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European Commission

2018

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[1], 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, 29 March 2019

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

"In DG SANTE's 2018 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 annexes is, to the best of my knowledge, accurate and complete."

(e-signed)

Martin Seychell

Brussels, 29 March 2019

[1] C(2017)2373 of 19.04.2017.

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

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:** 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** 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.
Indicator 2: Percentage of staff who feel that the Commission cares about their well-being[2] **Source of data: Commission staff survey**			
Baseline: 42% in 2014 Staff survey	**Target**: gradual increase every year reaching above 50% by 2019	**Results 2017** The indicator dropped to 35% in the 2016 Staff Survey, the same figure as for the Commission overall. Factors contributing to this include the changes to DG's responsibilities at the beginning of this College, and the significant reorganisation in February 2016 in which around half of the middle managers changed responsibilities. **No Staff survey was organised in 2017. The next will be carried out in 2018.**	**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.
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**: keep DG SANTE within top 30% of best performing Commission services	**Results 2017** 65% in 2016 Staff Survey which is place 29 out of 54 DGs and services. This indicator declined slightly in 2016 Staff Survey, but is still above the Commission average. Factors contributing to this include the changes listed above and the cumulative impact on staff of year-to year reductions in resources, when at the same time the demands to implement the DG's legal obligations are increasing. **No Staff survey took place in 2017.**	**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.

[2] This indicator may be replaced by a fit@work index on which DG HR is currently working.

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**	**Main outputs**	
Towards Excellent SANTE: Training SANTE Managers on health at work	Training SANTE Managers on health at work Participation rate of SANTE managers in one or more initiatives organised in collaboration with the medical service	80% of managers participating to one or more activities	- DG SANTE organised 2 sessions of the training *Preventing Stress and Burnout in the Workplace* for managers in Brussels (total number of participants: 35 – ideal number of participants per session according to organisers: 15; - A few managers participated in more general trainings during the Health Week.	
Towards Excellent SANTE: Awareness raising actions around the 6 Fit@work priorities of the Commission: SANTE a healthy DG programme	Participation rate of SANTE Staff	70% of staff participating to one or more activities	The DG SANTE wellbeing Autumn was organised.	
Towards Excellent SANTE: Organise staff development actions to improve engagement and empowerment and to assist staff in taking a more active role in making things better.	Carry out training activities	Organisation of at least 5 trainings with a participation rate of on average 15 staff	**Results 2017** 6 teambuilding events were organised, 4 Units, 1 team of a Unit and 1 full Directorate.	**Results 2018** 10 teambuilding events were organised (9 Units and 1 entire Directorate)
Recruitment target of female managers: targeted career development programme for female aspirant middle managers	Number of female aspirant middle managers trained	10	Three SANTE female aspirant managers participated in the 2018 Female Talent Development Programme. A slight delay occurred with the implementation of the SANTE training action for aspirant managers which will be launched as from 01/2019. 7 female aspirant managers have been selected for the programme.	

Annex 2.2 Better Regulation

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 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 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.
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.

Source of data: Planning of impact assessments (2018/19), 2017 AAR, Better Regulation portal[3], Register of Commission Documents[4]

[3] http://ec.europa.eu/smart-regulation/impact/ia_carried_out/cia_2016_en.htm

[4] http://ec.europa.eu/transparency/regdoc/?fuseaction=ia&year=2018&serviceId=102&s=Search

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 (average from 2011- 2013)	**Interim Milestone 2016**	**Results 2017**	**Latest known results 2018**	**Target 2020**
50%	0% (0 out of 1)	50% (1 out of 2)	100% (1 out of 1)	60%

SANTE performance for 2018
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.

Although there is a positive trend of the indicator between 2016 and 2018, it should be noted that the number of Impact Assessments is insufficient to obtain a meaningful percentage and, thus, to allow any objective conclusion regarding the evolution of the assigned indicator.

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 2015 baseline is defined as the percentage of the DG's regulatory acquis covered by evaluations and Fitness Checks not older than five years (2010-2015).

Regulatory acquis
In 2015, DG SANTE identified 37 legal acts (Regulations and Directives) that required review in its acquis. However, the baseline set for 2015 by DG SANTE did not include legislative acts which:
a) were to be repealed by forthcoming new legislative acts in the areas of Plant Health, Animal Health, Official Controls, Tobacco (TPD); these acts are now adopted and should be counted as part of the DG's acquis;
b) acts adopted since 2015;
c) implementing acts.
In 2018, the acts referred to in a) and b) above have been adopted and are part of DG SANTE acquis (now totalling 43 major acts)[5].

In 2015, 11 legal acts were covered by evaluation/assessment/review and had already been evaluated in the respective five-year period (2010-2015).

The 2016 and 2017 milestones show a positive trend compared to baseline. In 2017 the DG completed the planned evaluations of four acts, while in 2016 it evaluated other two acts. Therefore, between 2015 (baseline) and 2017 the DG evaluated in total 17 acts, resulting in an indicator of 41% ((11+2+4)/41).

Source of data: Planning of Evaluations and studies (2008; 2016; 2017; 2018); Commission Reporting obligations under the SANTE legislation (own source)

Baseline 2015	**Interim Milestone 2016**	**Results 2017**	**Latest known results 2018**	**Target 2020**
30% of SANTE legislation (11 out of 37 legal acts)	35% of SANTE legislation (13 out of 37 legal acts)	41% of SANTE legislation (17 out of 41 legal acts)	40% of SANTE legislation (17 out of 43 legal acts)	Positive trend compared to baseline

[5] 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.

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.

SANTE performance for 2018
In 2018 DG SANTE completed the planned evaluation of the European Food Safety Agency (EFSA), – which is however not taken into account in calculating this indicator– while at the same time two new legal acts were adopted in 2018. Therefore, the indicator for 2018 is 40% [(11+2+4)/43].

It should be noted that seven of the 2018 on-going evaluations are planned to finish in the first half of 2019. Thus, a positive trend of the indicator is expected for 2019.

Indicator 3: Percentage of evaluations planned and finalised in the last year (2018)

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.

Baseline	Interim Milestone 2016	Results 2017	Latest known results 2018	Target 2020
Evaluations planned 2016-2020: 26[6]	Percentage of evaluations with final report 27%[7]	42%[8]	42%	100% of evaluations planned are finalised (final report)

SANTE performance for 2018
DG SANTE started 2018 with seven on-going evaluations from previous years. Of these ongoing, one evaluation was completed in 2018 as planned[9], while the other six were not completed in 2018 as planned. In addition, four evaluations started in 2018. Therefore, the indicator for 2018, taking into account the evaluations finalised in 2016 (2) and 2017 (4), is 42% [(2+4+1+4)/26].

Annex 2.3 Information Management

Already in 2016 DG SANTE exceeded the 2020 targets set for indicators 2 and 3. This achievement has been reconfirmed in 2018, although the percentage in 2018 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.

Although it seems that indicator 1 (0,68%) does not show an improvement compared to 2017 (0,51%), in 2018 DMO reports on registered documents, not filed, were sent regularly and followed up closely. Documents that are still not filed for 2018 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 2018.

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

7 See 2016 Management Plan, Annex 3.

8 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)

9 See 2018 Management Plan, Annex 3.

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[10] (ratio) **Source of data:** *Hermes-Ares-Nomcom (HAN)[11] statistics*				
Baseline 2015		Target (2020)	Results 2017	**Latest known results 2018**
1.24%		0%	0,51%	**0,68**%
Indicator 2: Number of HAN files readable/accessible by all units in the DG **Source of data:** *HAN statistics*				
Baseline 2015		Target (2020)	Results 2017	**Latest known results 2018**
98%		75%	97,98%	**97,90**%
Indicator 3: Number of HAN files shared with other DGs **Source of data:** *HAN statistics*				
Baseline 2015		Target (2020)	Results 2017	**Latest known results 2018**
98%		75%	97,98%	**97,90**%
Indicator 4: Percentage of units using collaborative tools to manage their activities				
Baseline (2015)	Interim Milestone (2018)	Target (2020	Results 2017	**Latest known results 2018**
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%	24%* (100% for activities applicable to all Units)	30% (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 2017	**Latest known results 2018**
100%	100% (in total 512 requests)	100%	100% (in total 732 requests	100% (in total 742 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 2017	**Latest known results 2018**
20%	60%	90%	50%	65%

** A new version of the collaborative platform, to be deployed in 2019, will allow all Units to have a new uniform way of managing their activities and projects. This planning, scheduled for 2018, had to be revised towards delivery in 2019, due to significant technical and procedural obstacles.*

Annex 2.4 External Communication

Annual communication spending (based on estimated commitments):			
Baseline (2017):	Target (2018):	Total amount spent	Total FTEs working on external communication
€1 391 902	**€1 225 000**	**€1 379 334[12]**	**8,5[13] FTE**

[10] 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.

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

[12] The total amount spent in 2018 covers all activities for external communication, including SANTE's contribution to a joint stand with DG AGRI at international events such as the International Green Week (IGW) and the Salon International de l'Agriculture (SIA).

Tables on the objectives contributing to SANTE Strategic Plan 2016/2020 with the presentation of the main outputs

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 2018: **Specific communication actions in the main areas: Vaccination, Reform of General Food Law (GFL), State of Health, Antimicrobial Resistance (AMR), European Reference Networks (ERN) and Food Waste**			
Output	**Indicator**	**Target 2020**	**Results 2018**
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, online views of graphic material	50 000[14] (Baseline 2015: 222 710 099)	✓ 32 528 044 contacts in 2018[15] ✓ 27 840 707 contacts in 2017[16]

Main outputs in 2018[17]			
Output	**Indicator**	**Target**	**Latest know results 2018**
Media and social media actions on the proposal and adoption of the Council recommendation on vaccination, and the Vaccines Confidence Report	- Number of page views to SANTE web section on vaccination - National print media coverage of adoption of Council Recommendation - Number of journalists attending the media briefing or roundtable with the Commissioner (tbc) + outputs - Twitter reach (including Commissioner's accounts) (regular and paid)	- 10% increase (baseline 2017: 17,920 visits) - Media coverage by at least 20 EU countries - 10 including those from countries with high scepticism (e.g. France) and low vaccination rates (e.g. Romania and Bulgaria), 70% of which publish articles within 3 months - 50,000 Twitter accounts reached &	Number of page views to SANTE's web section on vaccination: 32,446 Approx. 15-20 journalists attended the press conference There was media coverage in more than 20 EU countries (including the priority Member States) with at least 54 news items (written and audiovisual media) published. 6 440 032 impressions (regular and paid promotion of key messages, infographics and video animations) on Twitter

[13] This figure includes all tasks related to external communication, but excludes unit management and internal communication.

[14] 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.

[15] Reach of communication activities in 2018 includes: DG SANTE Web unique page views (*10,305,181*), Twitter (19 583 200 impressions over the year – 3 540 400 for @Food_EU and 16 042 800 for @EU_Health according to Twitter Analytics), Facebook (1 433 857 reach – paid campaign for Vaccination Council Recommendation 2018 via the European Commission central account); visitors to stands IGW & SIA (230 000),; Press Releases and Memos (872,241 pageviews), e-news and newsletters (90,736 subscribers), publications (NA for the moment*); Infographs, Factsheets for food safety and health (12,829 page views)

[16] To be noted: the figure mentioned in 2017 (33 824 283 contacts) included the reach of the Citizens' Dialogues with the Commissioner (5.983.576) which is no longer taken into account as not organised by DG SANTE.

[17] The 2018 Management Plan announced media actions on the upcoming Communication on infectious diseases. However, this policy initiative was cancelled, so the item was removed from this reporting table.

Output	Indicator	Target	Latest know results 2018
		500,000 impressions	4 196 983 impressions (paid campaign) of Facebook (central account)
Promotion of factsheets, Eurobarometer results, video clip, press material, social media activities on antimicrobial resistance	- Number of page views to SANTE web section on AMR - Twitter reach (including Commissioner's accounts) (regular and paid) - National media coverage of final adoption of vet medicines and medicated feed legislation - National media coverage of European Antibiotic Awareness Day (EAAD)/ AMR Eurobarometer - Number of journalists attending EAAD media event including Commissioner interviews (tbc)	- 10% increase (baseline 2017: 88,026 visits) - 70,000 Twitter accounts reached & 700,000 impressions - Print media coverage by at least 15 EU countries, including both health and agriculture publications. - Media coverage by at least 20 EU countries - 10 journalists attending EAAD media event, 70% of which publish articles/interviews within 3 months	Number of page views to SANTE's web section on AMR: 58,433 (note: 2017 was the year when the new Action Plan was launched and no comparable action took place in 2018. Therefore interest on AMR decreased in 2018) 22 journalists from MS and also Brussels-based media participated at and covered the EAAD event widely. 3 journalists had one-to-one interviews with the Commissioner after the event. At least 140 news items (written and audiovisual) published. 1 948 088 impressions (regular and paid promotion) on Twitter
Impact of the proposal on the transparency and sustainability of the food and feed risk assessment model	- Number of page views to SANTE web section General Food Law General Food Law - Media coverage of adoption of legislative proposal - Twitter reach (including Commissioner's accounts) (regular and paid)	- 10% increase (baseline 2017[1]: 41.930 page views) - Print (both general and specialised) media coverage by at least 15 EU countries - 30 000 accounts reached and 300 000 impressions	Number of page views to SANTE's web section on General Food Law: 54,011 Proposal was reported in most MS at time of adoption 588 493 impressions (regular and paid promotion) on Twitter
Participation with a stand in international events on "farm to fork", food waste and antimicrobial resistance.	- Number of visits to Salon de l'Agriculture (SIA), Grüne Woche (IGW) and Salone del Gusto	-For SIA: 143.470 visitors in the stand, 27.090 visitors engaged - For IGW: 214.416 visitors by the stand, 105.744 visitors engaged in the stand	For SIA: estimate of between 150-200.00 visitors by the stand, out of total 680.000 visitors For IGW: estimate of around **80.000 visitors participating in the animations at the stand,** out of 400.000 total visitors – the overall rate of active engagement is high even if target not met. 92 451 impressions on Twitter for food fairs (generic promotion) 785 133 impressions (regular and paid promotion) on

[1] Disclaimer: web statistics used as 2017 benchmarks are projected figures for the entire year based on user data collected between January and September. We have calculated these figures by adding to the collected data three times the average of the first nine months.

Output	Indicator	Target	Latest know results 2018
			Twitter for food waste topics
Launch of the "Health at a Glance: Europe 2018 report/State of Health in the EU" to media and stakeholders	- Number of page views to SANTE web section on State of Health - Number of visits to SANTE web section on State of Health - Twitter reach (including Commissioner's accounts), (regular and paid) - National media coverage of report - Number of the Commission Representations joining virtual press briefing	- 10% increase (baseline 2017[1]: 44,100 visits) - 100,000 Twitter accounts reached and 1,000,000 impressions - Print media coverage by at least 15 EU countries. - 6 technical media briefings in the Representations - At least 8 Commission Representations joining virtual press briefing	Number of page views to SANTE's web section on State of Health: 77,970 1 969 769 impressions (regular and paid promotion) on Twitter Technical press briefings or virtual press briefings with the Representations not organised in 2018 as it was only the Health at a Glance report and not the country profiles. At least 17 EU MS covered the report. 5 journalists from MS and Brussels-based media participated at the press conference. At least 70 news items (written and audiovisual) published.
Media actions around the 4th Conference of the European Reference Networks: a success story in the treatment of rare diseases	- Number of page views to SANTE web section on ERNs - Twitter reach (including Commissioner's accounts) (regular and paid) - Number of print media articles on success stories	- 10% increase (baseline 2017[1]: 85,779 visits) - 50,000 Twitter accounts reached & 500, 000 impressions - At least 10 articles published by several EU countries during the year	Number of page views to SANTE web section on ERNs: **37,303**, the reason being the diversion of traffic to individual ERN's websites 6 journalists from Member States and some Brussels-based journalists participated at the conference and published articles. 6 journalists had one-to-one interviews with the Commissioner. Also around the Rare Disease Day, in the context of the Brexit negotiations, and at other occasions media wrote about the ERNs. At least 10 articles have been published so far by the participating journalists. 3 105 899 impressions (regular and paid promotion) on Twitter
Media actions on the adoption of the Commission Communication on Digital Health and Care	- Number of page views to SANTE web section on e-health - Twitter reach (including Commissioner's accounts) (regular and paid) - Twitter reach (including Commissioner's accounts) (regular and paid)	- 10% increase (baseline 20171: 32,253 visits) - 30,000 Twitter accounts reached & 300,000 impressions	Number of page views to SANTE's web section on e-health: 35,198. At least 37 media items (written and audiovisual published. 259 674 impressions on Twitter due to delay of e-prescriptions launch to 2019

ANNEX 3: Draft annual accounts and financial reports

AAR 2018 Version 1

Annex 3 Financial Reports - DG SANTE - Financial Year 2018

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 (excluding Building Contracts)

Table 12 : Summary of Procedures (excluding Building Contracts)

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 2018 (in Mio €)					
			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	3,08	3,08	100,00 %
	05 04	Rural development	0,43	0,43	100,00 %
Total Title 05			3,51	3,51	100,00%
Title 07 Environment					
07	07 02	Environmental policy at Union and international level	0,23	0,23	100,00 %
Total Title 07			0,23	0,23	100,00%
Title 09 Communications networks, content and technology					
09	09 03	Connecting Europe Facility (CEF) - Telecommunications networks	2,678	2,678	100,00 %
Total Title 09			2,678	2,678	100,00%
Title 11 Maritime affairs and fisheries					
11	11 06	European Maritime and Fisheries Fund (EMFF)	0,275	0,275	100,00 %
Total Title 11			0,275	0,275	100,00%
Title 14 Taxation and customs union					
14	14 02	Customs	0,20	0,20	100,00 %
Total Title 14			0,20	0,20	100,00%
Title 17 Health and food safety					
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	19,972234	19,811183	99,19 %
	17 03	Public health	198,731397	182,502345	91,83 %
	17 04	Food and feed safety, animal health, animal welfare and plant health	269,436108	265,597173	98,58 %
Total Title 17			488,139740	467,910702	95,86%
Title 26 Commission's administration					
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,669394	0,513110	76,65 %
Total Title 26			0,669394	0,513110	76,65%
Title 33 Justice and consumers					
33	33 01	Administrative expenditure of the 'Justice and consumers' policy area	1,7819750	1,7819750	100,00 %
Total Title 33			1,7819750	1,7819750	100,00%
Total DG SANTE			497,4841096	477,0987869	95,90 %

** 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).*

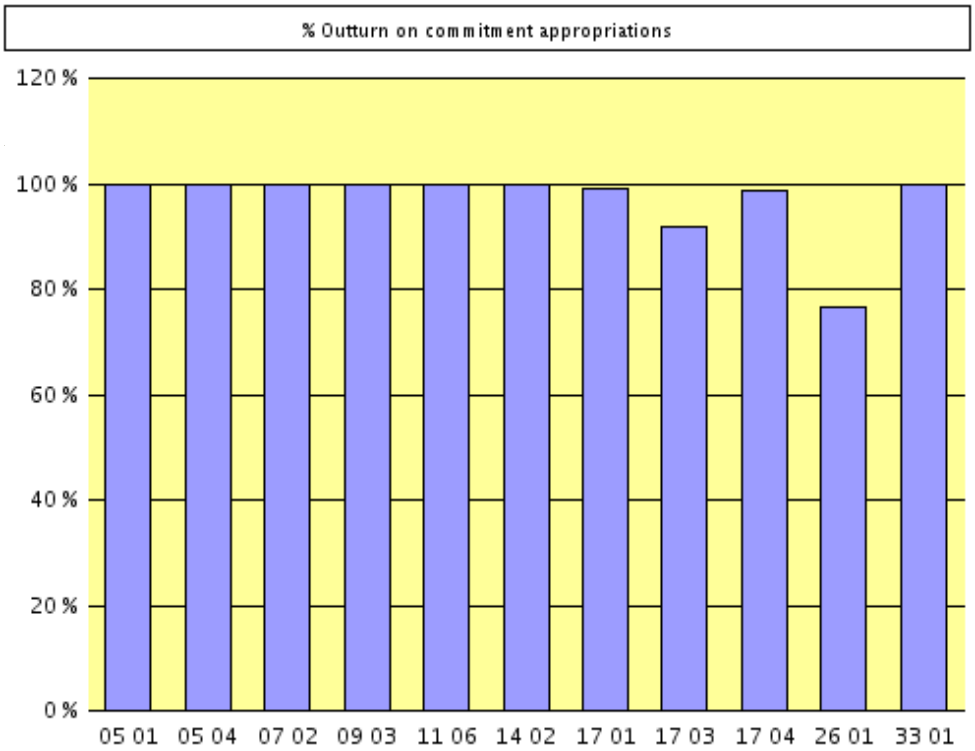
% Outturn on commitment appropriations
120 %
100 %
80 %
60 %
40 %
20 %
0 %
05 01
05 04
07 02
09 03
11 06
14 02
17 01
17 03
17 04
26 01
33 01

TABLE 2: OUTTURN ON PAYMENT APPROPRIATIONS IN 2018 (in Mio €)					
Chapter			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	3,0800000	3,0800000	100,00 %
	05 04	Rural development	0,1079060	0,1079060	100,00 %
Total Title 05			3,1879060	3,1879060	100,00%
Title 09 Communications networks, content and technology					
09	09 03	Connecting Europe Facility (CEF) - Telecommunications networks	2,3556280	2,3556280	100,00 %
Total Title 09			2,3556280	2,3556280	100,00%
Title 11 Maritime affairs and fisheries					
11	11 06	European Maritime and Fisheries Fund (EMFF)	0,2439500	0,2227747	91,32 %
Total Title 11			0,2439500	0,2227747	91,32%
Title 17 Health and food safety					
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	15,35544	12,54106	81,67 %
	17 03	Public health	196,88606	180,58915	91,72 %
	17 04	Food and feed safety, animal health, animal welfare and plant health	244,61511	240,06586	98,14 %
Total Title 17			456,85661	433,19606	94,82%
Title 26 Commission's administration					
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,8641215	0,4948866	57,27 %
Total Title 26			0,8641215	0,4948866	57,27%
Title 33 Justice and consumers					
33	33 01	Administrative expenditure of the 'Justice and consumers' policy area	1,78198	1,78198	100,00 %
	33 04	Consumer programme	0,02349	0,02349	100,00 %
Total Title 33			1,80546	1,80546	100,00%
	Total DG SANTE		465,31368	441,26272	94,83 %

** 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).*

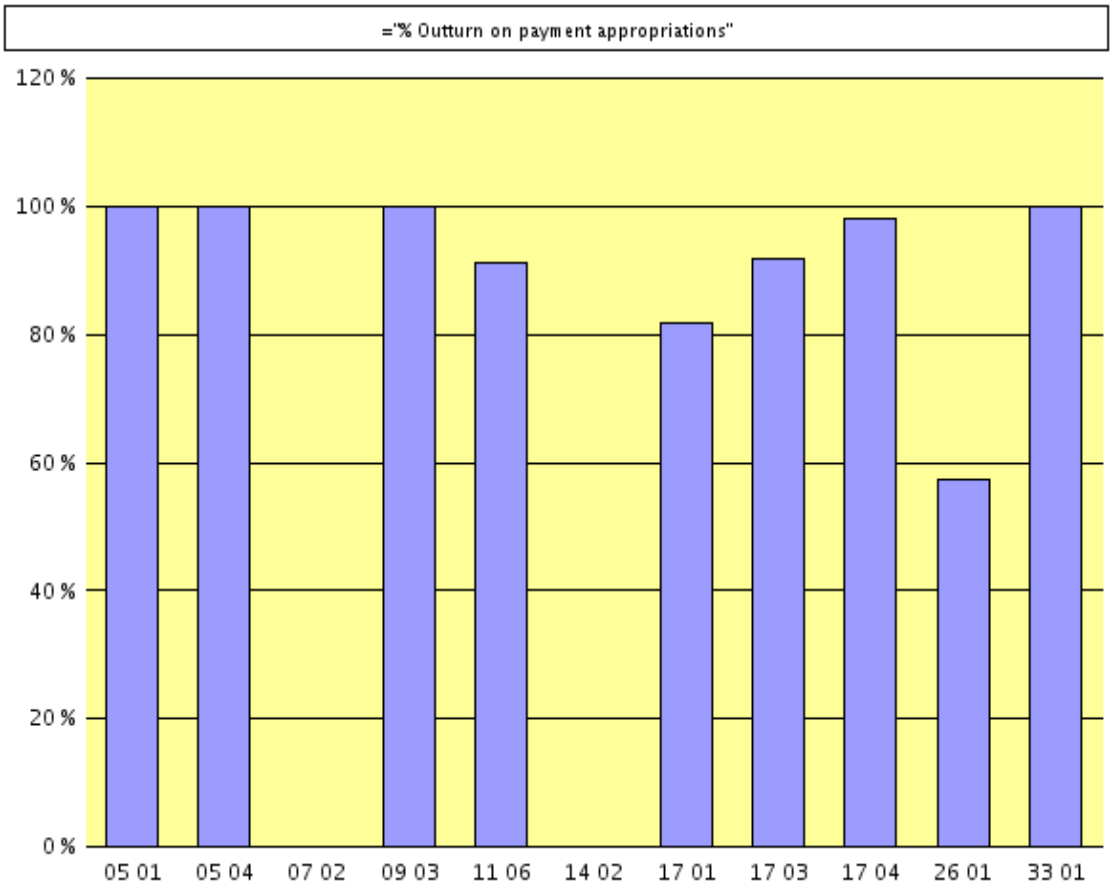
="% Outturn on payment appropriations"
120 %
100 %
80 %
60 %
40 %
20 %
0 %
05 01
05 04
07 02
09 03
11 06
14 02
17 01
17 03
17 04
26 01
33 01

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2018 (in Mio €)									
Chapter			2018 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 2018	Total of commitments to be settled at end of financial year 2017
			Commitments 2018	Payments 2018	RAL 2018	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
Title 05 : Agriculture and rural development									
05	05 01	Administrative expenditure of the 'Agriculture and rural development' policy area	3,08	3,08	0	0,00 %	0,00	0,00	0,00
	05 04	Rural development	0,43	0,00	0,43	100,00 %	0,08	0,51	0,19
Total Title 05			3,51	3,08	0,43	12,25%	0,08091615	0,51091615	0,18882211
Title 07 : Environment									
07	07 02	Environmental policy at Union and international level	0,23	0,00	0,23	100,00 %	0,00	0,23	0,00
Total Title 07			0,23	0,00	0,23	100,00%	0	0,23	0
Title 09 : Communications networks, content and technology									
09	09 03	Connecting Europe Facility (CEF) - Telecommunications networks	2,678	0,00	2,678	100,00 %	4,15	6,83	6,51
Total Title 09			2,678	0,00	2,678	100,00%	4,15040375	6,82840375	6,50603172
Title 11 : Maritime affairs and fisheries									
11	11 06	European Maritime and Fisheries Fund (EMFF)	0,275	0,00	0,275	100,00 %	0,03	0,31	0,25
Total Title 11			0,275	0,00	0,275	100,00%	0,03122533	0,30622533	0,254
Title 14 : Taxation and customs union									
14	14 02	Customs	0,2	0,00	0,2	100,00 %	0,00	0,20	0,00
Total Title 14			0,2	0,00	0,2	100,00%	0	0,2	0
Title 17 : Health and food safety									
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	19,81118333	14,68	5,13342061	25,91 %	0,00	5,13	6,14
	17 03	Public health	182,5023454	167,42	15,08347253	8,26 %	10,72	25,80	26,59
	17 04	Food and feed safety, animal health, animal welfare and plant health	265,5971735	62,95	202,6493182	76,30 %	76,29	278,94	282,61
Total Title 17			467,9107022	245,04	222,8662114	47,63%	87,01310991	309,8793213	315,33404
Title 26 : Commission's administration									
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,5131097	0,32	0,18923197	36,88 %	0,00	0,19	0,19
Total Title 26			0,5131097	0,32	0,18923197	36,88%	0	0,18923197	0,19472696
Title 33 : Justice and consumers									
33	33 01	Administrative expenditure of the 'Justice and consumers' policy area	1,781975	1,78	0	0,00 %	0,00	0,00	0,00
	33 04	Consumer programme	0	0,00	0	0,00 %	0,00	0,00	0,02
Total Title 33			1,781975	1,78	0	0,00%	0	0	0,0234851
	Total DG SANTE		477,0987869	250,23	226,8684433	47,55 %	91,27565514	318,1440985	322,501106

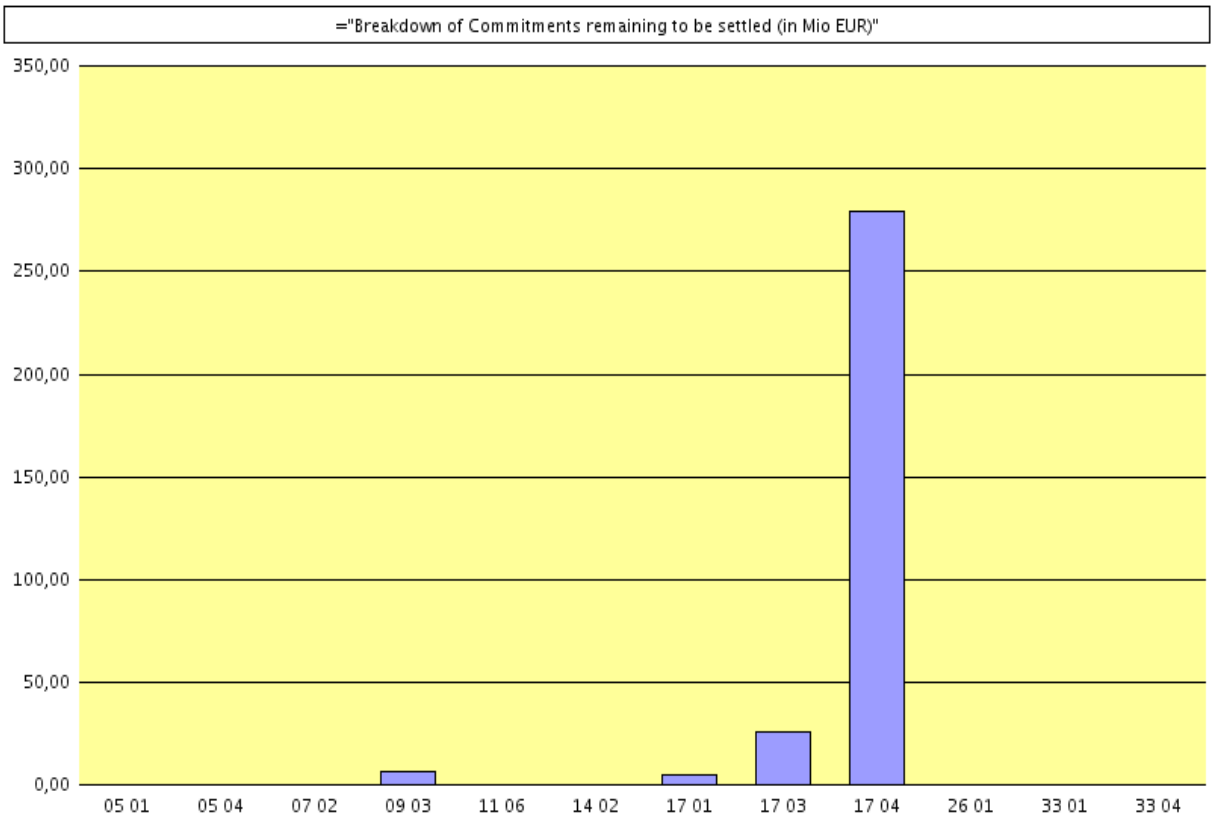
="Breakdown of Commitments remaining to be settled (in Mio EUR)"
350,00
300,00
250,00
200,00
150,00
100,00
50,00
0,00
05 01
05 04
07 02
09 03
11 06
14 02
17 01
17 03
17 04
26 01
33 01
33 04

TABLE 4 : BALANCE SHEET SANTE		

BALANCE SHEET	2018	2017
A.I. NON CURRENT ASSETS	16.115.244,25	17.123.583,50
A.I.1. Intangible Assets	2.902.780,63	2.902.780,63
A.I.2. Property, Plant and Equipment	11.864.371,15	13.315.413,02
A.I.5. Non-Current Pre-Financing	1.348.092,47	905.389,85
A.II. CURRENT ASSETS	30.219.189,65	29.813.758,55
A.II.2. Current Pre-Financing	17.313.523,45	17.929.766,82
A.II.3. Curr Exch Receiv &Non-Ex Recoverables	2.496.690,04	2.194.709,66
A.II.4. Inventories	10.405.285,00	9.683.858,70
A.II.6. Cash and Cash Equivalents	3.691,16	5.423,37
ASSETS	**46.334.433,90**	**46.937.342,05**
P.I. NON CURRENT LIABILITIES	- 4.110.661,10	- 6.163.396,71
P.I.3. Non-Current Financial Liabilities	- 4.110.661,10	- 6.163.396,71
P.II. CURRENT LIABILITIES	- 321.745.576,00	- 276.266.464,90
P.II.2. Current Provisions	- 153.205.282,85	- 86.601.166,45
P.II.3. Current Financial Liabilities	- 2.052.735,64	- 2.047.603,09
P.II.4. Current Payables	- 15.593.991,89	- 17.249.976,52
P.II.5. Current Accrued Charges &Defrd Income	- 150.893.565,62	- 170.367.718,84
LIABILITIES	**- 325.856.237,10**	**- 282.429.861,61**
NET ASSETS (ASSETS less LIABILITIES)	**- 279.521.803,20**	**- 235.492.519,56**

P.III.2. Accumulated Surplus/Deficit	1.995.433.923,33	1.497.128.587,53

Non-allocated central (surplus)/deficit*	- 1.715.912.120,13	- 1.261.636.067,97

TOTAL	**-**	**-**

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 5 : STATEMENT OF FINANCIAL PERFORMANCE SANTE		

STATEMENT OF FINANCIAL PERFORMANCE	2018	2017
II.1 REVENUES	- 4.517.424,72	283.241,19
II.1.1. NON-EXCHANGE REVENUES	- 9.302.796,42	- 3.765.463,18
II.1.1.5. RECOVERY OF EXPENSES	- 3.913.695,59	- 2.406.012,25
II.1.1.6. OTHER NON-EXCHANGE REVENUES	- 5.389.100,83	- 1.359.450,93
II.1.2. EXCHANGE REVENUES	4.785.371,70	4.048.704,37
II.1.2.1. FINANCIAL INCOME		- 2,35
II.1.2.2. OTHER EXCHANGE REVENUE	4.785.371,70	4.048.706,72
II.2. EXPENSES	467.667.919,88	498.022.094,61
II.2. EXPENSES	467.667.919,88	498.022.094,61
II.2.10.OTHER EXPENSES	107.621.005,10	102.694.898,45
II.2.2. EXP IMPLEM BY COMMISS&EX.AGENC. (DM)	200.695.482,76	241.380.674,69
II.2.3. EXP IMPL BY OTH EU AGENC&BODIES (IM)	158.919.073,57	153.938.044,27
II.2.4. EXP IMPL BY 3RD CNTR & INT ORG (IM)	152.118,04	- 134.125,20
II.2.5. EXP IMPLEM BY OTHER ENTITIES (IM)	256.984,21	203.315,88
II.2.6. STAFF AND PENSION COSTS	8.000,00	- 74.920,28
II.2.8. FINANCE COSTS	15.256,20	14.206,80
STATEMENT OF FINANCIAL PERFORMANCE	**463.150.495,16**	**498.305.335,80**

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.

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TABLE 5bis : OFF BALANCE SHEET SANTE		
OFF BALANCE	**2018**	**2017**
OB.1. Contingent Assets	-	-
GR for pre-financing	-	-
OB.2. Contingent Liabilities	- 13.352.501,71	- 362.327.252,56
OB.2.6. CL Other	- 13.352.501,71	- 7.327.252,56
OB.2.7. CL Legal cases OTHER	-	- 355.000.000,00
OB.3. Other Significant Disclosures	- 146.661.538,09	- 129.759.455,12
OB.3.2. Comm against app. not yet consumed	- 146.661.538,09	- 129.759.455,12
OB.4. Balancing Accounts	160.014.039,80	492.086.707,68
OB.4. Balancing Accounts	160.014.039,80	492.086.707,68
OFF BALANCE	**-**	**- 0,00**

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 FOR 2018 - DG 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)
16	1	1	100,00 %	9			
30	1448	1436	99,17 %	15,73050139	12	0,83 %	35,91666667
44	1	1	100,00 %	16			
45	6	6	100,00 %	12,5			
48	1	1	100,00 %	29			
60	78	77	98,72 %	24,67532468	1	1,28 %	63
90	260	186	71,54 %	70,54301075	74	28,46 %	128,6216216

Total Number of Payments	**1795**	**1708**	**95,15 %**		**87**	**4,85 %**	
Average Net Payment Time	**26,60222841**			**22,09543326**			**115,0804598**
Average Gross Payment Time	**38,73203343**			**31,42915691**			**182,1034483**

Suspensions

Average Report Approval Suspension	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	59	366	20,39 %	1795	154.383.101,79	36,17 %	426.793.154,88

Late Interest paid in 2018

DG	GL Account	Description	Amount (Eur)
SANTE	65010000	Interest expense on late payment of charges	0,00
SANTE	65010100	Interest on late payment of charges New FR	631,32
			631,32

TABLE 7 : SITUATION ON REVENUE AND INCOME IN 2018								
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	4.047.032,65	389.826,39	4.436.859,04	3.041.904,11	389.826,39	3.431.730,50	1.005.128,54
59	OTHER REVENUE ARISING FROM ADMINISTRATIVE MANAGEMENT	888.649,72	-	888.649,72	888.649,72	-	888.649,72	-
60	CONTRIBUTIONS TO UNION PROGRAMMES	203.820,00	-	203.820,00	203.820,00	-	203.820,00	-
66	OTHER CONTRIBUTIONS AND REFUNDS	17.048.736,28	277.403,39	17.326.139,67	17.048.736,28	132.148,88	17.180.885,16	145.254,51
Total DG SANTE		**22.188.238,65**	**667.229,78**	**22.855.468,43**	**21.183.110,11**	**521.975,27**	**21.705.085,38**	**1.150.383,05**

TABLE 8 : RECOVERY OF PAYMENTS
(Number of Recovery Contexts and corresponding Transaction Amount)

INCOME BUDGET RECOVERY ORDERS ISSUED IN 2018	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
2009	1	41.406,74	**1**	**41.406,74**	1	41.406,74	100,00%	100,00%
2010	2	1.531.073,08	**2**	**1.531.073,08**	2	1.531.073,08	100,00%	100,00%
2013	6	287.095,49	**6**	**287.095,49**	6	287.095,49	100,00%	100,00%
2014	8	1.236.631,63	**8**	**1.236.631,63**	8	1.236.631,63	100,00%	100,00%
2015	3	1.023.772,02	**3**	**1.023.772,02**	3	1.023.772,02	100,00%	100,00%
2016	2	4.244,10	**2**	**4.244,10**	2	4.244,10	100,00%	100,00%
2017					10	17.843.724,65		
Sub-Total	**22**	**4.124.223,06**	**22**	**4.124.223,06**	**32**	**21.967.947,71**	**68,75%**	**18,77%**

EXPENSES BUDGET	Error		Irregularity		OLAF Notified		Total undue payments recovered		Total transactions in recovery context(incl. non-qualified)		% Qualified/Total RC	
	Nbr	Amount	Nbr	Amount	Nbr	Amount	Nbr	Amount	Nbr	Amount	Nbr	Amount
INCOME LINES IN INVOICES												
NON ELIGIBLE IN COST CLAIMS			130	9.940.430,22			**130**	**9.940.430,22**	182	54.192.524,78	71,43%	18,34%
CREDIT NOTES			38	765.450,91			**38**	**765.450,91**	76	1.068.923,98	50,00%	71,61%
Sub-Total			**168**	**10.705.881,13**			**168**	**10.705.881,13**	**258**	**55.261.448,76**	**65,12%**	**19,37%**
GRAND TOTAL			**190**	**14.830.104,19**			**190**	**14.830.104,19**	**290**	**77.229.396,47**	**65,52%**	**19,20%**

TABLE 9: AGEING BALANCE OF RECOVERY ORDERS AT 31/12/2018 FOR SANTE						
	Number at 1/01/2018	Number at 31/12/2018	Evolution	Open Amount (Eur) at 1/01/2018	Open Amount (Eur) at 31/12/2018	Evolution
2011	1	1	0,00 %	145.254,51	145.254,51	0,00 %
2017	4		-100,00 %	521.975,27		-100,00 %
2018		2			1.005.128,54	
	5	3	-40,00 %	667.229,78	1.150.383,05	72,41 %

TABLE 10 : RECOVERY ORDER WAIVERS IN 2018 >= EUR 60.000						
	Waiver Central Key	Linked RO Central Key	RO Accepted Amount (Eur)	LE Account Group	Commission Decision	Comments

Total DG SANTE	

Number of RO waivers	

There are no waivers below 60 000 €

None of your Recovery Order Waivers (if any) reaches EUR 60.000

TABLE 11 : CENSUS OF NEGOTIATED PROCEDURES - DG SANTE - 2018

Negotiated Procedure Legal base	Number of Procedures	Amount (€)
Total		

TABLE 12 : SUMMARY OF PROCEDURES OF DG SANTE EXCLUDING BUILDING CONTRACTS

Internal Procedures > € 60,000

Procedure Legal base	Number of Procedures	Amount (€)
Open Procedure (Art. 104(1) (a) FR)	2	715.000,00
Open Procedure (Art. 127.2 RAP)	2	1.110.368,00
Open procedure (FR 164 (1)(a))	2	1.792.590,00
Restricted Procedure (Art. 104(1) (b) FR)	1	334.307,44
Total	**7**	**3.952.265,44**

Additional Comments:

TABLE 13 : BUILDING CONTRACTS

Legal base	Contract Number	Contractor Name	Description	Amount (€)

TABLE 14 : CONTRACTS DECLARED SECRET

LC Responsible Orga	LC Contract/Grant Ty	LC Date	Legal base	Contract Number	Contractor Name	Description	Amount (€)

TABLE 15 : FPA duration exceeds 4 years - 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.

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.

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

2. Type of expenditure: procurement in direct management

Following the transfer of implementation tasks to the Executive Agency for Consumers, Health, Agriculture and Food (CHAF-EA), 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 HR. 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 > €135.000 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 tenderes 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.

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

In 2018, 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 (CHAF-EA) with the implementation of about EUR 64,1 million which amounts to about 20% of the 2018 operational budget (without subsidy payments to agencies). Cross-sub-delegations were given to authorising officers of other DGs for a total of EUR 1,4 million of commitment credits and EUR 0,4 million of payment credits.

DG SANTE finances parts of the running costs of CHAF-EA through the payment of a subsidy of EUR 5,7 million to the executive agency's 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 2018

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 2018, 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 2018 (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)

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

DG SANTE is responsible for five EU agencies of which four received an annual subsidy from the EU budget [DG SANTE contributes to the running costs of ECHA for its biocides activities; the responsible DG for ECHA is DG GROW; CPVO is fully fee-financed].

- **European Centre for Disease Prevention and Control (ECDC)** located in Stockholm, Sweden[18] *(Budget 2018: total sum of human resources 285; EU funding 100%: EUR 58,1 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[19] *(Budget 2018: total sum of human resources 459; EU funding 100%: EUR 79,1 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 London, UK[20] *(Budget 2018: total sum of human resources 810; EU funding 9,6%: EUR 32,6 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 2018 budget amounted to EUR 337,7 million which is to a large extent fee-financed.
- **Community Plant Variety Office (CPVO)** in Angers, France[21] *(Budget 2018: 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 2018 budget amounted to EUR 16,9 million (fully fee-financed).
- **European Chemicals Agency (ECHA)** located in Helsinki[22] - relevant for DG SANTE are ECHA's biocides activities *(Budget 2018 for biocides: total sum of human resources 64; EU funding: 45%: EUR 4,9 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 2018 amounted to EUR 10,9 million.

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18 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.

19 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.

20 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.

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

22 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"[23] 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	**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%

[23] 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. For implementing the FR, the agency adopts detailed rules with the Commission's prior consent; DG SANTE, in co-operation with DG BUDG consults and monitors. All SANTE agencies have adopted Financial Regulations which are in line with the Framework Financial Regulation. 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 2015, due to the agencies' development of anti-fraud strategies; In 2016-2017, due to the agencies' and Commission's work on the whistleblowing procedure; In 2018-2019 due to the new FFR and Internal Control Framework.	**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

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 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 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. 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. 5. The "Template for Consolidated Annual Activity Report" for decentralised agencies foresees that the agencies	**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; 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)**
	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. 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 2018); - EFSA every 6 years (last completed 2018); - ECDC every 5 years (ongoing in 2018). 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 (see footnote above).	- 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 2018.

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

Not applicable to DG SANTE in 2018.

ANNEX 8: Decentralised agencies (if applicable)

DG SANTE does not provide Annex 8 since section 2.1 and Annex 5.2 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[24]
FINALISED								
3549	Evaluation of the European Food Safety Authority (EFSA)	L	Article 61(1) of Regulation (EC) No 178/2002 of the EP and the Council: Every 6 years, EFSA, in collaboration with the EC, shall commission an independent external evaluation of its achievements.	Evaluation		206,350		The 3rd independent external evaluation of EFSA 2011-2016
8148	Patients' Rights in the European Union Mapping eXercise	O	This report aims to provide an overview of patients' rights in all EU Member States, Norway and Iceland by mapping national patients' rights legislation, soft-law, structures and enforcement procedures ensuring the rights of patients. The mapping exercise was performed from January to September 2015 providing a cross-sectional view of the patients' rights situation in the 30 countries under study.	General study				Patients' Rights in the European Union Mapping exercise
3576	Study on cross-border health services: capitalising on existing initiatives for cooperation in cross-border regions	O	This study aims to yield a comprehensive picture of cross-border healthcare collaboration initiatives across the EU , including a mapping of cross-border collaboration projects, e.g. bilateral agreements between insurers and providers (between neighbouring countries or between regions) and to develop scenarios for possible pilots to foster European collaboration on cross-border healthcare.	General study		200,000		Study on cross-border health services: capitalising on existing initiatives for cooperation in cross-border regions
3587	Study on cross-border health services: enhancing information provision to patients	O	The study aims to yield an overview of good practices and enabling factors for providing information to patients via the National Contact Points (NCPs), including an analysis based on defined criteria for NCPs website accessibility for patients.	General study		150,000		Study on cross-border health services: enhancing information provision to patients
3575	Study on regulatory aspects of cross-border telemedicine services focusing on privacy, liability, professional standards, interoperability and reimbursement	O	Study on impact of regulatory provision of cross-border telemedicine services focusing on privacy, liability, professional standards, interoperability and reimbursement. SNOMED CT terminology. This study relates to the Commission's priority on Digital Single Market where telemedicine is identified as an area which could benefit from further standardisation.	General study	DG CNECT	285,000		Study on regulatory aspects of cross-border telemedicine services focusing on privacy, liability, professional standards, interoperability and reimbursement

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

Study project ID	Title of the study	Study Internal ID	Study overview	Study reason	Associated services	Study cost	Note	Title of the deliverable[24]
3565	Study on Health System Performance Assessment – Integrated care assessment	O	The first purpose of the study, largely analytical, is to review progress on integration of care in the European Union at national and regional level. Such analysis would contribute to taking decisions on the development of integrated interventions within and across health systems and could be useful for policy-makers when they design and implement reforms. The second purpose of the study is to propose and test a framework of indicators to assess the performance of integrated care.	General study		300,000		Study on Health System Performance Assessment – Integrated care assessment
6529	Feasibility study: analysis of skills for doctors and nurses. Health Workforce. OECD.	O	Analysis of skills for doctors and nurses with a feasibility study for scoping out a large scale survey of skills drawing on existing methodologies and surveys.	General study		150,000		Feasibility study on health workforce skills assessment - Supporting health workers achieve person-centred care
6557	Patient safety OECD analysis on patient safety indicators (HCQI-Health Care Quality Indicators)	O - OECD	Data collection & analysis of patient safety indicators.	General study	Other institutions	150,000		Data and Analysis on Patient Safety within the OECD Health Care Indicators Project
3564	Review of the EU regulated quality pests and development of risk analyses for a list of Union Quality Pests to be established by the European Commission in the frame of the new Regulation on protective measures against pests of plants ("EU quality pest project")	L	The study reviews all quality pests today regulated under the Marketing Directives for propagating material but which have not been updated during the last decades. Apart from the revision of the regulatory status, including assessment of economic impact, tolerance levels for the ones retained as RNQPs will be proposed, as well as inspection intensities for certified material. This will allow starting the implementation of this new concept of RNQPs in the new Plant Health Regulation with an updated list of RNQPs, and not just taking over old outdated existing lists. Therefore, this 2-year study is a needed and very useful, with a very concrete objective.	General study		299,150		Review of the EU regulated quality pests and development of risk analyses for a list of Union Quality Pests to be established by the European Commission in the frame of the new Regulation on protective measures against pests of plants
6517	Study to develop a methodological approach for the implementation of a cost-effectiveness analysis in the food safety spending areas	O	Development of a methodological approach for the implementation of a cost-effectiveness analysis in the spending areas covered by Regulation (EU) No 652/2014, to be firstly used in the context of the ex-post evaluation.	General study		150,000	Recommendation from European Court of Auditors To be done by JRC ISPRA	Cost Effectiveness Analysis: Methodology for the Food Chain Area

Study project ID	Title of the study	Study Internal ID	Study overview	Study reason	Associated services	Study cost	Note	Title of the deliverable[24]
8116	Study on processed cereal-based food and baby food	O	The study will cover: - thematic scope: processed cereal-based food and baby food intended for infants and young children, - operational scope: in preparation of the adoption of the delegated act on processed cereal-based food and baby food to be adopted under Regulation (EU) No 609/2013 on food for specific groups to collect evidence base information on: • the market of processed cereal-based food and baby food; • existing national and international food based dietary guidelines and recommendations in the context of infant and young child feeding; • on the role such foods play in the overall diet of infants and young children in the in various geographical area - temporal scope: current situation - geographical scope: EU 28 and relevant international aspects	General study		130,000		Feeding infants and young children: An analysis of national food-based dietary guidelines and specific products available in the EU market
6514	Reviews of scientific evidence and policies on nutrition and physical activity	O - Preparatory Action	Preparatory Action aiming at promotion healthy diets and physical activity by developing 8 comprehensive literature and policy reviews in the i) behaviour determinants and interventions; ii) foods, including sugary beverages and alcohol pops, and physical activity; iii) school and work performance; iv) early warning indicators; v) specific groups and guidelines.	General study		693,379		Reviews of scientific evidence and policies on nutrition and physical activity Objective area A1: behaviours contributing to positive energy balance Objective area A2: effectiveness and efficiency of policies and interventions on diet and physical activity Objective B1: a comprehensive review of the scientific evidence about the source of calories consumed and types and frequency of physical activity among Europeans Objective B2: consumption, energy intake and impact of fruit juices and of artificially and sugar sweetened beverages Objective area B3: a comprehensive review of the scientific evidence and policies on the consumption, energy intake and impact of

Study project ID	Title of the study	Study Internal ID	Study overview	Study reason	Associated services	Study cost	Note	Title of the deliverable[24]
								high fructose syrups on overweight and obesity and health Objective area C: a comprehensive review of the scientific evidence on the effect of overweight/obesity and/or inadequate physical activity on school or work performance Objective area D: early warning indicators Objective E: existence, need and usefulness of nutrition and physical activity guidelines for specific population groups
6511	Reducing health inequalities: building expertise and evaluation of action. HEPP - Maintaining a focus on health inequalities. Pilot project of the European Parliament	O - Pilot project	The aim of the pilot project is to support knowledge sharing and policy development to reduce health inequalities in the EU, with a focus on the lifestyle determinants of alcohol and nutrition and physical activity– particularly in Member States and regions with the greatest needs. The objectives of the contract are: a) updating scientific evidence and reviewing policies and actions, in particular within the area of lifestyle and behavioural economics; b) conducting case studies on policies and actions in different Member States aiming to reduce health inequalities; c) implementing workshops and expert exchange with the objective of breaking barriers to inter-sectorial action on health inequalities; d) ensuring synergies and support to the health determinants related Joint Actions; e) facilitating information exchange and collaboration between groups of experts and stakeholders.	General study		1,467,578		HEPP - Maintaining a focus on health inequalities - Deliverables: scientific reports, case studies, 6 national workshops, 28 country fiches, 2 policy briefs, Report on health inequalities in alcohol related harm Final conference 'Evidence into practice- Action on Health Inequalities' (Brussels, 6 December 2018)
6509	Developing evidence based strategies to improve the health of people living in isolated and vulnerable situations', Pilot project of the European Parliament	O - Pilot project	The overall aim of the pilot project is to support the development of actions to address the health needs (both physical and mental) of people living in isolated and vulnerable situations in the EU. A particular focus will be on those living in more (geographically and socially) isolated communities - including elderly and persons with disabilities -, identifying and highlighting differences for men's and women's health needs. The objectives of the contract are to a) gather and assess information on the particular health needs and risk factors faced by people living in isolated and vulnerable situations; b) review existing approaches and identify best practices	General study		694,875		VulnerABLE: Pilot project related to the development of evidence based strategies to improve the health of isolated and vulnerable persons

Study project ID	Title of the study	Study Internal ID	Study overview	Study reason	Associated services	Study cost	Note	Title of the deliverable[24]
			to promote health and prevent health problems; c) support the development and implementation of actions through establishing a group of experts for information exchange, d) facilitate capacity building and training, and e) disseminate project results in Member States.					
3563	Study supporting the report of the implementing the Action Plan on Childhood Obesity and the Strategy for Europe on Overweight and Obesity related health issues	L	The Council Conclusions on Nutrition and Physical Activity (10 June 2014) invite the Commission to report back to the Council by 2017 and again in 2020 on the progress made in implementing the EU Action Plan on Childhood Obesity 2014-2020 as well as on other initiatives implemented in the context of the Strategy for Europe on Nutrition, Overweight and Obesity related health issues.	General study		200,000		Supporting the mid-term evaluation of the EU action plan on childhood obesity The childhood obesity study
6899	Establishing best practices on the production, the processing and the marketing of meat from uncastrated or immunocastrated pigs	O - Pilot project	The study is the first part of a pilot project adopted in the Union's budget 2017 and accepted by the Commission which aims at the "Establishment of a harmonised internal market for pigmeat obtained from pigs that have not been surgically castrated". Meat obtained for uncastrated male pigs is rejected by most consumers because it has an unpalatable odour and flavour (boar taint). Hence, most male piglets are systematically castrated without anaesthesia. The pilot project (as a whole) aims at promoting on a voluntary basis the use of meat from uncastrated pigs in order to phase out systematic castration.	General study	DG AGRI	179,707		Establishing best practices on the production, the processing and the marketing of meat from uncastrated or immunocastrated pigs
6488	Pilot Project: Towards a fairer and more effective measurement of access to healthcare across the EU in order to enhance cooperation and know-how transfer	O	The fundamental aim of the pilot project is to enable the development of policies that address health inequalities and barriers to access on the basis of objective and comparable information and help improve the sustainability and performance of healthcare systems in Member States.	General study		245,352	O - Pilot project.	Towards a fairer and more effective measurement of access to healthcare across the EU in order to enhance cooperation and know-how transfer
6499	Study on Serious Adverse Events and Reactions in Blood and Tissues & Cells	O	Collection, analysing and reporting of 2016 and 2017 annual data on serious adverse events and reactions, reported by the EU Member States	General study		58,000		Report on Serious Adverse Events and Reactions in Blood and Tissues & Cells
6534	Economic burden of Antimicrobial Resistance (AMR) in OECD countries (OECD study)	O	Better estimates of economic impact arising from antimicrobial resistance will provide a better basis to determine proper level & balance of required investments to counteract AMR, and help evaluate the cost-effectiveness of measures. The hard data to result will also help galvanize long-term commitment globally.	General study	Other institutions, Directorate-General for Health and Food Safety	340,000	OECD Study	Stemming the Superbug Tide – Just a few dollars more
6490	Implementation analysis regarding the technical standards and other key elements for a future EU system for traceability	L	Project to assist in defining technical standards for the tracking and tracing systems, as well as security features and their possible rotation, as set out under Articles 15(11)(a) and (b) and 16(2) of the Tobacco Products Directive [Implementing and delegated acts]	Impact assessment	Other institutions	1,349,000		Implementation analysis regarding the technical specifications and other key elements for a future EU system for traceability and

Study project ID	Title of the study	Study Internal ID	Study overview	Study reason	Associated services	Study cost	Note	Title of the deliverable[24]
	and security features in the field of tobacco products. A study in support of an Impact Assessment							security features in the field of tobacco products
6504	Data-gathering study on the common financial framework for the management of expenditure under regulation 282/2014 (on the establishment of a third programme for the union's action in the field of health (2014-2020)) (the "Public Health Programme")	MFF	Impact study on long term impact and sustainability of the Health (and food) Programmes to meet requirements stemming from the Better Regulation in the context of a potential impact assessment for a Programme after 2020.	Impact assessment		152,578		Data-gathering study on the common financial framework for the management of expenditure under regulation 282/2014
6875	Data-gathering Study on the common financial framework for the management of expenditure Under Regulation 652/2014 (expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, "the Food Chain Programme")	MFF	Study linked to a potential Impact Assessment for the new MFF.	Impact assessment		143,150		Data-gathering Study on the common financial framework for the management of expenditure Under Regulation 652/2014
3588	Study in preparation of the IA on trans fats	O	The Commission report of 3 December 2015 concluded on the need to explore further the evidence base for setting legal limits for industrial TFA presence in foods. The objective of the study would be to support this investigation of the evidence base, particularly as regards impacts on food business operators (particularly SMEs).	Impact assessment	DG AGRI, DG ENV, DG GROW, DG MARE, DG RTD, SG, LS, DG TRADE	146,095		Study to support the impact assessment of the initiative to limit industrial trans fats in the EU

Study project ID	Title of the study	Study Internal ID	Study overview	Study reason	Associated services	Study cost	Note	Title of the deliverable[24]
CANCELLED								
3557	A study on the added value of the strategic and life-course approach to vaccination and a study on shortcomings related to low vaccination coverage in health care workers	O	The study on the added-value of a strategic and life-course approach to vaccination shall inform ongoing explorations regarding the Commission´s future vaccination policy, encouraging Member States in their efforts to share information, data and best practices regarding their vaccination policies and the monitoring of the impact of national vaccination programmes and to develop a holistic and life-course approach to vaccination. The study on the added-value of a strategic and life-course approach to vaccination shall inform ongoing explorations regarding the Commission´s future vaccination policy, encouraging Member States in their efforts to share information, data and best practices regarding their vaccination policies and the monitoring of the impact of national vaccination programmes and to develop a holistic and life-course approach to vaccination.	General study		220,000	Study cancelled due to a procurement issue: late reply from contractor to Commission's request, exceeding the formal deadline.	
6497	Mapping of EU market access paths for medical technologies with a focus on Health Technology Assessment	CWP	The study should allow for a better understanding of the current organisational and methodological framework for HTA of medical technologies across EU in order to identify the particularities of HTA for sector, as well as the potential needs and limitations of the EU HTA collaboration.	Impact assessment	Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Directorate-General for Research and Innovation	200,000	The planned study was not carried out. The budget has been globally committed to CHAFEA and part of it has been used to organise a Workshop on regional cooperation initiatives relevant for HTA. The objective of the workshop was to map ongoing initiatives at regional level to see how this would fit on broader EU wide cooperation.	
6546	Study to evaluate the impacts and the feasibility of options for the development of secondary legislation laying down rules for official controls on animals and goods entering the Union	O	Study to evaluate the impacts and the feasibility of options for the development of secondary legislation laying down rules for official controls on animals and goods entering the Union	General study		250,000	Study cancelled as the Impact Assessment of the Official Controls Regulation and the internal analysis of the respective empowerment proved sufficient.	

ANNEX 10: Specific annexes related to "Financial Management"

Table: Overview of the estimated cost of controls at Commission (EC) level#:

Grants to Member States in direct management							
Ex ante controls			Ex post controls			Total	
EC total costs (in EUR)	**funds managed (in EUR)***	**Ratio (%)*:** *Total ex ante control cost in EUR ÷ funds managed in EUR*	**EC total costs (in EUR)**	**total value verified and/or audited (in EUR)**	**Ratio (%):** *Total ex post control cost in EUR ÷ total value verified and/or audited in EUR***	**EC total estimated cost of controls (in EUR)**	**Ratio (%)*:** *Total cost of controls ÷ funds managed*
2.652.685	244.888.872	1,1%	349.028	30.497.974	1,1%	3.001.713	1,2%
Public procurement in direct management							
Ex ante controls			Ex post controls			Total	
EC total cost (in EUR)	**funds managed (in EUR)***	**Ratio (%)*:** *Total ex ante control cost in EUR ÷ funds managed in EUR*	**EC total costs (in EUR)**	**total value verified and/or audited (in EUR)**	**Ratio (%):** *Total ex post control cost in EUR ÷ total value verified and/or audited in EUR***	**EC total estimated cost of controls (in EUR)**	**Ratio (%)*:** *Total cost of controls ÷ funds managed*
2.432.848	38.240.371	6,4%	-	-	-	2.432.848	6,4%
Subsidy payments to agencies							
Ex ante controls			Ex post controls			Total	
EC total cost (in EUR)	**funds managed (in EUR)***	**Ratio (%)*:** *Total ex ante control cost in EUR ÷ funds managed in EUR*	**EC total costs (in EUR)**	**total value verified and/or audited (in EUR)**	**Ratio (%):** *Total ex post control cost in EUR ÷ total value verified and/or audited in EUR***	**EC total estimated cost of controls (in EUR)**	**Ratio (%)*:** *Total cost of controls ÷ funds managed*
1.017.333	180.432.208	0,6%	-	-	-	1.017.333	0,6%

OVERALL estimated cost of control at EC level							
Ex ante controls			**Ex post controls**			**Total**	
EC total cost (in EUR)	**funds managed (in EUR)***	**Ratio (%)*:** *Total ex ante control cost in EUR ÷ funds managed in EUR*	**EC total costs (in EUR)**	**total value verified and/or audited (in EUR)**	**Ratio (%):** *Total ex post control cost in EUR ÷ total value verified and/or audited in EUR***	**EC total estimated cost of controls (in EUR)**	**Ratio (%)*:** *Total cost of controls ÷ funds managed*
6.102.866	463.561.451	1,3%	349.028	30.497.974	1,1%	6.451.895	1,4%

The method of calculating the costs of controls is explained in section 2.1.1.4.

* 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.

** The total value verified and/or audited represents the EU contribution audited during ex-post control missions actually carried out in 2018 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 2018.

DG SANTE's ex-ante on-the-spot control missions are included in the column "ex-ante controls". To note that in 2018 DG SANTE carried out an unusually high number of ex-ante control missions due to the Avian Influenza crises (see explanations in section 2.1.1.1.1).

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

DG SANTE does not provide Annex 11 since section 2.1 already includes all information requested on the effectiveness of the internal control system.

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** (2017)	**Target** (2020) Europe 2020 target
69.2%	72.2%	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** (2017)	**Target** (2020) Europe 2020 target
122.8 million [Baseline adjusted: before:122.7]	112.9 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** 2018
0	**14**	**28**	**25**

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** 2018
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): 27 1.2.B. (ii): 27 1.2.B. (iii): 20

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 Member States			
Baseline 2014	**Interim Milestone** 2018	**Target** 2020	**Latest known results** 2018
168[25]/7800[26]	Decreasing value	Decreasing value (internal target)	411/7800
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** 2018
19/25[27]	Increasing	Increasing (internal target)	19/25

[25] 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

[26] 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

[27] 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[28] **Source of data:** Data can be procured using the Survey programs submitted by Member States			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	2017	2020 (agreed in Commission proposal COM(2013)327 final)	2018
50%	70%	100%	85%
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[29] **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)	2018
100%	100%	100%	85%
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 Member States (electronic system Europhyt-Outbreaks)			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	2017	2020	2018
42 days	20 days	8 days	23 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)	2018
0%	60%	95%	No data available[30]

[28] This indicator is also used in the CFF Programme Statement.

[29] This indicator is also used in the CFF Programme Statement.

[30] 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 2018:			
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
Human diseases			
Joint Action on vaccination	*Launch of the Joint Action*	*Q2 2018*	*Launched Q3 2018, kick-off meeting on 4-5 September 2018*
Joint action on preparedness and points of entry	*Launch of the Joint Action*	*Q2 2018*	*Launched Q2 2018, kick-off meeting 12-13 June*
Actions under Multiple Framework Contracts for the "Scripting, planning, conduction and evaluation of exercises, training and assessment implementing the Decision no 1082/2013/EU on serious cross-border threats to health"	*A table top exercise will focus on business continuity planning, and regional workshops on the implementation of the International Health Regulations.*	*Q3 2018*	*Q1-4* *Hybrid threat exercise: 30-31 January* *Workshop on the state of play on preparedness and response planning (including IHR implementation): 25-27 April* *Business continuity exercise: 9-10 October*
Animal and plant diseases			
Eradication/monitoring programmes:			
Bovine brucellosis	*No. of programmes which received co-financing*	*3*	*3*
Bovine tuberculosis	*No. of programmes which received co-financing*	*6*	*6*
Ovine/caprine brucellosis	*No. of programmes which received co-financing*	*5*	*5*
Bluetongue	*No. of programmes which received co-financing*	*15*	*15*
Swine diseases	*No. of programmes which received co-financing*	*16*	*16*
Avian influenza	*No. of programmes which received co-financing*	*25*	*25*
Transmissible Spongiform Encephalopathies (TSE), Bovine spongiform encephalopathy (BSE) and scrapie	*No. of programmes which received co-financing*	*27*	*26*

Output	Indicator	Target	Latest known results
Rabies	*No. of programmes which received co-financing*	*12*	*12*
Lumpy Skin Disease (LSD)	*No. of programmes which received co-financing*	*3*	*3*
National survey programmes for organisms harmful to plants	*No. of Member States with programmes which received co-financing*	*24*	*24*
Emergency measures	*Adoption*	*In course of 2018*	
Animal health emergency measures	*Signed grant decisions/grant agreements*		*25*
Plant health emergency measures (national dossiers)	*Signed grant decisions*		*10*
Other important outputs			
Output	**Indicator**	**Target**	**Latest known results**
Human diseases			
Commission Communication on protecting citizens against health threats from infectious diseases (PLAN/2017/1475)	*Adoption*	*Q3 2018*	*Suspended, pending further consideration by the next Commission*
Council Recommendation on strengthened cooperation against vaccine preventable diseases (PLAN/2017/1949)	*Adoption*	*Q2 2018*	*Commission Proposal adopted on 26/04/2018 – Council Recommendation adopted on 07/12/2018*
Commission Implementing Decision on the operational procedures of the epidemiological surveillance network (PLAN/2017/2137)	*Adoption*	*Q2 2018*	*Delayed until Q3 2019 due to highly technical nature of act and the lengthy administrative procedures.*
Staff Working Document on HIV/AIDS; tuberculosis and hepatitis (PLAN/2016/18 – SANTE)	*Publication*	*Q3 2018*	*Adopted on 19 July 2018 (SWD(2018)387)*
Adoption of Commission recommendation on personal data protection guidelines under Article 16(9)a of Decision	*Adoption*	*Q2 2018*	*Delayed until Q1 2019 to take account of and comply with the upcoming revision of Regulation 45/2001 on the*

Output	Indicator	Target	Latest known results
1082/2013/EU (PLAN/2017/2139)			*protection of individuals with regard to the processing of personal data by the Community.*
Foodborne diseases			
Revision of Commission Decision 2004/478/EC concerning the adoption of a general plan for food/feed crisis management (PLAN/2017/1095)	*Adoption*	*Q1 2018*	*Delayed until Q1 2019 due to wide level of consultations required.*
Animal diseases			
Commission Implementing Regulation on categorisation of listed animal diseases and listing of animal species (AHL) (PLAN/2017/1097)	*Adoption*	*Q3 2018*	*Delayed until Q1 2019 due to its link with delegated act for list of diseases, which is subject to scrutiny by Parliament and Council.*
Commission Delegated Regulation concerning list of transmissible animal diseases (AHL)(PLAN/2017/1098)	*Adoption*	*Q3 2018*	*Adopted on 25/07/2018*
Commission decisions on handling evolving epidemiological situations	*Adoption of emergency Decisions as necessary, according to the epidemiological situation*	*In course of 2018*	*43*
Commission rules on safe imports, trade and related aspects	*Adoption of Commission implementing rules.*	*In course of 2018*	*13*
Plant diseases			
Commission Delegated Act on the establishment of European Union reference laboratories for plant health (OCR) (PLAN/2017/1612)	*Adoption*	*Q1 2018*	*Adopted on 07/02/2018*
Commission Implementing Regulation on listing high risk plants and plants to be exempted from phytosanitary certificates (PHL) (PLAN/2017/1035)	*Adoption*	*Q4 2018*	*Adopted on 18/12/2018*
Commission Decisions on emergency measures against some specific pests	*Adoption of Decisions as necessary according to (new) outbreak situations*	*In course of 2018*	*7*
Commission Decisions with specific import requirements for trade	*Adoption of Decisions as necessary*	*In course of 2018*	*5*

Output	Indicator	Target	Latest known results
lines where there are too many import interceptions	*according to import interception notifications from Member States*		
Commission decisions on derogations for import from non-EU countries	*Adoption*	*In course of 2018*	*3*

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 [31] **Source of data:** ECDC surveillance data on human cases, Annual joint EFSA/ECDC report on zoonoses			
Baseline (2012)	**Milestone (2018)**	**Target (2020[18])**	**Latest known results (2018)**
94,278 confirmed cases of human salmonellosis	67000 cases	60000 (sustained negative trend in incidence cases)	91,662

Result indicator 1.2.B[32]: 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 of DG SANTE to provide data on the compliance rate.

Baseline	Interim Milestone	Target	Latest known results
2015	**2017**	**2020**	**2018**
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%[33]**	80%	85%	29/31=94%[34]

[31] This indicator is also used in the CFF Programme Statement.

[32] 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.

[33] 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.

[34] 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.

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 of DG SANTE to provide data on the compliance rate.			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	**2017**	**2020**	**2018**
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%	90%

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** 2018
0/0	5/5	5/5

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 2018:			
All new initiatives and REFIT initiatives from the Commission Work Programme			
Output	**Indicator**	**Target**	**Latest known results**
Fitness check of General Food Law, Regulation EC 178/2002 (2015/SANTE/427) Annex II of the CWP 2016	*Publication of the SWD*	*Q1 2018*	*Published on 15/01/2018*
REFIT evaluation of Nutrition and Health Claims Regulation (2015/SANTE/595) Annex II of the CWP 2016	*Publication of the SWD*	*Q2 2018*	*Delayed until Q2 2019 due to complexity of topic and the requirement for comprehensive collection of evidence.*
REFIT Evaluations on plant protection products and pesticides residues (2016/SANTE/197) Annex II of the CWP 2016	*Evaluation study by external contractor*	*Q2 2018*	*External study completed in June 2018 and published in October 2018.*
Evaluation of Food Contact Materials (FCM) (PLAN/2016/436)	*Evaluation study by external contractor, public consultation*	*Q4 2018*	*Study commenced Q3 2018. Public consultation to be launched Q1 2019.*
Evaluation of the feed additives Regulation (PLAN/2017/988)	*Publication of the SWD*	*Q3 2018*	*Delayed until Q4 2019 to incorporate results of an ongoing study.*

Output	Indicator	Target	Latest known results
Evaluation of the EU legal framework on food irradiation (PLAN/2016/506)	*Launch of external study*	*2018*	*The external study was launched on 17 September 2018*
Commission Regulation establishing a legal limit for the industrial trans fats content in foods (2016/SANTE/143) Reference in the text of CWP 2016	*Finalisation of impact assessment*	*Q3 2018*	*Internal DG SANTE work on the Impact Assessment was finalised on 29 August 2018, which was followed by an Inter-Service Consultation. The Commission proposal was voted by Member States on 7 December 2018.*
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
Control programmes on Salmonella	*No. of programmes which received co-financing*	*25*	*24*
Study to support the preparation of delegated Regulation on processed-cereal based food and baby food	*Completion*	*Q1 2018*	*The study was completed on 30 April 2018*
Food labelling database	*Operation of the database*	*Q3 2018*	*Delayed until Q2 2019 due to competing pressures*
Operational support services for the EU Platform on Food Losses and Food Waste	*Operation of digital platform and user activity*	*Q4 2018*	*Operational since November 2017*
EU Platform on food waste': 2 meetings in Lithuania and Belgium	*Carried out*	*Q2 2018 and Q4 2018*	*Meeting in Vilnius on 24 May 2018 and in Brussels on 6 December 2018*
Scientific and technical support for work of the EU Platform on food waste in areas related to food waste measurement and analysis of the effectiveness of food waste prevention initiatives (JRC or external contractor)	*Support provided*	*Q4 2018*	*Administrative agreement with JRC for Scientific and technical support for EU action on food waste prevention -signed in March 2018*
Innovation in food processing technologies (Portal for e-authorisations)	*Start of implementation on a Portal for e-authorisations for novel foods*	*Q1 2018*	*The e-submission system for submitting novel food applications and notifications was operational as of 4 January 2018. The Food innovation portal, which will integrate and provide a single point of entry for the food sectors, will be operational by mid-2019.*

Output	Indicator	Target	Latest known results
Other important outputs			
Commission Proposal for a Regulation on transparency and sustainability of the EU food and feed safety risk assessment model (PLAN/2017/2216)	*Adoption*	*Q2 2018*	*Adopted on 11 April 2018*
Implementing Regulation on voluntary food origin labelling (2015/SANTE/670)	*Adoption*	*Q2 2018*	*Adopted on 28 May 2018*
Regulatory measures on contaminants in feed and food following EFSA opinions	*Adoption*	*In course of 2018*	*One (1) measure adopted*
Authorisations for health claims made on foods and referring to children's development	*Adoption*	*In course of 2018*	*Delayed until Q4 2019 due to competing pressures.*
Report from the Commission on front-of-pack / simplified nutrition information (PLAN/2017/923)	*Adoption*	*Q4 2018*	*Delayed until Q1/Q2 2019 due to requirement for further discussion and evidence*
Guidelines for use of former foodstuff as feed (2016/SANTE/073)	*Publication*	*Q1 2018*	*Adopted on 13 April 2018*
Plant protection products and biocides			
Renewal/non-renewal of active substances for plant protection products	*Adoption*	*Ongoing regular activity in 2018*	*Regulations concerning the renewal/non-renewal of existing approvals were adopted for 20 active substances, 11 were renewals and 9 were non-renewals.* *Regulations concerning the approval/non-approval of new active substances were adopted for 4 active substances, 3 were approvals and 1 was a non-approval.* *Regulations concerning the approval/non-approval of basic substances were adopted for 3 basic substances, 2 were approvals and 1 was a non-approval.*
Guidance Document on the risk assessment of plant protection products	*Adoption*	*Q1 2018*	*Delayed until Q1 2019 due to complexity of file and ongoing discussions with Member States*

Output	Indicator	Target	Latest known results
on bees (2016/SANTE/036)			
Report to the Ombudsman on confirmatory information (12/2013/MDC) – (a request of the Ombudsman of 18 February 2016 and additional request of 8 June 2017)	*Transmission*	*February 2018*	*The Commission report was transmitted within the 2-year deadline to the Ombudsman by letter dated 14 February 2018.*
Commission Regulation on uniform principles for evaluation and authorisation of plant protection products (2016/SANTE/039)	*Adoption*	*Q1 2018*	*Delayed until Q4 2020 due to complexity of file*
Establishing maximum residues levels (MRL) for pesticides	*Adoption*	*Ongoing regular activity in 2018*	*1) Regulations adopted setting MRLs for 55 substances based on applications and/or implementing Codex MRLs. 2) Regulations adopted with a complete review of all existing MRLs for 11 substances.*
Establishing list of non-acceptable co-formulants in plant protection products	*Adoption*	*In course of 2018*	*Work is on-going. A first draft list was presented to the Standing Committee in December 2018 but is not yet agreed/voted due to the need for further consultations with Member States and stakeholders.*
Commission implementing Regulations renewing the approval of biocidal active substances	*Adoption*	*Ongoing regular activity in 2018*	*No Regulations adopted*
Commission implementing Regulations for approval or non-approval of biocidal active substances included in the review programme	*Adoption*	*Ongoing regular activity in 2018*	*10 approvals and 1 non approval*
Commission notice concerning a list of potentially low-risk active substances approved for use in plant protection products (PLAN/2017/1470)	*Adoption*	*Q1 2018*	*Adopted on 27/07/2018*

Output	Indicator	Target	Latest known results
Endocrine disruptors (ED)			
Amendment to Implementing Regulation (EU) No 844/2012 to adapt the renewal procedure in view of the new criteria for endocrine disrupting properties (PLAN/2016/483)	*Adoption*	*Q1 2018*	*Adopted on 07/11/2018*
Adapting data requirements in the Annexes to the BPR to the ED criteria (PLAN/2017/1636)	*Adoption*	*Q3 2018*	*Delayed until Q4 2019 due to ongoing discussions with Member States and need for additional experience with the implementation of the ED criteria in practice based on the agreed guidance with Member States' authorities*
Implementation of ED criteria – review programme biocidal active substances (PLAN/2017/1637)	*Adoption*	*Q2 2018*	*Delayed until Q4 2019 due to ongoing discussions with Member States and need for additional experience with the implementation of the ED criteria in practice based on the agreed guidance with Member States' authorities*
Implementation of ED criteria – early review of approved biocidal active substances (PLAN/2017/1638)	*Adoption*	*Q1 2018*	*Delayed until Q1 2021 due to the need for gaining additional experience with the implementation of the ED criteria in practice to assess whether there is a need for an implementing Regulation on the early review of active substances*
Implementation of ED criteria – renewal of biocidal active substances (PLAN/2017/1639)	*Adoption*	*Q2 2018*	*Delayed until Q4 2019 due to ongoing discussions with Member States and need for additional experience with the implementation of the ED criteria in practice based on the agreed guidance with Member States' authorities*
Implementation of ED criteria – early review of authorised biocidal products (PLAN/2017/1641)	*Adoption*	*Q1 2018*	*Delayed until Q1 2021 due to the need for gaining additional experience with the implementation of the ED criteria in practice to assess whether there is a need for an implementing Regulation on the early review of authorised products*
Commission Notice on guidance for the implementation of ED criteria for biocidal	*Adoption*	*Q2 2018*	*Delayed until Q4 2019 due to ongoing discussions with Member States and need for additional experience with the implementation of the ED*

Output	Indicator	Target	Latest known results
products (PLAN/2017/1654)			*criteria in practice based on the agreed guidance with Member States' authorities*
GMOs			
Commission Directive aiming to update of the Environmental Risk Assessment requirements in Directive 2001/18 concerning GMO (2015/SANTE/428)	*Adoption*	*Q1 2018*	*Adopted on 08/03/2018*
Repeal of the Guidelines on the Environmental Risk Assessment of GMOs (PLAN/2016/167)	*Adoption*	*Q1 2018*	*Adopted on 16/11/2018*
Authorisations of GMO's food and feed uses, and for cultivation	*Adoption*	*In course of 2018*	*27 authorisations for food and feed*
Authorisations of substances			
Commission Regulation on Bisphenol A as food contact material (2015/SANTE/534)	*Adoption*	*Q1 2018*	*Adopted on 12/02/2018*
Authorisations for new substances and new uses of already authorised substances used as food additives, food flavourings, novel foods, or substances used in plastic food contact materials	*Adoption*	*In course of 2018*	*- 21 novel foods including new uses of already authorised novel foods and traditional foods from third countries* *- Amendments made to the conditions of use of 16 authorised additives* *- Authorisation of one new flavouring* *- Amendments made to the conditions of authorisation of 14 flavouring substances* *- 6 new substances were authorised for use in plastic food contact materials, and the conditions of use were amended for another 5 authorised substances.*
Authorisation of recycling processes for plastics used in food contact materials	*Adoption*	*Q3 2018*	*Delayed until Q2 2019 due to the preparation of the approximately 138 Decisions.*
Withdrawal of certain substances (flavourings)	*Adoption*	*In course of 2018*	*Withdrawal of three flavouring substances*
Withdrawal of certain already authorised	*Adoption*	*In course of 2018*	*Withdrawal of three food additives*

Output	Indicator	Target	Latest known results
additives for which no applications were submitted and as a follow-up to the EFSA safety re-evaluation			
Feed additives/Feed hygiene			
Re-evaluations of authorisations, new authorisations , denial of authorisation, modifications of authorisations and renewal and non-renewal of authorisations of feed additives	*Adoption*	*In course of 2018*	*45 implementing Regulations (7 re-evaluation of authorisations, 28 new authorisations, 2 renewal, no non-renewal) approving 135 feed additives and denying 4 additive authorisations).*
Guidelines on the interpretation of Feed Hygiene Regulation (PLAN/2017/1270)	*Adoption*	*Q1 2018*	*Delayed until Q1 2019 due to ongoing legal consultations*
Implementation of the new Novel Food Regulation			
Implementing act clarify the procedures for requesting confidentiality treatment in novel food applications (PLAN/2016/267)	*Adoption*	*Q4 2018*	*Cancelled on 13/07/2018. This Implementing Act required by the new Novel Food Regulation is not mandatory. It has been decided that it is not necessary to prepare this act as the requirements on confidentiality laid down in the Regulation are sufficiently clear.*
Delegated act on updating and adjusting the definition of "engineered nanomaterials" to technical and scientific progress (PLAN/2016/269)	*Adoption*	*After the planned revision of the definition provided in Commission Recommendation 2011/696/EU has been finalised*	*The decision on the way forward with the file is deferred to the next College.*
Implementation of the legislation on plant reproductive material			
Implementing Decision of the European Parliament and the Council recognising EU equivalence for the certification of fodder plant seeds, oil and fibre plants and vegetable	*Adoption*	*Q4 2018*	*Adopted on 14/11/2017*

Output	Indicator	Target	Latest known results
seeds in Brazil and Moldova, for the purpose of their import into the EU (PLAN/2017/917)			
Animal Welfare			
Report to the European Parliament and the Council on the application of broilers Directive (2016/SANTE/114)	*Adoption*	*Q1 2018*	*Adopted on 13/04/2018*
Report to the European Parliament and the Council on protection of fish at the time of killing (2016/SANTE/138)	*Adoption*	*Q1 2018*	*Adopted on 06/03/2018*
Commission Implementing Regulation on designation of an EU reference centre for animal welfare (OCR) (PLAN/2017/1609)	*Adoption*	*Q1 2018*	*Adopted on 05/03/2018*

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[35]

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** 2018
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

[35] 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.

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**

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 2018:			
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
Legal proposal on a possible financial instrument for EU action on health under the new MFF	*Impact assessment Legal proposal adopted*	*02/2018 Mid-year 2018*	*The proposal was adopted by the Commission on 30 May*
Compass conference on mental health	*Conference*	*Q1 2018*	*3rd Mental Health Compass Forum took place on 8-9 February*
Implementation and scaling up of best practice: resource centre on health promotion and prevention and management of non-communicable diseases	*Web based tool established*	*Q2/2018*	*The best practice portal went online in April 2018*
Support to Member States in relation to alcohol related harm	*Service contract signed*	*Q3 2018*	*Contract signed Q4 2018, kick-off meeting scheduled for February 2019*
Framework Contract: support services to manage expert groups	*Contract signed*	*Q3/2018*	*The evaluation of the offers is still ongoing. Signature expected in Q1-Q2 2019.*
Direct Grant to the WHO/FCTC	*Contract signed*	*Q3/2018*	*Contract signature delayed until Q1 2019 in light of an increased funding allotment*
Direct agreement with the Joint Research Centre	*Contract signed*	*Q2/2018*	*Signed on 03/12/2018*
Reporting on delegated and implementing powers	*Adoption*	*Q3 2018*	*Report on Implementation of the third Programme of the Union's action in the field of health in 2015 – adopted on 12 December 2018*
JRC literature review on Front-of-Pack labelling	*Completion*	*Q3 2018*	*Completed and will be published at the same time as publication of the Commission report on front-of-pack (Q1/Q2 2019)*

Output	Indicator	Target	Latest known results
Other important outputs			
Q&A on Food Information to Consumers	*Adoption*	*Q1 2018*	*Adopted in May 2018*
Delegated act lowering the minimum protein content of follow-on formula as set out in Delegated Regulation (EU) 2016/127 (PLAN/2017/1369)	*Adoption*	*Q1 2018*	*Adopted on 29/01/2018*
Commission's report on Front-of-Pack labelling (PLAN/2017/923)	*Adoption*	*Q4 2018*	*Delayed until Q1/Q2 2019 due to requirement for further discussion and evidence*
Report on evaluation of the Consumers, Health, Agriculture and Food Executive Agency (CHAFEA) (PLAN/2016/406)	*Completed*	*Q4 2018*	*Delayed until Q1 2019 due to bundling of reporting from all executive agencies.*

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		2018
4	8	12	18	22

Result indicator 1.4.B: Level of average EU consumption of antibiotics in human **Source of the data**: European Centre for Disease Prevention and Control (ECDC)			
Baseline 2013	**Interim Milestone** 2017	**Target** 2021	**Latest known results** 2017
24.33[36] 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 less than 24.03 Defined daily doses/1000 inhabitants/day consumed in the Community and hospital sectors combined	30% reduction in EU consumption of antibiotics in human less than 16.7 Defined daily doses/1000 inhabitants/day consumed in the Community and hospital sectors combined	**23,4** defined daily doses/1000 inhabitants/day consumed in the Community and hospital sectors combined

[36] The indicator is based on the most recent report from ECDC on antimicrobial consumption (Nov 2017). https://ecdc.europa.eu/sites/portal/files/documents/Final_2017_EAAD_ESAC-Net_Summary-edited%20-%20FINALwith%20erratum.pdf. In this report the baseline for 2013 has slightly changed (due to the methodology): P.5, table 1: 22.3 EU/EE, p.10, table 3: 2.03 EU/EEA. The total for the baseline in 2013 is therefore 24.33, and consequently the 30% reduction target for 2021 is 17.03. As a result of this change in methodology, the baseline is slightly different from the baseline indicated in the SANTE Strategic Plan (23.9).

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 2018:			
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
State of Health in the EU: voluntary exchanges	*Completion*	*Q4 2018*	*7 voluntary exchanges took place during Q2 and Q3 2018*
State of Health in the EU: Launch of the second cycle.	*Health at a Glance published*	*Q4 2018*	*Report published on 22 November 2018*
Joint Action on Health Information	*Launch of the Joint Action*	*Q1 2018*	*Launch of Joint Action in March 2018*
Direct grant agreement with OECD to support the work on AMR, implementation of best practices and patient reported measures	*Contract signed*	*Q2 2018*	*Direct grant agreement with OECD to support patient reported measures signed on 18 December 2018*
Direct grant agreement with European Observatory on Health Systems and Policies	*Publication of a mapping and analysis of good practices and a book of evidence on good practices and enablers / obstacles to their transfer in the area of AMR.*	*Q4 2018*	*Final draft received and approved for payment December 2018. Publication expected Q1 2019.*
Commission Report on the operation of the Cross-border Healthcare Directive 2011/24/EU	*Adoption*	*Q3 2018*	*21/09/2018 COM(2018) 651 final*
Study on cooperation in cross-border regions and toolbox for authorities and stakeholders	*Completion*	*Q2 2018*	*Published on SANTE website on 27 March 2018*
Study on cross-border health services: enhancing information provision to patients, Guiding Principles for National Contact Points	*Completion*	*Q2 2018*	*Published on SANTE website on 20 July 2018*
Communication on Digital transformation of health and care in the context of	*Adoption*	*Q1 2018*	*Adopted on 25/04/2018*

Output	Indicator	Target	Latest known results
the DSM (PLAN/2017/1353)			
Joint Action supporting the eHealth network	*Launch of the Joint Action*	*Q2 2018*	*The Joint Action was signed on 19/06/2018 with starting date 01/08/2018*
eHealth Digital Service Infrastructure: building core services and national access, the eHealth Member State Expert Group	*6 national access points set up*	*Q2 2018*	*7 national access points (National Contact Points for eHealth) were set up in 2018. 4 of those were authorised to start exchanging data on 13 November 2018*
Study on regulatory aspects of cross-border telemedicine	*Completion*	*Q4 2018*	*The Study had been completed end of 2018 and made public in January 2019*
Expert Panel on Health's Opinions on topical challenges in health systems	*Publication*	*Q4 2018*	*Opinions were published at the end of 2018 and early 2019*
Evaluation of legal framework and Union legislation on blood and tissues and cells	*Completion*	*Q4 2018*	*The evaluation will be completed in Q2 2019, and was delayed due to a high number of Open Public Consultation respondents and inputs which had to be taken into account.*
Other important outputs			
Transposition check of the cross-border healthcare Directive 2011/24/EU: identification of gaps in national laws and start relevant procedures	*Advance discussions and pilots with Member States*	*Q4 2018*	*14 own-initiative investigations were opened (including 10 EU pilots and one infringements)*

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[37] **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**:		**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**
	2016	2018		2018
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**	**Target**	**Latest known results**
	2018	2020	2018
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[38]	1) On average around 87,700 pages viewed per day[39] 2) 5,926 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**	**Target**	**Latest known results**
	2018	2020	2018
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: 84; EU birth population covered: approx. 38% (approx. 2 million)

[37] This indicator is also used in the Health Programme Statement.

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

[39] 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 2018:			
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
Support to approved ERNs	*Multi- annual grants signed and operational*	*Q4 2018*	*Grants under adaptation (Grant Agreement Preparation – GAP). To be signed in Q1 2019*
Implementation support contract for ERNs' functioning networking, communication, developing of guidelines, capacity building	*Contract(s) signed*	*Q4 2018*	***Taxonomy**: SANTE/2017/B3/083 signed on 26/07/2017;* ***Admin support to ERN-CG**: SANTE2018/B3/042 signed on 21/12/2018;* ***Training & methodology**: SANTE/2018/B3/041 No applications received;* ***Clinical guidelines**: SANTE/2018/B3/030 deadline for submission 15/03/19 contract to be signed Q2 2019* ***Research capabilities**: SANTE/2018/B3/012 signed on 26/06/2018*
Assessment of healthcare providers wishing to join existing ERNs	*Contract signed*	*Q4 2018*	*Contract signed on 29 May 2018 / completed (under payment)*
Orphanet and orphacodes	*Contracts signed*	*Q3 2018*	*Orphanet signed on 19 Oct 2018* *Orphacodes signed on 06 Dec 2018*

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[40] **Source of data:** Commission internal (DG SANTE)		
Baseline (2014)	**Target** (2018) (agreed on the basis of available data to DG SANTE)	**Latest known results (2018)**
60% for recommendations from reporting cycles 2011 - 2013	70% for recommendations from reporting cycles 2014-2016	71% for recommendations from reporting cycle 2014-2016

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 2018:			
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
EU Reference Laboratories	*No. of laboratories funded*	*45*	*45*
Better Training for Safer Food	*No. of trainings organised*	*170*	*165*
Computerised systems + IT (e.g. TRACES, ADIS, ADNS, EUROPHYT)	*No. of computer systems funded*	*7*	*7*
Other important outputs			
Output	**Indicator**	**Target**	**Latest known results**
Commission Report to the European Parliament and the Council on the overall operation of official controls performed in Member States to ensure the verification of compliance with feed and food law, animal health and welfare rules (2014/SANTE/011)	*Adoption*	*Q2 2018*	*Adopted on 14/09/2018*
Commission Implementing Regulation	*Adoption*	*Q3 2018*	*Delayed until Q2 2019 due to the need to re-consult Legal*

[40] This indicator is also used in the CFF Programme Statement.

Output	Indicator	Target	Latest known results
listing the animals and goods to be subject to mandatory official controls at their entry into the Union, indicating their codes from the Combined Nomenclature (OCR) (PLAN/2017/1611)			*Service following the adoption of a revised list of CN codes by DG TAXUD*
Commission Implementing Decision establishing standard model forms for the submission of the annual report on the operation of their multi-annual national control plan by Member States (OCR) (PLAN/2017/1182)	*Adoption*	*Q4 2018*	*Delayed until Q1 2019 due internal procedural delays resulting in the postponement of the Inter-Service Consultation launching.*
210 Health and food audits and fact-finding missions	*80% of programmed audits completed 90% of the number of programmed and new audits completed*	*end 2018*	• *178 food audits and other on-the-spot visits completed (83% of programmed food audits completed and 91% of the number of programmed and non-programmed food audits completed).* • *42 health audits and other on-the-spot visits completed.*
Other DG SANTE activities to improve the performance of control systems:			
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:* *6 plenary meetings (all Member States) and 4 subgroup meetings (limited membership)*	*end 2018*	*4 meetings of the MANCP Network* *- 1 meeting of a MANCP Network subgroup* *- 2 meetings of the National Audits System (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:* *as per published SANTE audit and analysis work programme 2018*	*end 2018*	*The following meetings were organised:* • *Two on Sustainable Use of Pesticide Directive,* • *One on EUROPHYT Outbreaks,* • *One on EUROPHYT Interceptions,* • *One on Pesticide Risk Indicators* • *One on enforcement of Pesticide meeting* • *Three on animal welfare during transport* • *One on reducing the routine tail docking of pigs*

Output	Indicator	Target	Latest known results
			(not only MS, also NGOs and industry). *The meetings of the sub-groups of the AW Platform:* • *Two on animal welfare of animals during transport* • *One on reducing the routine tail docking of pigs* *In addition, six BTSF meetings to discuss results of overview reports on SANTE audits and fact-finding missions with Member States.*
Evaluation of facilities of Border Inspection Posts	*Number of evaluations:* *on average 15*	*end 2018*	*12 applications (10 from Member States and two from EEA-EFTA countries) were received in 2018 for evaluation of the layouts for new or for reconstruction of the existing BIP/IC facilities. Of these, 10 were approved in 2018 and two are in the process of being approved.*
Evaluation of Member States' and non-EU countries' residue monitoring plans	*Number of evaluations: 28 Member States plans and up to 50 non-EU country plans*	*end 2018*	*All 28 Member States' plans were evaluated. In addition 34 third country plans were evaluated (24 desk studies and 10 reviewed as part of the preparation of audits that took place in 2018)*
Management of lists of approved non-EU country establishments for the production of food of animal origin	*Approx. 500 requests from authorised countries to update individual commodity lists each year*	*end 2018*	*In 2018 there were 461 requests resulting in 973 additions, 907 deletions and 712 modifications to the lists in TRACES (2592 changes overall).*
Operation and further development of the notification system for plant health interceptions, EUROPHYT and reporting on plant pests	*Europhyt monthly and annual statistics and reports*	*end 2018*	*<u>Europhyt-Interceptions:</u>* *12 monthly statistics and one annual report (2017) published on SANTE.Europa* *<u>Europhyt-Outbreaks:</u>* *The 2017 annual report will be combined with the 2018 report and published in 2019.*
Plant health surveys	*Four reports on harmful organisms*	*end 2018*	*12 surveys were presented to the Standing Committee on Plants, Animals, Food and Feed (DG SANTE has replaced the reports with the presentation of surveys to the PAFF Committee.)*

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** (2017)	**Target** (2020)
17.1%	17.6 %	20%
Bookmark		
Impact indicator 2.2: Intra-EU trade in goods (% of GDP) **Source of the data**: Eurostat		
Baseline (2014)	**Latest known value** (2015)	**Target** (2020)
20.3% [Baseline adjusted: before: 20.4%]	20.2 %	Increase
Bookmark		

SANTE specific data[41]

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

	2009	2010	2011	2012	2013	2014	2015	2016	2017
EU28	4.63	4.64	4.61	4.64	4.63	4.64	4.61	4.62	4.56

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
	1.60	1.65	1.75	1.80	1.89	1.86	1.84	1.88	1.95

Source: Eurostat

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

	Jan.-Dec. 2013	Jan.-Dec. 2014	Jan.-Dec. 2015	Jan.-Dec. 2016	Jan.-Dec. 2017
IMPORT	86,194,576,113	90,755,763,919	99,907,896,892	100,912,609,562	103,535,904,574
growth (%)	0.3	5.3	10.1	1.0	2.6
EXPORT	75,968,307,498	78,826,380,613	81,979,596,790	83,965,519,303	87,531,762,228
growth (%)	6.7	3.8	4.0	2.4	4.2

Source: Eurostat

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

	Jan.-Dec. 2013	Jan.-Dec. 2014	Jan.-Dec. 2015	Jan.-Dec. 2016	Jan.-Dec. 2017
IMPORT	254,076,953,724	258,706,779,570	271,639,479,548	280,099,009,822	298,812,515,741
growth (%)	5.2	1.8	5.0	3.1	6.7
EXPORT	258,530,668,136	263,750,633,269	275,236,026,736	283,428,063,568	300,700,641,530
growth (%)	5.6	2.0	4.4	3.0	6.1

Source: Eurostat

[41] 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).

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	2018
2	12	22	29	22

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 2018:			
All new initiatives and REFIT initiatives from the Commission Work Programme			
Output	**Indicator**	**Target**	**Latest known results**
Commission initiative on strengthening of EU cooperation on Health Technology Assessment (2016/SANTE/144)	*Adoption*	*Q1 2018*	*Adopted on 31/01/2018*
Important items from work programmes/financing decisions/operational programmes			
Output	Indicator	Target	
Health Technology Assessments reports under EUnetHTA Joint Action	*- Reports prepared* *- Implementation and uptake of joint work*	*- 8 (Pharma) and 8 (other technologies) in course of 2018* *- in at least 10 Member States*	*22 reports prepared (15 on pharma, 7 on others), with an uptake by 10 Member States on average*

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** 2018
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	92.4% All new centrally authorised MA decisions 83.3% new MA Commission decisions for which there was an accelerated assessment by EMA[42]

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 2018:			
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
Study to support reporting requirement on centralised and decentralised procedures for pharmaceutical products	*Start*	*2018*	*On-going*
Report on additional monitoring of human medicines	*Adoption*	*Q2 2018*	*Delayed until Q2 2019 due to additional time needed to assess and consolidate the submitted information*
Report on EU pharmacovigilance activities (additional monitoring of certain medicines)	*Adoption*	*Q4 2018*	*Delayed until Q2/2019 due additional time needed to consolidate the submitted information*
Evaluation of EMA fee system	*Completion*	*Q3 2018*	*On-going and in final stage; delayed due to extended consultations with National Competent Authorities on*

[42] 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 for 2017.

Output	Indicator	Target	Latest known results
			their costs and involvement with EMA
Study on legislation on medicines for rare diseases	*Launch*	*Q1 2018*	*The study was launched in April 2018.*
Economic study on pharmaceutical incentives and rewards – to be completed	*Completion*	*Q1 2018*	*Study completed in May 2018*
Study on medicines for rare diseases and children including incentives	*Launch*	*2018*	*Same study as referenced above ("Study on legislation on medicines for rare diseases"; launched in April 2018)*
Marketing authorisation of medicines Authorisations of new medicines and variations to marketing authorisation of existing medicines, orphan designations for medicines for rare diseases	*Adoption*	*In course of 2018*	*169 orphan designations authorised in 2018; 22 orphan medicinal products authorised in 2018.*
Other important outputs			
Output	**Indicator**	**Target**	**Latest known results**
Report to the European Parliament and the Council on the penalties in the field of falsified medicines (2015/SANTE/469)	*Adoption*	*Q1 2018*	*Adopted on 26/01/2018*
Commission Decision acknowledging the full functionality of the clinical trials portal and database	*Adoption*	*Q4 2018*	*Delay with the development of the IT portal (postponed to 2021)*
Commission implementing Decisions establishing a list of non-EU countries with equivalent standards for active substances for medicinal products for human use pursuant to the falsified medicines Directive[43]	*Recognition of authorities of non-EU countries*	*Q4 2018*	*Positive assessment of Korea in December 2018. Commission implementing Decision to be adopted in 2019*

[43] Output refers to several separate country files; progress on individual files may vary.

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** 2018
0	5	15	7

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 2018:			
Other important outputs			
Output	**Indicator**	**Target**	**Latest known results**
Report to the Council Working Party on Public Health at Senior Level on Integrated care	*Publication*	*Q1 2018*	*Published in March 2017 (erroneous inclusion in 2018 Management Plan)*
Report to the Council Working Party on Public Health at Senior Level on Efficiency of Health Systems	*Finalisation*	*Q4 2018 (Publication 2019)*	*Report to be published in spring 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: 2018	**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 29% Exports 34% Total 32% Services: Imports 12% Exports 12% Total 12% FDI stocks: Imports 9% Exports 12% Total 11%	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%
(1) Goods bookmark to the denominator and goods per partner country in the nominator			
(2) Services bookmark to the denominator and services per partner country in the nominator			
(3) FDI stocks bookmark to the denominator and FDI stocks per partner country in the nominator			
(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
SHARE	4.8	4.5	4.5	4.5	4.7	5.0	5.2	5.4	5.1

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
SHARE	5.3	4.9	4.8	4.9	5.0	5.3	6.1	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 2017**	**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 2018**
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%	75%

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 2018**
Expansion of ICH membership The current members of ICH are 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[44]
Implementation of ICH guidelines by new members 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 50% of all ICH guidelines are implemented by new ICH members.
Increased harmonisation through Guideline development. 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[45]**	15 new or revised ICH guidelines	25 new or revised ICH guidelines	20[46]

[44] 5 Regulatory Members and 3 Industry Members.

[45] 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)

[46] Amongst these ICH harmonisation documents, there are 7 new or revised ICH guidelines.

Result indicator 3.1.C: WTO cases[47] brought against the EU **Source of data:** WTO			
Baseline (2014)	**Interim Milestone**	**Target** 2020	**Latest known results**
	2017	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.	2018
8	**7**	**5**	**12**

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 2018:			
Other important outputs			
Output	**Indicator**	**Target**	**Latest known results**
Coordinated EU positions on WHO resolutions	*Delivered*	*20*	*25*
EU co-sponsored WHO resolution	*Delivered*	*1*	*1*
EU statements for WHO meetings	*Delivered*	*9*	*22*
Coordination of positions in UN Meetings	*Delivered*	*2*	*2*
Common positions coordinated with EU Member States to facilitate the alignment of existing and planned EU legislation and initiatives with Codex standards	*Delivered*	*120*	*126 coordinated common positions (CAC and committees)*
Common positions coordinated with EU Member States to facilitate the alignment of the work of the Codex Task Force on antimicrobial resistance with existing and planned EU legislation and initiatives	*Development of two Codex texts: - Proposed Draft Revision of the Code of Practice to Minimize and Contain Antimicrobial Resistance - Proposed Draft Guidelines on Integrated Surveillance of Antimicrobial Resistance*	*In course of 2018*	*2 EU position papers Coordinated EU input for eWGs on the revision of the CoP and on the guidelines for AMR surveillance*
Coordinated EU position for the OIE's aquatic and terrestrial Code and Manual	*Delivered*	*4*	*121*
Coordinated EU	*Delivered*	*In*	*43*

[47] 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.

Output	Indicator	Target	Latest known results
Statements for the OIE General Assembly		*course of 2018*	
Coordinated EU positions in OECD meetings	*Delivered*	*In course of 2018*	*6*
Coordinated EU positions in documents and guidelines of the International Union for the Protection of New Varieties of Plants (UPOV)	*Delivered*	*In course of 2018*	*125 (1 meeting)*
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 2018*	*0 (no meeting)*
Coordinated EU positions in the WTO SPS Committees	*Delivered*	*In course of 2018*	*37*
Bilateral trade negotiations (SPS Chapter)	*Negotiate safe, secure and harmonised export conditions for EU products with non-EU countries*	*Balanced SPS Chapter within the ongoing FTA agreements*	*- Substantial progress on the enlargement of the current EU- Swiss Confederation agreement* *- Negotiation for the EU/Indonesia made an important step forward during the 6th round.* *- The second round of the SPS chapter of the EU/Australia trade agreement took place in Nov 2018 where good exchanges took place paving the way for quick progress.* *- The second round of negotiation of the SPS chapter of the EU/New Zealand trade agreement was organised in Wellington in October 2018. NZ wishes to keep a separate "veterinary agreement".* *- On the Mercosur negotiation, the EU has agreed to establish, in addition to the SPS Chapter, a separate Chapter on Dialogues that will include cooperation on biotechnology; food safety; animal and plant health*

Output	Indicator	Target	Latest known results
			science; animal welfare; and the fight against antimicrobial resistance. Technical work concluded in June 2018. *- With Chile, EU already has a SPS agreement, but the negotiation re-started for a comprehensive text.* *- The EU/India Agreement is an ambitious project, in which each topic will be subject of intense and difficult negotiations.* *- The EU/US TTIP negotiation, on hold since end 2016, has not resumed. Essential steps were, however, achieved during Summer 2018.* *- The EU/Japan Economic Partnership agreement negotiations were, successfully concluded, and the signature of the agreement took place on 17 July 2018.* *- On 25 June 2018, the Commission and Vietnam agreed on a final text for the EU-Vietnam Free Trade Agreement* *- With China, the second export market for EU agro-food products, negotiations remain intense, but an agreement is not foreseen in the short term. Step by step, the Chinese door is slowly opening and allows for an exponential growth of exports of EU agri-food products.*
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	*Delivered*	*Q4 2018*	*17*

Output	Indicator	Target	Latest known results
and gene drives for the Conference of the Parties of the Convention on Biological Diversity			

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	2018
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 2015	**Interim Milestone**	**Target**	**Latest known results**
	2017	2020	2018
4	3	1	3

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 2018:			
Other important outputs			
Output	**Indicator**	**Target**	**Latest known results**
Mutual Recognition Agreement: Contribution to the recognition of Member State Good manufacturing practices inspectorates by the US through the support of audits in the framework of Joint Audit	*Recognition of around 15 EU authorities as equivalent*	*Q4 2018*	*12 authorities recognized in 2018 as equivalent by the US FDA, indicator and target met* *Total: 20 authorities in total so far*

Output	Indicator	Target	Latest known results
Programme; implementation of the agreement			
Mutual Recognition Agreement: inclusion of veterinary medicines in the operational scope; process and timelines for the capability assessment of EU Member States by FDA and equivalence assessment of FDA by the EU	*Planning of audits*	*Q1/Q2 2018*	*Planning of audits for veterinary medicines endorsed by the Member States in 2018* *Audits conducted in UK, Bulgaria and France conducted in 2018*
Food Safety Systems Recognition exercise: Reduction in burden on EU Food Business Operators and Competent Authorities	*US to have completed assessment of seven pilot Member States with consequent decision taken on the need or otherwise for further assessments. EU to have completed assessment of the US food safety system*	*Q4 2018*	*In 2018 FDA completed the assessment of 4 MS (Denmark, Hungary Italy and Ireland);* *In July 2018, DG SANTE completed the assessment of the food control system of FDA.*
Organise a meeting of the EU-US Animal Health Technical Working Group: Facilitate trade in animal products and better cooperation on animal health issues (e.g. regionalisation) with the US	*Meeting held*	*Q4 2018*	*Meeting was held in December 2018*