annual report (2017 DAS) on the implementation of the 2017 budget. The structure of the Court's annual 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

In 2018, the Court of Auditors carried out five audits: on animal welfare, on food safety, on organic products, on cross-border health care access and on anti-microbial resistance (AMR).

By the end of March 2019, the Court published three special reports (on animal welfare, on food safety and on organic products) and submitted the draft audit report on cross-border health care access. The audit on AMR was still on-going in March 2019. First results are expected in late 2019.

In its special reports, the Court did not raise any critical issue neither for the Commission nor for the Member States (see detail below).

(2.1) Special report on animal welfare (SR 2018/31) of 14 November 2018

The Court started this audit in March 2017 and published the report in November 2018. The Court's conclusions do not contain any critical issue neither for the Commission nor for the Member States.

The audit examined the welfare of farm animals and the overall implementation of the latest EU strategy of 2012, focusing on the strategy's two key objectives: to achieve compliance with the minimum standards and to optimise synergies with the CAP (DG AGRI was associated to this audit).

The Court concluded that EU actions on animal welfare have improved compliance with animal welfare requirements and supported higher standards with a clear positive impact on animal welfare. However, certain weaknesses persist in some areas related to welfare issues on the farm (in particular, the routine tail docking of pigs), during transport and at slaughter (use of the derogation for slaughter without stunning and inadequate stunning procedures). In addition, Member States took a long time to address some of the recommendations made by the Commission following its audits.

The Court addressed five recommendations to DG SANTE. DG SANTE accepted all recommendations and will address them by (i) carrying out an evaluation of the 2012 strategy; (ii) on the basis of the evaluation results, considering the need for a new strategy, with a possible review of the legislation; (iii) defining baseline and target indicators to measure Member States' degree of compliance; (iv) enhancing its procedures for the monitoring and enhancement of all food and health legislation, which covers the follow up to recommendations arising from DG SANTE's audits in Member States; (v) determining, together with Member States, possible improvements in the TRACES system to support the preparation of the Member States' risk analyses for inspections on the transport of live animals.

In early 2019, DG SANTE drafted an action plan to implement all recommendations by the end of 2021. Several actions have already been launched: DG SANTE initiated a two-year project (2019-2020) which includes, as specific objective, to identify indicators for animal welfare at farm level. The Commission intends to establish a new reporting template for farm animal welfare from 2020 that will incorporate these indicators and will serve to define the baseline. A new reporting template for welfare during transport is also being developed and is expected to be available in 2020. In addition to its established and on-going audit follow-up cycle, DG SANTE is reviewing regularly open recommendations to identify cases where enforcement actions would be appropriate. This will improve the effectiveness of the follow-up system. A dedicated function was created to coordinate enforcement in relation to the Commission's audit recommendations addressed to Member States.

(2.2) Special report on food safety (SR 2019/02) of 15 January 2019

The audit on food safety started in September 2017 and focussed on "chemical hazards" in food. The subject of the audit was to examine whether the EU food safety model is based on sound principles, and whether the way it is implemented is effective in keeping the products we consume in the EU safe.

The Court published its audit report in January 2019 with the main message that the EU food safety model is soundly based and respected worldwide. However, the Court also found that the model is currently over-stretched, as the Commission and Member States do not have the capacity to implement it fully.

The audit report makes three recommendations: (i) to assess potential changes to the legislation governing chemical hazards in the light of the capacity to apply it consistently and further encourage complementarity, so that Member State public authorities can rely more extensively on checks carried out by the private sector; (ii) to explain what action the Commission will take on pesticide residues in food to maintain the same level of assurance for both EU produced and imported food while remaining compliant with WTO rules; (iii) to give Member States further guidance on the application of enforcement measures and enhance its procedures for monitoring compliance with EU food rules and put into action the opportunities it has identified to enhance its procedures for monitoring compliance with EU food rules.

DG SANTE accepted all three audit recommendations. Actions are already on-going, for example, in the framework of the ongoing REFIT exercise on the pesticides legislation; the Commission's legislative proposal amending the General Food Law addresses, amongst others, the sustainability of the EU risk assessment in the food chain, and more specifically the scientific capacity of the EFSA; in addition, DG SANTE is working to enhance its procedures for the monitoring and enforcement of all food and health legislation which will cover the follow up to recommendations arising from Commission audits. Full implementation is planned for late 2020.

(2.3) Special report on organic products (SR 2019/04) of 14 March 2019

The audit on "organic products" was actually an extended follow-up audit of a previous audit of the Court finalised in 2012 to examine whether the control system governing the production, processing, distribution and import of organic products can provide confidence in organic products.

The audit started in DG SANTE in September 2017 with DG AGRI as lead service and DG SANTE involved with its audit activities in the Member States and third Countries. The Court published the final audit report with the Commission replies on 14 March 2019.

The Court found that the control system had improved and that the previous audit recommendations of 2012 had generally been implemented. However, the Court also found that some challenges remained and recommended improving the supervision of imported organic products through better cooperation as well carrying out more complete traceability checks. One recommendation was addressed directly to DG SANTE: to follow-up on the remaining weaknesses the Court found in the Member States' control systems. DG SANTE accepted this recommendation and actions are already on-going. DG SANTE's procedures for follow up of audit recommendations foresee that Member States provide action plans addressing the shortcomings in the relevant national control system and provide evidence that they are implemented. The remaining weaknesses identified by the Court of Auditors will be taken on board in the frame of this exercise or treated in targeted actions (bilateral discussion, and trainings).

(2.4) Special report on cross-border health care access, including eHealth

The audit on cross-border health care started in September 2017 and is still on-going. The subject of the audit was to examine whether the implementation of the Directive to date has been effective, and whether cross-border healthcare is delivering benefits to patients. The Court looked into the Commission's monitoring and supervision of the implementation of the Directive, the results achieved to date, and the effectiveness of the EU funding framework and the actions funded. Priority areas were eHealth and rare disease treatment. DG SANTE was the lead DG with CHAF-EA and DGs CNECT and JRC associated.

The Court submitted its draft audit report on 22 February 2019. As discussions with the Court were still on-going in March 2019, it is too early to say what the Court will conclude on DG SANTE's activities in the area of cross-border health care access and eHealth. The report is scheduled for publication in early June 2019.

(2.5) Special report on Antimicrobial Resistance (AMR) – audit fieldwork on-going

In June 2018, the Court started its audit on the EU actions to fight antimicrobial resistance (AMR). The auditors plan to assess whether the Commission and relevant agencies manage well key activities and resources to support Member States and EU research aimed at fighting antimicrobial resistance (AMR). The audit will focus on the One Health Action Plans, on the EU framework for monitoring antimicrobial resistance and consumption in the animals sector, and on the Commission and agencies' coordination, targeting and evaluation mechanisms for EU support to AMR research.

The Court plans to finalise its audit work on AMR in late 2019 and to publish its report in the first quarter of 2020.

2.1.2.1.2 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 was the lead DG for a total of 23 recommendations still open at 1 January 2018. Eleven have been closed in 2018 and 12 have deadlines in 2019 and 2020.

(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.

In 2018, only one recommendation remained open: 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[123].

(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 and two discharge recommendations by the Parliament were addressed to DG SANTE. DG SANTE implemented twelve recommendations in 2017 and 2018, mainly having (a) developed a strategic roadmap for the Health Security Committee; furthermore, DG SANTE contributed to an action plan for the HSC on preparedness and the implementation of the International Health Regulations; (b) upgraded the Early Warning Response System

[123] 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).

in full co-operation with the ECDC and the Member States ; (c) established a more structured coordination between different Commission services for health security activities. Most of the actions took longer than expected due to the broad co-ordination work between the Commission and the Health Security Committee, working groups and networks.

Still open are two recommendations: (1) actions to improve the sustainability of the results from co-funded actions for health threat protection under the third programme of the Union's action in the field of health (2014-2020) are on-going since several years and will continue until the end of the programme in 2020; (2) one action is well advanced but delayed as the development of two Standard Operating Procedures with other services and WHO proved to be more complex than initially planned.

(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 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 were 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. A total number of ten recommendations (three from the Court and seven from the Parliament) were 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 from late 2018 to late 2020. All actions are on-going and refer to long-term measures developed by the Commission in close co-operation with the Member States. Although no recommendation could be closed in 2018, many milestones have already been achieved. The integrated action plan to tackle food waste published as part of the Circular Economy Package was developed jointly by concerned services of the Commission and has been implemented according to the timetable laid down in the Circular Economy Action Plan:

- The EU Platform on Food Losses and Food Waste (established in 2016) has, as of end December 2018, met five times in plenary and four dedicated sub-groups have been established to address key issues ("food waste measurement", "food donation", "action and implementation" and "date marking and food waste prevention").
- The revised Waste Framework Directive, adopted on 30 May 2018, introduces new obligations for Member States to reduce food waste levels at each stage of the food supply chain, in line with Sustainable Development Goals, and to monitor and report annually on food waste levels.
- On 16 October 2017 the Commission adopted the EU guidelines on food donation and on 13 April 2018 the guidelines for the feed use of food no longer intended for human consumption to clarify relevant EU legislation without compromising on food and feed safety.
- In order to support food business operators in adopting safe food donation practices and complying with EU rules on food hygiene, the Commission requested a scientific opinion from the European Food Safety Authority. The opinion, published in October 2018, proposes simplified food safety management systems in order to help food business operators including food banks and other charities in managing possible risks associated with food donation. The

Platform's sub-group on food donation met twice in 2018 and is preparing a document illustrating how EU rules are implemented at national level to facilitate food donation (expected publication in June 2019).

- In January 2018, a Pilot Project on food redistribution was launched in order to further investigate existing regulatory, policy and operational frameworks in the context of food redistribution in the EU and facilitate the dissemination of the EU guidelines on food donation and engagement with stakeholders in the EU28. By the end of 2018, preliminary analysis on policy, regulatory and operational frameworks were provided. The Pilot Project is expected to be finalised in the first quarter 2020.
- In February 2018, DG SANTE published the market study on date marking and other information provided on food labels and food waste prevention. In April 2018 the Commission established a sub-group of the EU Platform on Food Losses and Food Waste to consider the recommendations of the study and define a coordinated action plan needed to address date marking in relation to food waste prevention. Technical guidance to facilitate more consistent date marking practices by food business operators and control authorities is under preparation for possible adoption in 2019.

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 2018.

2.1.2.2.1 IAS limited conclusion on 2018

The IAS contributed to DG SANTE's Annual Activity Report for 2018 by submitting a "limited conclusion on the state of internal control" on 15 February 2019. Based on the audit work performed in the period 2016 to 2018, the IAS points to four open recommendations rated 'very important', and as a result concludes that "the internal control systems in place for the audited processes are effective, except for the observations giving rise to the 'very important' recommendations" as listed below.

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 below.

(1) IT audit on TRACES: two 'very important' recommendations open at 31/01/2019

The IAS issued the final audit report on 27 June 2018. The objective of the audit was to assess whether the IT tool TRACES[124] is adequately managed to provide and maintain over time, a reliable and efficient service supporting official controls and trade operations. The audit covered issues of IT governance, IT security, business continuity, project management and operations. The IAS made four recommendations: two recommendations were rated "very important" and two "important". DG SANTE accepted all recommendations and produced an action plan. Several actions are already on-going with deadlines in late 2019 or 2020[125].

DG SANTE believes that thanks to the mitigating measures already in place the effectiveness of DG SANTE's internal control system into question.

[124] TRAde Control and Expert System (TRACES) established by Commission Decision 2004/292/EC pursuant to Council Directive 90/425/EEC

[125] Full implementation of DG SANTE's action plan depends on the application of the new control regulation (Regulation (EU) 2017/625) on 14 December 2019. By this date the use of TRACES will be officially covered by an active legal base and its usage will be mandatory for the business process supported by DG SANTE.

The main IAS conclusions and DG SANTE actions are the following:

Recommendation 1 on IT governance

- IAS observations: The IAS found that under the current governance arrangements, DG SANTE did not have a High Level IT Steering Committee at DG or DDG level and no formal body or committee at TRACES that would bring together the various DGs using TRACES to discuss and agree key strategic IT issues. Furthermore, the project steering committees for each TRACES domain still had to be formally established. Although some working arrangements had been set up with other DGs, they were not fully consistent and were lacking clear criteria for charging back and sharing costs. In addition, the information reflected in GovIS2 (tool for reporting to the Commission IT governance bodies) as regards structure, ownership and budget was not fully consistent and complete.
- DG SANTE started implementing the recommendation on TRACES governance; work is on-going as regards TRACES steering committee and project steering committees. In addition, as regards food and feed safety, DG SANTE has set up a Working Group with the Member States to work on an IMSOC implementing act on the functioning of the IMSOC[126] ; this Working Group is actually the primary governance body for the certification implementation in TRACES. With regard to IT governance in general, DG SANTE's policy pillar meetings, chaired by the Director-General, started to include more general and specific steer on IT matters.

Recommendation 2 on IT security

- IAS observations: TRACES users with privileged access were not regularly reviewed to check whether the level of access granted is actually needed in practice. The IAS observed weaknesses in the production environment and in the testing and user training environments. In addition, the IAS found that DG SANTE had not yet formalised and/or finalised a number of key IT security procedures for example, those related to control access and to vulnerability assessment and performance testing. Certain actions identified in the TRACES IT security plan were still to be implemented and the cost-benefit of secure hosting for TRACES was not yet formally assessed. The IAS also found that the involvement of DG SANTE's Local Informatics Security Officer (LISO) in TRACES security was limited.
- DG SANTE has taken actions without delay: the weaknesses identified by the IAS are addressed mainly by developing an "Access Control and Authentication Management Plan" and a "logging and monitoring policy document"; DG SANTE is also reinforcing its code review procedure and seeing to the full implementation of the existing IT security plan. The procedure of vulnerability assessment and performance testing, as applied since a few years, was formalised in late 2018.

(2) IAS audit on "DG SANTE's food safety crisis preparedness": two 'very important' recommendations open at 31/01/2019

In December 2017, the IAS finalised its performance audit on certain aspects of DG SANTE's activities related to food safety crisis preparedness. Two recommendations were rated "very important", one was rated "important". DG SANTE accepted all recommendations and produced an action plan. Most of the actions were completed in 2018 and full implementation is expected by June 2019.

DG SANTE believes that the mitigating measures already in place do not put the effectiveness of DG SANTE's internal control system into question.

The main IAS conclusions and DG SANTE actions are the following:

[126] IMSOC: information management system for official controls; Article 134 of Regulation (EU) 2017/625 on official controls

Recommendation 1 on the general plan for crisis management in the field of the safety of food and feed and related mechanisms to respond to food safety crisis

- IAS observations: 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 actions: DG SANTE prepared a Commission Decision on a general plan for crisis management in the field of the safety of food and feed further to external consultations with Member States and EFSA as well as a public consultation[127]. The existing Standard Operating Procedures were adapted accordingly. The documents address the weaknesses the IAS had identified in the areas of communication, redeployment arrangements and aspects of business continuity management as well as roles and responsibilities of all relevant stakeholders.

  Further to the IAS recommendation to encourage Member States to share information on their national contingency plans, DG SANTE included a standing item on the agendas of the Member States crisis coordinators' meetings, organised by DG SANTE, to give room to Member States presentations. Four presentations were given in 2018.

Recommendation 2 on exercising the 'general plan' in practice

- IAS observations: 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 actions: to test the arrangements for crisis management, DG SANTE conducted a simulation exercise with all Member States and some EFTA countries in late 2018 with an external service provider. The next step is to identify the needs on the basis of lessons learned which will feed into the design of subsequent exercises to address emerging issues as well as the timing and frequency of such exercises.

2.1.2.2.2 Other audits of the IAS in 2018

(1) IAS audit on monitoring and enforcement of EU health law in DG SANTE (final audit report of 11 December 2018): no 'very important' recommendation

The IAS submitted the final audit report on 11 December 2018. The overall objective of the audit was to assess whether DG SANTE has put in place internal control systems that ensure the effective and efficient monitoring and enforcement of EU health law.

[127] Commission implementing decision (EU) 2019/300 of 19 February 2019

The IAS made no critical or very important observations, but considered that there is room for further improvement in some areas, in particular with regard to the compliance assessment process (i.e. checking the timely, comprehensive and correct transposition of directives by each Member State), the planning and prioritisation of tasks, reporting on progress and in providing guidance to operational/policy staff.

DG SANTE accepted all recommendations and produced an action plan. All actions are already on-going, mainly by finalising an internal guidance document and by ensuring effective quality control of the data in the KOEL IT system (Knowledge Online on European Legislation). Full implementation is expected by the end of 2019.

(2) IAS audit on Connecting Europe Facility (CEF) Telecom Governance (final audit report of 31 January 2019), DG SANTE associated to DG CNECT: no 'very important' recommendation addressed to DG SANTE

In July 2018, the IAS included DG SANTE in its audit on CEF for which DG CNECT is the lead DG. One recommendation rated 'important' was addressed to DG SANTE, in co-operation with DG CNECT and DIGIT: to agree on the Memorandum of Understanding within a sensible timeframe, to clarify responsibilities related to DSIs and to improve the set of result-oriented Key Performance Indicators and define related targets. DG SANTE prepared an action plan in late February 2019 in co-operation with DG CNECT.

2.1.2.2.3 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.

In 2018, the IAS finalised the following follow-up audits:

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

The IAS had submitted its final audit report in May 2016 and issued three recommendations rated "very important". The IAS closed the audit in June 2018 having concluded that DG SANTE had implemented all the audit recommendations in an adequate and effective manner. In particular,

- DG SANTE reinforced its leverage effect on the agencies' programming by Commission Decisions on the agencies' Strategic Programming Documents (SPD 2017-2019) according to the instructions given by DG BUDG and SG. This new tool was applicable for the first time in 2016 and was again applied in 2017 and 2018.
- Since its 2017 Management Plan, DG SANTE gives 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 on the agencies' activities.
- To strengthen DG SANTE's control approach towards the agencies, in late 2017, DG SANTE updated both its Control Strategy and its document on coordination and working arrangements with decentralised agencies. The document was used throughout 2018.

(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".

The IAS closed the audit in June 2018 having concluded that DG SANTE had implemented all the audit recommendations in an adequate and effective manner. In particular,

- DG SANTE provided guidance information on the process for the management of procurements and grants pertaining to pilot projects and preparatory actions by a Note to the Management Board and by discussions in the Decentralised Financial Cell meetings.

- DG SANTE's Control Strategy Document of December 2017 includes a specific section on Pilot Projects and Preparatory Actions.

(iii) DG SANTE's management of funds in Veterinary Programmes

The IAS had already closed several recommendations in previous years. The IAS closed the audit in June 2018 with the conclusion that DG SANTE had implemented all the audit recommendations in an adequate and effective manner. As a last action to be implemented, the IT system (Qlikview) became fully operational in early 2018; it is used during the procedure for adoption national programmes and the re-allocation exercise – inter alia – to ensure an adequate audit trail.

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 2018, the Commission's Internal Audit Service (IAS) points to four 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 and from the IT audit on TRACES finalised in June 2018. 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 audits 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 2018, the following major changes to DG SANTE's control environment took place:

- In late September 2018, the Director-General left DG SANTE; he was DG SANTE's authorising officer by delegation for three years. The new Director-General joined DG SANTE on 1 October 2018. The outgoing Director-General handed over all tasks and responsibilities to the incoming new Director-General. In his handover note he 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.

- In July 2018, the Deputy Director-General for Food Safety left DG SANTE having been Authorizing Officer by Sub-Delegation for only two months from 4 June 2018 to 31 July 2018. She handed over her tasks to the Director of Directorate D "food chain stakeholder and international relations" who disposed of a dedicated financial team in the Unit D4 "food safety programme emergency funding".

  The Director-General ensured continuity of operations as Deputy Director-General for the policy area Food and Feed Safety.

- The Director of Directorate D left DG SANTE in November 2018. He handed over his tasks as Authorising Officer by Sub-Delegation to the Director of Directorate A "resources management and better regulation", who also ensured continuity of operations as Director of Directorate D.

  In his handover note the outgoing Authorising Office by Sub-Delegation 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.

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.

DG SANTE followed the methodology proposed in the "implementation guide of the internal control framework of the Commission" and participated in the dedicated work shops and trainings.

2.1.3.2.1 Annual assessment methodology

The annual assessment on the implementation of the Internal Control Principles started in the fourth quarter of 2018 and finished in the first quarter 2019 with the endorsement of a summary note by the Directors' Steering Committee on 21 March 2019 and the adoption by the Management Board on 27 March 2019. The assessment was organised by the internal control officer who collected information through the following 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", including non-compliance events or cases of "confirmation of instructions"[128];

(b) Analysis of the 2018 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 2016 to 2018;

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

(d) Staff questionnaire on management and internal control matters to get a better insight into the effectiveness of certain controls, especially those which DG SANTE had prioritises since several years (DG SANTE's questionnaire was designed to complement DG HR's staff survey of 2018 – see below);

(e) DG HR staff survey which was launched in November 2018; DG SANTE received the DG specific results in mid-March 2019.

In the framework of the preparation of the 2018 Management Plan, the DG SANTE Management Board adopted in November 2017 a list of internal control monitoring indicators to define its own baseline for each internal control principle, as best adapted to its specificities and risks. In the first half of 2018, DG SANTE reviewed the monitoring criteria to assess whether they were still suitable, especially given the need to respond to the reality of the new working organisation of the Commission, for example, the HR AMCs.

The review concluded that the identified indicators are expected to provide a reliable value for the assessment for the 2018 Annual Activity Report. In June 2018, the Directors' Steering Committee confirmed the monitoring criteria to be used in the overall assessment in the context of the 2018 Annual Activity Report.

2.1.3.2.2 Results of the annual assessment

- Throughout the year, the functioning of the internal control system was closely monitored by the systematic registration of so-called "exceptions", non-compliance events and internal control weaknesses. The underlying causes behind these exceptions and weaknesses were analysed and discussed in the Directors' Steering Committee on 21 March 2019. Although some issues were recurrent, management assessed that, overall, the existing controls are sufficient and that the procedures in place function well. In the meeting, the importance of exception reporting was underlined to ensure that all instances that constitute an exception are covered by an appropriate report.

  The second-level financial verifying agent, the central function for managing procurement procedures and the public procurement committee assisted the authorising officers by sub-delegation in the review and validation of transactions and procedures. Their ex-ante controls and checks, embedded in the procedures, did not reveal any significant internal control weaknesses.

- With regard to budget implementation in 2018, all authorising officers by sub-delegation prepared their annual reports for the Director-General. The Directors in charge of EU decentralised agencies also prepared a report on any policy, financial and/or control issue or risk that came to attention and could have an impact on the Director-General's declaration. DG SANTE assessed that the issues highlighted do not impact negatively on the Director-General's declaration of assurance.

[128] Article 92(3) of the Financial Regulation 2018

- By the end of 2018, DG SANTE implemented all recommendations issued by DG BUDG in July 2017 to improve the use of local systems in DG SANTE. DG BUDG concluded 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 the DG does not meet the validation criteria laid down by the Accounting Officer of the Commission.

- The feedback received from the Court of Auditors did not reveal any significant internal control issues and no OLAF investigation, IDOC report or Ombudsman case was addressed to DG SANTE that would point to serious control weaknesses.

- The audit observations of the IAS rated "very important" and open in 2018 are related to DG SANTE's food crisis management and IT tool TRACES. The main actions to address the weaknesses in DG SANTE's food crisis management were implemented in 2018 (Commission Decision on a "general plan for crisis management in the field of the safety of food and feed"; Standing Operating Procedures; simulation exercise with all Member States and some EFTA countries). With regard to the TRACES audit, actions are on-going. DG SANTE believes that the mitigating measures it has in place do not put the effectiveness of DG SANTE's internal control system into question.

- DG SANTE's centralised function to follow up on audit recommendations ensures a timely management of and reporting on the implementation of audit recommendations. Auditors did not point to any long outstanding audit recommendations with undue delays.

- In addition to the control results above, the annual assessment of the Internal Control Principles also used the internal control monitoring criteria defined by DG SANTE in late 2017. The assessment of internal control under the new model led to a positive conclusion on the effectiveness of the internal control system, meaning that the components and principles are present and functioning. Without putting the positive assessment into question, some principles require further attention in 2019:

    - In 2018, the Commission's HR community still saw the need to consolidate and fine-tune the HR delivery model introduced as pilot in 2017. Since February 2017, the HR central service model consists of Account Management Centres (AMCs) and DG SANTE's HR unit was transformed into a small local HR Business Correspondent. However, the centralisation continues to require an important investment of DG SANTE's resources. In 2018, the main issues remain, for example, the central HR services still rely heavily on the DGs to ensure the coordination of basic HR transactions which directly impacts on DG SANTE's staff. It also impacts on DG SANTE's implementation of internal control principles with regard to ethics, staff allocation and professional development – functions which are only partially under DG SANTE management.

    - The mid-term evaluation of CHAF-EA, finalised in October 2018, pointed to weaknesses in DG SANTE's control activities related to CHAF-EA. DG SANTE will review – inter alia – the Memorandum of Understanding with CHAF-EA and the other parent DGs to implement the recommendations made in the mid-term evaluation. With regard to control activities, improvement is also needed on certain aspects of IT security in the IT tool TRACES as pointed out by the IAS (see part 2.1.2.2.1 above). The issues are addressed already partially and actions are on-going according to the action plan to implement the audit recommendations.

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 annual Management Plan starts each year in September and is finalised in November. Further to the input received from all Units, the results of the risk assessment are discussed in the Director's Steering Committee and the Management Board to identify DG SANTE's critical risks to be reported in the Management Plan.

With a view to monitoring the implementation of the action plans, each year in August/September DG SANTE prepares a progress report and communicates it to the Commissioner in the context of the mid-term report. The Director-General discussed the 2018 report with the Commissioner in a bilateral meeting on 18 September 2018.

In 2018, no major event impacting the Director-General's declaration of assurance occurred. However, the following issues are worth mentioning:

- **Horizontal risk due to Article 50 consequences**

  The UK's withdrawal from the EU will impact many areas across DG SANTE (human and veterinary medicines, substances of human origin, sanitary and phytosanitary controls, plant protection products evaluations, etc.). The uncertainty surrounding this process presents additional risks. In coordination with the Secretariat General, Brexit Preparedness Group and Task Force 50, several preparedness and contingency actions have been taken, such as communication with stakeholders through notices and meetings, technical expert seminars, legal measures, etc.

- **African Swine Fever (ASF) could have a negative effect on the Commission's reputation**

  In 2018, African Swine Fever represented an extreme challenge both in terms of dynamics of the disease and in terms of impact. Due to the combined action of unmanaged wild boar population, intra-EU transports and 'human factor', the disease could be spreading everywhere. Since it first appeared in 2014, ASF has presented a major problem both for the wild boar population and for the EU's pork sector. It has already affected thousands of wild boar in various countries and at the same time it has caused heavy economic losses, with serious trade restrictions imposed by third countries on affected EU Member States.

  In the course of 2018, DG SANTE pursued its strategy to fight AFS by applying prevention and control measures whenever the presence of the virus was suspected or confirmed. In particular, DG SANTE closely monitored the evolution of the epidemiologic situation, which featured significant outbreaks in Romania and Bulgaria, as well as in Belgium. In order to respond to these evolutions, DG SANTE consistently amended the Commission Implementing Decision of 9 October 2014 (2014/709/EU) on regionalisation to update it to the situation on the ground, the latest amendment dating from 17 December 2018. Moreover, in 2018 DG SANTE organised two ASF Better Training for Safer Food initiatives in March and in November.

  Eradication of ASF in the EU and the long-term management of wild boar populations were also the focus of the Ministerial Conference organised by DG SANTE which took place in Brussels on 19 December 2018. However, successful disease evolution depends on Member States effectively implementing EU disease control rules and operators and stakeholders properly complying with them.

- **Late delivery of the IT portal for clinical trials could have a negative impact on the Commission reputation**

  The application of the 2014 clinical trial regulation is dependent on the availability of an IT portal to be developed by EMA, which however is experiencing major delays and escalating costs. Those observations have already been made by the Court of Auditors in 2017 (see report on the annual accounts of the European Medicines Agency for the financial year 2016). In the meantime, the situation has become critical as EMA is still not able to give a clear timeline for the delivery of the IT portal. This situation has an impact on the policy objective to improve the conduct of

clinical trials in the EU and a reputational impact as it is delaying the implementation of the EU Regulation adopted in 2014.

As far as mitigating actions are concerned, DG SANTE is chairing the coordination group with EMA, the Heads of the BE, DE, DK, PT Medicines Agencies and the chair of the EMA Management Board. In addition, DG SANTE has set-up a new monitoring group which aims at monitoring the new forthcoming IT contract.

2.1.3.4 Conclusion on the effectiveness of the internal control systems

DG SANTE has assessed its internal control system during the reporting year and has concluded that it is effective and that the components and principles are present and functioning as intended.

In addition, on some principles, even though they are present and functioning overall, improvements are needed as minor deficiencies were identified related to the HR delivery model and human resource allocation (see section 2.2.1 below) as well as minor deficiencies in control activities involving CHAF-EA (see section 2.1.1.1.3-B above).

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.

2.1.4 Conclusions as regards assurance

This section reviews the assessment of the elements reported above (in Sections 2.1.1, 2.1.2 and 2.1.3), the sub-conclusions above, and draws the overall conclusion 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 2018, DG SANTE's average residual error rate of 1,9% did not exceeded the materiality threshold of 2%. 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[129] is between 1,1% and 1,4%. This is the weighted average detected error rate which implies an overall amount at risk at payment between EUR 4,6 and 5,9 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[130] are EUR 1,5 million. This is the

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

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

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 3,1 and 4,4 million.

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

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

Overall Conclusion

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

2.1.5 Declaration of Assurance

DECLARATION OF ASSURANCE

I, the undersigned,

Director-General of DG SANTE

In my capacity as authorising officer by delegation

Declare that the information contained in this report gives a true and fair view[131].

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 work of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for years prior to the year of this declaration.

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

(e-signed)

Brussels, 29 March 2019

Anne Bucher

Authorising Officer by Delegation

[131] 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 2018 DG SANTE continued to develop initiatives to improve efficiency and economy. DG SANTE delivered on the initiatives listed in the 2018 Management Plan as follows:

- DG SANTE announced the intention to use existing IT applications to realise efficiency gains in its procurement procedures. Having finalised the necessary preparations to use DG DIGIT e-submission module, DG SANTE applied the tool starting from October 2018 to its full capacity. The first experience with three open calls for tender using e-submission has shown that the tool reduces the administrative burden, especially in the opening procedure of public procurements (no manual interventions, automatic registering and reporting, paperless filing and archiving). To complement e-submission, in late 2018, DG SANTE started its preparations to also use e-ordering for the automatic generation of procurement contracts. This tool will reduce the workload, especially for the numerous IT contracts DG SANTE manages each year, by facilitating the processing and control of timesheets and the payment of invoices.

- DG SANTE continues its participation in the SEDIA tool[132] (business owner is DG RTD) which provides on-line services used by economic operators for their interactions with the Commission in public procurement and grants. Within the SEDIA framework, the Research Executive Agency (REA) is entrusted with the participants' legal validation and preparation of their financial capacity assessment. DG SANTE, having launched e-submission in October 2018, will soon be able to roll out SEDIA and realise efficiency gains in the area of its contract management.

- In the framework of its stakeholder relations, in January 2018, DG SANTE started to use the new IT solution AGM[133], a standard solution in the Commission with PMO as system owner and DIGIT as system provider. The tool assists DG SANTE in managing the entire process from planning a meeting to inviting and reimbursing experts using one single electronic tool. AGM became fully operational in the second half of 2018 and is expected to reduce DG SANTE's administrative burden considerably especially by significantly reducing the number of manual interventions. The next step is to link AGM with WEBDOR which should reduce the administrative burden for the DGs even further.

2.2.1 Human resource management

2018 was for the Commission's HR community a year of consolidation and further fine tuning of the HR delivery method introduced as pilot in 2017. The exercise revealed to be more complex and time consuming than initially expected. It resulted in a delay in concluding on the pilot project, which continued to run throughout the whole year.

Despite the above-described unexpected additional workload, DG SANTE succeeded in ensuring sufficient HR focus on sustaining the recruitment processes. In September 2018, DG SANTE's HR-BC function changed its position in DG SANTE's organisation and is since then directly reporting to the Director-General. Ensuring that SANTE Units are adequately staffed, within the overall resources available, to cope with the many challenges and legal obligations to be delivered remained one of the main objectives of HR activity.

- **Recruitment**

  In 2018 DG SANTE welcomed 47 Officials and Temporary Agents, 27 Contract Agents, 11 National Experts and 43 Trainees. The vacancy rate of 4,4% remained 2%-points lower than the Commission and DG family rate of 6,5%.

[132] SEDIA: Single Electronic Data Interchange Area

[133] AGM: A new Gateway to EU Meetings

Moreover DG SANTE succeed in recruiting one additional female middle manager which proved again the DG's continued commitment to the important goals of the Commission talent management and equal opportunities initiative. With five female middle managers recruited (1st appointments until 16/12/2018), DG SANTE exceeded its specific 2019 target of appointing three first time female managers by two.

- **Pre-management guidance**

  In 2018 DG SANTE intensified also the assistance provided to its talented Officials who expressed their interest in steering their career towards management positions. DG SANTE management agreed in summer on specific guidance for pre-management functions which was presented and discussed with all Deputy Heads of Unit. In collaboration with DG HR career guidance officers, DG SANTE proposed support for individual understanding of skills, competencies and areas of improvement to each interested Deputy Head of Unit. This was followed by a shared reflection and coaching, where appropriate, in view of designing individual development plans. This offer was extended to all female candidates who expressed their interest in participating in the Female Talent Development Programme.

- **Fit@Work**

  Under the 'Fit@Work' initiative DG SANTE organised the SANTE Wellbeing Autumn 2018. DG SANTE is concerned about improving the wellbeing of colleagues at the workplace and, as part of its "Towards Excellence SANTE" initiative (follow up to the staff survey), an important series of events were organised between mid-September and end 2018 in collaboration with corporate services.

  The aim was to focus on issues close to the heart of DG SANTE policies, affecting the physical, mental and social well-being of colleagues, including aspects linked to work/life balance.

- **SANTE for the future**

  Finally, important work started to prepare SANTE for the future. This inclusive process covers both, the strategic reflection for the future, and the review of the internal working methods towards more transparency and collaboration. A short on-line questionnaire was prepared to collect Staff's views and strategic ideas. The process will run into 2019 with a management seminar by the end of January 2019 followed by a SANTE day in the beginning of April 2019.

2.2.2 Better regulation

DG SANTE has an internal dedicated Better Regulation support function, which assists policy units in respecting the Better Regulation principles throughout the policy cycle.

DG SANTE adopted in 2018 a new online tool for **mapping the regulatory acquis**: Knowledge Online on European Legislation (KOEL)[134]. KOEL is integrated with Decide since the first quarter of 2019 allowing an automatic update of the regulatory acquis of DG SANTE.

A number of **awareness raising** activities on Better Regulation took place in 2018. These include four Knowledge Hours on the feedback mechanism, the new acquis mapping tool KOEL, public consultations, and data, information and knowledge. In addition, an internal newsletter on Better Regulation updates (e.g. Better Regulation stocktaking, RSB annual report) was prepared and circulated quarterly within DG SANTE.

Based on the acquis mapping, DG SANTE continued to evaluate the acquis under its remit,

[134] See https://webgate.ec.europa.eu/koel/index.cfm

collecting evidence for better policy-making and assessing the impacts of future legislation. The Better Regulation unit worked in 2018 with policy units on a number of evaluations and impact assessments.

As planned in the 2018 Management Plan, the following **Better Regulation items** were **finalised** in 2018:

Impact Assessment on the next Multiannual Financial Framework (MFF post 2020). The DG finalised two Impact Assessments aimed to assess the added value on an EU initiative post-2020 in the area of public health and food chain policies. Two external studies supported the impact assessments to establish a robust baseline scenario, to develop monitoring indicators and to gather data on alternative policy options under the Single Market program. A legislative proposal, including health and food chain policy proposals under the Single Market and European Social Fund^{+} respectively, was adopted on 2 May 2018.

The Impact Assessment of Trans fatty acids (TFA)[135] responded to the needs highlighted by the Commission report of 3 December 2015, to consolidate the evidence base for setting legal limits for industrial TFA presence in foods.

Fitness check of General Food Law[136]***.*** A Commission Staff Working Document was finalised in January 2018 and presented the findings of the Fitness Check of the General Food Law, based on an external study and a public consultation.

Eighteen **studies**[137] were successfully completed in 2018, mostly with the support of external contractors (see Annex 9). On-going fieldwork delayed one study[138], initially planned to be finalised in 2018. After careful consideration and prioritisation, taking into account available resources, DG SANTE decided to cancel three studies[139] which were included in the 2017 and 2018 Management Plans.

Work on the following **evaluations could not be finalised in 2018** as planned, and will continue in 2019[140]:

- *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[141];*
- *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[142].*
- *Evaluation of the food contact materials (FCM) legislation[143];*

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[135] http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_143_trans_fats_en.pdf

[136] https://ec.europa.eu/food/sites/food/files/gfl_fitc_executive_summary_2018_en.pdf

[137] This number does not include studies supporting evaluations and impacts assessments.

[138] Support to the design and implementation of measures to reduce the exposure of children to marketing of foods high in fat, sugar or salt.

[139] 1. Mapping of EU market access paths for medical technologies with a focus on Health Technology Assessment (instead of this study, a workshop was organised to map regional cooperation initiatives relevant for HTA);

2. A study on the added value of the strategic and life-course approach to vaccination and a study on shortcomings related to low vaccination coverage in health care workers (study cancelled due to a procurement issue: late reply from contractor to Commission's request, exceeding the formal deadline);

3. Study to evaluate the impacts and the feasibility of options for the development of secondary legislation laying down rules for official controls on animals and goods entering the Union (study cancelled as the Impact Assessment of the Official Controls Regulation and the internal analysis of the respective empowerment proved to be sufficient).

[140] More information on the most recent status of the ongoing evaluations is to be found on the Inter-institutional Studies Database: http://studiesdb.opoce.cec.eu.int/studiesdb/Home.xhtml

[141] http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3526

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

[143] Evaluation expected to be finalised in 2020, see https://webgate.ec.testa.eu/publications/studiesdb/Consultation.xhtml?studyProjectId=3551

- *Evaluation of the Union policy framework for blood and tissues & cells*[144]*;*
- *Evaluation of the fee system of the European Medicines Agency (EMA)*[145]*;*
- *Evaluation of the Consumers Health Agriculture and Food Executive Agency (CHAFEA)*[146]*.*
- *REFIT Evaluation on MRL legislation pesticides (regulation 396/2005) and Regulation 1107/2009 concerning the placing on the market of plant protection products*[147]*.*

The following **new evaluations started in 2018**, as indicated in the 2018 Management Plan:

- *Evaluation of legislation related to the irradiation of food and food ingredients*[148]*;*
- *Evaluation of Paediatric Regulation (EC) No 1901/2006 and of Orphan Medicinal Products Regulation (EC) No 141/2000*[149]*.*

Work on the *Evaluation of the European Centre for Disease Prevention and Control (ECDC)*[150] also started in 2018, although it was planned to start in 2019.

2.2.3 Information management aspects

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 2018, 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 current relevant topics such as personal data protection (on the new Data Protection Regulation), how to manage PRESIDENT mail, the updated Better Regulation Guidelines -with a focus on stakeholders consultations-, the use of the newly adopted database for managing DG SANTE acquis (KOEL), and data, information and knowledge management in DG SANTE. Training courses aimed 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.

- **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 launched in the first quarter of 2018 a pilot project for publishing documents released on the basis of access to documents requests. First conclusions about its implementation should be drawn in the first half of 2019.

[144] http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3550
[145] http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3546
[146] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4843509_en
[147] http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3547
[148] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2017-4196327_en
[149] https://webgate.ec.testa.eu/publications/studiesdb/Consultation.xhtml?studyProjectId=6501
[150] https://webgate.ec.testa.eu/publications/studiesdb/Consultation.xhtml?studyProjectId=6512

- **KOEL (Knowledge Online on European Legislation)**

  Following extensive preparatory work, DG SANTE adopted a web-based application, KOEL) and performed regularly quality checks and updates. The tool maps the large DG SANTE acquis and helps managing it more effectively, efficiently and transparently and gives 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). In addition, DG SANTE developed searching capabilities in external and internal data and knowledge repository while exploring ways to map and optimise the storage of the latter.

- **eGovernment**

  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 2018, DG SANTE deployed 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. In the domain of eHealth, ERNs and CPMS have been flourishing and eHDSI has been used for the first electronic prescription exchanges among MS. 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.

Personal data protection

A mapping exercise of the existing processing of personal data in DG SANTE started in the first half of 2018 with a view to identifying areas in which actions were needed in preparation of the entry into application of the Regulation (EU) No 2018/1725. The aim was to ensure compliance with data protection principles and rules, in particular as regards lawfulness, data minimisation and storage limitation.

In parallel also existing privacy statements were revised in order to ensure compliance with this Regulation.

The process of identifying processing of personal data requiring Data Protection Impact Assessment (DPIA) was launched. The data protection coordinator in DG SANTE chaired the Data Protection Coordinators' working group on the Data Protection Impact Assessment. The working group drafted the standard template for the data protection impact assessment in line with the new data protection legislation. The final template was approved by the Commission's Data Protection Officer and will be used by all Commission services for data protection impact assessments carried out within the Commission. The first data protection impact assessment in DG SANTE was already completed in January 2019. This exercise has served as a pilot case for the entire Commission.

The results of the mapping have been used also for the purpose of converting existing notifications into records, an exercise which started when the new IT tool became available in December 2018. So far, DG SANTE identified only one case in which there might be the need to restrict the rights of data subjects. It is the mechanism allowing administrative assistance and cooperation between competent authorities responsible for

enforcing agri-food legislation in the Member States. An amendment to the corresponding Implementing Decision regarding restriction of rights of data subjects is in the process of being adopted and internal consultations are still ongoing. The adoption is planned for the second quarter of 2019.

2.2.4 External communication activities

DG SANTE's communication activities for 2018 contributed to the Commission's political priorities and more specifically to the "EU Protects" narrative and actions, while supporting the Health and Food Safety policy objectives.

Following President Juncker's State of the Union speech in September 2017, **vaccination** became one of the priority areas, while citizens' concerns as regards transparency in the authorisation of pesticides gave way to a new initiative in the context of the **General Food Law**. Other communication priorities built on ongoing files with a clear European added-value such as **European Reference Networks (ERN)**, the fight against **anti-microbial resistance (AMR)**, **food waste**, the ***State of Health in the EU*** cycle and **eHealth**. The actions carried out put the emphasis on the key policy deliverables in each policy areas.

a) The proposal by the Commission and the adoption of the Council Recommendation on **vaccination** and all promotion actions around them became even more needed considering the growing trends on vaccine hesitancy and its consequences on vaccine coverage, which led to unprecedented outbreaks of diseases such as measles in several EU countries. EU and national media regularly reported about the role and policy ambitions of the Commission, while intermediate deliverables (such as the Vaccination Confidence Report) were actively promoted through social media;

b) Following the European Citizens Initiative proposing to "ban glyphosate and protect people and the environment against toxic pesticides", the **General Food Law** proposal was presented to the media by Vice-President Timmermans and Commissioner Andriukaitis and got wide, neutral coverage, contributing to a better image of the Commission in the very sensitive area of pesticides.

c) Aside from the recurrent reporting on the roll-out of the One-Health Action Plan on **Antimicrobial Resistance**, media and social media communication focused on two major deliverables: the adoption of the new legislation on Veterinary Medicines Products and Medicated Feed and the publication of a new Eurobarometer at the occasion of the European Antibiotics Awareness Day;

d) Communication on **Food waste** focused on the achievements of the dossier – notably the publication of food donation guidelines - and of the results of the Platform, mainly promoted on social media and the Berlin and Paris agri/food fairs;

e) In the autumn of 2018, DG SANTE kicked-off the second ***State of Health in the EU*** cycle with the publication of the joint OECD-Commission publication "Health at a Glance: Europe 2018", which was also the opportunity to look back at the achievements of the first cycle and give visibility to the uptake by the Member States;

f) The **European Reference Networks** became fully operational in 2018 with the first diagnoses and treatments of patient cases using the new Clinical Patient Management System. The 4th ERN conference in November provided the opportunity to present an overview of the state-of-play to the media and to launch among others the video under the *EU protects* campaign following close collaboration with DG COMM.

g) The adoption of the initiative on the **digital transformation of health and care** was communicated to media and stakeholders, in close cooperation with DG CNECT, and laid the basis for regular follow-up communication on the theme of eHealth;

DG SANTE's communication activities in 2018 also included a particular follow-up and managing of sensitive files – for example, pesticides, New Breeding Techniques, tobacco and Health Technology Assessment - which have been regularly present in traditional and social media. Actions included the preparation of press material and defensives (LTTs) with a view to supporting and defending the Commission's views.

In 2018, a particular attention was paid to the several outbreaks of **African Swine Fever** to respond to the growing media and stakeholders' interest in the file since the disease has affected additional Member States.

In the context of the adoption of the **Multiannual Financial Framework (MFF)** and in line with corporate guidelines, SANTE developed specific on-line material to explain the future financing of health and food safety actions in the overall proposal and the added value of its varied policies for the future of Europe.

In all the above mentioned activities DG SANTE made proactive, strategic use of its **social media** accounts (@EU_Health and @Food_EU), including through cooperation with strategic partners and stakeholders and, where appropriate, social media buying.

DG SANTE actively contributed to the launch of the Commission **corporate communication campaign** *EU protects*, from the preparation of the Terms of Reference and contribution of relevant policy information for the website to supporting the development specific story-chains dedicated to **ERNs, Ebola** and **RASSF**. DG SANTE also continued to give visibility to projects that have benefitted from EU investments or whose projects have been enabled by EU support, as part of the *InvestEU* campaign through its own communication channels. Lastly, DG SANTE made contributions to the relevant policy information on the website and for factsheets, as part of the *EUandMe* campaign. Throughout 2018, DG SANTE regularly promoted relevant content from all of the campaigns via social media.

Work continued on the **Digital Transformation** front: DG SANTE's online content has been revised and streamlined in the past years (60% content cutting for the public health website and 40% at the food safety website). SANTE's website surpassed the 10 million unique page views threshold in 2018, which places it among the 10 most viewed current DGs' websites.

Electronically signed on 29/03/2019 13:45 (UTC+01) in accordance with Article 4.2 (Validity of electronic documents) of Commission Decision 2004/563