European Commission

2019

Annual Activity Report

Annexes

DG Health and Food Safety (SANTE)

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ANNEX 1: Statements of the Director and the Deputy Director-General

Director in charge of risk management and internal control

"I declare that in accordance with the Commission's communication on the internal control framework, I have reported my advice and recommendations on the overall state of internal control in the DG to the Director-General.

I hereby certify that the information provided in Section 2 of the present Annual Activity Report and in its annexes is, to the best of my knowledge, accurate and complete."

(e-signed)

Matthew Hudson

Brussels, 31 March 2020

Deputy Director-General for Health responsible for Directorates B and C

"In DG SANTE's 2019 Annual Activity Report, Section 1, I have reported to the Director-General on the achievements of the operational objectives in the policy area Public Health.

I hereby certify that the information provided in Section 1 of the present Annual Activity Report and in its related annexes is, to the best of my knowledge, accurate and complete.

(e-signed)

Martin Seychell

Brussels, 31 March 2020

ANNEX 2: Reporting – Human Resources, Better Regulation, Information Management and External Communication

This annex is the annex of section 2.2 "Other organisational management dimensions".

Annex 2.1 Human Resources

DG SANTE Human Resources[1]	Staff of DG SANTE Establishment plan posts	
	At 31/12/2019	At 31/12/2018
Administrators	**432**	**431**
Assistants and secretaries	**208**	**212**
Contractual agents	**97**	**92**
National experts	**35**	**43**
Total	**772**	**778**

In 2019, DG SANTE continued its substantial progress towards achieving the 2020 targets and indicators identified in the Strategic Plan, as indicated in Annex 2.1.

In 2019 a major focus was put on implementing the project 'Preparing SANTE for the future', launched in December 2018. The project is an inclusive process aiming at setting the foundations of how we would like to see DG SANTE in the next Commission.

The project's aim was twofold. The first part has a strategic reflexion angle looking ahead to jointly identify strategic ideas for the next College; the second part focusses on the work environment and practices improvement to ensure high staff engagement and thus efficient and effective organisational performance.

The exercise kicked off with a short on-line questionnaire to collect the views and strategic ideas of colleagues. Complementary all senior managers organised, with the assistance of the Heads of Unit, strategic discussions in each Directorate. Equipped with this information, DG SANTE managers gathered in SANTE Grange and discussed priority topics and working methods. The outcomes of the seminar helped to prepare a first outline of areas for action on internal working methods. During the months of February and March 2019, the topics were further developed and detailed.

When the staff survey results became available by mid-February, staff were immediately informed about the specific SANTE results. Moreover Directors and HoUs discussed with their staff their specific Directorate's results.

In April, the results were presented and discussed in a one-day all DG SANTE Staff Seminar. For the first time since the creation of the DG in 1999, all colleagues from SANTE's three geographical sites joined. The strategic reflection papers were further developed and colleagues identified and discussed 21 initiatives aimed at bringing positive changes for SANTE's daily work. Staff also discussed SANTE in the wider political context with Vice-President Katainen and were instructed by a professional communicator, expert on rhetoric and persuasion, about ways to bring across the SANTE messages to a broader public.

[1] 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.

As a result, the briefing package for the new Commission was finalised and 6 working groups (clusters) were set up, each of them focussing on a specific package of actions with the objective to improve DG SANTE's overall organisational performance.

Further to discussions on the cluster approach, senior management identified for each cluster a Director sponsor to steer the work. The project teams elaborated concrete proposals with the assistance of horizontal units and relevant actors, and launched their implementation. The different projects are included in SANTE's organisational development plan.

The project 'Preparing SANTE for the future' shows DG SANTE's commitment to ensure greater involvement of staff in shaping the work and organisational culture of the DG. As announced in the 2019 Annual Management Plan boosting internal communication, staff engagement and participation have been the guiding principles throughout 2019.

Objective: The DG deploys effectively its resources in support of the delivery of the Commission's priorities and core business, has a competent and engaged workforce, which is driven by an effective and gender-balanced management and which can deploy its full potential within supportive and healthy working conditions.			
Indicator 1: Percentage of female representation in middle management **Source of data:** Sysper			
Baseline: 27% at end 2015	**Target 2020:** recruitment of 3 new female HoUs between 01/05/2017 and 01/11/2019 in accordance with the specific quantitative targets specified in decision SEC(2017)359 updating decision SEC (2015) 336.	**Results 2017 and 2018** In 2017 SANTE recruited four new female Heads of Unit which allowed SANTE to reach already 100% of its 2019 target. In 2018 SANTE recruited one new female Head of Unit exceeding its target by 2.	In 2019 no new Heads of Unit were recruited, hence no new first female appointments
Indicator 2: Percentage of staff who feel that the Commission cares about their well-being **Source of data: Commission staff survey**			
Baseline: 42% in 2014 Staff survey	**Target 2020**: gradual increase every year reaching above 50% by 2019	**Results 2018** In 2018 the indicator increased to 52% which is an important improvement compared to 2014 and 2016. DG SANTE's important effort towards implementing the Commission's fit@work programme are bearing fruit. The organisation in 2018 of DG SANTE's Health Autumn is one example.	In 2019 no Staff survey was carried out
Indicator 3: Staff engagement index **Source of data: Commission staff survey**			
Baseline: 69% in 2014 Staff survey and place 17 out of 54 DGs and services	**Target 2020**: keep DG SANTE within top 30% of best performing Commission services	**Results 2018** The results of the 2018 Staff survey show an increase towards 69% but keeps DG SANTE at the Commission average. A further increase is expected from the inclusive exercise launched by the end of 2018 to prepare DG SANTE for the future.	In 2019 no Staff survey was carried out**.**

Objective: The DG deploys effectively its resources in support of the delivery of the Commission's priorities and core business, has a competent and engaged workforce, which is driven by an effective and gender-balanced management and which can deploy its full potential within supportive and healthy working conditions.			
Description	**Indicator**	**Target 2020**	**Main outputs 2019**
Implement an inclusive approach towards preparing DG SANTE for the next College	Organisation of a SANTE management study day and a SANTE staff engagement day	By end of spring management day with participation of all SANTE managers and Deputy HoUs. By end of summer staff day with all DG SANTE staff	SANTE organised its management seminar at the end of January and its first all DG SANTE Staff seminar in April.
Staff wellbeing: Contribute to reducing excessive workload by ensuring optimal use of available resources. Vacancy rate	Vacancy rate	At least 25% lower than Commission average	DG HR is developing new vacancy rate indicators. Until then no information on vacancy rates is available.
Talent management: Organise staff development actions to allow staff to keep up with the developments in SANTE's fields of expertise and competence.	Establish and implement specific training activities (job shadowing, conferences, expert classes, etc.)	Organisation of expert trainings benefitting at least 30 staff.	Specialised trainings on in vitro diagnostics, Medical Device Regulation Vigilance, Heat were organised. Moreover for several Units specific study visits were organised
Talent management – Equal opportunities: Continue to implement SANTE's 2018 policy on pre-management functions with special focus on female staff members	Establish and develop preparatory management career development programmes	Plans for 10 Staff members of which at least 6 are female	Individual programmes developed for 17 DHoU + 7 colleagues with leadership potential, of which 11 female • PerformanSE: Test to identify professional behaviours, preferences and driving forces in the professional environment – including identifying comfort and effort zones for 12 key behavioural skills for managers • Discuss and identify professional development actions during a 'face to face' discussion with a career guidance coach • Coaching offered – and most participants used it
Action plan as follow-up of staff opinion survey 2018	Approval of action plan by Director-General	By end of Q2 2019	SANTE's project 'Preparing SANTE for the future' delivered by Autumn 2019 the SANTE development plan.

Annex 2.2 Better Regulation

In 2019, DG SANTE continued to prepare its policy initiatives and manage the acquis under its responsibility pursuant to the Commission's Better Regulation Guidelines. DG SANTE has an internal dedicated Better Regulation support function, which assists policy units in applying the Better Regulation principles throughout the policy cycle.

The online IT system 'Knowledge Online on European Legislation (KOEL)[2], introduced in SANTE in 2018, centralises SANTE's regulatory acquis and is linked to the IT system 'Decide'[3] thus allowing an automatic update of the acquis through the upload of new initiatives. Updates and new functionalities were made in 2019: link to case-law pertaining to legislative acts, clear indication of empowerments and relevant deadline (where present).

A number of **awareness raising** activities on Better Regulation took place in 2019. These include three Knowledge Hours[4] on citizens' right of access documents of the EU institutions, the handling non-classified documents and information and SANTE's local data inventory initiative[5]. 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 legislative and non-legislatives measures under its remit, collecting evidence for better policy-making and assessing the impacts of future legislation. In 2019, the Better Regulation unit worked with policy units on a number of evaluations and impact assessments.

As planned in the 2019 Management Plan, the following **Better Regulation items** were **finalised** in 2019:

1. Evaluation of the Union policy framework for blood and tissues & cells[6];
2. Evaluation of the fee system of the European Medicines Agency (EMA)[7].

Two **studies**[8] were successfully completed in 2019, mostly with the support of external contractors (see Annex 9).

Work on the following **evaluations** of SANTE legislation **could not be finalised in 2019** as planned due to unexpected complexity in gathering data and other priorities in DG SANTE. Work will continue in 2020[9] as follows:

1. 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[10];

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2 See https://webgate.ec.europa.eu/koel/index.cfm

3 The European Commission's internal decision-making process tool.

4 https://myintracomm.ec.europa.eu/dg/sante/communication/knowledge-hours/Pages/knowledge-hour_2019.aspx

5 In the context of the 2019 Knowledge Week and as part of the Commission's data, information and knowledge management policy

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

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

8 This number does not include studies supporting evaluations and impacts assessments.

9 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

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

2. REFIT Evaluation on MRL legislation pesticides (regulation 396/2005) and Regulation 1107/2009 concerning the placing on the market of plant protection products[11].
3. 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[12].
4. Evaluation of legislation related to the irradiation of food and food ingredients[13];
5. Evaluation of Paediatric Regulation (EC) No 1901/2006 and of Orphan Medicinal Products Regulation (EC) No 141/2000[14].
6. Evaluation of the food contact materials (FCM) legislation***[15]***.

In addition, DG SANTE contributed to the ECDC-managed evaluation of the European Centre for Disease Prevention and Control (ECDC)[16] and also to the Evaluation of the Consumers Health Agriculture and Food Executive Agency (CHAFEA)[17] which are both under finalisation in early 2020.

One new evaluation and two impact assessments started in 2019[18]:

1. The Evaluation of the EU Animal Welfare Strategy (2012-2015)***[19]***;
2. a proportionate Impact Assessment to support the setting of migration limits for lead, cadmium and possibly other metals from ceramic and vitreous food contact materials***[20]***;
3. The impact assessment to support the preparation of a revision of the European Medicines Agency fee system***[21]***.

The Evaluation of Directive 2009/128/EC on the Sustainable Use of Pesticides, initially to be started at the end of 2019, will be launched in early 2020.

[11] http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3547

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

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

[14] https://webgate.ec.testa.eu/publications/studiesdb/Consultation.xhtml?studyProjectId=6501

[15] Evaluation expected to be finalised in 2020, see https://webgate.ec.testa.eu/publications/studiesdb/Consultation.xhtml?studyProjectId=3551

[16] https://webgate.ec.testa.eu/publications/studiesdb/Consultation.xhtml?studyProjectId=6512

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

[18] The planned Evaluation of the European Reference Networks has been removed from the IISDB as this is not an ex-post evaluation of the policy or legislation as per Better Regulation criteria, but rather a technical assessment of the existing ERNs required by the legislation.

[19] https://webgate.ec.testa.eu/publications/studiesdb/Consultation.xhtml?studyProjectId=9731

[20] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-325847_en

[21] https://ec.europa.eu/info/law/better-regulation/initiatives/ares-2019-538311_en

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

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

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

Baseline and milestone

As DG SANTE did not submit any new impact assessments in 2014 and 2015, the baseline used is an average success rate between years 2011 and 2013. Although there is a positive trend of the indicator between 2016 and 2018[22], the number of impact assessments is insufficient to obtain a meaningful percentage and, thus, to conclude objectively on the evolution of the indicator.

Source of data: List of impact assessments and the accompanying opinions of the Regulatory Scrutiny Board[23], 2018 AAR

Baseline (average from 2011- 2013)	**Interim Milestone 2016**	**Target 2020**	**Results of previous years**	**Latest known results**
50%	0% (0 out of 1)	60%	2017: 50% (1 out of 2) 2018: 100% (1 out of 1)	None in 2019

SANTE performance for 2019: No impact assessment was submitted by DG SANTE to the Regulatory Scrutiny Board in 2019.

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

Explanation: Better Regulation principles envisage that regulatory acquis is evaluated at regular intervals. As evaluations help to identify any burdens, implementation problems, and the extent to which objectives have been achieved, the availability of performance feedback is a prerequisite to introduce corrective measures allowing the acquis to stay fit for purpose. In line with the Commission guidelines, this indicator does not cover non-legislative initiatives.

Baseline and milestone

The baseline is defined as the percentage of the DG's regulatory acquis covered by evaluations and Fitness Checks not older than five years. In 2015, 11 legal acts (out of 37 legal acts) were covered by evaluation/assessment/review and had already been evaluated in the 2010-2015 period. In 2016 the DG evaluated two other acts and it completed the planned evaluations of four acts in 2017. In 2018, DG SANTE's acquis increased to 43 major legal acts[24], of which 40% (17 acts) were evaluated.

Source of data: Knowledge Online on European Legislation (KOEL)[25], Planning of Evaluations and studies (2008; 2016; 2017; 2018); Commission Reporting obligations under the SANTE legislation (own source).

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[22] In 2016, DG SANTE submitted to the RSB one impact assessment, which received a positive opinion on second submission. In 2017, DG SANTE submitted to the RSB two impact assessments, of which one received positive opinion on first submission while the other one on second submission. In 2018 DG SANTE submitted for review to the RSB one impact assessment, which received a positive opinion on first submission. In addition, DG SANTE carried out two impact assessments for food safety and health spending under the MFF 2021-2027. These are included in the impact assessments for the Single Market Programme and the ESF+ and received a positive opinion on first submission.

[23] https://ec.europa.eu/transparency/regdoc/?fuseaction=ia&year=2019&serviceId=102&s=Search

[24] In 2018, compared to the 41 legal acts in 2017, two new legislative acts were adopted:

REGULATION (EU) 2019/6 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2018 on veterinary medicinal products and repealing Directive 2001/82/EC.

REGULATION (EU) 2019/4 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 11 December 2018 on the manufacture, placing on the market and use of medicated feed, amending Regulation (EC) No 183/2005 of the European Parliament and of the Council and repealing Council Directive 90/167/EEC.

[25] https://webgate.ec.europa.eu/koel/index.cfm?action=legislation.fullAcquis

Objective: Prepare new policy initiatives and manage the EU's acquis in line with better regulation practices to ensure that EU policy objectives are achieved effectively and efficiently.				
Baseline (2015)	**Interim Milestone 2016**	**Target 2020**	**Results of previous years**	**Latest known results**
30% of SANTE legislation (11 out of 37 legal acts)	35% of SANTE legislation (13 out of 37 legal acts)	Positive trend compared to baseline	2017: 41% of SANTE legislation (17 out of 41 legal acts) 2018: 40% of SANTE legislation (17 out of 43 legal acts)	2019: 38% of SANTE legislation (17 out of 45 legal acts)

SANTE performance for 2019
Two new legal acts were adopted in 2019[26] and whilst one new evaluation (on the EU Animal Welfare strategy) started in 2019 which concerned a non-legislative measure. Therefore, the score for 2019 is 38% [(11+2+4)]/45]. Delays were incurred due to an unexpected complexity in gathering data and other priorities in DG SANTE.

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

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

Baseline and milestone:
The baseline is considered as the number of evaluations planned in the period 2015-2020, as indicated in the DG SANTE Strategic Plan 2016-2020.

Source of data: SANTE strategic plan 2016-2020, SANTE Management Plan 2016, 2017, 2018, 2019.

Baseline	**Interim Milestone 2016**	**Target 2020**	**Results of previous years**	**Latest known results**
Evaluations planned 2016-2020: 26[27]	Percentage of evaluations with final report 27%[28]	100% of evaluations planned are finalised (final report)	2017: 42%[29] 2018: 42%	2019: 38.5%

SANTE performance for 2019
DG SANTE started 2019 with six on-going evaluations from previous years. Of these, two were completed in 2019 as planned, while the other four were not completed in 2019 as planned. In addition, one evaluation (EU Animal Welfare Strategy) started in 2019. Therefore, the score for 2019, taking into account the evaluations finalised in 2016 (2), 2017 (4), 2018 (1) and 2019 (2) is 38.5% [(2+4+1+2+1)/26].

[26] In 2019, two new legislative acts were adopted: Regulation (EU) 2019/1381 on the transparency and sustainability of the EU risk assessment in the food chain and Regulation (EU) 2019/5 amending Regulation (EC) No 726/2004 on medicinal products, EMA.

[27] See the SANTE Strategic Plan 2016-2020: https://ec.europa.eu/info/publications/strategic-plan-2016-2020-health-and-food-safety_en

[28] See 2016 Management Plan, Annex 3.

[29] DG SANTE started 2017 with eight on-going evaluations from previous years. Of these ongoing, four evaluations were completed in 2017 as planned. In addition, all five new evaluations started on time in 2017, as planned. Two evaluations have already been finalised in 2016. Considering the above, the indicator value for 2017 is equal to 42% ((4+2+5)/26)

Annex 2.3 Information Management

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

DG SANTE's collaboration platform policy provides the standard framework and tools for the management of key horizontal activities of the Units, including coordinating work with operational Units and projects within DG SANTE. During 2019 numerous new projects have been launched, replacing the standard collaboration by e-mail and unit-file systems with Sharepoint. Following the strategy towards O365-collaboration, expected to be launched in the Commission during 2020, DG SANTE decided to join this corporate initiative and migrate its collaborative work and platform to O365 once the Local Data Center Consolidation (LDC) will be completed in the second quarter of 2020. This will allow SANTE to be amongst the forerunners in modern electronic collaboration and further change working methods towards more efficiency, sharing and dynamics in collaboration.

A series of Knowledge Hours were organised on current relevant topics such as access to documents, handling non-classified information, 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 and coaching sessions 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. The duration of the project was extended after the first positive conclusions about its implementation in the first half of 2019.

  In order to improve transparency, DG SANTE furthermore decided to proactively publish in principle several categories of draft acts of tertiary legislation submitted to vote to Regulatory Committees.

- **KOEL (Knowledge Online on European Legislation) and data information and knowledge management**

  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.

  On the broader data, information and knowledge management DG SANTE mapped its data assets and resources already available and increased their accessibility by staff from DG SANTE and other DGs. A total of 150 data assets were identified and

66 reported into the corporate data repository in a continuous improvement process. Three surveys have increased the understanding of data needs for policy making purposes. The support for data collection in relation to better regulation projects continued and has stepped up by developing an in-house search for data capability.

eGovernment

DG SANTE's 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 the subject of continuous evolution for all processes, systems and interactions with Member States, businesses and citizens. In particular during 2019, the usage of electronic signatures for sanitary and phytosanitary certificates for the food safety pillar has been extended. The applications now include more countries and new e-services, workflow systems for the authorisation of novel foods applications are further developed and deployed to support the requirements for transparency of GFL (General Food Law) collaborating electronically with EFSA and Member States. The evolution of eHealth, notably eHDSi, ERNs and CPMS continues with more uptake and user satisfaction.

Data protection

DG SANTE paid particular attention to all five objectives specified in the Commission's Data Protection Action Plan (C(2018)7432). In 2019 three legislative acts with important data protection aspects were adopted in the area of SANTE responsibilities:

- The implementing decision on the European Reference Networks[30], where data protection provisions mainly clarify the relationship between the Commission and the healthcare providers as joint controllers. Those provisions are specific and comprehensive, so that a separate arrangement between the joint controllers does not appear as necessary.
- The implementing decision on the eHealth Network[31], where data protection provisions govern the relationship between the Commission as processor and the Member States as controllers within the eHealth Digital Service Infrastructure. This act was adopted after consulting the European Data Protection Board according to the Article 42(2) of the EDPR, upon suggestion of the relevant Regulatory Committee, and
- The implementing regulation on the information management system for official controls[32], where data protection provisions mainly clarify the relationship between the Commission and competent authorities of the Member States as joint controllers. In view of the fact that those provisions are of general nature, they

[30] Commission Implementing Decision (EU) 2019/1269 of 26 July 2019 amending Implementing Decision 2014/287/EU setting out criteria for establishing and evaluating European Reference Networks and their Members and for facilitating the exchange of information and expertise on establishing and evaluating such Networks

[31] Commission Implementing Decision 2019/1765 of 22 October 2019 providing the rules for the establishment, the management and the functioning of the network of national authorities responsible for eHealth

[32] Commission Implementing Regulation (EU) 2019/1715 of 30 September 2019 laying down rules for the functioning of the information management system for official controls and its system components (the IMSOC Regulation)

will need to be complemented by a separate arrangement between joint controllers.

Two other cases in which the Commission is **joint controller with external entities** were identified in the area of policies managed by DG SANTE, namely the **Repository system for tobacco traceability**[33] (ensuring complete traceability and monitoring of movement of tobacco products within EU) and to **Early Warning Response System**[34] (system serving for exchange of heath data and contact tracing data of infected individuals, with the aim of preventing the spread of communicable diseases). Work on the arrangements with those entities was not yet completed.

The finalisation of draft records for processing operations already in place before the entry into force of Regulation (EU) 2018/1725 is expected to be completed by the end of the first quarter of 2020, depending on progresses made at Commission corporate level. It also included the revision of existing privacy statements and their adaptation to the new rules. New records (and new privacy statements already drafted based on the new legislation) were published relating to processing of personal data of (i) applicants and users of Healthcare Provider ERN Application Tool and (ii) patients and healthcare providers involved in communication activities related to European Reference Networks.

A thorough inspection of DG SANTE web pages located on europa.eu was carried out, to ensure that it complies with data protection rules.

In 2019, one Data Protection Impact Assessment (DPIA) was carried out (on European Reference Networks' Communication Activities) and two more started (relating to Clinical Patient Management System for European Reference Networks – carried out by an external contractor and IMSOC). These two DPIAs are expected to be finalised in 2020.

Objectives and indicators

Indicator 1 (0,51%) remains stable compared to the previous years. In 2019, DMO-reports on registered documents, not filed, were sent regularly and followed up closely. Documents from 2019 that are still not filed are expected to be filed soon. It is likely that statistics will show later in the year that the target of 0% is reached for 2019.

Already in 2016 DG SANTE exceeded the 2020 targets set for indicators 2 and 3. This achievement has been confirmed in 2019, although the percentage in 2019 is slightly lower than in 2016. The reason is DG SANTE's decision to open by default newly created files starting as from December 2016. Further to this decision, Units carefully re-evaluated the content of their files. Some files that contained sensitive information were therefore protected on request of the Units.

The 2020 target of indicator 5 on the management of briefings is achieved every year since 2015. Progress on indicator 4 is delayed since 2017 as the planning for a new version of the collaborative platform had to be revised towards delivery in 2019 due to significant technical and procedural obstacles. Once deployed, it will allow all Units to have a new uniform way of managing their activities and projects.

The percentage of information systems at the highest level of maturity operating as e-services (indicator 6) shows no evolution since 2018. The reason is that DG SANTE is preparing an IT modernisation plan and DIGITAL strategy action plan in 2020 addressing the necessary changes and evolution of IT systems for the coming years. The modernisation plan will be fully implemented in the course of the next 2-3 years, to be defined in 2020.

[33] Directive 2014/40/EU of the European Parliament and of the Council of 3 April 2014 on the approximation of the laws, regulations and administrative provisions of the Member States concerning the manufacture, presentation and sale of tobacco and related products

[34] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health

Objective: Information and knowledge in your DG is shared and reusable by other DGs. Important documents are registered, filed and retrievable				
Indicator 1: Percentage of registered documents that are not filed[35] (ratio) **Source of data:** *Hermes-Ares-Nomcom (HAN)[36] statistics*				
Baseline 2015		**Target 2020**	**Results of previous years**	**Latest known results**
1.24%		0%	2017: 0,51% 2018: 0,68%	2019: 0,51%
Indicator 2: Number of HAN files readable/accessible by all units in the DG **Source of data:** *HAN statistics*				
Baseline 2015		**Target 2020**	**Results of previous years**	**Latest known results**
98%		75%	2017: 97,98% 2018: 97,90%	2019: 97,91%
Indicator 3: Number of HAN files shared with other DGs **Source of data:** *HAN statistics*				
Baseline 2015		**Target 2020**	**Results of previous years**	**Latest known results**
98%		75%	2017: 97,98% 2018: 97,90%	2019: 96,97%
Indicator 4: Percentage of units using collaborative tools to manage their activities				
Baseline (2015)	**Interim Milestone (2018)**	**Target 2020**	**Results of previous years**	**Latest known results**
20% (9 out of 40 Units plus DG and Direction levels, 100% for activities applicable to all Units)	60% (100% for activities applicable to all Units)	100%	2017: 24% (100% for activities applicable to all Units) 2018: 30% (100% for activities applicable to all Units)	2019: 50% (100% for activities applicable to all Units)
Indicator 5: Percentage of briefings managed in accordance with a uniform business process and using a common tool **Source of data:** Briefings and Speeches Information System (BASIS)				
Baseline (2015)	**Interim Milestone (2015)**	**Target 2020**	**Results of previous years**	**Latest known results**
100%	100% (in total 512 requests)	100%	2017: 100% (in total 732 requests) 2018: 100% (in total 742 requests)	2019: 100% (in total 636 requests)
Indicator 6: Percentage of information systems and processes at the highest level of maturity (transformed government) operating as e-services for the digital single market. **Source of data:** Information systems follow up and annual IT Master Plan				
Baseline (2015)	**Interim Milestone (2018)**	**Target 2020**	**Results of previous years**	**Latest known results**
20%	60%	90%	2017: 50% 2018: 65%	2019: 65%

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

[36] Suite of tools designed to implement the e-Domec policy rules.

Main outputs in 2019 as planned in 2019 MP:			
Output	**Indicator**	**Target 2020**	**Results 2019**
Development of the role of a central contact point for data information and knowledge management in the DG.	*Central Data Knowledge Information (DKI) contact point appointed*	*Q4 2019*	*Local data correspondent appointed with defined role and responsibilities*
Better use of electronic workflows, to reduce errors caused by the double circulation and to reduce paper storage in eligible cases.	*Number of registered documents with a fully approved e-signatory (no paper circulation in parallel if ink signature not required).*	*70% of registered documents approved in full electronic mode (without paper signatories circulation).* *Q4 2019*	*73,8%**** *** Such statistics rely on the information provided in the relevant document management system by the Units responsible for the documents registered.*
Identification of the needs of the Directorate-General in terms of data information and knowledge	*Questionnaire sent to all Directorates for mapping their needs*	*40% of Directorates' needs mapped.* *Q4 2019*	*56% of directorates needs mapped*
HERMES Integration of newly developed IT systems	*Assessment of the fulfilment of the requirements for integration of newly developed IT systems*	*5% of the IT systems being developed assessed against the integration requirements.* *Q4 2019.*	*5% of the IT systems being developed were assessed against the integration requirements.* *Process for review of all systems set for 2020*
Registered documents are also filed.	*Percentage of registered documents that are not filed[1] (ratio)*	*Less than 1% by Q4 2019*	*99,49%*
Hermes Ares NomCom (HAN) files are readable/accessible by all units in the DG	*Number of Hermes Ares NomCom (HAN) files readable/accessible by all units in the DG*	*75% by Q4 2019*	*97,91%*
HAN files are shared with other DGs	*Number of HAN files shared with other DGs*	*75% by Q4 2019*	*96,97%*
Information systems and processes are at the highest level of maturity (transformed government) operating as e-services for the digital single market.	*Percentage of information systems and processes at the highest level of maturity (transformed government) operating as e-services for the digital single market.*	*45% by Q4 2019*	65%[37]
Better use of standard electronic tools to manage Units activities and store information	*Percentage of units using collaborative tools to manage their activities*	*45% by Q4 2019*	*50% in total* *100% for activities applicable to all Units*

[37] No change since 2018, DG SANTE is preparing an IT modernisation plan and DIGITAL strategy action plan to be delivered in 2020 addressing the necessary changes and evolution of IT systems for the coming years.

Annex 2.4 External Communication

DG SANTE's communication activities were carried out in a particular context, a transition year which required, almost simultaneously, to devote important efforts to give visibility to the legacy of the previous Commission in the area of Health and Food Safety and to the priorities of the new College in this area.

Among all priorities, **vaccination** was the most visible in 2019: the decreased vaccine confidence rates, increasing number of deaths and growing cases of vaccine-preventable diseases led the WHO to declare vaccine hesitancy as one of the main health threats for 2019 and thus put a lot of pressure on communication on this issue. The Special Eurobarometer published during the European Immunisation Week stressed a low level of knowledge and vaccine mistrust in some Member States. The Global Vaccination Summit, organised in partnership with WHO, received a massive coverage, both on traditional and social media.

In the autumn of 2019, DG SANTE published the **State of Health in the EU** (Country profiles and Companion Report), with a Brussels launch and numerous decentralised actions in the Member States.

AMR continued to raise interest, in particular linked to the adoption of the Veterinary Medicines legislation and some actions during the European Antibiotic Awareness Day.

As always, the communication during crisis management gave visibility to specific areas of work: **African Swine Fever** was widely reported in the Member States concerned and our communication highlighted the efficiency of Commission actions in this area.

Plant Health and EU actions to prevent the spread of plant diseases were picked up by non-specialist media as the new Plant Health Regulation entered into force in December 2019. A dedicated video on the new rules aimed at passengers was disseminated widely, garnering 43,000 impressions and 282 engagements on social media.

Communication on **Food waste** remained focused on the achievements of the dossier – notably the adoption of an EU methodology to measure food waste - and were publicised via stakeholders' meetings, such as the Platform meetings and international food-related fairs (Grüne Woche in Berlin and Salon International de l'Agriculture in Paris).

Closely linked to the authorisation of pesticides process (and in particular to the glyphosate renewal), the adoption, of the General Food Law revision raised considerable media interest.

Reactive communication on sensitive files – such as pesticides, New Breeding Techniques, tobacco and Health Technology Assessment – represented an important part of the media relations portfolio, involving regular preparation of press material and defensives (LTTs) with a view to supporting and defending the Commission's views.

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 Commission **corporate communication campaign** *EU protects*, including the development specific story-chains and videos dedicated to **ERNs, Ebola, RASSF, cancer** and **vaccination**. 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 relevant policy information on the website and for factsheets, as part of the *EUandMe* campaign.

The Food Safety and Public Health websites are fully in line with the Digital Transformation requirements and ready to migrate to the latest version of the corporate europa content management system. They are amongst the 10 most viewed current websites, with above 2,6 million visits for Health and 4,2 million for Food.

Annual communication spending (based on estimated commitments):			
Baseline (2018):	Target (2019):	**Total amount spent in 2019**	Total FTEs working on external communication
€1,225,000	€ 1,659,400	**€1,591,848**[38]	8,5 FTE (2019)

Objective: Citizens perceive that the EU is working to improve their lives and engage with the EU. They feel that their concerns are taken into consideration in European decision making and they know about their rights in the EU.				
Main outputs in 2019: **Specific communication actions in the main areas: Vaccination, Reform of General Food Law (GFL), State of Health, Antimicrobial Resistance (AMR), Animal Health, European Reference Networks (ERN) and Food Waste**				
Output	**Indicator**	**Target 2020**	Previous year results	**Results 2019**
Direct reach of the DG communication actions supporting SANTE's policy priorities via SANTE Web, press material, media seminars, media buying, media info session, social media, audio-visual material, events, publications, e-news and newsletters and graphic material	Number of DG SANTE unique page views, social media impressions, participants at events, reach of media buying, reach of media seminars and info session, page views of visual material, subscribers to e-news and newsletters, print runs	50 000[39] (Baseline 2015: 222 710 099)	32 528 044 contacts in 2018	**31,998,759** **(this does not include the overall reach during the Vaccination Summit – see below)** **Twitter accounts** **18,351,000** impressions (EU_Health 11,656,000 Food_EU 6,695,000) **DG SANTE unique page views**: **12.446.215** (17.561.829 page views / 6.922.642 visits) **Page views of visual material**: **29,587 page views** **Subscribers to e-news and newsletters**: **95,396** **Press Releases and Numbers**: **1,026,561** **Green Week/Salon de l'Agriculture (pending confirmation from AGRI):** **50.000** engaged

[38] The total amount spent in 2019 covers all activities for external communication

[39] This figure comes from the Strategic Plan 2016-2019: The baseline in 2015 took into account the reach of the Ex-Smokers campaign that ended in 2016 – no other major campaigns conducted afterwards.

Objective: Citizens perceive that the EU is working to improve their lives and engage with the EU. They feel that their concerns are taken into consideration in European decision making and they know about their rights in the EU.			
Main outputs in 2019:			
Output	**Indicator**	**Target 2020**	**Results 2019**
Tackling vaccination inequalities – awareness raising following the adoption of the Council recommendation on vaccination, European Immunisation Week, Release Eurobarometer, **Organisation of the Global Summit on Vaccination**	- Number of visits to SANTE web section on vaccination	- 10% increase (Baseline 2018: 32,446 page views)	72,100 page views
	- National print media coverage	- Media coverage by at least 20 EU countries	The Summit was widely covered in the traditional media (at least 90 media articles, with many leading European media outlets reporting). The EB also received considerable media attention, the Commissioner giving one-to-one interviews to select media.
	- Twitter reach (including Commission's accounts) (regular and paid)	- 500,000 impressions and 500 interactions (shares and likes)	3,508 Twitter Mentions and potential impressions **8.6M Twitter users on the day of the Summit** **Across all social media platforms** between 9 September and 19 September: #VaccinationSummit19 **Reach** **20335763** **Potential impressions** **202751723** #VaccinesWork Reach 43238465 Potential impressions 309613484[40]
Digital health and care – Media actions on the exchange of patient records and e-prescriptions	- Number of visits to SANTE web section on e-health	- 10% increase (Baseline 2018: 35,198 page views)	51,333 page views
	- Twitter reach (including Commissioner's accounts) (regular and paid)	- 300,000 impressions and 300 interactions (shares and likes)	388 804 impressions and 903 interactions on Twitter (organic and paid)

[40] Figures provided by DG COMM immediately after the Summit and subject to review

Main outputs in 2019:			
Output	**Indicator**	**Target 2020**	**Results 2019**
Publication of the Country Health profiles and the companion Report on the "State of Health in the EU" to media and stakeholders	- Number of visits to SANTE web section on State of Health	- 10% increase (baseline 2018: 77,970 page views)	105,632 page views
	- Twitter reach and engagement (including Commissioner's accounts), (regular and paid)	- 1,000,000 impressions and 1,000 interactions (shares and likes)	1 777 525 impressions and 21 352 interactions on Twitter (organic and paid)
	- National media coverage of report	- Print / audio-visual media coverage by at least 15 EU countries.	On the day of publication on 28 November, a press conference by the Commissioner and a technical briefing were held by DG SANTE, OECD and Observatory in Brussels. In addition, 16 national media +stakeholder launch events were held in Member States. More than 150 media articles all over the EU.
The European Reference Networks: a success story in the treatment of rare diseases	- Number of visits to SANTE web section on ERNs	- 10% increase (baseline 2018: 37,303 page views)	85,382 page views
	- Twitter reach (including Commissioner's accounts) (regular and paid)	- 500, 000 impressions and 500 interactions (shares and likes)	382 546 impressions and 1048 interactions on Twitter (organic and paid)
	- Number of print media articles on success stories	- At least 10 articles published by several EU countries during the year	OpEd by Commissioner on Rare Diseases Day was published in 20 Member States
General Food Law: explaining the concrete functioning of the new legislation after its adoption.	- Number of visits to SANTE web section on General Food Law	- 10% increase (baseline 2018: page views 54,011	42,851 page views
	- National print media coverage of adoption	- Media coverage by at least 15 EU countries	The issue of transparency in scientific studies on food was regularly picked up by media in the context of sensitive files, such as glyphosate and pesticides in general.
	- Number of journalists attending the media briefing or roundtable with the Commissioner (tbc)	- At least 10 articles published by several EU countries during the year	No particular briefing was organised on this topic

Main outputs in 2019:			
Output	**Indicator**	**Target 2020**	**Results 2019**
	- Twitter reach (including Commissioner's accounts) (regular and paid)	- 300,000 impressions and 300 interactions (shares and likes)	384 736 impressions and 1781 interactions on Twitter (organic and paid)
Animal Health, and in particular presence of African swine fever (**ASF**) in the Member States	- Number of visits to SANTE web section	10% increase (baseline 2018: 34,852 page views baseline 2017: 8,110)	ASF webpage: 40,833 page views (Animal Health web section: 117,668 page views)
	- National print media coverage of EU's actions if/when outbreaks are reported	- Media coverage by at least 10 EU countries	ASF was covered in all (10) Member States affected by the disease throughout the year. Issue was also picked up in other Member States
	- Number of journalists attending media briefing or roundtable with the Commissioner (tbc)	- At least 10 articles published by several EU countries during the year	Since ASF was on the agenda on numerous AGRI Councils therefore triggering questions from media present.
	- Twitter reach (including Commissioner's accounts) (regular and paid)	- 200,000 impressions and 500 interactions (shares and likes)	1 144 569 impressions and 6614 interactions on Twitter (organic and paid)
Participation with a stand in international events on "farm to fork", AMR and on food waste.	- Number of visits to Salon de l'Agriculture (SIA) and Grüne Woche (IGW)	- For SIA: 144,000 visitors on the stand, 27,00 visitors engaged - For IGW: 215,000 visitors on the stand, 100,000,000 visitors engaged	**Pending confirmation of figures from DG AGRI** - For SIA: 633,000 visitors on the stand, 25650 visitors engaged - For IGW: 440,000 visitors on the stand, 24,000 visitors engaged

ANNEX 3: Financial Reports - DG SANTE - Financial Year 2019

Table 1 : Commitments

Table 2 : Payments

Table 3 : Commitments to be settled

Table 4 : Balance Sheet

Table 5 : Statement of Financial Performance

Table 5 Bis: Off Balance Sheet

Table 6 : Average Payment Times

Table 7 : Income

Table 8 : Recovery of undue Payments

Table 9 : Ageing Balance of Recovery Orders

Table 10 : Waivers of Recovery Orders

Table 11 : Negotiated Procedures

Table 12 : Summary of Procedures

Table 13 : Building Contracts

Table 14 : Contracts declared Secret

Table 15 : FPA duration exceeds 4 years

Additional comments

TABLE 1: OUTTURN ON COMMITMENT APPROPRIATIONS IN 2019 (in Mio €) for DG SANTE					
			Commitment appropriations authorised	Commitments made	%
			1	2	3=2/1
Title 05 Agriculture and rural development					
05	05 01	Administrative expenditure of the 'Agriculture and rural development' policy area	3,56	3,56	100,00 %
	05 04	Rural development	0,43	0,43	100,00 %
Total Title 05			**3,99**	**3,99**	**100,00 %**
Title 07 Environment					
07	07 02	Environmental policy at Union and international level	0	0	0,00 %
Total Title 07			**0**	**0**	**0,00 %**
Title 09 Communications networks, content and technology					
09	09 02	Digital single market	0	0	0,00 %
	09 03	Connecting Europe Facility (CEF) - Telecommunications networks	3,651	3,651	100,00 %
Total Title 09			**3,651**	**3,651**	**100,00 %**
Title 11 Maritime affairs and fisheries					
11	11 06	European Maritime and Fisheries Fund (EMFF)	0,32	0,32	100,00 %
Total Title 11			**0,32**	**0,32**	**100,00 %**
Title 14 Taxation and customs union					
14	14 02	Customs	0,2	0,2	100,00 %
Total Title 14			**0,2**	**0,2**	**100,00 %**
Title 17 Health and food safety					
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	11,97353933	11,90671796	99,44 %
	17 03	Public health	203,0188089	186,7725006	92,00 %
	17 04	Food and feed safety, animal health, animal welfare and plant health	277,1998929	272,7942417	98,41 %
Total Title 17			**492,1922412**	**471,4734602**	**95,79 %**
Title 20 Trade					
20	20 02	Trade policy	0	0	0,00 %
Total Title 20			**0**	**0**	**0,00 %**
Title 22 Neighbourhood and enlargement negotiations					
22	22 02	Enlargement process and strategy		0	
Total Title 22				**0**	

			Commitment appropriations authorised	Commitments made	%
			1	2	3=2/1
Title 26 Commission's administration					
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,70157961	0,57240629	81,59 %
Total Title 26			**0,70157961**	**0,57240629**	**81,59 %**
Title 33 Justice and consumers					
33	33 01	Administrative expenditure of the 'Justice and consumers' policy area	1,79984	1,79984	100,00 %
Total Title 33			**1,79984**	**1,79984**	**100,00 %**
Total DG SANTE			**502,8546608**	**482,0067065**	**95,85 %**

** Commitment appropriations authorised include, in addition to the budget voted by the legislative authority, appropriations carried over from the previous exercise, budget amendments as well as miscellaneous commitment appropriations for the period (e.g. internal and external assigned revenue).*

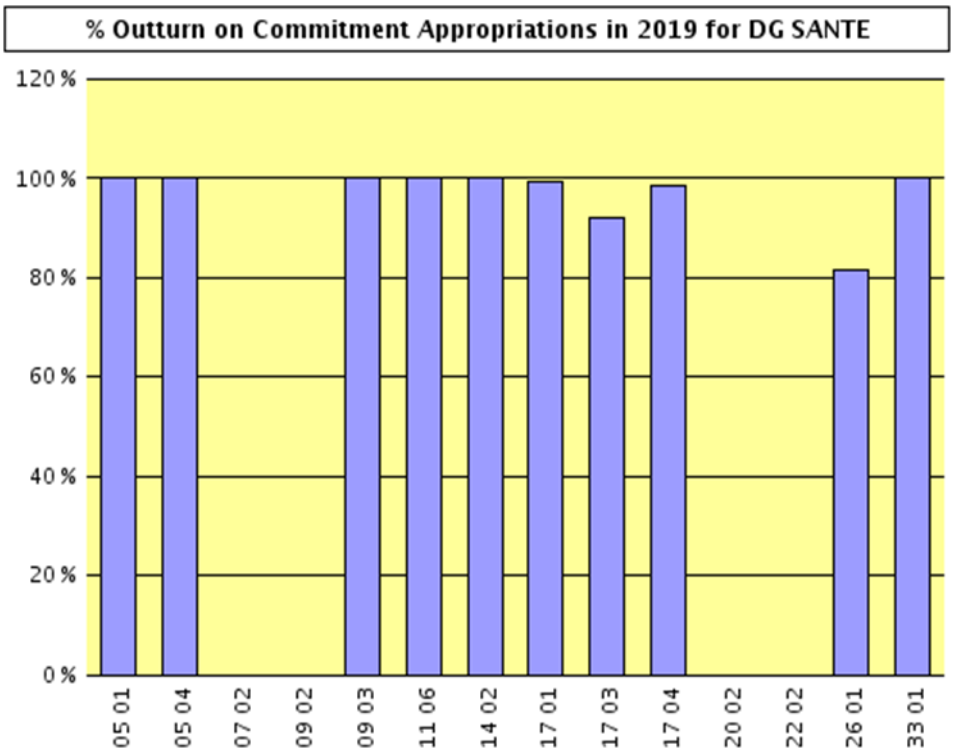

TABLE 2: OUTTURN ON PAYMENT APPROPRIATIONS in 2019 (in Mio €) for DG SANTE					
			Payment appropriations authorised *	Payments made	%
			1	2	3=2/1
Title 05 Agriculture and rural development					
05	05 01	Administrative expenditure of the 'Agriculture and rural development' policy area	3,56	3,56	100,00 %
	05 04	Rural development	0,13591503	0,13591503	100,00 %
Total Title 05			**3,69591503**	**3,69591503**	**100,00%**
Title 07 Environment					
07	07 02	Environmental policy at Union and international level	0,036	0,036	100,00 %
Total Title 07			**0,036**	**0,036**	**100,00%**
Title 09 Communications networks, content and technology					
09	09 02	Digital single market	0,27	0,27	100,00 %
	09 03	Connecting Europe Facility (CEF) - Telecommunications networks	3,31064495	3,31064495	100,00 %
Total Title 09			**3,58064495**	**3,58064495**	**100,00%**
Title 11 Maritime affairs and fisheries					
11	11 06	European Maritime and Fisheries Fund (EMFF)	0,22243841	0,22243841	100,00 %
Total Title 11			**0,22243841**	**0,22243841**	**100,00%**
Title 14 Taxation and customs union					
14	14 02	Customs	0,0555533	0,0555533	100,00 %
Total Title 14			**0,0555533**	**0,0555533**	**100,00%**
Title 17 Health and food safety					
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	18,001144	11,70184245	65,01 %
	17 03	Public health	198,7474183	181,8649306	91,51 %
	17 04	Food and feed safety, animal health, animal welfare and plant health	233,4752411	232,2843351	99,49 %
Total Title 17			**450,2238033**	**425,8511082**	**94,59%**
Title 20 Trade					
20	20 02	Trade policy	0,14	0,14	100,00 %
Total Title 20			**0,14**	**0,14**	**100,00%**
Title 26 Commission's administration					
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,88540158	0,52575417	59,38 %
Total Title 26			**0,88540158**	**0,52575417**	**59,38%**
Title 33 Justice and consumers					
33	33 01	Administrative expenditure of the 'Justice and consumers' policy area	1,79984	1,79984	100,00 %
Total Title 33			**1,79984**	**1,79984**	**100,00%**
Total DG SANTE			**460,6395966**	**435,907254**	**94,63 %**

** Payment appropriations authorised include, in addition to the budget voted by the legislative authority, appropriations carried over from the previous exercise, budget amendments as well as miscellaneous payment appropriations for the period (e.g. internal and external assigned revenue).*

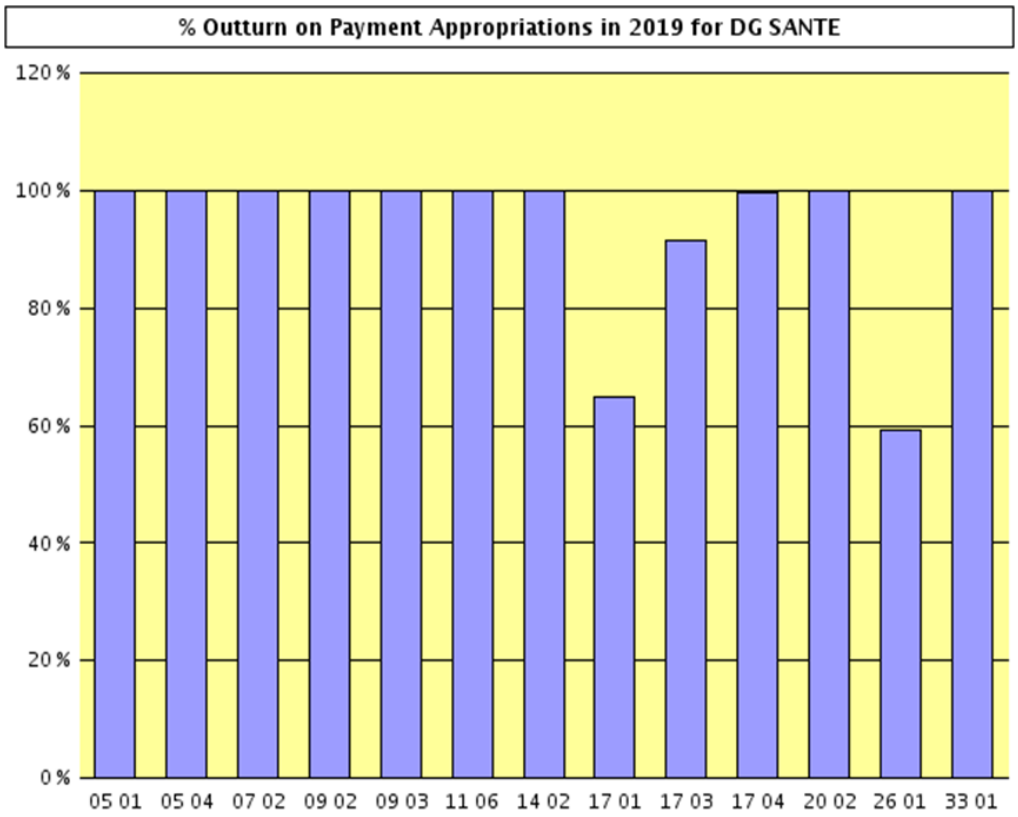

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2019 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2018	Total of commitments to be settled at end of financial year 2019	Total of commitments to be settled at end of financial year 2018
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
05	05 01	Administrative expenditure of the 'Agriculture and rural development' policy area	3,56	3,56	0,00	0,00%	0,00	0,00	0,00
	05 04	Rural development	0,43	0,00	0,43	100,00%	0,38	0,81	0,51
Total Title 05			**3,99**	**3,56**	**0,43**	**10,78%**	**0,38**	**0,81**	**0,51**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2019 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2018	Total of commitments to be settled at end of financial year 2019	Total of commitments to be settled at end of financial year 2018
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
07	07 02	Environmental policy at Union and international level	0,00	0,00	0,00	0,00%	0,19	0,19	0,23
Total Title 07			**0,00**	**0,00**	**0,00**	**0,00%**	**0,19**	**0,19**	**0,23**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2019 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2018	Total of commitments to be settled at end of financial year 2019	Total of commitments to be settled at end of financial year 2018
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
09	09 02	Digital single market	0,00	0,00	0,00	0,00%	0,00	0,00	0,27
	09 03	Connecting Europe Facility (CEF) - Telecommunications networks	3,65	0,00	3,65	100,00%	3,52	7,17	6,83
Total Title 09			**3,65**	**0,00**	**3,65**	**100,00%**	**3,52**	**7,17**	**7,10**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2019 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2018	Total of commitments to be settled at end of financial year 2019	Total of commitments to be settled at end of financial year 2018
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
11	11 06	European Maritime and Fisheries Fund (EMFF)	0,32	0,00	0,32	100,00%	0,08	0,40	0,31
Total Title 11			**0,32**	**0,00**	**0,32**	**100,00%**	**0,08**	**0,40**	**0,31**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2019 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2018	Total of commitments to be settled at end of financial year 2019	Total of commitments to be settled at end of financial year 2018
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
14	14 02	Customs	0,20	0,00	0,20	100,00%	0,16	0,36	0,20
Total Title 14			**0,20**	**0,00**	**0,20**	**100,00%**	**0,16**	**0,36**	**0,20**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2019 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2018	Total of commitments to be settled at end of financial year 2019	Total of commitments to be settled at end of financial year 2018
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	11,91	9,69	2,21	18,59%	0,00	2,21	2,25
	17 03	Public health	186,77	176,81	9,96	5,33%	18,48	28,44	24,05
	17 04	Food and feed safety, animal health, animal welfare and plant health	272,79	69,08	203,72	74,68%	106,06	309,78	278,67
Total Title 17			**471,47**	**255,58**	**215,89**	**45,79%**	**124,54**	**340,43**	**304,96**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2019 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2018	Total of commitments to be settled at end of financial year 2019	Total of commitments to be settled at end of financial year 2018
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
20	20 02	Trade policy	0,00	0,00	0,00	0,00%	0,00	0,00	0,14
Total Title 20			**0,00**	**0,00**	**0,00**	**0,00%**	**0,00**	**0,00**	**0,14**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2019 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2018	Total of commitments to be settled at end of financial year 2019	Total of commitments to be settled at end of financial year 2018
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
22	22 02	Enlargement process and strategy	0,00		0,00	0,00%	1,54	1,54	1,54
Total Title 22			**0,00**		**0,00**	**0,00%**	**1,54**	**1,54**	**1,54**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2019 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2018	Total of commitments to be settled at end of financial year 2019	Total of commitments to be settled at end of financial year 2018
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,57	0,35	0,22	38,89%	0,00	0,22	0,19
Total Title 26			**0,57**	**0,35**	**0,22**	**38,89%**	**0,00**	**0,22**	**0,19**

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2019 (in Mio €) for DG SANTE									
Chapter			Commitments to be settled				Commitments to be settled from financial years previous to 2018	Total of commitments to be settled at end of financial year 2019	Total of commitments to be settled at end of financial year 2018
			Commitments	Payments	RAL	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
33	33 01	Administrative expenditure of the 'Justice and consumers' policy area	1,80	1,80	0,00	0,00%	0,00	0,00	0,00
Total Title 33			**1,80**	**1,80**	**0,00**	**0,00%**	**0,00**	**0,00**	**0,00**

Total for DG SANTE	**482,0067065**	**261,29**	**220,7147189**	**45,79 %**	**130,4142667**	**351,1289856**	**315,178331**

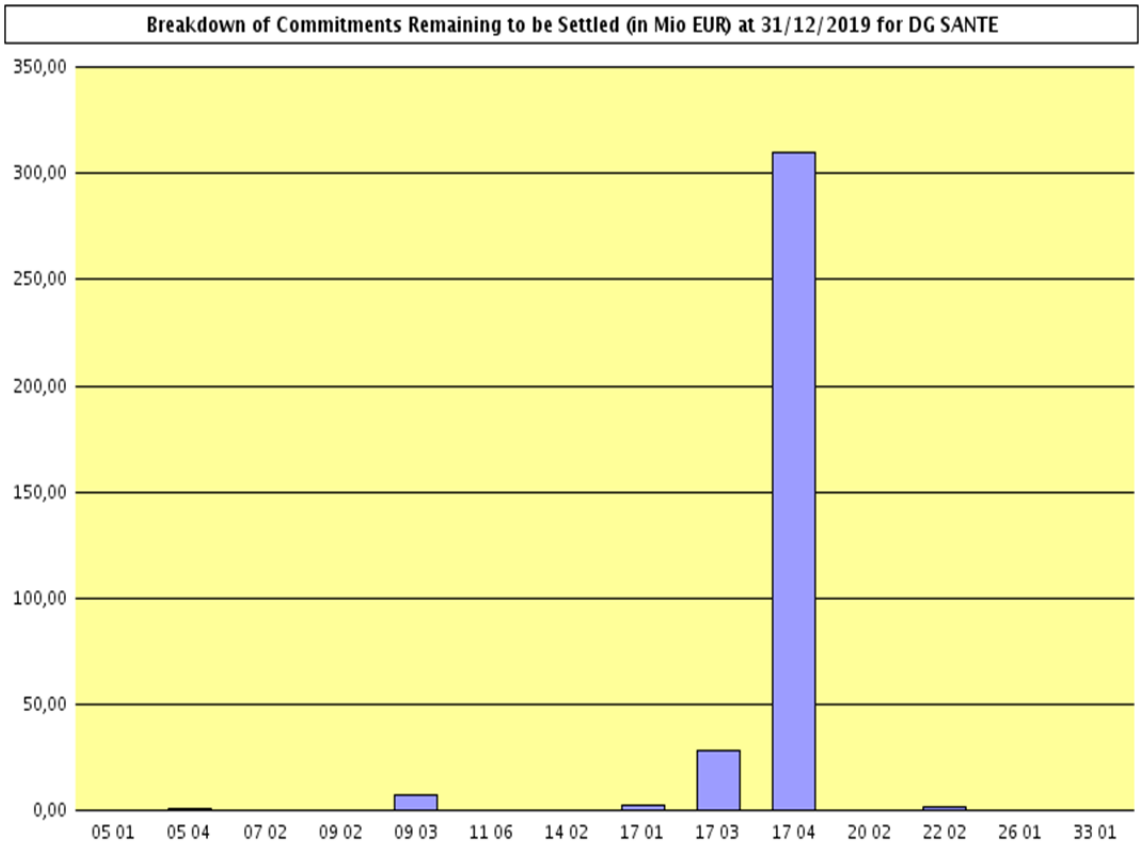
Breakdown of Commitments Remaining to be Settled (in Mio EUR) at 31/12/2019 for DG SANTE
350,00
300,00
250,00
200,00
150,00
100,00
50,00
0,00
05 01
05 04
07 02
09 02
09 03
11 06
14 02
17 01
17 03
17 04
20 02
22 02
26 01
33 01

TABLE 4 : BALANCE SHEET for DG SANTE

BALANCE SHEET	2019	2018
A.I. NON CURRENT ASSETS	28.213.116,30	16.115.244,25
A.I.1. Intangible Assets	2.902.780,63	2.902.780,63
A.I.2. Property, Plant and Equipment	10.414.364,87	11.864.371,15
A.I.5. Non-Current Pre-Financing	14.895.970,80	1.348.092,47
A.II. CURRENT ASSETS	1.209.001,58	30.219.189,65
A.II.2. Current Pre-Financing	-11.684.860,39	17.313.523,45
A.II.3. Curr Exch Receiv &Non-Ex Recoverables	1.282.811,99	2.496.690,04
A.II.4. Inventories	11.608.435,00	10.405.285,00
A.II.6. Cash and Cash Equivalents	2.614,98	3.691,16
ASSETS	**29.422.117,88**	**46.334.433,90**
P.I. NON CURRENT LIABILITIES	-2.057.096,10	-4.110.661,10
P.I.3. Non-Current Financial Liabilities	-2.057.096,10	-4.110.661,10
P.II. CURRENT LIABILITIES	-244.556.614,38	-237.022.930,41
P.II.2. Current Provisions	-70.205.337,10	-67.755.596,97
P.II.3. Current Financial Liabilities	-2.053.565,05	-2.052.735,64
P.II.4. Current Payables	-13.978.087,45	-16.321.032,18
P.II.5. Current Accrued Charges &Defrd Income	-158.319.624,78	-150.893.565,62
LIABILITIES	**-246.613.710,48**	**-241.133.591,51**
NET ASSETS (ASSETS less LIABILITIES)	**-217.191.592,60**	**-194.799.157,61**

P.III.2. Accumulated Surplus/Deficit	2.373.861.772,90	1.995.433.923,33

Non-allocated central (surplus)/deficit*	-2.156.670.180,30	-1.800.634.765,72

TOTAL DG SANTE	**0,00**	**0,00**

TABLE 5 : STATEMENT OF FINANCIAL PERFORMANCE for DG SANTE

STATEMENT OF FINANCIAL PERFORMANCE	2019	2018
II.1 REVENUES	-6.294.190,56	-29.687.066,20
II.1.1. NON-EXCHANGE REVENUES	-10.099.544,14	-34.472.437,90
II.1.1.5. RECOVERY OF EXPENSES	-505.941,31	-3.913.695,59
II.1.1.6. OTHER NON-EXCHANGE REVENUES	-9.593.602,83	-30.558.742,31
II.1.2. EXCHANGE REVENUES	3.805.353,58	4.785.371,70
II.1.2.2. OTHER EXCHANGE REVENUE	3.805.353,58	4.785.371,70
II.2. EXPENSES	445.090.497,52	408.114.915,77
II.2. EXPENSES	445.090.497,52	408.114.915,77
II.2.10.OTHER EXPENSES	63.456.349,56	55.145.261,37
II.2.2. EXP IMPLEM BY COMMISS&EX.AGENC. (DM)	203.021.870,13	193.618.222,38
II.2.3. EXP IMPL BY OTH EU AGENC&BODIES (IM)	175.027.620,86	158.919.073,57
II.2.4. EXP IMPL BY 3RD CNTR & INT ORG (IM)	3.331.194,73	152.118,04
II.2.5. EXP IMPLEM BY OTHER ENTITIES (IM)	239.286,69	256.984,21
II.2.6. STAFF AND PENSION COSTS	8.000,00	8.000,00
II.2.8. FINANCE COSTS	6.175,55	15.256,20
STATEMENT OF FINANCIAL PERFORMANCE	**438.796.306,96**	**378.427.849,57**

Explanatory Notes (facultative):

It should be noted that the balance sheet and statement of financial performance presented in Annex 3 to this Annual Activity Report, represent only the assets, liabilities, expenses and revenues that are under the control of this Directorate General. Significant amounts such as own resource revenues and cash held in Commission bank accounts are not included in this Directorate General's accounts since they are managed centrally by DG Budget, on whose balance sheet and statement of financial performance they appear. Furthermore, since the accumulated result of the Commission is not split amongst the various Directorates General, it can be seen that the balance sheet presented here is not in equilibrium.

Additionally, the figures included in tables 4 and 5 are provisional since they are, at this date, still subject to audit by the Court of Auditors. It is thus possible that amounts included in these tables may have to be adjusted following this audit.

TABLE 5bis : OFF BALANCE SHEET for DG SANTE		
OFF BALANCE	**2019**	**2018**
OB.1. Contingent Assets	0	0
GR for pre-financing	0,00	0,00
OB.2. Contingent Liabilities	-6107428,99	-5903449,29
OB.2.6. CL Other	-6.107.428,99	-5.903.449,29
OB.2.7. CL Legal cases OTHER	0,00	0,00
OB.3. Other Significant Disclosures	-177230344,7	-146661538,1
OB.3.2. Comm against app. not yet consumed	-177.230.344,73	-146.661.538,09
OB.4. Balancing Accounts	183337773,7	152564987,4
OB.4. Balancing Accounts	183.337.773,72	152.564.987,38
OFF BALANCE	**0,00**	**0,00**

Explanatory Notes (facultative):

It should be noted that the balance sheet and statement of financial performance presented in Annex 3 to this Annual Activity Report, represent only the assets, liabilities, expenses and revenues that are under the control of this Directorate General. Significant amounts such as own resource revenues and cash held in Commission bank accounts are not included in this Directorate General's accounts since they are managed centrally by DG Budget, on whose balance sheet and statement of financial performance they appear. Furthermore, since the accumulated result of the Commission is not split amongst the various Directorates General, it can be seen that the balance sheet presented here is not in equilibrium.

Additionally, the figures included in tables 4 and 5 are provisional since they are, at this date, still subject to audit by the Court of Auditors. It is thus possible that amounts included in these tables may have to be adjusted following this audit.

TABLE 6: AVERAGE PAYMENT TIMES in 2019 for SANTE

Legal Times							
Maximum Payment Time (Days)	Total Number of Payments	Nbr of Payments within Time Limit	Percentage	Average Payment Times (Days)	Nbr of Late Payments	Percentage	Average Payment Times (Days)
30	1541	1510	97,99 %	17,28609272	31	2,01 %	36,64516129
44	2	2	100,00 %	31,5			
45	25	24	96,00 %	15,58333333	1	4,00 %	47
47	1	1	100,00 %	42			
60	74	73	98,65 %	22,2739726	1	1,35 %	66
90	283	259	91,52 %	65,05405405	24	8,48 %	105,9583333
211	3	2	66,67 %	198	1	33,33 %	410

Total Number of Payments	**1929**	**1871**	**96,99 %**		**58**	**3,01 %**	
Average Net Payment Time	**25,74079834**			**24,2928915**			**72,44827586**
Average Gross Payment Time	**39,81337481**			**36,57509353**			**144,2758621**

Suspensions							
Average Report Approval Suspension Days	Average Payment Suspension Days	Number of Suspended Payments	% of Total Number	Total Number of Payments	Amount of Suspended Payments	% of Total Amount	Total Paid Amount
0	69	392	20,32 %	1929	143.457.971,09	32,94 %	435.560.226,67

Late Interest paid in 2019			
DG	GL Account	Description	Amount (Eur)
SANTE	65010100	Interest on late payment of charges New	940,08
			940,08

TABLE 7 : SITUATION ON REVENUE AND INCOME in 2019 for DG SANTE								
Chapter		Revenue and income recognized			Revenue and income cashed from			Outstanding balance
		Current year RO	Carried over RO	Total	Current Year RO	Carried over RO	Total	
		1	2	3=1+2	4	5	6=4+5	7=3-6
57	OTHER CONTRIBUTIONS AND REFUNDS IN CONNECTION WITH THE ADMINISTRATIVE OPERATION OF THE INSTITUTION	150.537,64	1.005.128,54	1.155.666,18	150.537,64	1.005.128,54	1.155.666,18	0,00
59	OTHER REVENUE ARISING FROM ADMINISTRATIVE MANAGEMENT	688.859,75	0,00	688.859,75	688.859,75	0,00	688.859,75	0,00
60	CONTRIBUTIONS TO UNION PROGRAMMES	203.820,00	0,00	203.820,00	203.820,00	0,00	203.820,00	0,00
66	OTHER CONTRIBUTIONS AND REFUNDS	17.237.664,29	145.254,51	17.382.918,80	17.237.664,29	0,00	17.237.664,29	145.254,51
Total DG SANTE		**18.280.881,68**	**1.150.383,05**	**19.431.264,73**	**18.280.881,68**	**1.005.128,54**	**19.286.010,22**	**145.254,51**

TABLE 8 : RECOVERY OF PAYMENTS in 2019 for DG SANTE (Number of Recovery Contexts and corresponding Transaction Amount)

INCOME BUDGET RECOVERY ORDERS ISSUED IN 2019	Irregularity		Total undue payments recovered		Total transactions in recovery context(incl. non-qualified)		% Qualified/Total RC	
Year of Origin (commitment)	Nbr	RO Amount	Nbr	RO Amount	Nbr	RO Amount	Nbr	RO Amount
2013					1	505.941,31		
2016					2	2.000,00		
2017	1	29.864,31	**1**	**29.864,31**	1	29.864,31	100,00%	100,00%
2018					9	17.390.718,42		
No Link					1	0,00		
Sub-Total	**1**	**29.864,31**	**1**	**29.864,31**	**14**	**17.928.524,04**	**7,14%**	**0,17%**

EXPENSES BUDGET	Irregularity		OLAF Notified		Total undue payments recovered		Total transactions in recovery context(incl. non-		% Qualified/Total RC	
	Nbr	Amount	Nbr	Amount	Nbr	Amount	Nbr	Amount	Nbr	Amount
INCOME LINES IN INVOICES	1	3.079,20			**1**	**3.079,20**	1	3.079,20	100,00%	100,00%
NON ELIGIBLE IN COST CLAIMS	124	11.366.729,13			**124**	**11.366.729,13**	166	59.409.422,90	74,70%	19,13%
CREDIT NOTES	28	168.593,28			**28**	**168.593,28**	88	902.303,90	31,82%	18,68%
Sub-Total	**153**	**11.538.401,61**			**153**	**11.538.401,61**	**255**	**60.314.806,00**	**60,00%**	**19,13%**
GRAND TOTAL	**154**	**11.568.265,92**			**154**	**11.568.265,92**	**269**	**78.243.330,04**	**57,25%**	**14,78%**

TABLE 9: AGEING BALANCE OF RECOVERY ORDERS AT 31/12/2019 for DG SANTE

	Number at 1/01/2019	Number at 31/12/2019	Evolution	Open Amount (Eur) at 1/01/2019	Open Amount (Eur) at 31/12/2019	Evolution
2011	1	1	0,00 %	145.254,51	145.254,51	0,00 %
2018	2		-100,00 %	1.005.128,54		-100,00 %
	3	**1**	**-66,67 %**	**1.150.383,05**	**145.254,51**	**-87,37 %**

TABLE 10 :Recovery Order Waivers >= 60 000 € in 2019 for DG SANTE						
	Waiver Central Key	**Linked RO Central Key**	**RO Accepted Amount (Eur)**	**LE Account Group**	**Commission Decision**	**Comments**

Total DG SANTE	

Number of RO waivers	

Justifications:

TABLE 11 :Negociated Procedures in 2019 for DG SANTE

Internal Procedures > € 60,000

Negotiated Procedure Legal base	Number of Procedures	Amount (€)
Annex 1 - 11.1 (a) - Follow-up of an open/restricted procedure where no (or no suitable) tenders/requests to participate have been submitted	2	578.000,00
Annex 1 - 11.1 (b) - Artistic/technical reasons or exclusive rights or technical monopoly/captive market	1	105.000,00
Total	**3**	**683.000,00**

TABLE 12 : Summary of Procedures in 2019 for DG SANTE

Internal Procedures > € 60,000

Procedure Legal base	Number of Procedures	Amount (€)
Negotiated procedure middle value contract (Annex 1 - 14.2)	4	418.050,00
Negotiated procedure without prior publication (Annex 1 - 11.1)	3	683.000,00
Open procedure (FR 164 (1)(a))	3	6.770.461,20
Restricted procedure without Dynamic purchasing system (FR 164 (1)(b))	3	2.190.206,12
Total	**13**	**10.061.717,32**

Additional Comments:

TABLE 13 : BUILDING CONTRACTS in 2019 for DG SANTE

Legal Base	Procedure subject	LC/FW?	Contract/FW Number	Contractor Name	Contract/FW Subject	Amount (€)

TABLE 14 : CONTRACTS DECLARED SECRET in 2019 for DG SANTE

Legal Base	Procedure subject	LC/FW?	LC Contract/Grant type or FW type	LC Date	Contract/FW Number	Contractor Name	Contract/FW Subject	Amount (€)

TABLE 15 : FPA duration exceeds 4 years - DG SANTE

None of your FPA (if any) exceeds 4 years

ANNEX 4: Materiality criteria

With regard to budget implementation, the concept of materiality provides the authorising officer by delegation with a basis for determining significant weaknesses that should be subject to a formal reservation to the declaration of assurance. The criteria used in DG SANTE for making reservations are based on the standing instructions for the preparation of Annual Activity Reports.

Risks or weaknesses leading to a reservation should fall within the scope of the declaration which covers a narrower area than the AAR itself:

- ⇨ The AAR includes an assessment of the results achieved by DG SANTE with the resources allocated. It is a "mirror" image of DG SANTE's annual Management Plan (MP).
- ⇨ The declaration expresses the Director's General responsibilities conferred under the Charter for Authorising Officers by Delegation and is restricted to the following areas (i) control systems, (ii) sound financial management, and (iii) legality and regularity of transactions.

When defining whether a detected issue in internal control is material, DG SANTE assesses both qualitative and quantitative aspects:

1. Qualitative criteria

DG SANTE investigates the significance of any detected weakness and the expected potential for further weaknesses in qualitative terms by taking into account the nature and scope of the weakness, the possible impact of the weakness, as well as the existence of effective corrective actions.

1.1 Significant repetitive errors

Systematic errors caused by weaknesses in key controls and intentional misstatements are likely to entail a greater exposure to potential financial loss than random errors or faulty judgements.

In the context of grant management and certain procurements, the exposure to potential financial loss is highest for errors in final payments. For errors in pre-financing payments, the risk is much lower because firstly, these funds remain the property of the EU and secondly, errors detected in pre-financing or interim payments can still be corrected at the final payment stage.

1.2 Significant deficiencies in one of the control systems

Identified weaknesses in the design or operation of internal controls of DG SANTE, final beneficiaries or Member States could significantly influence the appreciation of the Director's General Declaration.

This could be the case notably,

- if significant conflicts of interest existed;
- if personnel were unqualified;
- if the systems failed to provide complete and accurate information due to design flaws or misapplication of procedures;
- if appropriate verifications, approvals, reviews and audits of transactions and procedures were absent or largely insufficient or inadequate;
- if duties were not separated; or
- if controls were intentionally overridden and/or wilfully circumvented.

1.3 Issues outlined by auditors or OLAF

A critical observation made by the Court of Auditors, the Commission's Internal Audit Service (IAS) or OLAF could lead to a reservation,

- if the observation is made in an area covered by the Director's Declaration, and
- if the issue is not solved immediately during the reporting period, and
- if the impact is material (financial loss exceeding 2 % of the implemented budget concerned (ABB activity; see point 2 below).

1.4 Significant reputational risks

Besides a possible quantitative aspect of a reputational risk, its impact on the declaration of assurance is assessed mainly on the basis of qualitative criteria, such as sensitivity of the policy area concerned, high public interest or serious legislative concerns. It encompasses issues that could cause lasting damage to the Commission's image due to, for example, financial fraud inside DG SANTE or serious breaches on provisions of legislation (including the Treaty), further to DG SANTE's activities.

2. Quantitative criterion

2.1 Erroneous transactions

In the framework of a transaction-based approach, DG SANTE considers that identified erroneous transactions which expose DG SANTE to an actual financial loss could lead to a reservation to the Director's General declaration under the following conditions:

(1) A significant weakness described in the AAR has been identified, and

(2) The weakness affects at least one the areas of the declaration of assurance: (i) control systems, (ii) sound financial management, or (iii) legality and regularity of transactions, and

(3) An actual financial loss or reputational issue has already occurred or is very likely to materialise, and

(4) The amount has actually exceeded or is very likely to exceed the threshold of 2 % of the relevant payment budget actually implemented, that means if the issue is not already corrected during the reporting period, for example by recovery orders or offsetting with future payments due.

For on-the-spot controls of payments, an error rate after corrective measures is called "residual error rate" and is calculated and measured against the 2% materiality criterion following the Commission's guidelines (see below):

- Errors found in ex-ante controls are typically corrected prior to the final payment.
- Errors found during ex-post controls (after the final payment) are typically corrected by recovery orders or other kinds of corrections.

2.2 Error rate calculation

For on-the-spot controls of payments, an error rate after corrective measures is called "residual error rate" and is measured against the 2% materiality criterion. It is calculated following Commission's guidelines built up along the lines of a "3+1 steps" approach:

Step 1: calculating the representative detected error rate in a sample of transactions and taking account of any corrections made for the calculation of the residual error rate in the entire population;

Step 2: estimating the financial exposure as (net) 'amount at risk' to the value of the relevant payments authorised during the reporting year, based on those error rates calculated for a population of transactions mostly authorised in previous years;

Step 3: relating the 'amount at risk' for the activity considered to the relevant (ABB) aggregation level for determining whether a reservation would be due;

Step 4: "if" a reservation is entered, then assessing its relative impact on the AOD's overall assurance and Declaration (the "scope"). The following 'de minimis' thresholds are applied: if the scope of the reservation is < 5% of total payments and the exposure is < EUR 5 million, then no financial reservation is to be made (without prejudice to a reservation for reputational reasons).

2.3 Non-representative sampling:

For selecting the sample of transactions to be controlled on the spot, DG SANTE applies a risk based and targeted approach rather than a statistical random method that would comply with the criteria of samples' representativeness. The risk based approach is considered more cost-effective given the heterogeneity and relatively small size of DG SANTE's audit population.

In this case the detected error rate is not representative and thus cannot be extrapolated to all payments made in the same policy area. When measuring against the 2% materiality level, DG SANTE calculates the weighted arithmetic average error rate from the audited sample and complements the information by a qualitative analysis of the origin, nature, impact and coverage of the errors found before deciding whether or not the materiality threshold of 2% is exceeded.

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ANNEX 5: Relevant Control Systems for budget implementation

Annex 5.1 Relevant Control System for budget implementation under direct management

This Annex is divided into two parts, firstly, DG SANTE's control strategy related to grants in the Food and Feed policy area and secondly, DG SANTE's control strategy for public procurement procedures.

5.1.1. Type of expenditure: grants to Member States in direct management

DG SANTE co-finances Member States' programmes for animal disease eradication and monitoring, veterinary emergency measures and phytosanitary measures through the reimbursement of eligible costs. Since 2016, the Common Financial Framework (CFF, Regulation (EU) No 652/2014) is the main basis for the corresponding expenditure.

The following descriptions focus on the national programmes for animal disease eradication and control as these account for about 70% of the grants in the Food and Feed policy area. The controls described below are implemented as far as applicable for other kinds of grants in the Food and Feed policy area.

This annex presents in schematic form the characteristics of the main management and control systems put in place by DG SANTE.

- **!** Information on the costs and benefits of control is not always available for each single control stage, but for the process as a whole.
- **!** Most of the benefits of control are non-quantifiable as they help ensure compliance and good quality of the funded actions which is impossible to quantify.
- **!** For some control indicators, mere numbers and percentages do not give reliable information on the control effectiveness; only a qualitative analysis of the reasons behind the figures is relevant and useful.

Grants to Member States				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 1a) Programming: legal base and annual invitation to Member States to submit applications; **1b) Evaluating the national programmes and their EU funding** ***Main control objectives:*** *ensuring that the Commission selects the national programmes that contribute the most towards the achievement of the policy objectives (effectiveness and best value for public money); compliance (legality & regularity); prevention of fraud (anti-fraud strategy)*				
a) **Eligibility, selection and award criteria** should be adequate to evaluate the proposed national programmes and to ensure that the policy objectives are achieved.	1. Regulation (EU) No 652/2014 (CFF) applicable to programmes submitted after 15 May 2014 lays down the provisions for the management of expenditure relating – inter alia – to the national programmes for animal disease eradication and control. 2. To ensure consistency with these criteria, standard requirements are set for Member States' applications to facilitate the process of submission, approval and assessment of progress during the implementation of the national programmes (Commission decision on a work programmes for the implementation of veterinary programmes). 3. DG SANTE provided mandatory electronic templates and application guidelines for the Member States' submissions; information meetings are held to explain the requirements. 4. Each year, DG SANTE invites the Member States to submit their proposed annual programmes according to the rules and timeframes.	The risk is assessed as low as the selection and attribution criteria, the submission modalities and the list of eligible programmes are rather stable over the last few years. Thus, at the programming stage the controls on an annual basis are quite low. They are embedded in stages 1b), 3) and 4) below.	**Cost of control**: - Included in general estimate of DG SANTE's staff costs for programming, evaluation and grant decision **Benefits of control:** As no significant errors are to be expected, the benefits are mainly administrative in nature and thus non-quantifiable in budgetary terms	- Ratio of rejected national programmes to total programmes submitted ⇨ Target: qualitative analysis of reasons for rejections and adjustments in relation to priority diseases - Timeliness of Commission work programmes ⇨ Target: by no later than 30 April of year N-1 for the submission of national programmes for year N by 30 May N-1

Grants to Member States				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
b) The main challenge is to fund only national programmes of **good quality to ensure a high impact on the achievement of the policy objectives at reasonable costs** and adequate requests for co-financing.	1. To ensure a high level of expertise in the evaluation exercise - Each national programme (technical and financial parts) is assessed by DG SANTE competent staff of the Unit concerned; - External experts, selected through an open call for expression of interest, advise in the technical evaluation; DG SANTE provides a guidance document with checklists and templates on the evaluation procedure; conflict of interest declarations. 2. To ensure high quality and reasonable costs of the national programmes, DG SANTE competent staff requests to Member States additional information or modifications to improve their programmes if deemed necessary. 3. Based on the results of the evaluation, DG SANTE facilitates the Member States' finalisation of their national programmes. 4. DG SANTE communicates to Member States (Standing Committee (PAFF)) by 30 November each year the list of national programmes technically approved and proposed for co-financing.	1a. 100% vetting of external experts for technical expertise and independence 1b. 100% of national programmes are evaluated following a standard procedure (technical and financial parts) 2. 100% supervision of work of external evaluators in DG SANTE 3. 100% of national programmes modified as requested by DG SANTE	**Cost of control**: - Included in general estimate of DG SANTE's staff costs for programming, evaluation and grant decision - Estimated costs of the appointed external experts and logistics for the evaluation **Benefits of control:** The evaluation of the proposed national programmes helps to ensure that national programmes are compliant with the legislation and of good quality. This control is a very significant to ensure value for money through improved quality, but the benefit is not quantifiable.	- Ratio of modified programmes to total programmes retained after evaluation ⇨ Target: qualitative analysis of reasons for rejections and modifications - Evaluation procedure finalised on-time to allow a timely launch of the national programmes. ⇨ Target: 100% on time fixed in the legislation

Grants to Member States				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 2 "Contracting": approving the national programmes and the EU financial contribution in a grant decision ***Main control objectives**: ensuring that the actions and funds allocation is optimal (best value for public money; effectiveness, economy, efficiency) and compliant (legality & regularity)*				
The national programmes for which a grant decision is taken by the authorising officer by delegation (AOSD) should correspond to (a) the programmes and amounts communicated to the PAFF and/or (b) the budgetary commitment.	1. DG SANTE approves the annual national programmes and associated funding by 31 January each year (awarding decision by the AOSD; communication to the PAFF). 2. Following ex-ante checks on administrative and legal aspects of the grant decisions, the AOSD approves formally in a grant decision (one for each Member State) the programmes and their associated funding. by 31 January each year.	1. 100% of programmes to be technically approved prior to preparing the grant decision 2. 100% of grant decisions checked prior to approval (depth of checks depends on risk criteria)	**Cost of control:** - Included in general estimate of DG SANTE's staff costs for programming, evaluation and grant decision; **Benefits of control:** Compliance	- Grant decisions taken on-time to allow a timely launch of the national programmes. ⇨ Target: 100% on time fixed in the legislation

Grants to Member States				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 3: Monitoring the implementation of national programmes and managing financial transactions ***Main control objectives**: ensuring that the operational results or progress from the national programmes are of good quality and meet the objectives and conditions (effectiveness & efficiency); ensuring that the related financial operations comply with regulatory and contractual provisions (legality & regularity); prevention of fraud (anti-fraud strategy); ensuring appropriate accounting of the operations (reliability of reporting, safeguarding of assets and information)*				
Controls have to prevent that the national programmes' objectives are only partially achieved or not at all and/or that ineligible amounts are paid.	1. Member States' reporting requirements for each programme are set forth in Regulation (EU) No 652/2014. 2. Competent staff assess intermediate technical and financial reports for each programme and, if need be, funds are reallocated between programmes and Member States. 3. Member States' present the results of their programmes to PAFF on their own initiative or when requested by DG SANTE. 4. Annual technical and financial reports are assessed by competent staff prior to initiating payments. 5. For a few programmes, ex-ante financial on-the-spot controls are carried out; under certain circumstances, the final payment is postponed and only first tranches are paid. 6. Payments follow DG SANTE's financial circuits with 1st and 2nd level financial verifications, authorisations and encodings in ABAC reviewed by DG BUDG. 7. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs apply) .	1 to 4. 100% covered by reporting requirements, monitored at the desk at interim and at final reporting stage (control depth depends on risk criteria) 5. Further to a risk assessment, a small number of programmes is audited on the spot prior to the final payment 6. 100% of payments and ABAC encodings 7. 100% if conditions are fulfilled	**Cost of control**: - Estimated staff costs for technical and financial monitoring of the Member States' programmes - Estimated staff costs for ex-ante audit activity - Mission costs for monitoring activities **Benefits of control:** - Estimated value of corrections made during 2nd level financial controls	- Programmes concerned by the reallocation exercise ⇨ Target: qualitative analysis of reasons for reallocation (e.g. change in legislation or modifications of the programmes) - Estimated value of the financial corrections made during ex-ante controls of the final payment ⇨ Target: <2 % - Files with relevance for OLAF adequately transmitted to OLAF and followed up ⇨ Target: 100% - Time between receipt of the Member States' final financial report and the final payment ⇨ Target: 100% on time - Timely reallocation decision ⇨ Target: 100% on time

Grants to Member States				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 4: Ex-post controls: on-the-spot controls and evaluation ***Main control objectives**:* *a) Measuring the effectiveness of ex-ante controls by ex-post controls; detect and correct any error or fraud remaining undetected after the implementation ex-ante controls (legality & regularity; anti-fraud strategy); addressing systemic weaknesses in the ex-ante controls, based on the analysis of the findings (sound financial management); ensuring appropriate accounting of the recoveries to be made (reliability of reporting, safeguarding of assets and information);* *b) Ensuring that the (audit) results from the ex-post controls lead to effective recoveries (legality & regularity; anti-fraud strategy); Ensuring appropriate accounting of the recoveries made (reliability of reporting);* *c) Monitoring disease eradication activities in Member States to improve the cost-benefit ratio of animal eradication programmes.*				
a) Certain issues (errors or attempted fraud) cannot be detected and corrected during ex-ante controls at the desk; thus, **ex-post on-the-spot controls** should complement the desk checks.	1a. DG SANTE's ex-post control strategy aims at optimising the control impact through a risk based selection of national programmes to be audited and a sufficient audit coverage to lower the residual error rate. 1b. The ex-post control strategy and the work plan are adopted annually by DG SANTE's Directors' Steering Committee. 2. Ex-post controls are carried out by competent staff or external audit services independent of the policy Unit and according to professional standards; the audit programmes foresee anti-fraud measures. 3. All audit reports undergo a contradictory procedure within DG SANTE and with the auditees (i.e. Member States). 4. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations of fraud and contacts with OLAF).	- Risk based audit sample - 20% minimum audit coverage to maximise audit correction .	**Cost of control**: - Estimated staff costs for ex-post controls - Estimated mission costs for ex-post controls - Cost of external audit services. **Benefits of control:** - Value of the financial corrections made during ex-post controls	- Detected error rate ⇨ Target: decreasing trend - Residual error rate in ABB activity ⇨ Target: < 2% - Number of files referred to OLAF. ⇨ Target: 0 - Time between audit visit and finalisation of audit report not exceeding the internal deadlines ⇨ Target: 100% on time - Implementation of the annual ex-post control work plan ⇨ Target: 100% - Percentage of audit recommendations accepted by the beneficiaries/Member States ⇨ Target: 100%

Grants to Member States				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
b) **Detected errors**, irregularities or suspicions of fraud should be **addressed adequately and in a timely manner.**	1. Systematic communication and registration of all results of ex-post controls. 2. Financial and operational validation of recovery orders or additional payments following DG SANTE's financial circuit.	1. 100% of final control results 2. 100% 2nd level financial control of recovery orders	**Cost of control**: - Estimated staff costs for technical and financial monitoring of the Member States' programmes **Benefits of control:** - Amount of actually corrected errors	- Audit results related to DG SANTE implemented ⇨ Target: 100% - "Time to recover" from final accepted audit report to debit note ⇨ Target: 100% on time
c) The main challenge is to **ensure a high impact on the achievement of the policy objectives at reasonable costs.**	1. Indicators defined by DG SANTE with experts to evaluate the implementation and management of eradication programmes, the effectiveness of the measures implemented and to measure progress or the deficiency in a specific area. The results of previous years are checked by disease, Member State and programme. 2. For specific diseases a task force sub-group has been created to give technical advice to the design and implementation of a programme .	1. All national programmes covered 2. Depending on the disease	**Cost of control**: - Estimated staff costs for monitoring **Benefits of control:** The evaluation of the proposed national programmes helps ensure that they 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.	- Percentage of recommendations of the task force implemented by Member States ⇨ Target: 100% - Evolution of the progress measured by DG SANTE staff: achievement of the objectives of the programmes (for eradication, control and monitoring) in relation to the evolution of the disease in previous years ⇨ Target: positive trend

5.1.2. Type of expenditure: procurement in direct management

Following the transfer of implementation tasks to the Executive Agency for Consumers, Health, Agriculture and Food (CHAFEA), public procurement in relation to the Public Health programmes as well as the procurement procedure for the initiative "Better Training for Saver Food" (BTSF) is managed by the agency. Consequently, the number of contracts managed by DG SANTE is very limited (see section 2.1.1.1.2 of the Annual Activity Report).

By far most of the procurement procedures are based on framework contracts of DG SANTE or another DG, in particular DGs DIGIT, COMM and BUDG. DG SANTE buys mainly services in the area of data collection, evaluation, training, information campaigns, IT and communication services, facilities management etc. The contractors are mainly institutes, laboratories, consultancy firms and other private companies.

This annex presents in schematic form the characteristics of the main management and control systems put in place by DG SANTE.

- **!** Information on the costs and benefits of control is available for the entire control process, but not always for each single control stage.
- **!** Most of the benefits of control are non-quantifiable as they help ensure compliance and good quality of the funded actions which is impossible to quantify.
- **!** For some control indicators, mere numbers and percentages do not give reliable information on the control effectiveness; only a qualitative analysis of the reasons behind the figures is relevant and useful.

Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 1a) Programming: legal base **1b) Needs assessment and definition of needs** **1c) Selection of the offers and evaluation** ***Main control objectives:*** *ensuring sound financial management (i.e. effectiveness, efficiency and economy); compliance (legality & regularity); prevention of fraud (anti-fraud strategy)*				
a) **Needs have to be well defined** (operationally and economically) and decision to procure have to be appropriate to meet the operational objectives. Poor planning or inadequate organisation of the procurement procedure could entail delays or interruptions of services leading to an underachievement of the policy objectives.	1. For operational credits in each policy area, a detailed annual work programme is adopted by the Commission specifying the areas for which calls for tenders or calls for proposals will be organised; it constitutes a financing decision. 2. Planned external studies are listed in a register kept by Secretariat General. 3. Each call for tenders fixes either a maximum value or a price range for the contract based on a pricing methodology. 4. The timing and organisation of a procurement procedure is supervised by the Authorising Officer responsible. 5. Timing is monitored and planning updated through budget implementation reports prepared by the central financial Unit for discussions in Directors' Steering Committees at least two times a year.	1. 100% of calls for tender are covered by a Commission financing decision. 2. 100% of external studies are listed in a special register at the level of the Secretariat General. 3. All calls for tender are based on a pricing methodology (depth depending on feasibility). 4-5. All public procurements in the annual work programmes are approved by the Management	**Cost of control**: - Estimated staff costs for programming and planning and execution of the procurement procedures. **Benefits of control:** - Amount of rejection of unjustified purchases or services discontinued.	- Number of open calls covered by the annual work programme not launched in the same year as the work programme. ⇨ Target: 0% - Depth of price calculation using the pricing methodology (according to template) ⇨ Target: 100% in-depth - Timely launch of procurement procedures as specified in the annual work programmes ⇨ Target: 100%

Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
b) **If the definition of tender specifications**, exclusion, selection and award criteria are poor, or if the publication of a tender is insufficient, the best possible bids might not be received.	1. To ensure a high level of expertise in drafting the tender specifications, DG SANTE competent staff of the policy Units write the specifications with the support of the central procurement team in the horizontal Directorate. 2. DG SANTE uses templates for terms of reference, exclusion and selection criteria that follow the Commission guidelines; the central procurement team organises the entire process and does a quality control. 3. The central procurement committee (CMP) reviews the tender specifications prior to publication for certain sensitive procurements on special request of the policy Unit. 4. The tender specifications are validated by the Authorising Officer responsible who launches the publication of the tender in pre-defined means.	1. Tender specifications are drafted in the Units concerned with central support on request (depth of the support depending on needs) 2. 100% where applicable 3. Central ex-ante review of tender specifications on special request 4. 100% validation by Authorising Officer	**Cost of control**: - Estimated staff costs for drafting tender specifications **Benefits of control:** - Value of a contract, possibly at 100% if significant errors occurred - Benefit of "best value for money" is non-quantifiable as quality aspect is impossible to quantify in an objective, meaningful and reliable way.	- Number of open calls for tenders for which no offer is received (reasons to be analysed) ⇨ Target: 0% - Number of cancellations of open tender procedures (reasons to be analysed) ⇨ Target: 0% - For open calls for tender, number of requests for clarifications, complains or litigation regarding open tenders in relation to offers received ⇨ Target: negative trend /benchmark (to be defined) --Timeliness of procurement procedures relative to Commission Work Programmes

Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
c) The most economically advantageous offer should be selected and the **evaluation process** should be **unbiased, fair and without error.** If procedures are not correctly followed, DG SANTE could be facing possible litigation and /or reputational damage.	1. The central procurement team in the horizontal Directorate organises the opening and evaluation procedures, sees to their correct implementation and documentation; members of committees are appointed by the Authorising Officer responsible. 2. Persons involved in the formal procedures sign declarations of absence of conflict of interest. 3. Bidders are checked against exclusion and selection criteria published with the tender specifications. 4. The central procurement committee examines open call tender procedures > €144.000 and gives an independent opinion to the Authorising Officer responsible. 5. The Authorising Officer responsible validates the evaluation results and takes the award decision. 6. After the award decision, a standstill period of two weeks applies in certain procedures before the contract is signed to give unsuccessful tenders the opportunity to raise concerns.	1. 100% of tender procedures are documented; for 100% of tender procedures > €60.000 committees are formally appointed 2. 100% of evaluators 3. 100% of bidders checked 4. For 100% of open call tender procedures above the threshold the CMP gives an opinion 5. 100% validated 6. 100% when conditions are fulfilled	**Cost of control**: - Estimated staff costs in the evaluation process **Benefits of control:** - Value of a contract, possibly at 100% if significant errors occurred - Benefit of "best value for money" is non-quantifiable as quality aspect is impossible to quantify in an objective, meaningful and reliable way.	- Number of valid complaints, Ombudsman cases or litigations received ⇨ Target: 0% - Number of cancellations of open tender procedures due to errors in evaluation process ⇨ Target: 0% --Ratio of average cost of control to budget spent on procurement

Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 2: Monitoring of the implementation of the contract and financial transactions ***Main control objectives**: ensuring that the implementation of the contract is compliant with the signed contract and that the purchased products or services are of good quality and meet the contract's objectives and conditions (effectiveness & efficiency); ensuring that the related financial operations comply with regulatory and contractual provisions (legality & regularity); prevention of fraud (anti-fraud strategy); ensuring appropriate accounting of the operations (reliability of reporting, safeguarding of assets and information)*				
The purchased products or services should be provided in accordance with the technical requirements and the contractor should deliver within the set schedule and price range.	1. The contract provisions follow the model contract of the Commission. 2. Competent staff monitors the implementation of the contract and the progress made (frequency and depth depending on the size and sensitivity of the contract). 3. Technical implementation reports are assessed and validated prior to initiating payments. 4. DG SANTE makes use of contractual provisions for refusing technical reports, cutting payments, termination of the contract, penalties etc. 5. Financial checks prior to payment are carried out according to DG SANTE's financial circuits with 1st and 2nd level financial verifications, authorisations and encodings in ABAC. 6. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).	1 to 4. 100% covered by model contracts, monitoring of progress, financial circuits with assessment and validation of technical and financial reports (control depth depends on risk criteria); 5. 100% if conditions are fulfilled	**Cost of control**: - Estimated staff costs for monitoring and financial transactions - Mission costs for monitoring activities **Benefits of control:** - Estimated value of the financial corrections made during ex-ante controls of the final payment - Benefit of "best value for money" is non-quantifiable as quality aspect is impossible to quantify in an objective, meaningful and reliable way.	- Estimated value of the financial corrections made during ex-ante controls of the final payment ⇨ Target: < 2% - Time-to-pay (target: maximum 30 or 60 days as the case may be) ⇨ Target: 100% on time - Rate of late interest or damage payments to total value of all procurement contracts ⇨ Target: 0%

Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 3: Supervisory measures ***Main control objectives**: Measuring the effectiveness of ex-ante controls by supervisory controls; ensuring to detect and correct any error or fraud remaining undetected after the implementation ex-ante controls (legality & regularity; anti-fraud strategy); addressing systemic weaknesses in the ex-ante controls, based on the analysis of the findings (sound financial management); ensuring appropriate accounting of the recoveries to be made (reliability of reporting, safeguarding of assets and information)*				
In some cases ex-ante controls at the desk might fail to prevent, detect and correct errors in procurement procedures or attempted fraud; **other internal controls** should be designed to prevent, detect or mitigate negative effects.	1. DG SANTE's ex-post control strategy includes procurement contacts of exceptionally high amounts or other high risks; the audit work programme foresees anti-fraud measures. 2. Follow-up on audit recommendations linked to procurement (Court of Auditors and IAS) 3. Exceptions and internal control weaknesses are reported and analysed. 4. The management of sensitive functions is centralised to ensure independent analysis and judgment. 5. If deemed necessary, the file is referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).	1. Risk based audit sample (no minimum audit coverage foreseen as only on exceptional basis) 2. 100% of accepted recommendations implemented within the deadlines 3. 100% of financial procedures 4. High risk operations 5. 100% if conditions are fulfilled	**Cost of control**: - Estimated staff costs for ex-post controls, internal audits and other supervisory controls - Estimated mission costs for audits or other controls - Cost of external audit services **Benefits of control:** - Value of the financial corrections made during ex-post audits or controls	- Detected error rate ⇨ Target: decreasing trend - Residual error rate ⇨ Target: < 2% Ratio of corrected control weaknesses to total detected weaknesses in procurement procedures ⇨ Target: 100% - Implementation of the annual work plans of audit and ex-post control on procurement ⇨ Target: 100% - Average cost per audit to average amount of audit correction ⇨ Target: > 100%

Annex 5.2 Relevant Control System for budget implementation through entrusted entities

This Annex is divided into two parts: one that shows DG SANTE's control strategy related to the executive agency and one related to EU decentralised agencies for which DG SANTE is "parent".

No control strategy is provided for cross-delegated funds to other Directors-General given that they are Authorising Officers by Delegation themselves and required to implement the appropriations subject to the same rules, responsibilities and accountability arrangements as DG SANTE. According to the cross-delegation agreements that DG SANTE signed with the authorising officers responsible, they report annually on the use made of the delegated appropriations.

5.2.1. DG SANTE transferred and cross-delegated budget implementation tasks

In 2019, DG SANTE managed financial operations under the following two policy areas: Public Health and Food and Feed Safety. DG SANTE entrusted the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) with the implementation of about EUR 65,6 million which amounts to about 20% of the 2019 operational budget (without subsidy payments to agencies).

DG SANTE finances parts of the running costs of CHAFEA through the payment of a subsidy of EUR 5,9 million to the executive agency's 2019 operating budget (two other parent DGs also pay their part: JUST and AGRI). The Director of the agency implements the agency's operating budget as authorising officer according to the standard financial regulation applicable to an executive agency. This means that the Director is accountable for the regularity and legality of this expenditure and is himself subject to the discharge decision of the Parliament.

The Act of Delegation specifies the agency's management tasks and duties, including internal control and risk management systems, and modalities on reporting relevant and reliable control results to the Commission. The Act of Delegation also specifies DG SANTE's scrutiny rights and obligations, including documentary and on-the-spot checks and audits at the agency.

! DG SANTE's control strategy for the executive agency encompasses both the delegated EU funds and the subsidy payments to the executive agency's operating budget as for both transactions the same internal control system applies.

! For some control indicators, mere numbers and percentages do not give reliable information on the control effectiveness; only a qualitative analysis of the reasons behind the figures is relevant and useful.

1. Budget implementation tasks delegated to the executive agency				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 1. "Mandate of the entrusted entity": establishment, prolongation or adjustment of the delegation act of the executive agency ***Main control objectives:*** *ensuring that the legal framework for the management of the relevant funds is fully compliant and regular (legality & regularity), delegated to an appropriate entity (best value for public money, economy, efficiency), without any conflicts of interests (anti-fraud strategy)*				
The **establishment (or prolongation) of the mandate of the executive agency** should be free of any legal issues, as these could undermine the legal basis for the agency's management of the EU funds transferred to it.	The legal framework ("statute") for executive agencies is laid down by Council Regulation (EC) 58/2003. 1. A cost-benefit study is carried out prior to both the establishment and the prolongation of the agency's mandate (last cost-benefit study of 2013). 2. The Member State Committee for executive agencies approves the Commission's proposals for establishing an agency and prolonging its mandate. 3. DG SANTE follows the Commission's models for the decisions on establishment and task delegation to the agency. 4. DG SANTE manages the interservice consultations and publications of the Commission Decisions.	**100% in-depth** controls at each stage on DG SANTE's and DG BUDG's side **Frequency:** - Once in 2004-2005 when the agency was established - 2013 when the mandate of the agency was prolonged from 2014 to 2020	**Cost of control**: Estimated SANTE staff costs for technical, financial and legal preparation of the agency's mandate, approval by the Member State Committee and adoption by the Commission **Benefits of control:** The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred	Number of legal issues a/o negative opinions during the interservice consultation ⇨ Target: 0 - Quality of the legal work not challenged by auditors or OLAF ⇨ Target: 0 - Timely adoption of all necessary legal acts for the extension of the agency ⇨ Target: not applicable in 2019

1. Budget implementation tasks delegated to the executive agency				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 2. Readiness assessment of the executive agency's control framework towards autonomy ***Main control objectives**: ensuring that the entrusted entity is fully prepared to start/continue implementing the delegated funds autonomously respecting the five control objectives set forth in the Financial Regulation: (i) legality and regularity, (ii) sound financial management, (iii) true and fair view reporting, (iv) safeguarding assets and information, (v) anti-fraud strategy*				
The **financial and control framework deployed by the executive agency** should be fully mature to guarantee that the control objectives are met.	1. DG SANTE carried out an ex-ante assessment of the agency's internal control system prior to granting full budget autonomy in 2007. This exercise was not repeated as the subsequent prolongations and amendments of the agency's mandate did not require a substantial change to the agency's control systems for the task delegated by DG SANTE. 2. According to the Act of Delegation, the agency submits to DG SANTE for approval any substantial change in its manuals and procedures, in its model grant agreements and procurement contracts. This is done through the Steering Committee.	1. **100% in-depth** control once when the agency was set up 2. Each request for substantial change is examined in-depth **Frequency:** - Once in 2005-2006 when the agency gained autonomy	**Cost of control:** Not applicable per year and not in 2019, as estimated staff costs for ex-ante assessment only once when agency is established **Benefits of control:** The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred	Granting budget autonomy without significant delay ⇨ Target: Not applicable in 2019 (agency gained full autonomy in 2007) - Time between establishment of the agency and granting of autonomy ⇨ Target: 100% on time according to internal planning *(comment: not applicable after 2007 when the agency gained full autonomy)*

1. Budget implementation tasks delegated to the executive agency				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 3: Operations: DG SANTE's monitoring and supervision ("control *with* the executive agency") ***Main control objectives**: ensuring that DG SANTE is fully and timely informed of any relevant management issues encountered by the executive agency, in order to possibly mitigate any potential financial and/or reputational impacts*				
DG SANTE should be informed timely of **relevant management issues encountered by the executive agency**; DG SANTE should react upon notified issues timely and adequately. If not, this could reflect negatively on the Commission's reputation.	The Act of Delegation specifies the agency's management tasks and duties, including internal control and risk management systems, and modalities on reporting relevant and reliable control results. The Act of Delegation also specifies DG SANTE's scrutiny rights and obligations, including documentary and on-the-spot checks and audits at the agency. 1. Regular meetings between the agency and DG SANTE are held at the level of the Units concerned to ensure the necessary co-ordination of activities. 2. Memorandum of Understanding (MoU) for the day-to-day co-ordination between DG SANTE and the agency are established; where necessary, the MoU is complemented by specific guidelines for certain delegated tasks. 3. The Steering Committee, chaired by DG SANTE, meets four times a year and adopts (i) the agency's annual work programme, after approval by the Commission, and (ii) the draft administrative budget, including the establishment plan, after adoption of the general EU budget by the budgetary	**Coverage**: 100% of the tasks delegated to the agency monitored and supervised **Depth** of control: risk based; DG SANTE has full access to the agency's internal control information, if need be **Frequency**: quarterly, annually and in day-to-day contacts as deemed necessary	**Cost of control**: - Estimated SANTE staff costs for monitoring and supervising the agency's activities - Mission costs for monitoring activities **Benefits of control:** The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred	--Regular programme meetings between the agency and DG SANTE at operational level ⇨ Target: to be defined per delegated programme - Steering Committee meetings with adequate quorum for voting ⇨ Target: 4 times a year - Reported monitoring issues, supervisory control failures and/or exception reports relative to DG SANTE's monitoring of and co-operation with the agency ⇨ Target: qualitative analysis of reasons for the reported issues - Budget execution rates of the operational budget transferred to the agency ⇨ Target: 99% for commitments 100% for payments - Director's annual report on control results and error rates endorsed by Steering Committee prior to finalisation of DG SANTE's Annual Activity Report ⇨ Target: qualitative analysis

1. Budget implementation tasks delegated to the executive agency				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
	authority. 4. The agency reports quarterly to the Steering Committee and to the operational Units concerned on the achievement of objectives, budget implementation, audit and control issues. 5. DG SANTE's central financial Unit reports regularly (several times a year) on the implementation of the budget delegated to the agency. 6. The agency's Annual Activity Report follows the Commission's instructions, is adopted by the Steering Committee and published in the same way as DG SANTE's Annual Activity Report. 7. If deemed necessary, issues are referred to OLAF (DG SANTE's SOPs on handling allegations and contacts with OLAF).			- Timely endorsement by the Steering Committee of the agency's annual work programme and administrative budget (target: December N-1 at the latest) ⇨ Target: 100% on time - Ratio of annual supervision costs to annual operational budget delegated and subsidy paid to the annual administrative budget of the agency ⇨ Target: Commission benchmark (not yet available)

5.2.2. DG SANTE paid subsidies to the operating budgets of EU decentralised agencies

DG SANTE is responsible for five EU agencies. While one of these agencies is fully fee-financed (CPVO), DG SANTE pays annual subsidies from the EU budget to four agencies, including the Chemicals Agency (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[41] *(Budget 2019: total sum of human resources 285; EU funding 100%: EUR 59,2 million)*
  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, operates the early warning and response system (*EWRS*) and provides scientific and technical assistance and training.

- **European Food Safety Authority (EFSA)** in Parma, Italy[42] *(Budget 2019: total sum of human resources 467; EU funding 100%: EUR 79,9 million)*
  EFSA provides independent scientific opinions and scientific and technical advice on food and feed safety, animal and plant health. EFSA's outputs form 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)** in Amsterdam, The Netherlands[43] *(Budget 2019: total sum of human resources 854; EU funding 10,6%: EUR 35,5 million)*
  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 form the basis for the Commission's decision-making on the authorisation of medicines. EMA's total 2019 budget amounted to EUR 332,9 million which is to a large extent fee-financed.

- **Community Plant Variety Office (CPVO)** in Angers, France[44] *(Budget 2019: total sum of human resources 51; EU funding 0%: EUR 0 million)*
  CPVO supports the innovative patenting of new plant varieties throughout the EU; it decides on applications for Community plant variety rights on the basis of a formal examination and a technical examination of the candidate variety. CPVO does not receive any EU subsidies; its 2019 budget amounted to EUR 18,4 million (fully fee-financed).

European Chemicals Agency (ECHA) located in Helsinki[45] - relevant for DG SANTE are ECHA's biocides activities *(Budget 2019 for biocides: total sum of human resources 67 for the biocides activities; EU funding: 26%: EUR 3,1 million)*.
ECHA's biocides activities encompass the implementation of technical and scientific tasks in accordance with the Biocidal Products Regulation (EU) No 528/2012, which came into force on 1 September 2013. ECHA's biocides activities provide the scientific basis for the Commission's decision-making on the authorisation of biocidal products and approval of active substances. ECHA's budget for biocides in 2019 amounted to EUR 11,9 million.

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

42 EFSA was established by Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002; OJ L 31/1 of 1.2.2002.

43 EMA was established by Council Regulation (EEC) No 2309/93 of 22 July 1993, which was replaced by Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004; OJ L 214/1 of 24.8.1993 and OJ L 136/1 of 30.4.2004. With regard to the location of the seat of the EMA see Regulation (EU) 2018/1718 of the European Parliament and of the Council amending Regulation (EC) No 726/2004, OJ L 291, 16.11.2018, p. 3). EMA left its London premises on 1 March 2019 to relocate to Amsterdam.

44 The CPVO was created by Council Regulation (EC) No 2100/94 of 27 July 1994; OJ L 227/1 of 01/09/1994.

45 ECHA was set up by Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2016; OJ L 396, 30.12.2006, p. 1.

2. Subsidy payments to EU decentralised agencies				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 1. "Mandate of the agency": founding regulation ***Main control objectives:*** *ensuring that the legal framework for the management of the relevant funds is fully compliant and regular (legality & regularity), that the agency spends the money as intended (best value for public money, economy, efficiency), without any conflicts of interests (anti-fraud strategy)*				
The **establishment (or amendment) of the mandate of an EU agency** should be free of any legal issues, as these could undermine the legal basis for the agency's management of the EU funds paid by DG SANTE to subsidise its running costs.	The legal framework of the EU agency is laid down in its founding regulation (see above) without expiry date. Amendments follow the Commission's legislative procedures and, since July 2012 the "Common Approach"[46] laid down by the Interinstitutional working group on EU agencies, e.g. - An impact assessment is carried out prior to establishing an EU agency and when amending its mandate; - Standard provisions including appropriate legal provisions are used as a reference point when a new agency is created or when existing founding acts are revised on a case by case basis. 1. In case of an establishment of an agency or an amendment of its founding regulation, DG SANTE manages the interservice meetings/consultations. 2. DG SANTE also manages all subsequent procedural steps (Council, Parliament, etc.) towards the adoption of the regulation by the Council and the Parliament.	**100% in-depth** once in establishment phase **100% in-depth** case by case if amendment or review is foreseen **Frequency:** In 2018 for the amendment of EMA's founding regulation; in 2018/2019 for the amendment of EFSA's founding regulation	**Cost of control**: - Estimated SANTE staff costs involved in establishing an EU agency or the review or amendment of its founding regulation - Cost for external service contract for impact assessments, etc. **Benefits:** The total annual budget amount paid as subsidy to the agency's running costs possibly at 100% if significant legal errors occurred.	Number of legal issues a/o negative opinions during interservice consultations ⇨ Target: 0 - Quality of the legal work not challenged by auditors or OLAF ⇨ Target: 100%

[46] http://europa.eu/about-eu/agencies/overhaul/index_en.htm

2. Subsidy payments to EU decentralised agencies				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 2. Assessment of the agency's control framework and financial rules ***Main control objectives**: ensuring that the entrusted entity is fully prepared to start/continue implementing the delegated funds autonomously respecting the five control objectives set forth in the Financial Regulation: (i) legality and regularity, (ii) sound financial management, (iii) true and fair view reporting, (iv) safeguarding assets and information, (v) anti-fraud strategy*				
The **financial and control framework deployed by the EU agency** should be fully mature to guarantee that the control objectives are met.	1. Implementing rules to the Staff Regulations (SR) adopted by the Commission apply by analogy to the agencies. The agency's Management Board, after having obtained the Commission's agreement, may decide to depart from these rules, not apply them or adopt rules on other subjects. DG SANTE, in co-operation with DG HR, consults and monitors. 2. The agency's Management Board adopts the financial regulation (FR) of the agency based on the Commission's "framework financial regulation" (FFR) for EU agencies. Deviations from the FFR need the Commission's prior consent; DG SANTE, in co-operation with DG BUDG consults and monitors. All SANTE agencies have adopted in 2019 Financial Regulations which are in line with the Framework Financial Regulation.[47] 3. Each agency adopts its rules of "independence" and "conflict of interest". DG SANTE actively monitors compliance with the Commission's guidelines on independence in DG SANTE's task force with the agencies and through bilateral contacts with the agencies. In addition to monitoring compliance, DG SANTE identifies and disseminates good practices in collaboration with the agencies.	**100% in-depth** per agency as need be, e.g. if amendments are to be made **Frequency:** In 2018-2019 due to the new FFR and Internal Control Framework; Annual meeting of the DG SANTE inter-agency task force on independence	**Cost of control:** Included in general estimate of SANTE's staff costs for monitoring and supervising the agency's activities **Benefits of control:** The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred	- EU agencies adopting their own control framework in compliance with the Commission's framework ⇨ Target: all agencies - EU agencies adopting their own rules of independence and conflict of interest compliant with the Commission's guidelines ⇨ Target: all agencies

[47] The CPVO as fully self-financed agency is not bound by the FFR, but aligned its 2019 financial rules largely with the FFR. The deviations were consulted with the Commission and the Court of Auditors.

2. Subsidy payments to EU decentralised agencies				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 3: Operations: DG SANTE's monitoring and supervision ("control with the EU agency") ***Main control objectives**: ensuring that DG SANTE is fully and timely informed of any relevant management issues encountered by the agency, in order to possibly mitigate any potential financial and/or reputational impacts*				
DG SANTE should be informed timely of **relevant management issues encountered by the EU agency;** DG SANTE should react upon notified issues timely and adequately; if not, this could reflect negatively on the Commission's reputation.	1. A coordinating Unit in DG SANTE ensures a coherent approach towards all agencies and exchange of good practises following the "guidance paper on relations with decentralised agencies"; the Commission guidelines for the programming document and the template for the activity report (since 2015) are applicable. 2. Regular bilateral meetings with the agencies take place with the aim to ensure efficient exchange of information and good co-operation at the level of (i) operational and financial Units and (ii) Directors/DDG/DG. In addition, DG SANTE regularly convenes meetings bringing together all Heads of its partner agencies and DG SANTE management. 3. The Management Board (MB) of an EU agency meets about 4 times a year with participation of DG SANTE; it adopts the agency's Single Programming Document (SPD, combining multiannual and annual strategic and resource programming) as well as "strategy documents", e.g. on independence. DG SANTE comments through the MB and prepares a formal Commission Opinion on the SPD. 4. The agency reports to its MB (DG SANTE being a member) on the achievement of objectives, budget implementation and all other important issues relating to operational and financial management and internal audit; in addition, if applicable, DG SANTE participates in the agency's Audit Committee meetings.	**Coverage**: all of the agency's activities are monitored and supervised **Depth** of control: risk based; if need be, DG SANTE has access to the agency's internal control information **Frequency**: depending on legal obligations of the agency (e.g. n° of MB meetings per year); working relations established with DG SANTE; in addition on special request or in specific cases	**Cost of control**: - Included in the general estimate of DG SANTE's staff costs for monitoring and supervising the agency's activities; - Mission costs for monitoring activities. **Benefits of control:** The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred	- Regular meetings between the agency and DG SANTE at management and technical level ⇨ Target: to be defined with each agency - Management Board meetings with DG SANTE participation ⇨ Target: depends on the agency (about 3 to 4 times per year) - Relevance and reliability of control data reported by the agency ⇨ Target: qualitative analysis done for the document sent to the Management Board

2. Subsidy payments to EU decentralised agencies				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
	5. The "Template for Consolidated Annual Activity Report" for decentralised agencies foresees that the agencies report on the "Assessment of the effectiveness of the internal control systems". All SANTE agencies that receive a Union subsidy adhere to this template. DG SANTE monitors that the information is provided and assesses. 6. After adoption by the MB, the agency publishes its annual report, final accounts and report on financial management. 7. If need be, DG SANTE informs the Internal Audit Service (IAS), refers issues to OLAF or as member of the MB triggers the "warning system" (SG note to all DGs Ref. Ares(2013)231088 - 21/02/2013).			

2. Subsidy payments to EU decentralised agencies				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 4: Audit and evaluation, discharge ***Main control objectives**: ensuring that independent sources provide DG SANTE with information which may confirm or contradict the management reporting received from the agencies themselves*				
DG SANTE should get sufficient **information from independent sources on the EU agency's management achievements** to draw conclusions on the assurance for the subsidies paid to the agency; if not, this might reflect negatively on the Commission's reputation.	1. The Internal Audit Service of the Commission (IAS) is the internal auditor of EU agencies and has the same rights and obligations towards EU agencies as towards the Commission (exception: the fully fee financed CPVO). 2. Every year, the European Court of Auditors (ECA) audits the accounts and transactions of the agency and issues a declaration of assurance; in addition, the ECA issues Special Reports on agencies; DG SANTE monitors the agency's follow-up on the Court's recommendations. 3. Every year, the agency undergoes the discharge procedure; DG SANTE monitors the agency's follow-up on the recommendations made by the discharge authorities. 4. Founding regulations foresee regular external evaluations of the agencies: - EMA every 10 years (ongoing in 2019); - EFSA every 6 years (last completed 2018); - ECDC every 5 years (last completed 2019). DG SANTE participates in the Steering Committee and Technical Evaluation Committee. 5. Through its representation in the agency's Management Boards and Audit Committees, DG SANTE encourages that evaluation reports and audit reports are timely sent to DG SANTE and that adequate actions are defined and timely implemented by the agency to address the issues identified in those reports.	**Coverage**: 100% of the agency's activities audited and evaluated **Depth** of control: risk based; auditors have full access to the agency's internal control information **Frequency**: - Regularly by the IAS - Annually by the Court of Auditors - Frequency of external evaluations varies with the agencies	**Cost of control**: - Included in the general estimate of SANTE's staff costs for monitoring and supervising the agency's activities **Benefits of control:** The total amount of the subsidy paid to the agency per year possibly at 100% if significant legal errors occurred	- DG SANTE's analysis of critical and very important audit findings of internal and external auditors and the agency's implementation of the audit findings ⇨ Target: all analysed and discussed - Court of Auditors' assurance on the accounts and operating budget ⇨ Target: positive assurance ⇨ Target: all recommendations implemented - Discharge authorities grant discharge to the agency ⇨ Target: discharge granted ⇨ Target: all recommendations of the discharge authorities implemented - External evaluation concluding positively on the agency's activities

2. Subsidy payments to EU decentralised agencies				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Cost-Effectiveness indicators (three E's: effectiveness, efficiency, economy)**
Stage 5: DG SANTE's payments of the subsidy ***Main control objectives**: ensuring that DG SANTE fully assesses the management situation at the EU agency, before either paying out the (next) instalment of the subsidy to the agency or deciding to cut, suspend or interrupt the (next) payment (legality & regularity, sound financial management, anti-fraud strategy)*				
DG SANTE might not be aware of management issues that could lead to financial and/or reputational damage for the Commission as it pays the subsidy to the agency.	1. On the basis of the agency's annual budget and work programme adopted by the Management Board, DG SANTE pays the subsidy to the agency's administrative budget in several instalments: - An instalment is paid in year N on request of the agency based on a cash forecast; - Prior to the subsidy payment, financial checks are carried out according to DG SANTE's financial circuits with 1st and 2nd level financial verifications, authorisations and encodings in ABAC; 2. All instalments remain pre-financing payments until the agency's accounts have been audited by the Court of Auditors and the agency has submitted its final accounts (in general by July N+1); 3. On the basis of the agency's final accounts, DG SANTE clears all pre-financing payments in year N+1 and, if applicable, recovers unspent amounts of the instalments paid to the agency; no additional payment is made.	**Coverage**: 100% of DG SANTE's subsidy payments through the established financial circuits **Depth** of control: risk based **Frequency**: Administrative budget of the agency annually audited by the Court of Auditors	**Cost of control**: - Estimated staff costs for budget and finance in central financial Unit; **Benefits of control:** The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred.	- Number of reported monitoring issues, incidences of payment suspensions or reductions and/or exception reports relative to DG SANTE's subsidy payment to the agency ⇨ Target: qualitative analysis of reasons for the reported issues; all issues adequately followed up - Ratio of recovery of the positive budgetary outturn of year N plus interest earned on subsidy paid in year N-1 - Files with relevance for OLAF adequately transmitted to OLAF and followed up ⇨ Target: 100% - Time-to-pay (target: maximum 30 days) ⇨ Target: 100% on time

ANNEX 6: Implementation through national or international public-sector bodies and bodies governed by private law with a public sector mission (not applicable)

Not applicable to DG SANTE in 2019.

ANNEX 7: EAMR of the Union Delegations (not applicable)

Not applicable to DG SANTE in 2019.

ANNEX 8: Decentralised agencies

DG SANTE does not provide Annex 8 since Annexes 5.2 and 10.1.1.3 already include all information requested in Annex 8:

- List of EU decentralised agencies and the policy area concerned;
- Per agency, the annual budgetary amount entrusted, namely the DG's subsidy paid for the administrative/operating budget, and/or any operational funds provided and their contribution;
- Per agency, information on assurance.

ANNEX 9: Evaluations and other studies finalised or cancelled during the year

Study project ID	Title of the study	Study internal ID	Study overview	Study reason	Associated services	Study cost	Note	Title of the deliverable[48]
FINALISED								
3550	Evaluation of the Union policy framework for blood and tissues & cells.		Ex-post evaluation of the legal framework in place at Union level for the regulation of blood and tissues and cells intended for human application. The current legislative frameworks which lay down quality and safety standards for these substances will be evaluated: basic acts 2002/98/EC and 2004/23/EC and their technical Directives.	Evaluation		150,000		Commission Staff working document - Evaluation of the Union legislation on blood, tissues and cells SWD(2019) 375 final
3546	Evaluation of fee system of European Medicines Agency (EMA)		Data on workload / cost of MS and European Medicines Agency (EMA) to be used for a possible future revision of EMA fees. Foreseen by recital of Regulation on Pharmacovigilance fees Regulation (EU) No 658/2014. To verify the costing model for remuneration of MS Evaluation of costs of EMA and costs of the tasks carried out by the national competent authorities. Economic Study of the time estimations provided by the data gathering project of EMA's Management Board.	Evaluation		250,000		Commission Staff working document - Evaluation of the European Medicines Agency's fee system SWD(2019) 335 final
CANCELLED								
6491	Evaluation of European Reference Networks in accordance with the Article 12 of the Directive on patients' rights		The aim of the evaluation will be to assess the performance, achievement of objectives and outcomes of the Network and the contribution of its members.	Evaluation		NA	This study is a technical assessment of the existing ERNs required by the legislation, and not an ex-post evaluation, as per Better Regulation criteria	

[48] Where a hyperlink is not included, publication of the study is ongoing.

ANNEX 10: Specific annexes related to "Financial Management"

10.1 Effectiveness = the control results and benefits

10.1.1. 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.

10.1.1.1 Grants to Member States in 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 10.1 Food and Feed Safety

Commitment credits implemented by DG SANTE *(without CHAFEA)*[49]	**2019** **M€**	**2018** **M€**	**2017** **M€**
Animal disease eradication programmes (grants to Member States)	**130,6**	137,6	148,6
Veterinary emergency fund (grants to Member States)	**58,6**	49,9	51,9
Phytosanitary expenditure (grants to Member States)	**37,6**	15,9	0,5
Other veterinary, plant health and food safety expenditure (grants to Member States, EURL, etc.)[50]	**24,7**	41,6	17,3
Sub-total grants	**251,5**	245,0	218,3
Procurement DG SANTE	**18,2**	15,4	23,0
Administrative support credits[51]	**0,7**	1,1	1,3
Total budget implemented	**270,4**	261,5	242,6

Provisions for the management of expenditure for the policy area Food and Feed are set out in the Common Financial Framework (CFF)[52]. Direct financial contributions to Member States is by far (more than 80%) the most important budget implementation instrument:

- In 2019, 28 Member States implemented a total of 142 animal disease eradication and control programmes.
- In addition, a total of 14 files for cost reimbursements were handled in relation to the veterinary emergency fund, to combat, first and foremost, Avian Influenza

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

[50] 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).

[51] Without credits co-delegated to other DGs: EUR 0,8 million in 2019 (EUR 0,4 million in 2018; EUR 0,2 million in 2017).

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

(EUR 9,6 million) but also African Swine Fever (EUR 47,9 million), Lumpy Skin Disease (EUR 1,0 million) and Newcastle disease (EUR 0,1 million).

- Addressing the combat of organisms harmful to plants, 24 Member States submitted their 2019 "pest survey programmes"[53] of a total amount of EUR 13,1 million and 10 Member States submitted emergency plant health measures accounting for EUR 5,2 million. An additional amount of EUR 19,3 million was earmarked for animal and plant health emergency measures. Other grants to Member States included EUR 1,1 million financial aid towards a coordinated control plan for antimicrobial resistance in zoonotic agents[54].
- Other non-typical grants concern mostly the funding of the 46 European Reference Laboratories (EURLs) with EUR 16,5 million for their 2019 activities..
- Other measures to contain animal disease outbreaks are the purchase of vaccines. In 2019, DG SANTE earmarked EUR 2,5 million on vaccines and antigens through public procurement (see part 10.1.3 below).
- The administrative support credits (EUR 0,7 million) are used mainly for meetings, conferences, IT and communication services.

The 2019 commitment appropriations at the end of the year of EUR 270,4 million, and the 2019 payment credits of EUR 230,1 million, were each almost fully implemented (99,4% and 99,7% respectively)[55].

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 more than 50% of the grants in the Food and Feed policy area (see table 10.1 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 10.1.1.2 below.

Stage 1: Programming and evaluating the 2020 national programmes

In 2019, DG SANTE paved the way for the award of the 2020 animal disease eradication programmes of the Member States. In compliance with the Commission work programme[56] to implement the Common Financial Framework (CFF)[57] for the Food Chain, Member States submitted their 2020 disease eradication and control programmes by 31 May 2019. 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, one was rejected as they did not meet the eligibility or award criteria as set out in the work programme. The grant decisions were signed on 30 January 2020 meeting the legal deadline.

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

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[53] Commission Implementing Decision C(2018) 2491 on the adoption of the work programme for 2019-2020 for the implementation of survey programmes for pests amended by C(2019)3509, and the financing decision C(2018) 6531

[54] Commission Implementing Decision C(2019) 4203 of 11 June 2019 on the financing and the adoption of the work programme for 2019 for activities in the food and feed area

[55] In the Food and Feed Safety policy area, Annex 3 shows implementation rates of 98,4% for EUR 272,8 million of commitment credits and 99,5% for EUR 232,3 million of payment credits. The difference to the figures above are the administrative support credits of EUR 0,7 million (included in Annex 3 under administrative credits) and the subsidy payment to the EU decentralised agency ECHA-biocides which is included in Annex 3 under "Food and Feed Safety": EUR 3,1 million commitments and payments.

[56] 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

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

of the evaluation results, DG SANTE facilitated the Member States' finalisation of their programmes.

Stage 2: Approving the 2019 national programmes and Grant Decisions

The list of the 2019 national programmes for animal disease eradication and monitoring was technically approved in November 2018 and the final EU contribution allocated to each programme was communicated to the Standing Committee on Plants, Animals, Food and Feed (PAFF) in January 2019. Subsequently, the authorising officer by sub-delegation took the award decision and signed the corresponding grant decisions. As in previous years, in 2019 the deadlines fixed in the legislation were respected allowing a timely launch of the 2019 programmes in the Member States.

As a simplification measure, introduced in 2014, only one grant decision per Member State was signed, covering the eradication and control programmes for all diseases for each Member State. To reduce the burden of calculating eligible costs, the concept of unit costs was introduced in 2014 and updated in 2018[58]. Unit costs also help reduce the risk of errors in the cost claims. The IAS made an audit recommendation to improve the unit cost methodology and first actions have already been taken (see Annex 11.1.2 below).

Table 10.2.1 Indicators for grants at control stages 1 and 2

Indicators	*Targets*	2019	2018	2017
Stage 1: Programming and evaluation				
Ratio of rejected national programmes to total programmes submitted: 1 out of 147 programmes for 2020 submitted in 2019 (5 out of 147 in 2018; 4 out of 138 in 2017)	*n/a*	**1%**	3%	3%
Ratio of modified programmes to total programmes retained after evaluation: 85 out of 146 evaluated in 2019 (98 out of 142 in 2018; 89 out of 134 in 2017)	*n/a*	**58%**	69%	66%
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 2019 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 2018 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)[59]. The aim was to detect and

[58] 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 of 24 February 2014.

[59] The selection of operations for the second-level verification is supported by the IT application "MUS-DICE",

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 2019, this ex-ante on-the-spot control focused on the high risk areas as follows: veterinary emergency fund and plant health measures for which the request for funding exceeded EUR 2 million or other exceptionally high amounts.

In the period 2017 to 2019, the audit plan had to account for the specific situation arising from the Avian Influenza crisis in 2016-2017 and African Swine Fever crisis since 2018. Twelve Member States submitted cost claims (eight for Avian Influenza and four for African Swine Fever) exceeding EUR 2 million and were selected for ex-ante on-the-spot controls. The audit results show an average correction rate of around 13%. DG SANTE made the following main observations: (a) the Member States faced difficulties to understand some of the eligibility criteria or did not apply them correctly; (b) in several cases, Member States lacked sufficiently detailed data to evidence the costs in their claim as contracts with suppliers rarely include clauses for the provision of details on the work performed; (c) with regard to compensation for the animals culled an over-evaluation was noticed when animals were compensated based on experts' evaluations rather than pre-defined value scales. DG SANTE already addressed the main issues.

Table 10.2.2 Indicators for grants at control stage 3

Indicators	***Targets***	**2019**	**2018**	**2017**
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**	3	0
Instances of Article 93 FR[60]	*n/a*	**0**	0	0
Percentage of implemented final **commitment** appropriations after global transfers[61]	*99%*	**99,4%**	99,0%	99,5%
Percentage of implemented **payment** credits after global transfers[62]	*100%*	**99,7%**	98,6%	98,7%
Desk ex-ante 2nd-level verification coverage: % of transactions % of total amounts	*10%* *50%*	**21%** **74%**	20% 72%	19% 75%
Desk ex-ante 2nd-level verification: rejection rate % of amounts corrected	*< 2% in value*	**0,1%**	0,0%	0,2%
Late interest payments relative to total value of grants (in 2019: 1 case of €443,58; in 2018: 2 cases of €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)* - Veterinary emergency fund - Phytosanitary measures - Other grants	*n/a*	**13,0%**	- - 0,3%	11,2% **-**

based on a risk analysis with a set of risk criteria.

60 Article 93 of the FR(2018) on the financial irregularities panel

61 Annex 3 in 2019 shows a commitment implementation rate of 98,4% in the Food and Feed Safety policy area as it includes the subsidies to ECHA (European Chemicals Agency) of EUR 3,1 million with an implementation rate of 53,1%; see Annex 10.1.1.3.

62 Annex 3 in 2019 shows a payment implementation rate of 99,5% in the Food and Feed Safety policy area as it includes the subsidies to ECHA-biocides (European Chemicals Agency) of EUR 3,1 million with an implementation rate of 84,2%; see Annex 10.1.1.3.

The "exception reports" submitted in 2019 pertain to one case of non-compliance with the grant decision and the Financial Regulation for the reimbursement of eradication costs for African Swine Fever emergency measures. Another case involved an a-posteriori commitment due to mistakes made when amending a grant decision. In each case, DG SANTE judged that the non-compliance was justified by special circumstances. The strict application of the grant decision and Financial Regulation 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 and mitigating actions to prevent such cases were taken immediately.

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 in an overview table.

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 February 2019, the Directors' Steering Committee of DG SANTE adopted the 2019 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. While in 2017/2018, priority had to be given to ex-ante controls on cost claims for Avian Influenza, the 2019 audit plan included only three ex-ante audits on emergency files and 15 ex-post audits (ten audits on veterinary programmes and five on European Reference laboratories).

Of the 18 planned audit missions, 16 were carried out as planned. One audit had to be postponed to 2020 and one was cancelled mainly due to unforeseen staff constraints. The changes did not have a material impact on the assurance building capacity of the ex-post control function in 2019 as the planned audit coverage was almost fully achieved.

In 2019, a total of 18 ex-post controls were completed in 2019. This is about the average number of ex-post controls finalised in a year. The errors detected during the ex-post controls finalised in 2019 resulted in a detected error rate of 0,5% (EUR 0,2 million) for the audited national programmes for animal disease eradication and monitoring of the years 2014 to 2017. 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	**2019**	**2018**	**2017**	**2016**	**2015**	**2014**	**2013**
Residual error rate	**0,4%**	1,9%	2,5% (1%)	1,1%	1,2%	0,8%	2,3%
Reservation	**No**	No	No	No	No	No	Yes

Between January and March 2020, DG SANTE issued recovery orders for about 97% of the amounts to be recovered further to the 18 ex-post controls finalised in 2019.

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[63] below the materiality threshold.

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). A follow-up audit finalised by the Court in late 2019 concluded that all but one recommendation have been implemented (in most respects[64]). For one recommendation actions are still on-going: the planned merge of two IT systems, of which one is from the Commission (ADNS[65]) and one from the OIE (WAHIS)[66], is technically much more complex than initially planned and will thus not be finalised before early 2021.

Table 10.2.3 Indicators for grants at control stage 4

Indicators	***Target***	**2019**	**2018**	**2017**
Stage 4: Ex-post controls				
Ex-post control **detected error rate** (ABB activity: Food and Feed Safety)	*n/a*	**0,5%**	2,0%	2,7%
Ex-post control **residual error rate** (policy area Food and Feed) (Without one exceptional file)	***< 2,0%***	**0,4%**	1,9%	2,5% (1%)
Amount of net financial corrections identified in year N compared with amount of transactions audited	*n/a*	0,2 M€ 34,2 M€	0,9 M€ 45,3 M€	2,6 M€ 97,0 M€
Financial corrections in year N linked to audits finalised in year N (until 31/12/2019)	*n/a*	**0,0 M€ 0%**	0,05 M€ 5%	0,2 M€ 8%
Total financial correction of detected errors by 28/03/2020	*100%*	**0,2 M€ 97%**	0,4 M€ 47%[67]	2,6 M€ 100%[68]

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 2019 residual error rate amounts to 0,4% 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 since 2018 the annual error rate is based on a relatively low number of audits closed in the reporting year. As the audit findings are in line with previous years' observations on the same kind of cost claims, DG SANTE believes that it possible to conclude on the residual error rate in 2019. 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

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

[64] One action can only be finalised in the framework of the next Feed and Food programme 2021-2027.

[65] Animal Disease Notification System

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

[67] 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.

[68] With regard to 2018, a total of EUR 0,05 million was corrected in 2018; an additional amount of EUR 0,42 million was corrected by recovery orders introduced in 2019.

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 reasonable source of information in the assurance building process as the audit coverage (ex-ante and ex-post) is deemed sufficient and as 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.

10.1.1.2 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 10.3 Procurement in the two policy areas

Commitment credits implemented by DG SANTE *(without CHAFEA)* [69]	**2019 M€**	**2018 M€**	**2017 M€**
Health Programme implemented directly by DG SANTE	**11,5**	10,9	8,9
Administrative budget of the Health programme implemented by DG SANTE	**0,8**	1,3	1,4
Pilot projects/preparatory actions implemented by DG SANTE through procurement	**0,6**	0,8	0,5
Public Health total	**12,9**	13,0	10,8
Food and Feed Safety: DG SANTE procurement expenditure	**18,2**	15,4	23,0
Administrative budget Food and Feed implemented by DG SANTE	**0,7**	1,1	1,3
Food and Feed Safety total	**18,9**	16,5	24,3
Procurement other policy areas (operational credits mainly)	**4,6**	3,8	3,2
Building expenditure Ireland (administrative credits)	**5,0**	4,9	5,2
Total budget implemented	**41,4**	38,2	43,5

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

- The third **Programme of the Union's action in the field of health (2014-2020)** was adopted in March 2014[70]. 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[71]. The Commission decided on the specific Public Health work programme for 2019 on 29 March 2019[72] with a total programme budget of EUR 65,4 million. DG SANTE implemented 20% (EUR 12,3 million)[73] under direct management, almost exclusively through public procurement[74], 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. The administrative support credits (EUR 0,8 million) are used mainly for meetings, conferences, IT and communication services.

  In addition to the funds for the Health programme, DG SANTE received in 2019 EUR 0,6 million for one pilot project which will be implemented under public procurement 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 2019 (EUR 12,9 million) and payment credits (EUR 8,8 million) were almost fully consumed (99,7% and 92,2% respectively).[75].

- The work programme and the financing for the year 2019 of activities in **the food and feed area** to ensure the application of the food and feed legislation was adopted on 11 June 2019 (C(2019) 4203). It foresees EUR 6,2 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(2019) 5015) earmarked EUR 14,7 million for IT services (other expenditure in the Food and Feed policy area is described in part 10.1.1.1 on grants). Given the late approval of the work programmes, the Director-General approved an exception to launch some procurement procedures prior to the adoption of the work programme/financing decision due to the urgency of some activities linked to legal obligations and political commitments (see Annex 11.2 for more detail).

- The credits listed under "**procurement other policy areas**" encompass EUR 3,6 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 1,0 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%) for the services rendered as planned.

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

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

[72] C(2019) 2308

[73] The remaining 80% of the 2019 work programme for Public Health is implemented by the executive agency CHAFEA (see part 10.1.1.3 below as well as CHAFEA's 2019 AAR).

[74] 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.

[75] In the Public Health policy area, Annex 3 shows implementation rates of 92,0% for EUR 186,8 million of commitment credits and 91,5% for EUR 181,9 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 174,7 million commitment credits and EUR 173,9 payment credits with an implementation rate of around 91,5%.

- The **administrative expenditure for Grange, Ireland**, (EUR 5,0 million) relates to the office building in Grange which is managed directly by DG SANTE (not by OIB or OIL).

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

Stage 1: Assessing procurement needs and selecting the offer

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

With a view to achieving a good quality in terms of tender documents, harmonisation and efficiency gains, since mid-2014 DG SANTE has centralised its administrative management of public procurement procedures covering new procurement procedures above EUR 15.000, including specific contracts on Framework Contracts with re-opening of competition. The central team also gives support to all procedures involving pilot projects and preparatory actions, be it through public procurement or through grants. In 2019, 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 2019 calls above the Directive threshold (currently EUR 144.000) through the e-tendering platform of the Commission. Since the beginning of 2019, DG SANTE also uses e-submission as unique tool for the open calls and e-ordering for the automatic generation of the procurement contract.

Table 10.4 Procurement contracts above EUR 60.000[76]

Type of procedure	2019		2018		2017	
	N° of contracts	**Amount M€**	***N° of contracts***	**Amount M€**	***N° of contracts***	**Amount M€**
Open (Financial Regulation 164 (1)(a))	***3***	**6,8**	*2*	1,8		
Open other (previous Financial Regulation)			*4*	1,8	*6*	25,4
Negotiated without prior publication	***3***	**0,7**			*3*	9,3
Negotiated middle value contract	***4***	**0,4**				
Restricted (FR 164 (1)(b))	***3***	**2,2**	*1*	0,3	*3*	1,2
TOTAL	***13***	**10,1**	*7*	3,9	*12*	35,9

In the health policy area, following the open procedure, two contracts were awarded (i) to prepare clinical practice guidelines and other clinical decision support tools (EUR 4,0 million); (ii) to improve uptake and confidence in vaccines for patients with chronic diseases, families and communities (EUR 0,7 million).

Another open procedure was used to procure services related to DG SANTE's site management in Grange, Ireland, for EUR 2,1 million; one negotiated procedure was used to secure telephone services (EUR 0,1 million); in addition two restricted procedures bought environmental management consultancy services (EUR 0,07 million) and cleaning services (EUR 0,6 million).

[76] Annex 3 table 12

A restricted procedure was applied to EUROPEAID for EUR 1,5 million.

In the policy area Food and Feed Safety, DG SANTE used three negotiated procedures to purchase vaccines against sheep pox for EUR 0,5 million, educational materials on production, processing and marketing of meat from pigs (EUR 0,1 million) and dissemination services for a video on plant health (EUR 0,1 million).

In 2019, 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 10.4 above).

The share of different procedures thus fluctuates significantly from year to year: while in 2019, the negotiated procedure without prior publication was used in 23% of the cases (3 out of 13), it was not used at all 2018; in 2017 it was applied in 25% of the limited number of cases included in the table above (3 out of 12). Expressed in amounts, in 2019, 7% of the contract value was awarded through the negotiated procedure (in 2018: 0,0%; in 2017: 26%). 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. Another reason is that DG SANTE often needs services in specialised fields with only one or two suitable providers.

In 2019, DG SANTE continued its work on joint procurement. A voluntary cooperation was established[77] 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. The joint procurement of pandemic influenza vaccines was of particular importance, where DG SANTE played a key role in the tendering and negotiation of the framework contracts. The first framework contract was signed in March 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 2019, this voluntary additional check was not used (one case in 2018 and three cases in 2017).

Table 10.5.1 Indicators for procurement at stage 1

Indicators	***Targets***	**2019**	**2018**	**2017**
Stage 1: Assessing procurement needs and selecting the offer				
Rate of open calls for tenders for which - No offer was received *(in 2019: 1 out of 6; in 2018: 4 out of 10; in 2017: 1 out of 6)* - The procedure had to be cancelled *(1 in 2019; 1 in 2018; 3 in 2017)*	*0%* *0%*	**17%** **17%**	40% 10%	17% 50%
Rate of negotiated procedures[78] for which - No offer was received - The procedure had to be cancelled	*0%* *0%*	**0,0%** **8%**	0,0% 0,0%	0,0% 0,0%

[77] 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

[78] Procurement procedures above EUR 60.000

Indicators	*Targets*	2019	2018	2017
Positive (negative) opinions of the Public Procurement Committee (2019: 9 opinions; 2018: 5 opinions; 2017: 10 opinions)	*n/a*	**90%** (1 negative)	100%	100%
Public Procurement Committee opinions followed by the authorising officers responsible	*100%*	**100%**	100%	100%

In 2019, one open call for tender procedures had to be cancelled because no offer was submitted. Regarding negotiated procedures above EUR 60.000, one procedure (out of 13) had to be cancelled because the bid was not admissible.

In 2019, the Public Procurement Committee provided nine opinions on procurement contracts with a total maximum value of EUR 13,2 million. One opinion was negative, but the mistake in the procedure could be corrected. A second submission of the file to the Co before the award decision was taken. 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 10.5.2 Indicators for procurement at stage 2

Indicators	*Targets*	2019	2018	2017
Stage 2: Monitoring of contract implementat and financial management				
Ex-ante 2nd-level verifications coverage: % of transactions % of amounts	*10%* *50%*	**9%** **58%**	8% 44%	9% 44%
Ex-ante rejection rate of 2nd-level verifications: no cases of financial errors	*< 2% in value*	**0,0%**	0,0%	0,0%
Late interest payments relative to total value of contracts (in 2019: 2 cases of €496,50; in 2018: no cases; in 2017: no cases;)	*0%*	**0,0%**	0,0%	0,0%
Percentage of implemented final commitment appropriations	*99%*	**99,5%**	100%	99%
Percentage of implemented payment credits after global transfers	*100%*	**91,1%**	100%	96%

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 10.5.3 Indicators for procurement at stage 3

Indicators	***Targets***	**2019**	**2018**	**2017**
Stage 3: Supervisory measures				
Number of registered **"exception reports"** relative to procurement procedures	*n/a*	**3**	2	6
Instances of Article 93 FR[79]	*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*	**(1)** **0,5 M€**	(0) n/a	(1) 0,04 M€
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. The three "exception reports" of 2019 pertain to non-compliance events (à posteriori commitments and actions prior to the adoption of the work programme/financing decision). 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, including organisational changes, 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.

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

10.1.1.3 Budget implementation tasks entrusted to other services and entities

DG SANTE has entrusted parts of its budget for indirect management implementation by the Executive Agency CHAFEA. In addition, DG SANTE finances, partially or in full, the operating budgets of CHAFEA 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).

Consumers, Health, Agriculture and Food Executive Agency (CHAFEA)

The Consumers, Health, Agriculture and Food Executive Agency (CHAFEA, formerly the Executive Agency for Health and Consumers – EAHC[80]) 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 CHAFEA 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.

CHAFEA 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 10.6 Subsidies paid by DG SANTE to CHAFEA

CHAFEA (former EAHC)	**2019** **M€**	**2018** **M€**	**2017** **M€**
Subsidy for administrative budget	**5,9**	5,7	5,5
Operational budget transferred from SANTE	**65,6**	64,1	63,1

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 CHAFEA 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 2019.

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

[80] 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.

(from DG SANTE). Furthermore, in 2019, 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 CHAFEA 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 CHAFEA 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 2019, no serious control issue came to the attention of DG SANTE that would warrant a financial or reputational reservation in DG SANTE's 2019 Annual Activity Report. However, the following issues requested special attention:

- Although CHAFEA shows an implementation rate of the 2019 operational budget close to 100%, the level of individualisation of commitments by signing grants or procurement contracts is relatively low: 27% of the credits transferred to CHAFEA for the Health Programme and 31% for BTSF. A special monitoring was installed to ensure the full budget will be implemented in a timely manner in 2020.

The use CHAFEA 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 CHAFEA. The following observation does not call the Court's opinion into question: the Court criticised CHAFEA's use of "Time and Means" contracts although these are foreseen in the Commission's Framework Contract for IT services that CHAFEA applies. To ensure the correct use of these types of contracts, CHAFEA is implementing the guidelines on the use of IntraMuros IT Consultants that are being reviewed by the Commission.

In the CHAFEA's 2019 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 2019 Annual Activity Report). For the first time in 2019, CHAFEA reported a residual error rate of ex-post controls exceeding the threshold of 2% pertaining to the funds DG SANTE transferred to the agency)." As the residual error rate of 2,3% is close to the threshold and includes a case which CHAFEA considers to be non-representative and given that the "de mininimis" rule is not fulfilled[81], CHAFEA does not make a reservation.

Table 10.7 Indicators of control effectiveness as regards legality and regularity

Executive agency CHAFEA	***Targets***	**2019**	**2018**	**2017**
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 CHAFEA	*n/a*	**0**	0	0

[81] The overall impact of a potential reservation on the declaration (the "scope") is lower than 5% of the total payments and the exposure is lower than EUR 5 million).

Executive agency CHAFEA	*Targets*	2019	2018	2017
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 or Management Board prior to finalisation of DG SANTE's Annual Activity Report	*yes*	**yes**	yes	yes
Court of Auditors' assurance on the agency's accounts and implementation of the administrative budget of year N-1 without qualification	*yes*	**Yes**	yes	yes
Discharge granted for year N-1 and discharge recommendations implemented for year N-2	*yes*	**Yes**	yes	yes
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1 (€0,89/€5,7 million)	*n/a*	**11,8%**	15,6%	6,4%

In October 2018, DG SANTE finalised the mid-term evaluation of CHAFEA carried out by an external service provider. The evaluation covered CHAFEA'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 CHAFEA'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 CHAFEA 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 CHAFEA's human resources management and improving the information and transfer of knowledge from CHAFEA to the Commission through better standardised/harmonized reporting, better quality reports/data, more regularly scheduled meetings.

EU decentralised agencies

In 2019, 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[82].
  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[83].
  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.

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

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

- European Medicines Agency (EMA) located in Amsterdam, The Netherlands[84].
  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.
- Community Plant Variety Office (CPVO) located in Angers, France[85].
  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[86].
  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[87] (lead partner DG is EMPL) and EMCDDA[88] (DG HOME is the lead partner DG), but does not contribute to their running costs.

Table 10.8 EU decentralised agencies – subsidies

EU decentralised agencies	*Number of staff* *			EU contribution		
	2019	***2018***	***2017***	**2019 M€**	**2018 M€**	**2017 M€**
ECDC	***285***	***285***	*287*	**59,2**	**58,1**	58,0
EFSA	***467***	***459***	*463*	**79,9**	**79,1**	79,2
EMA[89]	***854***	***810***	*799*	**35,5**	**32,6**	29,3
CPVO[90]	***51***	***51***	*49*	**n/a**	**n/a**	n/a
ECHA-biocides[91]	***67***	***64***	*59*	**3,1**	**4,9**	3,9
Total	***1.724***	***1.669***	***1.658***	**172,2**	**174,7**	**170,4**

*: 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.

[84] 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. With regard to the location of the seat of the EMA see Regulation (EU) 2018/1718 of the European Parliament and of the Council amending Regulation (EC) No 726/2004, OJ L 291, 16.11.2018, p. 3). EMA left its London premises on 1 March 2019 to relocate to Amsterdam.

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

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

[87] 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.

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

[89] EMA's total 2019 budget amounted to EUR 332,9 million (in 2018: EUR 337,7 million; in 2017: EUR 322,1 million;), mainly financed by fees. The EU contribution is a balancing grant (in 2019: 10,6%; in 2018: 9,6%; in 2017: 9%).

[90] CPVO does not receive any EU subsidies; its 2019 budget amounted to EUR 18,4 million (2018: EUR 16,9 million; 2017: EUR 18,8 million).

[91] 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 2019 amounted to EUR 11,9 million (in 2018: 10,9 million; in 2017: EUR 11,1 million). The EU contribution is a balancing grant (in 2019: 59%; in 2018: 45%; in 2017: 35%).

Overall, the establishment plan posts of agencies have been decreasing slightly over the years 2013 to 2017[92], as foreseen in the Commission's communication on the programming of human and financial resources for decentralised agencies (2014-2020)[93]. 2018 was the first year of an increase in DG SANTE agencies' total number of staff, most importantly due to the reinforcement of EMA's workforce consisting mainly in additional time-limited contract agents to deal with the Brexit implications.

Compared to 2018, 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.

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 June 2019, the European Parliament and Council adopted an amendment to EFSA's founding Regulation.[94] This amendment provides for a targeted revision on the basis of the Commission's Fitness Check of the General Food Law[95] and a successful European Citizens' Initiative[96]. EFSA is assigned new tasks to improve the transparency and increase guarantees for the reliability of scientific studies in the food safety area. In line with the Common Approach on decentralised agencies, EFSA's Management Board will include from July 2022 a member from each Member State, and the Commission will carry out every five years an evaluation of the Agency's performance.

In addition, in November and December 2018, new legislation on veterinary medicinal products and medicated feed was adopted, which assigns additional tasks to the EMA and included a Regulation[97] 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)[98] for decentralised agencies. During 2019, all DG SANTE partner agencies aligned their financial rules to the new FFR. DG SANTE commented on the agencies' draft rules, in co-operation with DG BUDG.

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92 The CPVO Administrative Council as the Budgetary Authority of the agency authorised 45 establishment plan posts for 2017, 2018 and 2019. 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 and 2019. The Commission had agreed on the postponement of the reduction of one temporary agent post (which means 45 posts in 2017, 44 in 2018 and 43 in 2019).

93 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).

94 Regulation (EU) 2019/1381 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.

95 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.

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

97 Regulation (EU) 2019/5 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.

98 Commission Delegated Regulation (EU) 2019/715 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.

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

Bilateral meetings between DG SANTE and its partner agencies take place both at senior management and technical level. In addition, DG SANTE has convened in 2019 two meetings bringing together the Heads of all its partner agencies and DG SANTE management.

The relevant operational Units in DG SANTE are the primary interlocutors with the agencies. A horizontal Unit takes on a coordination role to promote a coherent approach towards all agencies and to exchange good practices, for example, 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 18 September 2019. In addition to monitoring compliance, DG SANTE identifies and disseminates good practices in collaboration with the agencies.

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[100].

- In 2019, the report of the third external evaluation of ECDC for the years 2013-2017 was finalised by the external contractor. The ECDC Management Board accepted the report in November 2019. At the end of 2019, the ECDC Management Board was working on its recommendations based on the evaluation.
- The report of the third external evaluation of EFSA for the years 2011-2016 was finalised in 2018. EFSA's Management Board adopted its analysis of the evaluation and ensuing recommendations in October 2018[101]. In 2019, EFSA held a mapping of ongoing and planned projects and processes to follow-up to the recommendations and plans for 2020 an assessment of their level of implementation.
- In 2019, the work on the study on the operation of centralised and decentralised and mutual recognition procedures for the authorisation and monitoring of medicinal products for human use continued. It is expected to be finalised in early 2020. The study includes among other aspects, an assessment of the effectiveness and

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

[100] According to their Founding Regulations, external evaluations are to be commissioned for ECDC every five years, for EFSA every six years (every five according to the amendment to EFSA's founding act adopted in 2019), for EMA every 10 years.

[101] 3rd external evaluation of EFSA – Recommendations from the Management Board, mb181010-a6 https://www.efsa.europa.eu/sites/default/files/MB_Recommendations.pdf

efficiency of the overall structure of EMA's committees, working parties, scientific advisory- and expert groups.

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 September 2019, 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 2018 accounts as well as for the legality and the regularity of the underlying transactions. The Court issued comments for all DG SANTE partner agencies except for EFSA. The weaknesses identified by the Court concerned for CPVO the use of interim workers and recruitment and procurement procedures; for ECDC the use of framework contracts and internal control of large meeting events; for ECHA a procurement procedure and lack of a sensitive post policy; for EMA the use of IT consultancy services. These comments did not call the Court's positive declarations of assurance into question. The agencies drafted action plans to implement the Court's audit recommendations and reported on the progress made[102].

In its annual report on EMA, the Court pointed to the change of the agency's seat from London to Amsterdam[103]. The move to the temporary premises in Amsterdam took place in March 2019. EMA included provisions of EUR 17,8 million into its 2018 accounts for related costs. The lease agreement for EMA's premises in London sets a rental period until 2039 with no exit clause. The notes to the accounts for the financial year 2018 disclose a contingent liability of EUR 465 million corresponding to the remaining rent during the lease period after the Agency's move to Amsterdam. In 2019, EMA signed a sublease agreement for the London building.

Discharge

In March 2019, taking into account the Court of Auditors reports on the agencies annual accounts 2017, the European Parliament granted the four agencies which receive a subsidy from the EU budget discharge in respect of the 2017 budget implementation.

[102] In 2019, the Court of Auditors made the following observations in its report on the agencies' 2018 accounts. The ongoing or outstanding actions reported hereafter do not include those which are not under the agency's control:

CPVO: The Court found that CPVO uses IT service contracts for the provision of labour from two IT consultants which is not in line with legal rules. The CPVO replied to have mitigated the risks. The Court also found weaknesses in one procurement and one recruitment procedure. The CPVO committed to remedial actions. Two observations from previous years were ongoing and one outstanding.

ECDC: The Court observed weaknesses of ex-ante controls of the use of framework-contracts and the internal control on large and more complex meeting events. By November 2019, ECDC considered the observations on framework-contracts closed and had adopted an action plan regarding the meeting events. All observations from previous years were closed.

ECHA: The Court called for adoption of a sensitive post policy and for a discussion on a new financing model (related to a finding concerning the REACH Regulation). The Court also observed weaknesses in the procurement procedure for an IT framework contract and pointed to the Internal Audit Service's 2018 report on "Conflict of Interest and Ethics in ECHA". Five observations from previous years were ongoing, only one of them relating specifically to biocides.

EFSA: The Court made no comments. One observation from previous years was ongoing.

EMA: The Court referred to its previous comments on EMA's excessive use of consultancy services for large IT projects. While acknowledging progress, the Court called on EMA to speed up the mitigating actions. The Court also pointed to the Internal Audit Service's 2018 report on "Signal Management in the EMA". The follow-up to four observations from the Court from previous years was ongoing; for one observation it was outstanding.

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

DG SANTE, within the limits of its role on the EU agencies' Management Boards and Audit Committees, if applicable[104], 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 10.9 below summarises the indicators of control effectiveness as regards legality and regularity).

Further to the Court of Auditors assurance received in October 2019, DG SANTE cleared all pre-financing payments made to the agencies in 2018 and made the final payments of the 2018 subsidies. Thus, no reservation to DG SANTE's declaration of assurance is warranted.

Table 10.9 Indicators of control effectiveness as regards legality and regularity

EU decentralised agencies	*Targets*	2019	2018	2017
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

Conclusion on legality and regularity of subsidy payments to agencies

For the 2019 reporting year, the executive agency CHAFEA has reported reasonable assurance on the delegated budget managed on DG SANTE's behalf. CHAFEA has 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 2019, the Court of Auditors gave a positive declaration of assurance for the year 2018. 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, CHAFEA, 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".

[104] 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.

10.1.2 Fraud prevention, detection and correction

The controls to prevent and detect fraud are basically the same as those intended to ensure the legality and regularity of the transactions. Risk of fraud was included in the annual risk management exercise finalised in November 2019. The fraud risks are addressed by specific controls designed and implemented to mitigate the risks.

DG SANTE has developed and implemented its own anti-fraud strategy since 2013, on the basis of the methodology provided by OLAF[105]. The strategy is updated regularly. It was last updated in July 2017 covering the years 2017 to 2020. 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 five 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;
- Standing operating procedures for the handling of allegations of fraud, other irregularities and OLAF cases;
- Arrangements for an appropriate level of cooperation with OLAF.

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

Relevant for the monitoring in 2019 were 26 actions related to the permanent tasks listed above. Two actions had to be postponed to 2020 due to other priorities. As they pertain to updates or reminders 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.

Table 10.10 Indicators for fraud prevention and detection

Indicators	*Targets*	2019	2018	2017
Update of the current anti-fraud strategy	*2020*	**n/a**	n/a	Adopted in July 2017
% of implementation of actions planned for 2019 in the anti-fraud strategy (Reference: 26 actions due in 2019; 31 in 2018; 13 in 2017)	*100%*	**92%**	90%	77%
% of financial officers reached in financial cell network meetings	*100%*	**100%**	100%	100%
EU decentralised agencies task force meeting on independence once per year with participants and contributions from all 5 EU agencies for which DG SANTE is parent	*100% (all 5 agencies)*	**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

[105] Last update of April 2019: Communication from the Commission 'Commission Anti-Fraud Strategy: enhanced action to protect the EU budget', COM(2019) 176 of 29 April 2019 – 'the CAFS Communication' – and the accompanying action plan

10.1.3 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 11,6 million at 31 December 2019. 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 2019.

The Common Financial Framework[106] 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[107].

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 Annexes 5.1 and 10.1.1.2). 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)[108]. The contractors' reports 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 2019 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 11,6 million vaccines stocks, was ensured throughout the year as stated in the reports received by the contractors.

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

[107] 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)

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

10.2 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 2019 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 2019 by type of expenditure are as follows:

10.2.1 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.

Table 10.11 Efficiency = the Time-to-indicators and other efficiency indicators related to grant management

Indicators per stage of the grant procedure	*Targets*	2019	2018	2017
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%*	**(92%)** **90%**	(83%) 84%	(97%) 95%
Average payment time	*90 days*	**55 days**	60 days	48 days
Stage 4: Ex-post controls and error corrections				
Timely implementation of the annual ex-post control work programme (16 out of 18 audit visits carried out in 2019; 14 audits in 2018; 19 audits in 2017)	*100%*	**88%**	88%	95%
"Time to recover": average days from finalising the control to issuing the debit note (no debit notes in 2019; 13 in 2018; 9 in 2017)	*n/a*	**n/a**	55 days	58 days

In 2019, 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 substantial temporary reduction in financial staff and a high work load due to the African Swine Fever crises. Thanks to corrective measures taken, the situation has much improved in comparison to 2018.

Although no recovery orders further to ex-post controls were sent out in 2019, DG SANTE issued recovery orders for about 97% of the amounts to be recovered further to the 18 ex-post controls finalised in 2019 until the end of March 2020.

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 10.12 Economy = the cost of controls related to grant management

Indicators per stage of the grant procedure (average FTE times standard annual costs) [109]		**2019 M€**	**2018 M€**	**2017 M€**
Stages 1 and 2: Programming, evaluation and operational monitoring				
Cost of operational staff in the policy Units concerned	2019: FTE: 7,6	**1,1**	1,0	1,0
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	2019: FTE: 9,8	**1,0**	1,0	1,0
Cost of staff involved in second-level ex-ante and other internal controls of the central financial Unit	2019: FTE: 2,2	**0,3**	0,2	0,3
Stage 4: On-the-spot controls (ex-ante and ex-post)				
Cost of DG's internal staff dealing with on-the-spot controls	2019: FTE: 4,3	**0,6**	0,6	0,5
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)	**FTE: 23,9**	**3,2**	3,0	3,0
Budget spent on "grants" ("benefit" of the controls)		**251,5**	245,0	218,3
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 2019 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 every year) to evaluate and monitor every year. In addition, more than 20 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[110]; 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.

[109] FTE = full time equivalent; standard annual costs in the 2019 AAR according to DG BUDG instructions to distinguish between administrators and assistants who are officials/temporary agents, seconded national experts and contractual staff in the different function groups.

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

Conclusion on cost effectiveness of controls related to grants

The control strategy for grants in direct management is considered cost-efficient overall. The main focus is on ensuring high quality of the actions co-financed, low error rate, on-time payments and reasonable costs of control.

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.

10.2.2 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.

Table 10.13 Efficiency = the Time-to-indicators and other efficiency indicators related to procurement

Indicators on control efficiency in procurem	***Targets***	**2019**	**2018**	**2017**
Stage 1: Rate of timely launched procurement procedures as specified in the annual work programmes	*100%*	**78%**	72%	61%
Stage 2: Average payment times	*30 days*	**19 days**	16 days	18 days
Ratio of payments made on time (in number) in amount	*95%*	**(98%) (99%)**	(99%) (99%)	(95%) (99%)
Stage 3: "Time to recover": average days from information/confirmation date to issuing the debit note (in 2019: 1 case; in 2018: 1 case; in 2017: 1 case related to procurement)	*n/a*	**72**	29	27

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

Table 10.14 Economy = the cost of controls related to procurement

Indicators for procurement (average FTE times standard annual costs) [111]		**2019 M€**	**2018 M€**	**2017 M€**
Stages 1 and 2: ex-ante controls				
Cost of operational staff in the policy Units concerned	2019: FTE: 6,6	**1,0**	0,7	0,5
Cost of staff involved in the CMP activities	2019: FTE: 0,1	**0,01**	0,01	0,03
Cost of staff involved in 2nd-level ex-ante and other internal controls of the central financial Unit	2019: FTE: 2,2	**0,3**	0,2	0,3
Cost of central staff involved in procurement and financial procedures	2019: FTE: 10,4	**1,2**	1,5	1,4
Stage 3: ex-post controls				
Cost of DG's internal staff dealing with on-the-spot controls	2019: FTE 0,0	**0,0**	0,0	0,0
Total annual cost (without overhead rate)	**FTE: 19,3**	**2,5**	2,4	2,2
Budget spent on "procurement" ("benefit" of the controls)		**41,4**	38,2	43,5
Total cost as % of total annual budget spent through procurement (commitment appropriations)		**6%**	**6%**	**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 2019 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".

Conclusion on cost effectiveness of controls related to procurement

The control strategy for public procurement in direct management is considered cost-effective overall. The main focus is on ensuring low errors in the procurement process and financial procedures, value for money, on-time payments and reasonable costs of control.

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 type, 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.

[111] FTE = full time equivalent; standard annual costs in the 2019 AAR according to DG BUDG instructions to distinguish between administrators and assistants who are officials/temporary agents, seconded national experts and contractual staff in the different function groups.

10.2.3 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 10.15 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)[112]		**2019 M€**	**2018 M€**	**2017 M€**
Cost of staff in the central Unit ensuring co-ordination within DG SANTE and with the agencies	2019: FTE: 0,9	**0,1**	0,3	0,1
Cost of operational staff involved in monitoring the operations of the agencies	2019: FTE: 4,0	**0,5**	0,5	0,7
Cost of staff involved in budgetary, financial, audit matters, evaluation of the agencies and other internal controls	2019: FTE: 2,1	**0,3**	0,2	0,3
Total annual cost (without overhead rate)	**FTE: 7,0**	**0,9**	1,0	1,1
Subsidies paid to the agencies		**188,9**	180,4	175,9
Total cost as % of total annual subsidies (commitment appropriations)		**0,5%**	0,6%	**0,6%**

Overall, the costs of monitoring and supervision represent less than 1% of the total subsidy payments to the agencies' administrative budget. It is worth noting that none of the EU decentralised agencies for which DG SANTE is responsible carry out budget implementation tasks on behalf of the Commission that would require an in-depth monitoring.

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.

[112] FTE = full time equivalent; standard annual costs in the 2019 AAR according to DG BUDG instructions to distinguish between administrators and assistants who are officials/temporary agents, seconded national experts and contractual staff in the different function groups.

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.

Table 10.16 Overview of the estimated cost of controls at Commission (EC) level on the basis of payments made

Title of the Relevant Control System (RCS)	Ex ante controls			Ex post controls			Total	
	(a)	(b)	(c) (a)/(b)	(d)	(e)	(f) (d)/(e)	(g) (a)+(d)	(h) (g)/(b)
	EC total costs (in EUR)	Funds managed [1] (in EUR)	Ratio %	EC total costs (in EUR)	Total value verified and/or audited [2] (in EUR)	Ratio %	EC total estimated cost of controls (in EUR)	Ratio %
Grants to Member States (direct management)	3.002.901	211.850.375	1,4%	537.237	29.420.591	1,8%	3.540.138	1,7%
Public procurement (direct management)	2.527.949	36.544.780	6,9%	-	-	-	2.527.949	6,9%
Subsidy payments to agencies (indirect management)	954.453	187.512.099	0,5%	-	-	-	954.453	0,5%
OVERALL total estimated cost of control at EC level	**6.485.303**	**435.907.254**	**1,5%**	**537.237**	**29.420.591**	**1,8%**	**7.022.540**	**1,6%**

[1] Funds managed = payments made

All funds managed are subject to ex-ante controls; ex-ante control costs include direct costs plus indirect costs such as central budget management, internal control, legal advice and central management of procurement procedures as well as accounting.

[2] The total value verified and/or audited represents the EU contribution audited during ex-post control missions actually carried out in 2019 by DG SANTE own staff and external audit services. This is compared to the estimated costs of the audits (staff costs and external audit firm) in 2019.

10.2.4 Initiatives to improve economy and efficiency

In its 2019 Management Plan, DG SANTE identified four initiatives to improve efficiency and economy. The following progress was made in the first eight months of 2019:

1) Public procurement procedures:

Since the beginning of 2019, DG SANTE is using e-Submission as unique tool for the open calls procedure. As expected, it reduces the administrative burden, especially in the opening procedure of public procurements (no manual interventions, automatic registering and reporting, paperless filing and archiving). Moreover, DG SANTE is since August 2019 on board with the Public Procurement Management Tool programme (PPMT – corporate tool), and has been testing it during the fourth quarter of 2019 before operating this IT solution to its full capacity in 2020. This web-based application will allow operational and procurement staff to support and monitor the procurement process from early need identification to contract signature, generating pre-filled templates and liaising automatically with ARES.

To complement e-submission, since February 2019, DG SANTE is using e ordering (standard solution) for the automatic generation of the procurement contract. In addition, the IT tool GEKKO (local development) is used for the processing and control of timesheets and for the payment of invoices for external IT contractors.

2) IT solution AGM: A new Gateway to EU Meetings

In the framework of its stakeholder relations, in January 2018, DG SANTE started to use the IT tool AGM, 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. Since late 2018 the use of AGM has broadened to include scientific committees and expert panels. This increases not only the efficiency of organising the meetings but also to reduce the financial risks and delays linked to a paper-based process for reimbursement of experts and paying the fees, notably to the members of the scientific committees. In October 2019, the link of AGM with WebDOR[113] became fully operational and helped reduce the manual encodings and thus, administrative burden even further.

3) Knowledge Online on European Legislation

Since April 2018, DG SANTE is implementing an IT tool called KOEL (Knowledge Online on European Legislation) to manage and share information about EU legislation. The primary objective is to better manage the administrative aspects of DG SANTE's vast acquis to ensure sound planning for the follow-up of existing and future obligations, valuable to both the Management and the Units to keep track of the evolution of the Commission's obligations and powers in SANTE's areas of competence. The KOEL system has been fully deployed and in the first half of 2019, the preliminary quality check of the SANTE acquis uploaded into KOEL has been completed. All legal (reporting) obligations are being verified and quality-checked.

The KOEL's interface on reporting obligations' has been improved by DG FISMA in order to better keep track of recurrent obligations. The system is now able to show the different dates on which recurrent reports are due, as well as to link several reports to a specific recurrent obligation.

4) Multi-annual grants for ERNs

Under the third Health Programme (2014-2020), the Commission contributes to the costs of European Reference Networks (ERN) on the basis of one-year specific grant agreements (SGAs) under the five-year framework partnership agreements (FPA). In 2018, DG SANTE took the first steps to move from one-year to three-year specific grant agreements covering the remaining period of the FPA's. The first multi-annual grant agreements were signed in early 2019. This multi-annual co-financing significantly reduces the administrative burden for both the Member States and the Commission as only one – instead of three – award procedures per ERN have to be managed. It also gives planning security to the ERNs to guarantee the sustainability of their actions.

[113] The WebDOR is a tool to book either a room, interpretation, or both, or to reimburse experts' charges (Web based "Demande d'Organisation d' une Réunion")

5) Simplification of financial circuits

In addition to the four areas identified in the 2019 Management Plan, DG SANTE continued simplifying its financial procedures as follows: every year, DG SANTE manages around 550 payments related to IT contracts. To increase the cost efficiency of DG SANTE's controls over IT invoices and to reduce the time spent on the verification of IT payments, DG SANTE replaced the 100% first-level financial verification in Unit A3 by a 10% sample verification based on the MUS-DICE application.

The visa of the Authorising Officer by Sub-delegation includes the operational and financial verification of each transaction. This circuit remains in line with the models of financial circuit in place in DG SANTE, with the Financial Regulation (Art. 74(5) of the FR), Internal Control Principle 12 and the Guidelines on Financial Circuits.

As a result, Unit A3 is expected to save a significant amount of time (90% less financial verification files of IT invoices to process, i.e. about 500 fewer visas), without significantly increasing the risk of errors. This should speed up the processing of IT payments. In order to monitor the effect of the new procedure on DG SANTE accounts, the accounting correspondent will include an additional check in the accounting review programme to assess the correctness of the accounting entries as of July 2019.

ANNEX 11: Specific annexes related to "Assessment of the effectiveness of the internal control systems"

11.1 Audit observations and recommendations

This part includes audits of the European Court of Auditors (Court) and the Commission's Internal Audit Service (IAS) as well as DG SANTE's audit follow-up.

11.1.1 European Court of Auditors

A. Court's financial audits: 2018 DAS

The structure of the Court's annual report on 2018 (DAS 2018) 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".

The Court did not report any error rate in DG SANTE's financial transactions. It points however to two weaknesses:

- In the policy area Food Safety, DG SANTE finalised its review of unit costs and ceilings used to approve national programme budgets two years later than initially planned, in 2018 instead of 2016. However, as a sufficient amount and quality of data to update the unit costs was only available in 2018, the approval of national programmes in 2016 and 2017 was still based on the best available data at the time.
- DG SANTE's checks of Member States' cost claims related to public procurement need to be clarified. DG SANTE adapted its internal guidelines clarifying the documentation required and in which cases the Member State's procedures will be examined.

B. Court's special reports on performance audits in DG SANTE

In 2019, the Court of Auditors finalised four audits on (i) organic products, (ii) cross-border health care access, (iii) anti-microbial resistance (AMR), and (iv) sustainable use of pesticides.

In addition, in 2019 the Court finalised three follow-up audits on the following performance audits of previous years: (a) animal diseases eradication, control and monitoring programmes (SR 2016/06); (b) cross-border threats to health (SR 2016/28); (c) combating Food Waste (SR 2016/34).

B.1 Audit on "organic products" (SR 2019/04)

The audit on "organic products" was 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 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 in close co-operations with DG AGRI.

B.2 Audit on "cross-border health care access" (SR 2019/07)

The Court published its report on cross-border health care access on 4 June 2019. 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. Priority areas were eHealth and rare disease treatment. DG SANTE was the lead DG with CHAFEA and DGs CNECT and JRC associated.

The audit report makes three recommendations addressed to DG SANTE: (i) provide more support for National Contact Points (ii) better prepare for cross border exchanges of health data; (iii) improve support to facilitate rare disease patients' access to healthcare.

DG SANTE accepted all three audit recommendations and drafted an action plan. Some actions strive to achieve long-term objectives such as the monitoring of the 2012 eHealth Action Plan and the 2018 eHealth strategy's implementation, or the assessment of the cost-effectiveness of the eHealth Digital Service Infrastructure. Most of the actions are expected to be finalised by the end of 2023.

B.3 Audit on AMR – anti-microbial resistance (SR 2019/21)

The auditors assessed how the Commission and the European Centre for Disease Prevention and Control (ECDC) managed resources aimed at supporting Member States One Health approach to antimicrobial resistance, and whether the framework to improve the prudent use of veterinary antimicrobials and monitor antimicrobial resistance in food was being well applied. The Court also examined how the Commission supported AMR related research. The final audit report was published on 15 November 2019.

The overall conclusion of the audit is that, while there was clear progress on veterinary issues, the Commission and ECDC's efforts to fight AMR have had limited success to date. The Court makes three recommendations which are acceptable to the Commission (i) improve the EU response to AMR through better support to Member States' national action plans, (ii) promote prudent use of veterinary antimicrobials and better surveillance of AMR, (iii) strengthen strategies for boosting AMR research in the EU.

While most of the actions have already been launched, DG SANTE drafted its action plan to ensure timely implementation of the audit recommendations.

B.4 Audit on the SUD – sustainable use of pesticides (SR 2020/05)

The overall objective of the audit was to assess whether EU action has reduced the risk related to the use of Plant Protection Products (PPP). The audit report, published on 5 February 2020, highlights that the Commission and the Member States have taken action to promote the sustainable use of PPPs, but that progress in measuring and reducing risks was still limited. Two recommendations were addressed to DG SANTE (i) to check that the Member States convert the general IPM principles into practical and measurable criteria and that they verify these criteria at farm level; (ii) to improve the harmonised risk indicators, or develop new ones that take into account, for Harmonised Risk Indicator II, agricultural areas or volumes of active substance, for Harmonised Risk Indicator I, the way PPPs are used. DG SANTE welcomes the recommendations and will see to their timely implementation. It should be noted that achieving the timeline by 2023 proposed by the Court will require Member State agreement to provide the relevant data.

C Follow-up audits on three previous performance audits

In late 2019 the first half of 2019, the Court started conducting three follow-up audits on special reports which were finalised in 2016:

(a) Eradication, control and monitoring programmes to contain animal diseases (SR 2016/06);

(b) Dealing with serious cross-border threats to health in the EU: important steps taken but more needs to be done (SR 2016/28);

(c) Combating Food Waste: an opportunity for the EU to improve the resource-efficiency of the food supply chain (SR 2016/34);

The purpose of these audits was to examine the progress the Commission has made to implement the audit recommendations. The conclusions of the Court are positive for DG SANTE as no undue delays were reported.

(a) Eradication, control and monitoring: three recommendations were implemented already in 2017/2018, although one will continue in the framework of the Multi-annual Financial Frame work 2021 to 2026. One action is delayed with a revised deadline in early 2021: the merge of two IT systems, of which one is from the Commission (ADNS) and one from OIE (WAHIS), is technically much more complex than expected and thus will be finalised two years later than planned.

(a) Cross-border threats to health in the EU: the Court concluded that DG SANTE fully implemented ten out of twelve recommendations in a timely manner. The remaining two recommendations were already implemented in most respects and still on-going actions are linked to the third Health Programme (2014-2020) and are thus expected to be finalised towards 2020.

(c) Combating Food Waste: the Court acknowledged that the three recommendations addressed to DG SNTE were already implemented in some respects. All actions refer to long-term measures developed by the Commission in close co-operation with the Member States. Although the implementation of the recommendations is an ongoing exercise, many milestones have already been achieved to

(i) Strengthen and better coordinate the EU strategy to combat food waste: the extension of the mandate of the EU Platform on Food Losses and Food Waste as well as the announced new priority for a European Green Deal[114] are indicative of the importance of combatting food waste in EU policy; some of the actions of the Circular Economy Action Plan are still ongoing and expected to be finalised in 2021;

(ii) 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: EFSA is involved in the groundwork for future guidance and with the support of the 'date marking' sub-group of the EU Platform on Food Losses and Food Waste, by the end of 2021, the Commission expects to simplify date marking and promote its better understanding and use by all actors concerned, in particular to elaborate EU scientific and technical guidance to promote more consistent date marking practices and clarify EU legal requirements.

[114] The European Green Deal, adopted on 11 December 2019, foresees the adoption of a 'Farm to Fork Strategy' to design a fair, healthy and environmentally-friendly food system. Food loss and waste prevention will be an integral part of this strategy.

(iii) 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: the external contractor's report on the policy and regulatory framework was finalised in December 2019 and the Commission plans to finalise its assessment and validation by mid-2020. The Pilot Project's report on the mapping and analysis of policy and regulatory frameworks in Member States in the area of food redistribution is expected to be finalised in early 2020.

11.1.2 Internal Audit Service of the Commission (IAS)

11.1.2.1 IAS limited conclusion on 2019

The IAS contributed to DG SANTE's Annual Activity Report for 2019 by submitting a "limited conclusion on the state of internal control" on 13 February 2020. Based on the audit work performed in the period 2017 to 2019, the IAS points to five 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.

(1) IT audit on TRACES: two 'very important' recommendations open at 31/01/2020

The IAS issued the final audit report on 27 June 2018. The objective of the audit was to assess whether the IT tool TRACES[115] 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[116].

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

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

<u>Recommendation 1 on IT governance</u>

- IAS observations: under the governance arrangements in place at the time of the audit, 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 and work is on-going as regards TRACES steering committee and project

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

[116] 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.

steering committees. With regard to IT governance in general, since early 2019, DG SANTE's policy pillar meetings, chaired by the Director-General, 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 being addressed mainly by developing an "Access Control and Authentication Management Plan" and a "logging and monitoring policy document"; DG SANTE is well advanced in updating its IT security plan and seeing to its full implementation. The procedure of vulnerability assessment and performance testing was formalised in late 2018.

(2) IAS audit on the efficiency and effectiveness of the Health and Food Audits and Analysis Directorate: two 'very important' recommendations open at 31/01/2020

In October 2019, the IAS finalised its performance audit on the efficiency and effectiveness of the work of DG SANTE's Directorate F "Health and food audits and analysis". Two recommendations were rated "very important". DG SANTE accepted the recommendations and produced an action plan in November 2019. Most of the actions are on-going and expected to be fully implemented by June 2020.

DG SANTE management assesses that the on-going mitigating actions have already reduced the residual risk to an acceptable level.

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

Recommendation 1 on the staffing of activities

- IAS observations: DG SANTE Audits and Analysis Directorate had experienced significant changes to the nature and extent of its responsibilities since its creation, which presented key challenges in relation to staffing of its activities. Although the situation was monitored, there was no detailed assessment of the human resources needed for audit and other activities in the medium to long term. The IAS recommended carrying out a comprehensive analysis of the impact of Directorate F's remote location in Grange, Ireland, and also of the recruitment needs per area in the next 3 to 5 years. This analysis should be used as a basis for developing a human resources strategy, covering in particular recruitment and training aspects. Regarding audit activities for other Commission services, the IAS recommended re-assessing the audit and resource needs in the medium to long term considering risks and legal obligations and, where relevant, proposing amendments to the existing working arrangements.
- DG SANTE has already taken actions to reduce Directorate F's policy work and will continue its analysis during the exercise to draft the 2020 Management Plan. Audit work for other DGs is evaluated on the basis of an assessment of risks and legal obligations. In co-operation with DG HR, DG SANTE will carry out an assessment of the impact of its location on recruitment and will develop a HR strategy for the medium and long term.

Recommendation 2 on time reporting and performance monitoring

- IAS observations: the IAS found room to improve Directorate F's performance monitoring of audit work and to further develop the work on the audit universe and risk based audit frequencies. The IAS recommended assessing the scope for introducing a time recording system in DG SANTE.F and collecting and analysing systematically performance information. The IAS also urged to finalise the development of the coverage of DG SANTE.F's audit universe by establishing risk based audit frequencies per audit areas and reassess these on a regular basis.
- DG SANTE has taken first steps to introduce a pilot time recording system in early 2020 and to produce a guidance document for SANTE.F management to enhance its performance monitoring of audit work. The documentation of the audits universe and risk based frequencies will be developed further during the preparations for the audit work programme 2021.

(3) IAS audit on the management of food and feed programmes, including emergency measures: one 'very important' recommendation open at 31/01/2020

In January 2020, the IAS finalised its financial audit in the food and feed policy area. One recommendation was rated "very important". DG SANTE accepted the recommendation and produced an action plan in late February 2020. Actions are on-going and expected to be fully implemented by 2023.

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:

Recommendation on the unit-cost methodology

- IAS observations: the IAS found weaknesses in DG SANTE's organisation of the process for reviewing the unit costs methodology, including the estimation of the value of each unit cost per Member State and per disease. These comprised gaps in relation to the internal consultation, the prior analysis and assessment of the impact of the proposed changes, the timing of internal and external communication and in the business continuity arrangements. The IAS recommended involving all relevant actors within the DG, consulting, as appropriate, other Commission services to use their expertise on the basis of clearly defined working modalities. DG SANTE should also inform Member States well in advance of the financial impact of any change in the methodology and of the resulting actual amounts of unit costs, lump sums and/or ceilings.
- DG SANTE actions are already under way and in late 2019, an administrative arrangement was signed with JRC to assist DG SANTE in improving the unit cost methodology.

11.1.3 DG SANTE's audit follow-up

DG SANTE addresses all audit recommendations by proportionate action plans and monitors their implementation regularly. The Director in charge of Risk Management and Internal Control (RMIC) 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.

11.1.3.1 Follow-up on audits of the Court

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 29 audit recommendations open at 31 December 2019 with target dates in 2020 or later. In addition to the four audits of 2019 (part 11.1.1-B above) and the three open audits of 2016 (part 11.1.1-C above), two additional audits of 2018 were open and followed up by DG SANTE.

(i) **Animal welfare in the EU**: closing the gap between ambitious goals and practical implementation (Special Report 2018/31)

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, during transport and at slaughter. The Court addressed five recommendations to DG SANTE. DG SANTE prepared an action plan in February 2019 (i) to carry out an evaluation of the 2012 strategy; (ii) on the basis of the evaluation results, to consider the need for a new strategy, with a possible review of the legislation; (iii) to define baseline and target indicators to measure Member States' degree of compliance; (iv) to improve the 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) to determine 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.

Several actions are already on-going: In October 2019, DG SANTE signed a service contract for an external evaluation study on the animal welfare strategy; DG SANTE runs 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 further improves 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. A review of the progress on the implementation of the action plans by the Member States involved is on-going.

(ii) **Chemical hazards in our food**: EU food safety policy protects us but faces challenges (Special Report 2019/02)

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 main message of the audit was 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.

In July 2019, DG SANTE finalised its action plan to address all three audit recommendations. Actions are on-going, for example, in the framework of the REFIT exercise on the pesticides legislation; the evaluation of the EU legislation on feed additives in animal nutrition and the evaluation of the EU legislation on Food Contact Materials, the new General Food Law which addresses, amongst others, the sustainability of the EU risk assessment in the food chain, and more specifically the scientific capacity of the EFSA. Furthermore, several delegated and implementing acts, published in October 2019 in accordance with the new Official Control Regulation (EU) 2017/625, address the Court's recommendations[117]. In addition, DG SANTE enhanced its procedures for the monitoring and enforcement of all food and health legislation. Full implementation is planned for late 2020.

11.1.3.2 Follow-up on audits of the IAS

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.

DG SANTE's management assesses that the follow-up of audit recommendations is satisfactory given the mitigating actions already put in place before the deadlines. No undue delays of audit recommendations rated "very important" occurred.

(i) DG SANTE's food safety crisis preparedness (Final audit report of 20 December 2017)

In December 2017, the IAS finalised its performance audit on certain aspects of DG SANTE's activities related to food safety crisis preparedness. Three recommendations were made (i) to improve the "general plan" and related mechanisms to respond to food safety crises and validate the related procedures regularly; (ii) to review the existing "general plan"; (iii) exercising the "general plan" in practice. In November 2019, the IAS concluded its follow-up audit and found that all recommendations were implemented adequately and effectively.

Most importantly, 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 (Commission implementing decision (EU) 2019/300 of 19 February 2019).

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.

To test the arrangements for crisis management in practice, DG SANTE conducted a

[117] https://ec.europa.eu/food/sites/food/files/oc_qa_ocregulation_20191212_delegated_implemented_acts_en.pdf

simulation exercise with all Member States and some EFTA countries in late 2018 with an external service provider. The next exercises will be organised under the Better Training for Safer Food initiative.

(ii) Monitoring and enforcement of EU health law in DG SANTE (Final audit report of 11 December 2018)

The overall objective of the audit was to assess whether DG SANTE put in place internal control systems that ensure the effective and efficient monitoring and enforcement of EU health law.

The IAS considered that there was room for further improvement in two areas (i) the compliance assessment process (i.e. checking the timely, comprehensive and correct transposition of directives by each Member State) and (ii) the monitoring activities on the application of EU health law.

DG SANTE addresses all recommendations, most importantly through the "internal guidelines for handling complaints, compliance checks of Directives and infringements", endorsed by the Management Board in May 2019, by having established a SANTE lawyers' network and by ensuring effective quality control of the data in the KOEL IT system (Knowledge Online on European Legislation). Full implementation is expected in the framework of the 2020 Management Plan to be drafted in March/April 2020.

11.2 Assessment of the effectiveness of internal control systems

11.2.1 Changes in DG SANTE's control environment

In 2019, no major changes to DG SANTE's control environment took place.

In 2019, DG SANTE continued its work on financial centralisation of certain types of expenditure to create economies of scale and simplify procedures. Since January 2019, all financial transactions related to public procurement, administrative budget implementation and grants to international organisations were transferred to the central financial Unit. When reviewing its Unit Management Plans (UMP) at mid-term, DG SANTE decided to take the financial centralisation further to the coordination of the drafting of the Annual Work Programmes for both policy areas, Health and Food and Feed, as well to the monitoring of the programmes' implementation as of January 2020.

At the end of 2019, the Head of Unit Finance, Budget and Controls left DG SANTE and drafted a hand-over report including a declaration of assurance as authorising officer by sub-delegation.

11.2.2 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.

11.2.2.1 Annual assessment methodology

The annual assessment on the implementation of the Internal Control Principles (ICP) was finalised in the first quarter of 2020 and brought to the attention of the Directors' Steering Committee on 12 March 2020 and endorsed by the Management Board in its meeting on 24 March 2020. The assessment was organised by the internal control officer on the basis of the following four elements:

(a) Internal control monitoring criteria: evaluation of the indicators as defined in the 2019 Management Plan; several indicators are based on the results of an internal staff questionnaire on management and internal control matters to get a better insight into the effectiveness of selected control principles;

(b) Exceptions to rules and procedures, including non-compliance events or cases of "confirmation of instructions" as well as issues raised in management reports received from the authorising officers by sub-delegation: scrutiny of the reports that could point to control deficiencies;

(c) Audit observations of the IAS and the Court of Auditors as well as findings from DG BUDG's validation of local systems: analysis of the results of the audits and audit follow-up work to assess the impact on the internal control system;

(d) Results of the internal desk review including contributions of key staff supporting important elements of the set up and functioning of internal controls and the follow-up of management action plans stemming from management's risk assessment and the anti-fraud strategy.

11.2.2.2 Results of the annual assessment

(a) Internal control monitoring criteria

The assessment on the basis of the defined internal control monitoring criteria led to a positive conclusion on the effectiveness of the internal control system, meaning that the components and principles are present and functioning, but some improvements are needed for minor deficiencies. These relate to the following five Internal Control Principles: ICP 1 on ethical values and integrity; ICP 4 on staff allocation and professional development, functions which are only partially under DG SANTE management; ICP 6 on "objective setting"; ICP 10 on control activities; ICP 11 on control activities over technology.

- ICPs 1 and 4: in 2019, the Commission's HR community still saw the need to consolidate and fine-tune the HR delivery model introduced as pilot in 2017. In 2019, 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.
- ICP 6: the staff surveys in 2018 and 2019 showed that staff perception of the role of DG SANTE senior management is rather week when it comes to guidance on "missions, objectives and tasks". Actions already took place to include all staff in DG SANTE shaping for the future, but the issue warrants further attention.
- ICPs 10 and 11: with regard to control activities, the IAS (see part 11.1.2 above) found a need to improve (i) the unit costs methodology applied in the policy area Food and Feed, (ii) the time reporting and performance monitoring in DG SANTE's Directorate "Health and food audits and analysis", and (iii) certain aspects of IT security in the IT tool TRACES. All issues are addressed already partially.

(b) Exceptions to rules and procedure

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.

- Late adoption of the 2019 Work Programmes and financing decisions in the policy areas Public Health and Food and Feed Safety: due to a longer than expected internal consultation process and internal changes, the work programmes were adopted only in late March and June/July 2019. Certain procurement procedures had to be launched prior to the adoption to ensure the continuity of those services for which the Commission is bound by legal obligations or political commitments.
- Reimbursement of animal disease eradication costs for 2018: in one case, DG SANTE reported a non-compliance event with the grant decision and the Financial Regulation for the reimbursement of eradication costs for African Swine Fever emergency measures. DG SANTE judged that the non-compliance was justified by special circumstances. The strict application of the grant decision and Financial Regulation would have put a disproportionately high burden on the beneficiaries.
- A-posteriori commitments: two cases were recorded to handle situations in which mistakes were made when amending a grant decision and when extending a service contract.

- Inadequate handling of a so-called "very low value" purchase: in one case just exceeding the threshold of a thousand euro, procedural steps were omitted to be able to keep an important deadline.

In each case, the underlying causes behind the exceptions and weaknesses were analysed and drawn to the attention of the Directors' Steering Committee. 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 from procedures, a non-compliance event or internal control weakness are covered by an appropriate report.

(c) Audit observations

- The feedback received from the Court of Auditors and the IAS 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 (see part 11.1.1 above for more detail).
- The audit observations of the IAS rated "very important" and open in 2019 are related to DG SANTE's IT tool TRACES, the work of the Directorate for "health and food audits and analysis" and the methodology of unit costs used in the Food and Feed expenditure. The main actions to address the weaknesses 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 (see part 11.1.2 above for more detail on the audits and DG SANTE's actions).
- 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.

(d) Results of the internal desk review

- The mid-term evaluation of CHAFEA, finalised in October 2018, pointed to weaknesses in DG SANTE's control activities related to CHAFEA. DG SANTE will review – inter alia – the Memorandum of Understanding with CHAFEA and the other parent DGs to implement the recommendations made in the mid-term evaluation.
- 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 2019, 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.

11.2.2.3 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 2019 report with the then Commissioner in a bilateral meeting on 1 October 2019.

In 2019, 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.). In coordination with the Secretariat General, Brexit Preparedness Group and Task Force 50, substantial preparedness actions have been put in place and thus the risk of disruptions is deemed to be under control. However, due to the UK's withdrawal, Member States will see an increase in their workload which could cause delays in in certain areas such as evaluations of plant protection products, biocides or medicinal products.

- **African Swine Fever (ASF) could have a negative effect on the Commission's reputation**

  In 2019, African Swine Fever continued to represent an extreme challenge both in terms of dynamics of the disease and in terms of impact. 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 2019, 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 order to respond to 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. In addition, DG SANTE updated the guidance in place for Member States and dispatched several missions of the EU Veterinary Emergency Team to give technical support to authorities and stakeholders.

- **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 continues close monitoring through its role on EMA's Management Board.

ANNEX 12: Performance tables

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

General objective 1 : A new boost for jobs, growth and investment in the EU		
Impact indicator 1.1: Employment rate population aged 20-64 **Source of the data**: Eurostat		
Baseline (2014)	**Latest known value** (2018)	**Target** (2020) Europe 2020 target
69.2%	73.2%	At least 75%
Bookmark		
Impact indicator 1.2: People at risk of poverty or social exclusion **Source of the data**: Eurostat		
Baseline (2013)	**Latest known value** (2018)	**Target** (2020) Europe 2020 target
122.8 million [Baseline adjusted: before:122.7]	110.2 million	At least 20 million people fewer than in 2008 (116.2 million)
Bookmark		

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

Tackling serious cross-border health threats

Specific objective 1.1: Effective preparedness, prevention, reaction and eradication of human, animal and plant diseases		Related to Health Programme	
Result indicator 1.1A: Number of Member States which have improved preparedness and response planning in accordance with Article 4 of Decision 1082/2013/EU on serious cross border health threats, in particular with regards to the implementation of the core capacity standards under the International Health Regulations (IHR) **Source of data:** Progress reports based on information provided by Member States in line with Article 4 § 2 of Decision 1082/2013/EU of the European Parliament and Council on serious cross-border threats to health			
Baseline 2015	**Interim Milestone** 2017	**Target** 2019 The first report was developed by SANTE C3 in June 2015 and presented to the Health Security Committee. The deadline for the implementation of IHR was set by WHO for 2009, however a number of Member States asked for extension of the deadline. Under Article 4 of Decision 1082/2013/EU Member States are obliged to consult each other with the aim to support the implementation of core capacity requirements under the IHR	**Latest known results** 2019
0	14	28	24

Result indicator 1.1B: Number of Member States with improved preparedness and response planning addressing arrangements aimed at ensuring interoperability between the health sector and other critical sectors , in particular: (i) coordination structures in place for cross-sectoral incidents; (ii) emergency operational centres (crisis centres); (iii) measures or arrangements aimed at ensuring the continuous delivery of critical services and products. **Source of data:** Progress report on preparedness based on information provided by Member States in line with Article 4 § 2 of Decision 1082/2013/EU of the European Parliament and Council on serious cross-border threats to health.			
Baseline 2015	**Interim Milestone** 2018	**Target** 2020	**Latest known results** 2019
1.2.B. (i): 18 1.2.B. (ii): 22 1.2.B. (iii): 16	24 25 22	28 28 28	1.2.B. (i): 26 1.2.B. (ii): 26 1.2.B. (iii): 21

Managing and isolating outbreaks of major animal disease

Specific objective 1.1: Effective preparedness, prevention , reaction and eradication of human, animal and plant diseases		Related to Food and feed expenditure Regulation (EU) No. 652/2014	
Result indicator 1.1C: Reduction of restrictions in the EU caused by outbreaks of major epidemic animal diseases (foot and mouth disease, classical swine fever, African swine fever, avian influenza and lumpy skin disease) **Source of data:** Commission internal from several sources: safeguard and regionalisation decisions, eradication and monitoring programmes against these diseases, Animal Disease Notification System (ADNS), other information by MS			
Baseline 2014	**Interim Milestone** 2018	**Target** 2020	**Latest known results** 2019
168[118]/7800[119]	Decreasing value	Decreasing value (internal target)	501/7800
Result indicator 1.1D: Containment of spread of major epidemic animal diseases in the EU after initial outbreak (foot and mouth disease, classical swine fever, African swine fever, avian influenza and lumpy skin disease) **Source of data:** Commission internal from several sources: safeguard and regionalisation decisions, eradication and monitoring programmes against these diseases, Animal Disease Notification System (ADNS)			
Baseline 2014	**Interim Milestone** 2018	**Target** 2020	**Latest known results** 2019
19/25[120]	Increasing	Increasing (internal target)	21/25

118 152 has been replaced with 168 due to a mistake in calculating the baseline - it included outbreaks of Newcastle disease instead of outbreaks of lumpy skin disease

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

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

Preventing plant disease

Specific objective 1.1: Effective preparedness, prevention , reaction and eradication of human, animal and plant diseases (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme)			Related to Food and feed expenditure Regulation (EU) No. 652/2014
Result indicator 1.1E: Percentage of the EU territory covered by surveys for plant pests, in particular for pests not known to occur in the Union territory **Source of data:** Data can be procured using the Survey programs submitted by MS			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	2017	2020 (agreed in Commission proposal COM(2013)327 final)	2019
50%	70%	100%	90 %
Result indicator 1.1F: Percentage of the EU territory covered by surveys for plant pests considered to be most dangerous, as defined under Directive 2000/29/EC **Source of data:** Monitoring results for pests subject to EU measures is completed by Member States and reported to the Commission on an annual basis.			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	2017	2020 (agreed in Commission proposal COM(2013)327 final)	2019
100%	100%	100%	100 %
Result indicator 1.1G: Time between finding and notification for plant pests not known to occur in the Union **Source of data:** Data can be procured using notification of outbreaks by MS (electronic system Europhyt-Outbreaks)			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	2017	2020	2019
42 days	20 days	8 days	13 days
Result indicator 1.1H: Success rate in eradicating plant pests not known to occur in the Union **Source of data:** Data can be procured using notification of outbreaks by MS (electronic system Europhyt-Outbreaks)			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2013	2017	2020 (agreed Commission proposal COM(2013)327 final)	2019
0%	60%	95%	No data available[121]

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

Outputs table:

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT	
Specific objective 1.1: Effective preparedness, prevention, reaction and eradication of human, animal and plant diseases	Related to spending programmes: - 3rd EU Health Programme - CFF for the Food Chain 2014-2020
Main outputs in 2019:	
Important items from work programmes/financing decisions/operational programmes[122]	

Output description	**Indicator**	**Target**	**Latest known results (situation on 31/12/2019)**
Human diseases			
A list of priority vaccines for research provided by the Joint Action on Vaccination	*Agreement*	*Q3 2019*	*List with four priority diseases provided*
Launch of an e-learning platform as regards research-based knowledge, best practices and lessons learned on vaccine hesitancy in the frame of the Joint Action on Vaccination	*Launch*	*Q1 2019*	*Launch of the platform is delayed, as the sustainability of the platform beyond the Joint Action needs to be clarified before launching it. Expected launch by Q3 2020*
Survey/interviews with relevant stakeholders on coordinated cross-border measles vaccination campaigns in the frame of the Joint Action on Vaccination	*Start*	*Q3 2019*	*The survey is underway. Results expected by Q3 2020*
Creation of a European Vaccination Portal in collaboration with the European Centre for Disease Prevention and Control.	*Operational*	*Q4 2019*	*A draft (prototype) version was launched in 12/2019. The formal launch was moved to the European Immunisation Week in 04/2020 to allow for translation of the contents into all EU languages*
Animal and plant diseases			
2019 Eradication, surveillance and monitoring programmes:			
Bovine brucellosis	*No. of programmes which received co-financing*	*3*	*3*
Bovine tuberculosis	*No. of programmes which received co-financing*	*6*	*5*

[122] For a complete listing of expenditure-related outputs please refer to the Programme Statements published together with the Draft Budget for 2019.

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
Ovine/caprine brucellosis	*No. of programmes which received co-financing*	*5*	*5*
Bluetongue	*No. of programmes which received co-financing*	*16*	*16*
Swine diseases	*No. of programmes which received co-financing*	*20*	*20*
Avian influenza	*No. of programmes which received co-financing*	*26*	*26*
Transmissible Spongiform Encephalopathies (TSE), Bovine spongiform encephalopathy (BSE) and scrapie	*No. of programmes which received co-financing*	*27*	*27*
Rabies	*No. of programmes which received co-financing*	*12*	*12*
Salmonella in poultry	*No. of programmes which received co-financing*	*25*	*88 individual programmes in 25 MSs*
Lumpy Skin Disease (LSD)	*No. of programmes which received co-financing*	*4*	*3*
Emergency measures	*Adoption*	*Throughout the year*	*44*
Other important outputs			
Human diseases			
Template proposal for a common physical EU vaccination card and an EU electronic vaccination card	*Completed*	*Q3 2019*	*Call for tender launched and contract signed in Q4. Kick-off meeting planned for Q1/2020*
Launching Conference of the Coalition for Vaccination	*Organisation of the meeting*	*Q1 2019*	*1st Meeting held in 03/2019*
Conference on improving EU vaccine manufacturing capacity and ensuring continuity of supply	*Organisation of the meeting*	*Q3 2019*	*Postponed to 2020 due to the move of EMA.*

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
Workshop on lessons learnt on joint procurement of vaccines	*Workshop organised*	*Q3 2019*	*Delayed until Q1 2020. The second procurement procedure for pandemic influenza vaccines must be finalized ahead of the workshop*
Global Vaccination Summit	*Organisation of the meeting*	*Q3 2019*	*Summit held on 12/09/2019*
Implementing acts under Decision 1082/2013/EU on the operational procedures of the epidemiological surveillance network (PLAN/2017/2137)	*Adopted*	*Q1 2019*	*Delayed until Q2 2020 due to the technical nature of the implementing act. Preparation is ongoing with ECDC*
Launch of Joint Action to strengthen preparedness against serious cross-border threats to health	*Launched*	*Q1 2019*	*Launched 01/04/2019*
Launch of Joint Action on health preparedness for terror attacks	*Launched*	*Q3 2019*	*Delayed until Q2 2020 due to procedural reasons and identifying the consortium leader for the Joint Action. Following the adoption of the Health Programme Work Programme (29.3.2019) and the nomination of competent authorities (11.6.2019), the proposal is currently being developed*
Animal diseases			
Commission decisions on handling evolving epidemiological situations	*Adoption of emergency Decisions as necessary, according to the epidemiological situation*	*In course of 2019*	*44*
Commission rules on safe imports, trade and related aspects	*Adoption of Commission implementing rules*	*In course of 2019*	*30*
Delegated Act on movement of terrestrial animals and products of animal origin (PLAN/2018/2576)	*Adoption*	*Q3 2019*	*Adopted C(2019) 4058- 17/12/2019*
Delegated Act on Movement of aquatic animals and products of animal origin from aquatic animals (PLAN/2018/2572)	*Adoption*	*Q3 2019*	*New foreseen adoption date: Q1 2020, due to complexity of the act and of technical discussions, and to long internal procedures*

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
Delegated Act on Entry into the EU of animals, general products and products of animal origin (PLAN/2018/2575)	*Adoption*	*Q3 2019*	*Adopted on 30/01/2020 due to complex of the act and to long internal procedures*
Delegated Act on Notification, reporting, surveillance, eradication programmes, disease freedom (PLAN/2018/2573)	*Adoption*	*Q3 2019*	*Adopted C(2019) 4056 - 17/12/2019*
Delegated Act on Disease control measures – List A, B, C diseases (PLAN/2018/2574)	*Adoption*	*Q3 2019*	*Adopted C(2019) 4057 - 17/12/2019*
Delegated Act on animals (terrestrial): Registration and approval of establishments, identification and registration of animals (PLAN/2018/2577)	*Adoption*	*Q3 2019*	*Adopted C(2019)4625 – 28/06/2019*
Delegated Act on approval of germinal product establishments, traceability and animal health requirements for the movements within the Union and entry into the Union of germinal products of certain kept terrestrial animals (PLAN/2017/1290)	*Adoption*	*Q1 2019*	*Adopted C(2019) 4055 - 17/12/2019*
Delegated Act on animal health requirements for the production, processing and distribution within the Union and entry into the Union of products of animal origin (PLAN/2017/1341)	*Adoption*	*Q3 2019*	*New foreseen adoption date: Q1 2020, due to the high legal complexity of the act*
Delegated Act on aquatic animals - registration and approval, types of establishments, transporters exempted, exemptions from record keeping (PLAN/2018/2571)	*Adoption*	*Q3 2019*	*New foreseen adoption date: Q1 2020, due to complexity of the act and of technical discussions, and to long internal procedures*

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
Plant diseases			
Implementing Act listing regulated pests, plants, plant products and other objects (PLAN/2017/1442)	*Adoption*	*Q4 2019*	*Adopted C(2019)8466 – 28/11/2019*
Delegated Act on rules on plant passports and criteria for professional operators issuing plant passports (article 81(2) PHL) (PLAN/2018/2570)	*Adoption*	*Q1 2019*	*Adopted C(2019)1882 – 13/03/2019*
Delegated Act on establishment of conditions concerning the authorisation for movement of quarantine pests and certain plants and plant products (PLAN/2017/1443)	*Adoption*	*Q4 2019*	*Adopted C(2019)1922 – 14/03/2019*
Delegated Act on establishment of a list of priority pests (PLAN/2017/1440)	*Adoption*	*Q4 2019*	*Adopted C(2019)5637 – 01/08/2019*
Commission Decisions on emergency measures against some specific pests	*Adoption according to (new) outbreak situations*	*In course of 2019*	*4 decisions adopted*
Commission Decisions with specific import requirements for trade lines where there are too many import interceptions	*Adoption according to import interception notifications from Member States*	*In course of 2019*	*1 decision adopted*

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

Specific objective 1.2: Safe and sustainable food and food production systems		Related to spending programmes : **No**	
Result indicator 1.2.A: The number of cases of diseases in humans in the EU linked to food safety or zoonoses **Source of data:** ECDC surveillance data on human cases, Annual joint EFSA/ECDC report on zoonoses			
Baseline (2012)	**Milestone (2018)**	**Target (2020)**	**Latest known results (2019)**
94,278 confirmed cases of human salmonellosis	67000 cases	60000 (sustained negative trend in incidence cases)	91,857

Result indicator 1.2.B[123]**:** Compliance rate with legal deadlines for presentation of a draft Review Report and regulatory decision on approval/non-approval or renewal/non-renewal of approval for pesticides to the Standing Committee on Plants, Animals, Food and Feed (PAFF) within 6 months after an EFSA conclusion
Source of data: Operational Units to provide data on the compliance rate.

Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	**2017**	**2020**	**2019**
Number of draft Review reports which were actually submitted to PAFF Committee / Number of draft review reports which should have been submitted to PAFF Committee **12/20 = 60%**[124]	80%	85%	19/27= 70 %[125]

Result indicator 1.2.BB: Compliance rate of approvals with legal deadlines for presentation of a draft proposal authorising the new use or change in the condition of use of food additive to the Standing Committee on Plants, Animals, Food and Feed (PAFF) within 9 months after an EFSA conclusion
Source of data: Operational Units to provide data on the compliance rate.

Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	**2017**	**2020**	**2019**
Number of draft Review reports which were actually submitted to PAFF Committee / Number of draft review reports which should have been submitted to SCPAF **7/8= 87,5%**	90%	100%	75%

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

Baseline 2015	**Target** 2018	**Latest known results** 2019
0/0	5/5	4 /5

[123] DG SANTE had to split the indicator 1.2.B between pesticides and food additives as the data was not compatible and could be misleading. The split indicator still measures compliance rate with legal deadlines but separately for authorisations of pesticides and food additives. As the split indicator is calculated differently the new calculations had to be made to establish the baseline.

[124] The figure for the number of draft review reports that should have been submitted to the PAFF Committee in 2017 is based on the number of EFSA conclusions adopted in the time period 1 July 2016 until 30 June 2017. The deadline for the Commission is 6 months from receiving the Conclusion from EFSA to present a draft review report to the PAFF Committee. The number of outputs may have been influenced partially by the introduction of new, more time consuming administrative procedures.

[125] The figure for the number of draft review reports that should have been submitted to the PAFF Committee in 2018 is based on the number of EFSA conclusions adopted in the time period 1 July 2017 until 30 June 2018. The deadline for the Commission is 6 months from receiving the Conclusion from EFSA to present a draft review report to the PAFF Committee. The figure for the number of draft review reports are counted as the first presentation of the draft review reports in the time period 1 January 2018 until 31 December 2018.

Outputs table:

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT	
Specific objective 1.2: Safe and sustainable food and feed production systems	Related to spending programme CFF for the Food Chain 2014-2020
Main outputs in 2019:	
Delivery on legislative proposals pending with the legislator	

Output description	**Indicator**	**Target**	**Latest known results (situation on 31/12/2019)**
Negotiation with Council and Parliament of a proposal for a Regulation on the transparency and sustainability of the EU risk assessment in the food chain - 2018/088 (COD)	*Political agreement*	*Q2 2019*	*Final adoption of Regulation on the transparency and sustainability of the EU risk assessment in the food chain by co-legislators on 13/06/2019*
Initiative on possibility for the Member States to restrict or prohibit the use of genetically modified food and feed on their territory - 2015/0093 (COD)	*Continue to monitor progress in the Parliament and the Council*	*Q2 2019*	*No progress made in the absence of meetings in the Council to discuss the proposal*
Initiative on cloning of animals of the bovine, porcine, ovine, caprine and equine species kept and reproduced for farming purposes (2013/SANCO/007)	*Continue to monitor progress in the Parliament and the Council*	*Q2 2019*	*No progress made in the absence of meetings in the Council to discuss the proposal*
Initiative on placing on the market of food from animal clones (2013/SANCO/007)	*Continue to monitor progress in the Parliament and the Council*	*Q2 2019*	*No progress made in the absence of meetings in the Council to discuss the proposal*
Important items from work programmes/financing decisions/operational programmes[126]			
Food Labelling Information System	*Operation of the database*	*Q4 2019*	*Due to issues related to IT implementation the FLIS database is foreseen to be operational in Q2 2020*
Evaluation of Nutrition and Health Claims Regulation (2015/SANTE/595) Annex II of the CWP 2016	*Publication of the SWD*	*Q2 2019*	*The Staff Working Document was put on hold by the previous College and will be adopted together in Q1 2020*

[126] For a complete listing of expenditure-related outputs please refer to the Programme Statements published together with the Draft Budget for 2019.

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
Evaluation of Regulations on plant protection products and pesticides residues legislation (2016/SANTE/197) Annex II of the CWP 2016	*Publication of SWD and of Report to Parliament and Council*	*Q2 2019*	*The Staff Working Document and Report were put on hold by the previous College and will be adopted together in Q1 2020*
Evaluation of the feed additives legislation (PLAN/2017/988) [REFIT Scoreboard 2017]	*Adoption of SWD*	*Q4 2019*	*New foreseen adoption date Q4 2020. Due to complexity of the sector there was a delay in the preparation of the study that serves as a basis for the SWD.*
Operational support services for the EU Platform on Food Losses and Food Waste	*Operation of digital platform and user activity*	*Ongoing regular activity in 2019*	*Operational since 11/2017*
Operations of Horizon 2020 REFRESH as part of SANTE food waste prevention digital tools	*Operation of website*	*Q2 2019*	*Full operation foreseen in Q2 2020 due to assumption of moderation by DG SANTE only in 08/2019*
Report analysing the effectiveness of food waste prevention initiatives (implemented by JRC)	*Publication*	*Q4 2019*	*Publication on 12/12/2019*
Meetings of the EU Platform on food waste	*2 meetings and 1 event to disseminate Platform recommendations for action in food waste prevention held*	*Q2, Q4 2019*	*One meeting (06/05) and one public event (12/12)*
Delegated Act on measurement methodology (PLAN/2018/2496)	*Adoption*	*Q1 2019*	*Adopted C(2019)3211-03/05/2019*
Implementing act on format for reporting data on food waste (PLAN/2018/3473)	*Adoption*	*Q1 2019*	*Adopted C(2019)8577-28/11/2019*
EP Pilot project on food redistribution: reports on Tasks 1 and 2 – mapping and analysis of policy, regulatory and operational frameworks	*Publication*	*Q1 2019*	*Task 1: the draft report was delivered and is currently under validation in order to be published; Task 2: Due to quality concerns related to the work of the external contractor carried out in relation to Task 2, this task was delated from the contract and the budget was reduced accordingly.*
Action grant to support European Federation of Food Banks (strengthening and	*Adoption of grant agreement*	*Q3 2019*	*Grant agreement signed in 11/2018, with budget amended in 11/2019.*

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
expansion of network in the EU)			
Implementation of grants programme to support action of Member States and actors in the food value chain to prevent food waste and strengthen sustainability	*Completed*	*Q4 2019*	*List of activities to be co-funded under the next Single market Programme (SMP) Regulation including the grants programme has been finalized. Working programmes are now under preparation*
Innovation in food processing technologies (Portal for e-authorisations of food improvement agents and novel foods)	*Operation of the portal*	*Q4 2019*	*The work on the portal for food improvement agents (FIAs) is ongoing. The progress was influenced by resource constrains of IT Unit. It is expected that the FIAs e-portal will be operational in Q2 2020.* *The e-submission portal for novel foods has been operational as of 03/01/2018*
Other important outputs			
Implementation of Regulation on the transparency and sustainability of the EU risk assessment in the food chain, if adopted by co-legislators	*Adoption*	*Q4 2019*	*Initial target of "adoption" was erroneous. Work on implementation started in 2019 after the adoption of the Regulation by the co-legislators (06/2019), with foreseen date for completion Q3 2020*
Implementing act establishing a legal limit for the industrial trans fats content in foods (2016/SANTE/143) Reference in the text of CWP 2016	*Adopted*	*Q1 2019*	*Adopted C(2019)2902 – 24/04/2019*
Commission guidance document on origin indication of the primary ingredients of food (PLAN/2018/4501)	*Adoption*	*Q4 2019*	*Publication expected in 02/2020, due to the number of comments received during the CIS*
Report from the Commission on front-of-pack / simplified nutrition information (PLAN/2017/923)	*Adoption*	*Q1 2019*	*Adoption of the report was put on hold by the previous College. New foreseen adoption date Q1 2020*
Regulatory measures on contaminants in feed and food following EFSA opinions	*Adoption*	*In course of 2019*	*3 measures adopted Regulations (EU) 2019/1869, 2019/1870 and 2019/1901*
Authorisations for health claims made on foods and referring to children's	*Adoption*	*In course of 2019*	*No adoption in 2019 due to other priorities (evaluation SWD)*

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
development			
Authorisations of health and nutrition claims, generic descriptors, vitamins and mineral substances etc.	*Adoption*	*In course of 2019*	*Adoption of one Regulation rejecting one health claim*
Outline of specific compositional requirements for baby foods and processed cereal-based foods for the purpose of consultation with the European Food Safety Authority	*Completion*	*Q4 2019*	*Outline not finalised due to the complexity of the matter. A number of MS expert group took place but the discussion is not finalised. New adoption date: Q3 2020*
Delegated act amending the maximum vitamin D and erucic acid content permitted in infant formulae (PLAN/2018/3475)	*Adoption*	*Q1 2019*	*Adopted C(2019)1883 – 14/03/2019*
Measure on ceramic food contact material (PLAN/2017/2348)	*Publication of IA*	*Q3 2019*	*Delay due to the need for a study to be contracted to support the proportionate impact assessment. New foreseen date for adoption: Q3 2021*
Plant protection products and biocides			
Renewal/non-renewal of active substances for plant protection products	*Adoption*	*Ongoing regular activity in 2019*	*18 decisions adopted*
Decisions establishing maximum residues levels (MRL) for pesticides	*Adoption*	*Ongoing regular activity in 2019*	*19 Regulations adopted relating to MRLs for 107 substances*
Decisions establishing list of non-acceptable co-formulants in plant protection products	*Adoption*	*In the course of 2019*	*Delayed to 2020 due to prolonged need for consultations*
Implementing Regulations renewing the approval of biocidal active substances	*Adoption*	*Ongoing regular activity in 2019*	*6 extensions for active substance-product type combinations for assessing the renewal of approval*
Implementing Regulations for approval or non-approval of biocidal active substances included in the review programme	*Adoption*	*Ongoing regular activity in 2019*	*1 active substance – product type combination approved* *7 active substance-product type combinations non-approved* *7 active substances included in Annex I of the Biocidal Products Regulation that are eligible for simplified authorisation procedure*

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
Sustainable use of pesticides			
Report to the Council and the European Parliament on the implementation of the Sustainable Use of pesticides Directive (SUD) (PLAN/2018/4570)	*Adoption*	*Q4 2019*	*Adoption of the report was put on hold by the previous College. New foreseen adoption date Q1 2020*
Commission Directive on Harmonised Risk Indicators in the context of the Sustainable Use of Pesticides Directive (PLAN/2018/2731)	*Adoption*	*Q1 2019*	*Adopted C(2019)3580 – 15/05/2019*
Endocrine disruptors (ED)			
Implementation of the new ED criteria in the approval/renewal of active substances	*Implemented*	*Ongoing regular activity in 2019*	*Criteria are being applied in 39 ongoing procedures under the Biocidal Products Regulation. Criteria have been applied for decision-making on 12 approvals/renewals of approval since 11/2018 under the Plant Protection Products Regulation. Criteria are implemented for 33 ongoing procedures*
GMOs			
Authorisations of GMO for food / feed and cultivation uses	*Adoption*	*Ongoing regular activity in 2019*	*72 authorisations for food and feed and 1 for non-food*
Authorisations of substances			
Authorisations for new substances and new uses of already authorised substances used as food additives, food flavourings, or substances used in plastic food contact materials	*Adoption*	*Ongoing regular activity in 2019*	*8 substances authorised under the Food Contact Materials Regulation (2008/282). Amendment of conditions of use for one existing flavouring substance (Reg 2019/36)*
Authorisation of 138 recycling processes for plastics used in food contact materials	*Adoption*	*In course of 2019*	*Delayed until 2020, as Regulation 282/2008 first needs to be amended before the individual recycling processes can be authorised, all in one go*

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
Feed additives/Feed hygiene/Feed marketing			
Re-evaluations of authorisations, new authorisations, denial of authorisation, modifications of authorisations and renewal and non-renewal of authorisations of feed additives	*Adoption*	*Ongoing regular activity in 2019*	*48 implementing regulations approving 117 feed additives*
Establishment of requirements for the feed business operators importing feed from non-EU countries	*Preparation*	*Q4 2019*	*The initiative has not been prepared due to the fact that the proposed evaluation of the Feed Hygiene Regulation (starting in 2021) could result in new possible requirements for the import of feed*
Revision of existing dietetic feed authorisation and authorisation of new dietetic feeds (2015/SANTE/111)	*Adoption*	*Q2 2019*	*New foreseen adoption date: Q1 2020, due to delays in the evaluation of one new dietetic feed took*
Implementation of the Novel Food Regulation			
Authorisation of novel foods under the Regulation on Novel Foods	*Adoption*	*85 authori-sations expected in course of 2019*	*14 authorisations have been adopted*
Authorisation of traditional foods from third countries under the Regulation on Novel Foods	*Adoption*	*15 authori-sations expected in course of 2019*	*No authorisations for traditional foods have been adopted*
Decisions on data protection under the Regulation on Novel Foods	*Adoption*	*Ongoing regular activity in 2019*	*5 authorising regulations with data protection were adopted*
Implementation of the legislation on plant reproductive material			
Amendment to delete references to regulated non-quarantine pests from the marketing Directives for seeds and propagating material and several implementing measures (PLAN/2018/4394)	*Adoption*	*Q4 2019*	*Act was voted in the Committee in 11/2019; adoption delayed to 2020*
Amendment of the list of vegetable genera and	*Adoption*	*Q1 2019*	*Adopted C(2019)4308 – 17/06/2019*

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
species covered by the marketing Directives (PLAN/2018/2643)			
Bio-chemical and bio-molecular techniques in seed certification (PLAN/2018/3686)	*Adoption*	*Q4 2019*	*New foreseen adoption date: Q4 2020, due to other priorities*
Update of the requirements for soy bean seed. (PLAN/2018/3687)	*Adoption*	*Q2 2019*	*Cancelled 26/11/2019 - this amendment is covered by Implementing Act listing regulated pests, plants, plant products and other objects (PLAN/2017/1442, adopted C(2019)8466 on 28/11/2019)*
Guidelines for variety reference sample and maintenance of varieties (PLAN/2018/3864)	*Adoption*	*Q4 2019*	*Guidelines have been agreed as Commission Working documents in 2019 in the Committee*
Quantitative restrictions for not-yet-listed varieties of maize (PLAN/2018/3865)	*Adoption*	*Q4 2019*	*Cancelled - 13/11/2019 - the requesting Member State did not provide substantial arguments to proceed with the initiative.*
Extension of the validity of decisions concerning equivalence of seed potatoes from third countries (PLAN/2018/3704)	*Adoption*	*Q1 2019*	*Adopted C(2019)247 – 24/01/2019*
Amendment of the fees payable to the Community Plant Variety Office (PLAN/2018/3685)	*Adoption*	*Q4 2019*	*Adopted C(2019)8379 – 26/11/2019*
Update of variety testing protocols (PLAN/2018/3708)	*Adoption*	*Q4 2019*	*Adopted C(2019)8372 – 28/11/2019*
Denomination rules for variety registration (PLAN/2018/3863)	*Adoption*	*Q3 2019*	*New foreseen adoption date: Q2 2020, due to ongoing consultation with CPVO.*
Animal Welfare			
Meetings of the Platform on Animal Welfare	*2 meetings held*	*Q4 2019*	*2 meetings held*
Meetings of the subgroups *of the Platform on Animal Welfare*	*4 meetings held*	*Q4 2019*	*2 meetings of the transport subgroup;* *2 meetings of the pig subgroup*
Evaluation of Animal Welfare Strategy	*Launched*	*Q4 2019*	*Evaluation launched. Contract signed on 10/10/2019.*
Commission Implementing Regulation on the designation of an EU reference centre for animal welfare (PLAN/2018/3717)	*Adoption*	*Q2 2019*	*Adopted C(2019)7072 - 04/10/2019*

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
Audit reports in the context of the indicators project	*4 audit reports published*	*Q4 2019*	*Final audit reports published for FI and SE. Audit reports in preparation for NL and DE*
Stakeholder meeting in the context of the indicators project	*1 meeting held*	*Q4 2019*	*Meeting cancelled as topic was discussed at meeting with Member States in 02/2019*
Audit reports and final report in the context of the pig tail docking project	*4 audit reports and project final report published*	*Q4 2019*	*Final audit reports published for HU and PT. Audits reports in preparation for AT and FR*
TAILs reports in the context of the pig tail docking project	*2 reports launched*	*Q2 2019*	*Two reports issued for ES and NL*
Overview reports in 2019 in the context of the project on animal welfare during transport	*2 overview reports published*	*Q3 2019*	*Overview reports to be published under the new College*

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

Specific objective 1.3 : Cost effective health promotion and disease prevention			**Related to Health Programme**
Result indicator 1.3.A: The number of Member States having an integrated National Plan to address (major) chronic diseases in place, implementing the WHO non-communicable diseases (NCD) targets. **Source of data:** Member States reporting			
Baseline (based on the Global Capacity Survey in 2015)	**Interim Milestone**	**Target** Baseline information based on mapping exercise of WHO Europe	**Latest known results**
2015	2017	2019	2017
12	19	28	15[127]

Result indicator 1.3.B: Number of EU countries with a national initiative on: 1) the reduction of saturated fat, 2) the reduction of salt, 3) the reduction of sugar 4) reduction of alcohol-related harm. **Source of data:** country questionnaires and High Level Group on Nutrition and Physical Activity			
Baseline 2015	**Interim Milestone** 2017	**Target** 2020 Gradual coverage of all MS as final target	**Latest known results** 2019
1) 21 2) 20 3) 20 4) 21	1) 26 2) 26 3) 26 4) 26	1) 28 2) 28 3) 28 4) 28	1) 23 2) 26 3) 24 4) 26

Result indicator 1.3.C: Number of EU countries in which a European accreditation scheme for breast cancer services is implemented **Source of data:** Member States reporting on implementing the European Commission Initiative on Breast Cancer			
Baseline (2017: guidelines under development until 2017)	**Interim Milestone** 2018	**Target** 2019 (Commission Communication on action against cancer: European partnership)	**Latest known results** 2017
0	18	24	15

[127] Updated WHO figures are expected in 2020. Member States do not necessarily implement NCD strategies using the form of an "NCD plan". Consequently, the indicator reflects only part of the efforts undertaken by Member States.

Outputs table:

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT	
Specific objective 1.3: Cost effective health promotion and disease prevention	Related to 3rd EU Health Programme
Main outputs in 2019:	
Important items from work programmes/financing decisions/operational programmes[128]	

Output description	**Indicator**	**Target**	**Latest known results (situation on 31/12/2019)**
Joint Action on implementation of validated best practices	*Launch*	*Q4 2019*	*Grant agreement to be signed in April 2020 following discussions among and with Member States*
Administrative Agreement with Joint Research Centre	*Signature*	*Q2 2019*	*There are 2 Administrative Agreements signed with the JRC. The latest one (for a behavioural insight on vaccine hesitancy study) was signed in December 2019*
Call for tender to support Member States in reducing alcohol related harm	*Launch*	*Q4 2019*	*Launched – 24/12/2019*
Call for tender Mapping of Fiscal Measures and Pricing Policies Applied to Food, Non-alcoholic and Alcoholic Beverages	*Launched*	*Q3 2019*	*Launched - 30/10/2019*
Direct Grant to be decided	*Launch*	*Q4 2019*	*The direct grant is intended for UNICEF, but has not yet been signed due to delays within CHAFEA*
Colorectal cancer screening guidelines (implemented by JRC)	*Completed*	*Q4 2019*	*Completed*
Breast cancer accreditation scheme (implemented by JRC)	*Completed*	*Q4 2019*	*Completed*
Public procurement guidelines for healthy food in public settings (implemented by JRC)	*Completed*	*Q4 2019*	*Not completed in 2019. The guidelines will be further developed within the Joint Action on Best Practice Implementation, which will be launched in 2020*
Other important outputs			
Manage the Joint Action on tobacco control based on the JRC administrative agreement	*Delivered*	*Q4 2019*	*Delivered (regular on-going activity in 2019)*

[128] For a complete listing of expenditure-related outputs please refer to the Programme Statements published together with the Draft Budget for 2019.

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
Start of the track and trace system to control illicit tobacco trade	*Launch*	*Q2 2019*	*Launched – 20/05/2019*
Launch of the second stage of the compliance checks for the Tobacco Products Directive	*Delivered*	*Q4 2019*	*Launched*
3rd wave of priority setting and best practices selection by the Steering Group	*Completed*	*Q4 2019*	*In June 2019 the SGPP decided to collect best practices to encourage parents to ensure their children receive the 2nd dose of measles vaccine*
Recognition ceremony for institutions contributing to the Best Practices Portal	*Ceremony organised*	*Q2 2019*	*Held on 20 June in Brussels in the frame of the Tartu Call Plus 2 years conference, organized by DGs SANTE, EAC and AGRI*
OECD report on the societal costs of unhealthy diet, physical inactivity and alcohol consumption	*Completed*	*Q2 2019*	*The report has two parts - one on obesity (published on 10 October 2019) and one on alcohol (will be further developed in 2020)*

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

Specific objective 1.4: Effective, accessible and resilient healthcare systems in the EU			Related to spending programme: **Connecting Europe Facility (CEF)**
Result indicator 1.4.A: Number of countries having capacity to the health date exchange and join the Cross-Border eHealth Information Services **Source of data:** Reported number of National Contact Points for eHealth set up, eHealth Network			
Baseline 2015	**Interim Milestone** - set up a NCPeH		**Target** **2020** (The first year after the ending of the CEF financing programme)	**Latest known results**
	2017	2019		2019
4	8	12	18	14

Result indicator 1.4.B: Level of average EU consumption of antibiotics in humans **Source of the data**: European Centre for Disease Prevention and Control (ECDC)			
Baseline 2013	**Interim Milestone** 2017	**Target** 2021	**Latest known results** 2018
21.5[129] Defined daily doses/1000 inhabitants/day consumed in the Community and hospital sectors combined	Overall decline in EU consumption of antibiotics in human achieved with respect to 2013. 2017 value 20.2 defined daily doses/1000 inhabitants/day = 6% decline compared to 2013.	30% reduction in EU consumption of antibiotics in human less than 15.05 Defined daily doses/1000 inhabitants/day consumed in the Community and hospital sectors combined	20.1 defined daily doses/1000 inhabitants/day consumed in the Community and hospital sectors combined

Outputs table:

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT	
Specific objective 1.4: Effective, accessible and resilient healthcare systems in the EU	Related to 3rd EU Health Programme
Main outputs in 2019:	
Important items from work programmes/financing decisions/operational programmes[130]	

Output description	**Indicator**	**Target**	**Latest known results (situation 31/12/2019)**
Finalising the adoption of the revised Commission Implementing Decision on eHealth Network (PLAN/2018/2808)	*Adopted*	*Q2 2019*	*Adopted C(2019)7460 – 22/10/2019*
State of Health in the EU: 28 country health profiles and Commission Companion Report	*Published*	*Q4 2019*	*Published 28 November 2019*

[129] The indicator is based on the most recent report from ECDC on antimicrobial consumption (Nov 2018). https://www.ecdc.europa.eu/sites/default/files/documents/Antimicrobial-consumption-EU-EEA.pdf. In this report the baseline for 2013 has slightly changed (due to the methodology): P.5, table 1: The total for the baseline in 2013 is now therefore 21.5, and consequently the 30% reduction target for 2021 is 15.05. As a result of this change in methodology, the baseline is lower than the baseline indicated in the SANTE Strategic Plan (23.9).

[130] For a complete listing of expenditure-related outputs please refer to the Programme Statements published together with the Draft Budget for 2019.

Output description	Indicator	Target	Latest known results (situation 31/12/2019)
Staff Working Document to finalise the evaluation of the Directives on blood (2002/98/EC) and tissues and cells (2004/23/EC) (PLAN/2016/154)	*Published*	*Q1 2019*	*Adopted SWD(2019)375 – 10/10/2019*
Service Contract EU Networking and support for reference laboratory functions for antimicrobial resistance	*Launch*	*Q4 2019*	*Delay in tender procedure. Launch expected Q2 2020*
Other important outputs			
Delegated act on the requirements and methods for gathering data on antimicrobial resistance (sale and use of antimicrobials) (PLAN/2018/4495)	*Launched*	*Q4 2019*	*Launched*
Delegated act on the criteria for designation of antimicrobials reserved for human use (PLAN/2018/4510)	*Launched*	*Q4 2019*	*Launched*
Implementing act on the complete format for the collection of data on antimicrobials (PLAN/2018/3984)	*Launched*	*Q4 2019*	*Launched*
Implementing act on the list of antimicrobials reserved for human use (PLAN/2018/3966)	*Launched*	*Q4 2019*	*Launched*
Overview report on a series of audits to assess the effectiveness of the implementation of EU legislation on AMR monitoring in food-producing animal populations and food in Member States	*Completion*	*Q2 2019*	*Final overview report published on 19/07/2019*
Overview report concerning Member States' implementation of EU guidelines for the prudent use of antimicrobials in veterinary medicine	*Completion*	*Q2 2019*	*Final overview report published on 19/07/2019*
AMR One Health country visits (with the ECDC)	*4 visits completed*	*Q4 2019*	*There were 3 visits requested and completed in 2019: to Estonia, Ireland and Portugal.*
Ministerial Conference on AMR under Romanian Presidency	*Meeting organised*	*Q2 2019*	*Organised on 1 March 2019 in Bucharest*
Launch of a call for projects to contribute to implementation of the EU Action Plan on AMR by implementing the EU guidelines on prudent use of antimicrobials in human health	*Call launched*	*Q3 2019*	*Call launched Q3 2019.*
Conformity checks for the Cross-border Healthcare Directive (final stage): country analyses, bilateral structural dialogues on major issues,	*Delivered*	*Q4 2019*	*Final conformity checks completed for 20 Member States in 2019. Member State conformity checks*

Output description	Indicator	Target	Latest known results (situation 31/12/2019)
infringement cases			*are an ongoing process and closure depends on changes in national legislation to comply with the Directive*
Management of Cross-Border Healthcare Expert Group and sub-group National Contact Points	*Delivered*	*2019*	*2 meetings organised in May and October 2019*
Opinions of the Expert Panel on effective ways of investing in Health (EXPH)	*Published*	*3 reports*	*4 reports published*
Report of the Expert Group on Health Systems Performance Assessment published		*Q 1 2019*	*Report on Tools and methodologies to assess the efficiency of health care services - February 2019*
Provision of administrative support, documentation, testing and auditing services, legal and data protection advice and funding for the cross-border exchange of ePrescriptions and patient summaries	*Delivered*	*Q4 2019*	*Monthly eHealth Operational Management Board meetings. Audits and tests in the context of eHealth Digital Service Infrastructure the cross-border exchange of ePrescriptions and patient summaries. The Commission Implementing Decision 2019/1765 adopted on 22 October 2019*
Two meetings of the eHealth Network and four meetings of the eHealth Member State Expert Group	*Meetings organised*	*Q4 2019*	*EHealth Network meetings held on 11-12 June and 28-29 November 2019. eHealth Member State Expert Group meetings held 11 March, 16-17 May, 16-17 October*
eHealth audits of National Contact Points	*Approx. 12 audits completed*	*Q4 2019*	*8 audits organised (no additional request received)*
Feasibility study of an active substance based review system ('monographs') and other potential alternatives for the environmental risk assessment of veterinary medicinal products	*Launched*	*Q4 2019*	*We have started the procedure, not awarded yet*

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

Specific objective 1.5: Increased access to medical expertise and information for specific conditions			Related to **Health Programme; CEF financing programme**	
Result indicator 1.5.A: Number of established European Reference Networks **Source of data:** Information system on ERN, minutes of the Board of Member States on ERN meetings, licences of the ERN trademark licensed				
Baseline (2015)	**Interim Milestone**: 2016	**Interim Milestone**: 2018	**Target** 2020 (forecast as the establishment of ERNs dependent on the no. of proposals received to the Call for ERN and the no. of approvals decided by the competent body (ERN Board of MS)	**Latest known results** 2019
0	**10**	**20**	**30**	**24**

Result indicator 1.5B: Number of data requests from the database **Source of data:** Orphanet database			
Baseline 2015	**Interim Milestone** 2018	**Target** 2020	**Latest known results** 2019
1)On average around 90,000 pages viewed per day 2) 4,726 diseases annotated with prevalence or incidence data	1) Maintain number of the website requests 2) To increase number of annotated diseases	1) To increase number of website requests 2) To increase number of annotated diseases[131]	1) On average around 46,400 pages viewed per day[132] 2) 5,158 diseases annotated with prevalence or incidence data

Result indicator 1.5C: Number of stakeholders included in the European Platform on Rare Diseases Registration and the size of the EU population covered by surveillance networks **Source of data:** The European Platform on Rare Diseases Registration			
Baseline 2015	**Interim Milestone** 2018	**Target** 2020	**Latest known results** 2019
Number of stakeholders included in the Platform: 39; EU birth population covered: 30% (approx. 1.5 million)	Keep and consolidate the existing parameters	Extend inclusion to all interested parties	Number of stakeholders included in the Platform: 91; EU birth population covered: 25% (EUROCAT) and 10% (SCPE) of the EU birth population

[131] The wording of the target has been changed to assure comparability with the baseline and the milestone.

[132] In 2017 Orphanet changed the structure of the website and initial decrease in pages viewed following that change means that users had a more direct access to the information they needed. The number of sessions was stable from 2016 to 2017.

Outputs table:

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT	
Specific objective 1.5: Increased access to medical expertise and information for specific conditions	Related to 3rd EU Health Programme
Main outputs in 2019:	
Important items from work programmes/financing decisions/operational programmes[133]	

Output description	**Indicator**	**Target**	**Latest known results (situation on 31/12/2019)**
Rare diseases registries for European Reference Networks	*Call launched*	*Q2 2019*	*Call was launched on 21 May 2019 and closed on 10 October 2019*
Other important outputs			
Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
Three meetings each of the Board of Member States and Coordinators Group	*Meetings organised*	*Q4 2019*	*Meetings of the Board of Member States organised on 26 March, 25 June and 15 November 2019.* *Meetings of the Coordinators Group organised on 25 March, 24 June and 14 November 2019*
Finalise the amendment of Commission Implementing Directive on European Reference Networks (2014) (PLAN/2018/2544)	*Finalised*	*Q1 2019*	*Adopted C(2019)5470 – 26/07/2019*

[133] For a complete listing of expenditure-related outputs please refer to the Programme Statements published together with the Draft Budget for 2019.

Specific objective 1.6: Effective, efficient and reliable controls

Specific objective 1.6: Effective, efficient and reliable official controls		Related to **Food and feed expenditure Regulation (EU) No. 652/2014**
Result indicator 1.6.A: Percentage of DG SANTE's recommendations following its audits that Member States (MS) have satisfactorily addressed with corrective action. **Source of data:** Commission internal (DG SANTE)		
Baseline (2014)	**Target** (2019) (agreed on the basis of available data to DG SANTE)	**Latest known results**
60% for recommendations from reporting cycles 2011 - 2013	70% for recommendations from reporting cycles 2015-2017	70% for recommendations from reporting cycle 2015-2017

Outputs table:

Relevant general objective 1: A NEW BOOST FOR JOBS, GROWTH AND INVESTMENT			
Specific objective 1.6: Effective, efficient and reliable official controls			Related to spending programme CFF for the Food Chain 2014-2020
Main outputs in 2019:			
Important items from work programmes/financing decisions/operational programmes[134]			
Output description	**Indicator**	**Target**	**Latest known results (situation 31/12/2019)**
Better Training for Safer Food	*No. of trainings organised*	*170*	*189*
Computerised systems + IT (e.g. TRACES, ADIS, ADNS, EUROPHYT)	*No. of active end-users*	*40,000*	*44,500*
European Reference Laboratories	*Number of laboratories funded*	*44*	*44*
European Reference Centres	*Number of centres funded*	*2*	*2*
Other important outputs			
Launch of the BTSF Academy	*Launched*	*Q4 2019*	*Testing phase open in November 2019*
Commission Implementing Regulation on a standard model form for Member States annual report on the operation of their multi-annual national control plans (PLAN/2017/1182)	*Adoption*	*Q1 2019*	*Adopted C(2019)3190 – 02/05/2019*

[134] For a complete listing of expenditure-related outputs please refer to the Programme Statements published together with the Draft Budget for 2019.

Output description	Indicator	Target	Latest known results (situation 31/12/2019)
Delegated act on additional categories subject to border controls (composite products, Hay and Straw) (PLAN/2017/1682)	*Adoption*	*Q2 2019*	*Adopted C(2019)26 – 14/01/2019*
Delegated act on animals and goods exempt from official controls at border control posts (PLAN/2018/2666)	*Adoption*	*Q2 2019*	*Adopted C(2019)7006 – 10/10/2019*
Delegated act on border Control Staff Training (ISC/2018/05883)	*Adoption*	*Q1 2019*	*Adopted C(2019)1786 – 08/03/2019*
Delegated act on CHED as an accompanying document (PLAN/2018/3725)	*Adoption*	*Q2 2019*	*Adopted C(2019)2910 – 23/04/2019*
Delegated act on border control posts: rules on transhipment, transit and onward transportation of animals and goods (PLAN/2018/2661)	*Adoption*	*Q2 2019*	*Adopted C(2019)7003 – 10/10/2019*
Delegated act on documentary checks during transhipment, transit of plants, plant products and other products (PLAN/2018/2662)	*Adoption*	*Q2 2019*	*Cancelled; the matter is covered by PLAN/2018/2661 (measure adopted)*
Delegated act on rules on official controls that may be performed at places other than the border control post of first arrival (PLAN/2018/2664)	*Adoption*	*Q2 2019*	*Adopted C(2019)7004 – 10/10/2019*
Delegated act on derogations from certain border control post requirements (PLAN/2017/1681)	*Adoption*	*Q2 2019*	*Adopted C(2019)1847 – 12/03/2019*
Delegated act on rules on the performance of specific official controls and on measures for cases of non-compliance given the specificities of certain categories of animals and goods coming from third countries (PLAN/2018/2667)	*Adoption*	*Q2 2019*	*Adopted C(2019)4500 – 24/06/2019*
Implementing act on border controls - Lists of animals and good with Common Nomenclature (PLAN/2017/1611)	*Adoption*	*Q2 2019*	*Adopted C(2019)8098 – 18/11/2019*

Output description	Indicator	Target	Latest known results (situation 31/12/2019)
Implementing act on operations to be carried out during and after the documentary, identity and physical checks at the Border Control Posts (PLAN/2018/2669)	*Adoption*	*Q2 2019*	*Adopted C(2019)7002 – 25/11/2019*
Implementing act on frequency of identity and physical checks at Border Control Posts (PLAN/2018/2663)	*Adoption*	*Q2 2019*	*Adopted C(2019)7001 – 25/11/2019*
Implementing act on prior notification of certain consignments of animals and goods entering the Union through a Border Control Post (PLAN/2018/2658)	*Adoption*	*Q2 2019*	*Adopted C(2019)2775 – 16/04/2019*
Implementing act on border control post listing (PLAN/2018/2659)	*Adoption*	*Q2 2019*	*Adopted C(2019)4199 - 12/06/2019*
Implementing act on border control post facilities (PLAN/2018/2660)	*Adoption*	*Q2 2019*	*Adopted C(2019)4199 – 12/06/2019*
Implementing act on intensified controls (PLAN/2017/1695)	*Launched*	*Q4 2019*	*Adopted C(2019)7906 – 07/11/2019*
Implementing act on certification for ship suppliers and rules on channelling and transit / follow up of consignments accompanying documents (PLAN/2018/3167)	*Adoption*	*Q2 2019*	*Adopted C(2019)7000 – 12/11/2019*
Implementing Act on the designation of the European Union reference laboratories for pests of plants (PLAN/2018/2674)	*Adoption*	*Q1 2019*	*Adopted C(2019)2268 - 27/03/2019*
Delegated Regulation establishing specific rules for official controls on meat & live bivalve mollusc production and relaying area (PLAN/2017/1547)	*Adoption*	*Q2 2019*	*Adopted C(2019)10 – 08/02/2019*
Implementing Regulation on practical arrangements for official controls of food of animal origin	*Adoption*	*Q2 2019*	*Adopted C(2019)13 – 15/03/2019*

Output description	Indicator	Target	Latest known results (situation 31/12/2019)
(PLAN/2017/1786)			
Delegated Regulation laying down import conditions for food (PLAN/2017/1684)	*Adoption*	*Q2 2019*	*Adopted C(2019)11 – 04/03/2019*
Implementing Regulation listing third countries for import of products of animal origin (PLAN/2017/1930)	*Adoption*	*Q2 2019*	*Adopted C(2019)3799 – 05/03/2019*
Implementing Regulation on health certificates for products exported to the EU (PLAN/2017/1926)	*Adoption*	*Q2 2019*	*Adopted C(2019)12 – 08/04/2019*
Other DG SANTE activities to improve the performance of control systems:			
Audits in the area of food safety and quality, animal health, animal welfare and plant health	*Approx. 165 audits completed*	*Q4 2019*	*159 audits completed*
Joint assessments of Notified Bodies in the sector of medical devices	*Approx. 40 assessments completed*	*Q4 2019*	*34 joint assessments (no additional requests were received)*
Good Manufacturing Practices (GMP) for medicinal products for human use from non-EU countries	*Up to 4 audits completed*	*Q4 2019*	*2 audits completed*
Organisation of regular meetings of networks of Member State officials responsible for the multi-annual national control plans and national audits to facilitate exchanges of experiences and the preparation of guidance	*Number of meetings held*	*4 plenary meetings; 4 subgroup meetings*	*All planned meetings took place 3 plenary meetings and one subgroup meeting of the MANCP Network; 2 plenary meetings and 1 subgroup meeting of the NAS Network*
Organisation of meetings with Member State experts in a number of areas such as animal welfare or the sustainable use of pesticides to discuss common problems and exchange best practices identified	*Number of meetings held*	*As per published SANTE audit and analysis work programme 2018*	*Animal welfare, 4 meetings (1 plenary meeting, 3 working meetings with some Member States). 2 working groups on the Sustainable Use of Pesticides Directive (SUD) in May 2019 and November 2019. 1 workshop on Integrated Pest Management in May 2019. 1 working group on Enforcement and Formulation (marketing and use of pesticides) in January 2019.*

Output description	Indicator	Target	Latest known results (situation 31/12/2019)
			1 BTSF Workshop on Biocide (Overview report) in June 2019
Evaluation of facilities of Border Inspection Posts (BIPs)	*Number of evaluations carried out*	*Ca. 15. Due to Brexit, more BIPs may require approval (expanded facilities or new facilities).*	*48 evaluations carried out, out of 52 received applications (plus 2 from 2018).*
Evaluation of Member States' and non-EU countries' residue monitoring plans	*Number of evaluation carried out*	*27 Member States plans; up to 50 non-EU country plans*	*28 Member State plans reviewed.* *44 non-EU country plans reviewed*
Management of lists of approved non-EU country establishments for the production of food of animal origin	*Number of request managed*	*Approx. 500 requests (subject to Brexit)*	*500 requests were processed or in train out of 533 received. 33 requests did not proceed (incomplete, incorrect or not required).*
Operation and further development of the notification system EUROPHYT for plant health interceptions, outbreaks and reporting on plant pests	*Publication on Europhyt monthly and annual statistics and reports*	*In course of 2019*	*Published monthly.* *The Annual Report was published on 6/8/2019*
Plant health surveys	*Number of Member States' survey results to for harmful organisms presented to Standing Committee on PAFF*	*13*	*6, in agreement with priorities set by the Standing Committee on PAFF*
Biannual reviews of temporary harmonised import controls on certain food and feed of non-animal origin	*Completed*	*Q3 2019*	*2 reviews adopted (C/2018/8825 – 08/01/2019; C/2019/5400 – 22/07/2019)*

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

General objective 2: A Deeper and Fairer Internal Market with a strengthened industrial base		
Impact indicator 2.1: Gross value added of EU industry in GDP **Source of the data**: Eurostat		
Baseline (2014)	**Latest known value** (2018)	**Target** (2020)
17.0%	17.1%	20%
Bookmark		
Impact indicator 2.2: Intra-EU trade in goods (% of GDP) **Source of the data**: Eurostat		
Baseline (2014)	**Latest known value** (2018)	**Target** (2020)
20.3% [Baseline adjusted: before: 20.4%]	21.7%	Increase
Bookmark		

SANTE specific data[135]

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

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
EU28	4.63	4.64	4.60	4.63	4.62	4.63	4.60	4.61	4.55	Data not available[136]

Source: Eurostat

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

PERIOD	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
	1.60	1.66	1.75	1.81	1.89	1.85	1.84	1.88	1.95	1.91

Source: Eurostat

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

	Jan.-Dec. 2014	Jan.-Dec. 2015	Jan.-Dec. 2016	Jan.-Dec. 2017	Jan.-Dec. 2018
IMPORT	90,755,707,991	99,907,350,137	100,917,743,408	103,539,834,812	104,100,296,906
growth (%)	5.5	10.1	1.0	2.6	0.5
EXPORT	78,826,378,995	81,977,772,208	83,960,187,803	87,550,127,578	86,921,377,820
growth (%)	4.5	4.0	2.4	4.3	-0.7

Source: Eurostat

[135] The data may differ slightly from the data included in the SANTE Strategic Plan 2016-2020 and subsequent Annual Activity Reports as Eurostat constantly revises data to improve its quality (correcting erroneous data, improving the completeness of the data by limiting data omissions and replacing estimates by collected data).

136 Data not available at time of submission

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

	Jan.-Dec. 2014	Jan.-Dec. 2015	Jan.-Dec. 2016	Jan.-Dec. 2017	Jan.-Dec. 2018
IMPORT	258,702,207,090	271,648,759,242	280,100,883,959	298,868,584,679	302,691,406,428
growth (%)	1.8	5.0	3.1	6.7	1.3
EXPORT	263,751,108,472	275,249,609,877	283,423,643,951	300,711,892,796	304,349,394,672
growth (%)	1.8	4.4	3.0	6.1	1.2

Source: Eurostat

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

Specific objective 2.1: Effective EU assessment of medical products and other treatment			Related to **Health Programme**
Result indicator 2.1: Number of health technology assessment reports produced by Joint Action EUnetHTA and of their national adaptations **Source of data:** EUnetHTA Joint Action			
Baseline	**Interim Milestone**		**Target**	**Latest known results**
2012	2016	2018	2019	2019
2	12	22	29	29

Outputs table:

Relevant general objective 2: A DEEPER AND FAIRER INTERNAL MARKET WITH A STRENGTHENED INDUSTRIAL BASE			
Specific objective 2.1: Effective EU assessment of medicinal products and other treatment			Related to 3rd EU Health Programme
Main outputs in 2019:			
Delivery on legislative proposals pending with the legislator			
Output description	**Indicator**	**Target**	**Latest known results (situation on 31/12/2019)**
Negotiation with Council and Parliament on Proposal for a Regulation on Health Technology Assessment (HTA) (2016/SANTE/144)	*Political agreement*	*Q4 2019*	*Negotiation still ongoing*

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

Specific objective 2.2: Stable legal environment and optimal use of current authorisation procedures for a competitive pharmaceutical sector and patients' access to safe medicines		Related to spending programme(s) **No**
Result indicator 2.2: New medicines authorised within the legal deadlines, particularly innovative medicines of major interest for public health **Source of data:** Commission services' database on product specific authorisation		
Baseline 2014	**Target** 2017	**Latest known results** 2019
85% all Commission decisions for marketing authorisations (MA) of new centrally authorised medicinal products for human use adopted 100% Commission decisions adopted in 2014 for new centrally authorised MA for medicines for human use that had an accelerated review by European Medicines Agency (EMA)	90% All new centrally authorised MA decisions 100% new MA Commission decisions for which there was an accelerated assessment by EMA	98,4 % All new centrally authorised MA decisions 100 % new MA Commission decisions for which there was an accelerated assessment by EMA[137]

Outputs table:

Relevant general objective 2: A DEEPER AND FAIRER INTERNAL MARKET WITH A STRENGTHENED INDUSTRIAL BASE			
Specific objective 2.2: Stable legal environment and optimal use of current authorisation procedures for a competitive pharmaceutical sector and patients' access to safe medicines			Related to 3rd EU Health Programme
Main outputs in 2019:			
Important items from work programmes/financing decisions/operational programmes[138]			
Output description	**Indicator**	**Target**	**Latest known results (situation on 31/12/2019)**
Evaluation of the Regulations on orphan medicines (141/2000) and paediatric medicines (1901/2006) (including study, stakeholder outreach, and Staff Working Document) (PLAN/2017/2099)	*Completed*	*Q3 2019*	*Delayed to Q3 2020 due to the delay in the study on the Orphan Regulation which was completed October 2019*
Impact Assessment for the EMA Fees legislation (PLAN/2018/4193)	*Completed*	*Q4 2019*	*Adoption date Q3 2020 following delays with the evaluation study and the*

[137] This decrease in the Commission decisions adopted relates to procedural steps that are not under the control of the Commission. DG SANTE will continue to work with EMA to meet the 90% and 100% targets originally scheduled for 2017.

[138] For a complete listing of expenditure-related outputs please refer to the Programme Statements published together with the Draft Budget for 2019.

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
			finalisation of additional data analysis
Report on the experience acquired as a result of the procedures for authorisation and monitoring of medicinal products for human use	*Completed*	*Q2 2019*	*Delayed until Q4 2020. The consultant report is delayed and will be finalised by Q1 2020. The Commission report will be prepared by the end of 2020*
Report on the experience of the use of the list of human medicinal products subject to additional monitoring	*Completed*	*Q1 2019*	*Adopted COM(2019) 591 - 15/11/2019*
Other important outputs			
Guidelines on Good Clinical Practice Specific to Advanced Therapy Medicinal Products (PLAN/2018/3056)	*In Progress*	*Q3 2019*	*Adopted C(2019)7140 – 10/10/2019*
Authorisation of new medicinal products, variations to existing marketing authorisations, including Brexit related modifications, decisions following referral procedures, Periodic Safety Update Reports, orphan designations etc.	*Adoption of more than 1000 decisions*	*In course of 2019*	*1662 decisions*
Veterinary Medicines			
Delegated act on restructuring Annex II to the basic act (technical documentation necessary for an application for a marketing authorisation) (PLAN/2018/4493)	*Launched*	*Q4 2019*	*Launched*
Implementing act on the list of variations without assessment(PLAN/2018/3968)	*Launched*	*Q4 2019*	*Launched*
Implementing act on the veterinary medicinal product database (PLAN/2018/3969)	*Launched*	*Q4 2019*	*Launched*
Delegated act on the detailed rules on exports from third countries (PLAN/2018/4503)	*Launched*	*Q4 2019*	*Launched*
Implementing act on the good distribution practice for veterinary medicinal products (PLAN/2018/3983)	*Launched*	*Q4 2019*	*Launched*

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
Implementing act on the good distribution practice for active substances (PLAN/2018/3965)	*Launched*	*Q4 2019*	*Launched*
Implementing act on the good pharmacovigilance practice (PLAN/2018/3967)	*Launched*	*Q4 2019*	*Launched*
Implementing act on the content of the pharmacovigilance system master file (PLAN/2018/3982)	*Launched*	*Q4 2019*	*Launched*
Implementing act on the common logo for online sales (PLAN/2018/3981)	*Launched*	*Q4 2019*	*Launched*

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

Specific objective 2.3: Common Member States' tools and methodologies used for EU health systems performance assessments		Related to **Health programme**	
Result indicator 2.3A: Number of Member States that refer in national policy documents to the recommendations and findings of the expert group on HSPA **Source of data:** Commission analysis			
Baseline 2015	**Interim Milestone** 2017	**Target** 2020 The target was decided by the Semester Core DGs	**Latest known results** 2019
0	5	15	0

Outputs table:

Relevant general objective 2: A DEEPER AND FAIRER INTERNAL MARKET WITH A STRENGTHENED INDUSTRIAL BASE			
Specific objective 2.3: Common Member States' tools and methodologies used for EU health systems performance assessments		Related to 3rd EU Health Programme	
Main outputs in 2019:			
Important items from work programmes/financing decisions/operational programmes[139]			
Output description	**Indicator**	**Target**	**Latest known results (situation on 31/12/2019)**
Report on measurement of efficiency of health systems	*Completed*	*Q1 2019*	*Published in Feb 2019*
Launch and progress on the report on measurement of resilience of health systems	*Draft report completed*	*Q4 2019*	*Draft report done. Final report to be published Q1 2020*
Initial work on new report to be developed in 2020	*Background paper completed*	*Q4 2019*	*Work initiated at meeting in Dec 2019*
Carry out tailored seminars and workshops in Member States on the national health performance assessment systems.	*Meetings organised*	*In course of 2019*	*Done, combined with technical assistance support from SRSS*

[139] For a complete listing of expenditure-related outputs please refer to the Programme Statements published together with the Draft Budget for 2019.

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

General objective 3: **A balanced and progressive trade policy to harness globalisation**			
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 **Source of the data**: Eurostat for the raw indicators (1,2,3) and DG Trade for the list of countries covered by trade and investments agreements (4)			
Baseline Goods average for 2014-2016, Services and FDI average for 2013-2015	**Latest known value** Goods, services and FDI average for 2015-2017 FTA status: 2019	**Milestone**** (2018)	**Target**** (2020)
Goods: Imports 27% Exports 32% Total 29% Services: Imports 10% Exports 9% Total 9% FDI stocks: Imports 4% Exports 7% Total 6%	Goods: Imports 34% Exports 39% Total 37% Services: Imports 18% Exports 20% Total 19% FDI stocks: Imports 15% Exports 16% Total 16%	Goods: Imports 32% Exports 37% Total 34% Services: Imports 15% Exports 15% Total 15% FDI stocks: Imports 9% Exports 13% Total 11%	Goods: Imports 51% Exports 61% Total 56% Services: Imports 54% Exports 52% Total 53% FDI stocks: Imports 55% Exports 59% Total 57%
Goods Bookmark to the denominator			
Services bookmark to the denominator			
FDI stocks bookmark to the denominator			
(4) DG Trade trade and investments agreements (see agreements under "In place" and "Agreements partly in place") * The milestone and target figures are based on expectations of provisional application/entry into force of agreements that are currently under negotiation (see also result indicator 1.1 : "Number of on-going EU trade and investment negotiations and number of applied EU trade and investment agreements" of DG TRADE's Strategic Plan 2016-2020).			

SANTE specific data

Table 5 Share (%) of EU-extra trade in food and live animals in total of EU extra trade (EU28)

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
SHARE	4.8	4.4	4.5	4.5	4.7	5.0	5.2	5.4	5.1	4.9

Source: Eurostat

Table 6 Share (%) of EU-extra trade in medicinal and pharmaceutical products in total EU-extra trade

	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
SHARE	5.3	4.9	4.8	4.9	5.0	5.3	6.1	6.3	6.3	6.3

Source: Eurostat, International trade in medicinal and pharmaceutical products: tables and figures

Specific objective 3.1: Increased EU influence in international fora

Specific objective 3.1: Increased EU influence in international fora			Related to spending programme(s) **No**
Result indicator 3.1.A: Percentage of the total number of WHO Governing Body Resolutions adopted annually which contain coordinated EU inputs. **Source of data:** Reports of WHO governing body meetings			
Baseline **2014**	**Interim Milestone** **2018**	**Target** **2021** (internal decision based on the year coinciding with the end of the posting of the next SANTE official to the UN in Geneva)	**Latest known results** **2019**
WHO Executive Board: 85% resolutions negotiated	90%	95%	90 %
World Health Assembly: 60% resolutions negotiated	75%	90%	80%
WHO Regional Committee for Europe: 50% resolutions negotiated	70%	90%	70 %

Result indicator 3.1.B: Number of countries which recognise International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidelines **Source of data:** ICH			
Baseline 2015	**Interim Milestone** 2018	**Target** 2020	**Latest known results** **2019**
<u>Expansion of ICH membership</u> The founding regulatory and industry members and standing regulatory members of ICH are from the US, EC, Japan, Canada and Switzerland. With the establishment of the association, new regulators and industry association have the opportunity to apply. **Number of new members: 0**	5 new ICH members	10 new ICH members	8
<u>Implementation of ICH guidelines by new regulatory members</u> ICH members will have to gradually implement the corpus of ICH guidelines and associated harmonisation documents. **There are approximately 60 ICH guidelines (100%)**	On average 70 % of all ICH guidelines are implemented by new ICH members	On average 85 % of all ICH guidelines are implemented by new ICH members	*On average 61 % of all ICH guidelines are implemented by new ICH members.*
<u>Increased harmonisation through Guideline development.</u> Adoption of ICH Harmonisation documents (new or revision of existing ICH guidelines, questions and answers and others such as implementation guides). These ICH harmonisation documents are implemented by the ICH founding and standing regulatory members (EC, US, Japan, Canada, Switzerland) and are expected to be implemented by the new regulatory members. **Number of ICH harmonisation documents adopted in 2015: 4**[140]	15 new or revised ICH guidelines	25 new or revised ICH guidelines	*2 new ICH guidelines, 2 revisions and 1 revised Q&A*

[140] There was a mistake in the baseline for 2015 in the SANTE's Strategic Plan 2016-2020. Instead of 3 ICH harmonisation documents, there were 4 (3 Q&A and 1 guideline)

Result indicator 3.1.C: WTO cases[141] brought against the EU **Source of data:** WTO			
Baseline (2014)	**Interim Milestone** 2017	**Target** 2020 A diminishing number of cases brought against the EU by other WTO Members is in line with our policy to align EU legislation to international standards.	**Latest known results** 2019
8	7	5	14

Outputs table:

Relevant general objective 3: A balanced and progressive trade to harness globalisation			
Specific objective 3.1: Increased EU influence in international fora			Related to spending programme(s): NO
Main outputs in 2019:			
Important items from work programmes/financing decisions/operational programmes[142]			
Output description	**Indicator**	**Target**	**Latest known results (situation 31/12/2019)**
Present EU positions (ensuring alignment with EU legislation and policy on pharmaceuticals) in International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) meetings, particularly as regards ICH guidelines (with the scientific support of the European Medicines Agency), defend and advance EU interests and the EU regulatory model for pharmaceuticals.	*Delivered*	*In course of 2019*	*Delivered at least 20 positions*
Present EU positions in IPRP meetings (International Pharmaceutical Regulators Programme); promote the EU regulatory system for pharmaceuticals	*Delivered*	*In course of 2019*	*Delivered at least 5 positions*
World Health Organisation (WHO) Senior Official meeting	*Meeting organised*	*Q3 2019*	*12 July 2019*
Internal assessment of cooperation to implement Vilnius Declaration	*Prepared*	*Q3 2019*	*July 2019*

[141] For the purpose of this report, the term 'cases' needs to be understood as the number of 'Specific Trade Concerns' raised by WTO Members against the EU in the plenary of the SPS Committee meetings.

[142] For a complete listing of expenditure-related outputs please refer to the Programme Statements published together with the Draft Budget for 2019.

Output description	Indicator	Target	Latest known results (situation 31/12/2019)
Other important outputs			
Coordinated EU positions on WHO resolutions	*Delivered*	*20*	*35*
EU co-sponsored WHO resolution	*Delivered*	*1*	*6*
EU statements for WHO meetings	*Delivered*	*9*	*30*
Coordination of positions in UN meetings	*Delivered*	*2*	*1*
Coordinated EU positions in OECD meetings	*Delivered*	*In course of 2019*	*0*
Common positions coordinated with EU Member States to promote the alignment of existing and planned EU legislation and initiatives with Codex standards	*Delivered*	*In course of 2019*	*132*
Coordinated EU position for the OIE aquatic and terrestrial Code and Manual	*Delivered*	*In course of 2019*	*23*
Coordinated EU Statements for the World Organisation for Animal Health (OIE) General Assembly	*Delivered*	*In course of 2019*	*16 statements*
Coordinated EU positions in documents and guidelines of the International Union for the Protection of New Varieties of Plants (UPOV)	*Delivered*	*In course of 2019*	*58 positions*
Coordinated EU positions in the resolutions of the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)	*Delivered*	*In course of 2019*	*20 positions*
Coordinated EU positions in the World Trade Organisation SPS	*Delivered*	*In course of 2019*	*42*
Bilateral trade negotiations (SPS Chapter)	*Negotiate comprehensive SPS Chapter that includes all the necessary tools to ensure safe and secure trade and facilitate the access of EU products to non-EU markets.*	*Balanced SPS Chapter within the ongoing FTA agreements*	*Indonesia* *Australia* *New Zealand* *Mercosur* *ESA (Madagascar, Zimbabwe, Mauritius, Comoros, Seychelles)*

Output description	Indicator	Target	Latest known results (situation 31/12/2019)
Negotiate with non-EU countries harmonised export conditions that ensure the cohesion of the EU as regards exports (EU single entity) by ensuring that the same conditions are applied to all the EU territory having the same sanitary or phytosanitary level	*Negotiate harmonised export certificates for EU products*	*In course of 2019*	*48 [Australia (1), Chile (2), New Zealand (30) Moldova (13) Ukraine (2)]*
Coordinate EU position in negotiations of Agreements with non-EU countries	*Delivered*	*In course of 2019*	*Delivered*
Coordinate EU position on the management of the SPS Committees of the Agreements in force	*Delivered*	*In course of 2019*	*Delivered*
Coordinated EU statements and position, as well as negotiations, for the Conference of the Parties of the Cartagena Protocol on Biosafety and Coordinated EU position regarding synthetic biology and gene drives for the Conference of the Parties of the Convention on Biological Diversity	*Delivered*	*In course of 2019*	*Delivered*
Contribution to intersessional activities under the Convention on Biological Diversity (CBD) and the Cartagena Protocol on Biosafety – participation in on-line forum and Ad hoc technical expert groups on synthetic biology and gene drives and on risk assessment of living modified organisms	*Delivered*	*In course of 2019*	*Delivered*
Contribution to the CBD's Fourth National Report on the implementation of the Cartagena Protocol on Biosafety	*Delivered*	*In course of 2019*	*Delivered*

Specific objective 3.2: A balanced agreement with the US on pharmaceutical products and in SPS area

Specific objective 3.2: A balanced agreement with the US on pharmaceutical products and in SPS area	Related to spending programme(s) **No**

Result indicator 3.2.A: Number of Member States which are authorised for export of beef, sheep/goat meat, Grade A (pasteurised) Dairy Products and Egg Products to the US
Source of data: Market access database of DG TRADE

	Baseline	**Interim Milestone**	**Target**	**Latest known results**
	2015	2017	2020	2019
Beef	2	4	8	4
Sheep/Goat meat	1	1	3	1
Grade A Dairy Products	0	0	3	0
Apples and Pears	0	0	8 (current number of applications)	0
Egg Products	1	1	3	1

Result indicator 3.2.B: Number of barriers not in line with international standards, linked to Sanitary and Phytosanitary (SPS) measures
Source of data: Market access database of DG TRADE

Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	2017	2020	2019
4	3	1	9

Outputs table:

Relevant general objective 3: A balanced and progressive trade to harness globalisation	
Specific objective 3.2: A balanced agreement with the US on pharmaceutical products and in SPS area	Related to 3rd EU Health Programme
Main outputs in 2019:	
Important items from work programmes/financing decisions/operational programmes[143]	

Output description	**Indicator**	**Target**	**Latest known results (situation on 31/12/2019)**
EU-US mutual recognition agreement on good manufacturing practices on pharmaceuticals	*For human medicines: 8 authorities to be recognised by the US Food and Drug Administration* *For veterinary medicines: conduct of audits in the veterinary agencies: around 6 audits in 2019 (12 in 2018-2019)*	*Q4 2019*	*For the human side, US recognised the 8 remaining authorities. This completes US recognition of all 28 EU authorities.* *For the veterinary side, 6 audits of veterinary-only authorities have been conducted in 2019.* *For the human side, US recognised the 8 remaining authorities*
Food Safety Systems Recognition exercise: Reduction in burden on EU Food Business	*US to have completed assessment of seven pilot Member States with consequent*	*Q4 2019*	*Assessments completed for both EU and US*

[143] For a complete listing of expenditure-related outputs please refer to the Programme Statements published together with the Draft Budget for 2019.

Output description	Indicator	Target	Latest known results (situation on 31/12/2019)
Operators and Competent Authorities	*decision taken on the need or otherwise for further assessments. EU to have completed assessment of the US food safety system*		
Organise meetings of the EU-US Animal Health Technical Working Group and Plant Health Technical Working Group: Facilitate trade and better cooperation on animal and plant health issues with the US	*Meetings held*	*Q4 2019*	*Meeting held on 24-25 June 2019 in Washington DC*
Shellfish equivalence: Implementing Decisions allowing trade of bivalve molluscs between EU and US (PLAN/2017/1799 and PLAN/2018/3849)	*Publication of the Implementing Decisions*	*Q1 2019*	*PLAN/2017/1799: adopted C(2018)7207 – 06/11/2018 PLAN/2018/3849: new foreseen adoption date to be decided once progress is made on US side*