ANNEX 1: Statement of the Resources Director

"I declare that, in accordance with the Commission's communication on clarification of the responsibilities of the key actors in the domain of internal audit and internal control in the Commission[1], I have reported my advice and recommendations to the Director-General on the overall state of internal control in the DG.

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

Signed

Matthew Hudson
Brussels, 23 March 2018

[1] Communication to the Commission: Clarification of the responsibilities of the key actors in the domain of internal audit and internal control in the Commission; SEC(2003)59 of 21.01.2003.

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

This annex refers to 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: NA	**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.	**Latest known results** (2017) In 2017 SANTE recruited four new female Heads of Unit which allowed SANTE to reach already 100% of its 2019 target.
Indicator 2: Percentage of staff who feel that the Commission cares about their well-being[1] **Source of data: Commission staff survey**		
Baseline: 42% in 2014 Staff survey	**Target**: gradual increase every year reaching above 50% by 2019	**Latest known results** (2016/2017). 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.**
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	**Latest known results** (2016/2017) 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.**

[1] 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.			
Main outputs in 2017:			
Description	**Indicator**	**Target**	**Latest known results**
Towards Excellent SANTE: 360° feedback exercise for senior and middle managers.	All managers have received an individual report on personal strengths and weaknesses.	100%	Completed for senior managers. For middle managers DG SANTE will participate in the DG HR led exercise which is under development.
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.	Roll out a series of training activities	Organisation of at least 5 trainings with a participation rate of on average 15 staff	6 teambuilding events were organised, 4 Units, 1 team of a Unit and 1 full Directorate.
Towards Excellent SANTE: Organisation of dedicated SANTE Fit@work activities in Brussels premises.	Number of sessions and participation rate	Between 5 and 10 sessions with a participation rate of on average 6 - 10 staff	2 new wellbeing activities launched in 2017 and all previous ones ongoing; number of participants varies (average in line with expectations). All sessions were advertised to other DGs.
Recruitment of female managers: fill vacant management posts.	Number of new female HoUs recruited	+2 female managers	Four new female HoUs were recruited.

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 will take 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.

SANTE did not submit any new impact assessments in 2014 and 2015. Therefore we have decided to take for a baseline an average success rate between years 2011 and 2013. In 2016, SANTE will aim to maintain the positive opinion rate at the baseline level. This will be a challenge given the increased standards introduced by the Better Regulation rules and the specific nature of SANTE policies whose impacts are very difficult to quantify and the complexity of some of our upcoming impact assessments. In the long-term, we aim to increase our positive opinion rate to 60%.

Baseline: average from 2011- 2013	Interim Milestone 2016	Target 2020	Latest known results
50%	50%	60%	n/a

SANTE performance for 2017

In 2017 DG SANTE submitted one Impact Assessment for review to the RSB. A positive opinion was granted upon re-submission. This was the only Impact Assessment completed by the DG in 2017 and the second in the last 3 years. It is expected that the number of Impact Assessments during the years to come will remain insufficient to obtain a representative sample or 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 foresee 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. DG SANTE has identified 37 legal acts (Regulations and Directives) in its acquis when setting the baseline back in 2015. 11 legal acts were covered by evaluation/assessment/review and had already been evaluated in the respective 5 year period (2010-2015). In line with the Commission guidelines soft policies have not been covered by this indicator.

Relevance of Indicator 2: The application of better regulation practices would progressively lead to the stock of legislative acquis covered by regular evaluations to increase.
Source of data: Planning of Evaluations and studies (2008; 2016); Commission Reporting obligations under the SANTE legislation (own source)

Baseline 2015	Interim Milestone 2016	Target 2020	Latest known results
Percentage of the DG's regulatory acquis covered by evaluations and Fitness Checks not older than five years (2010-2015). Baseline: 30% of SANTE legislation has been evaluated in the last 5 years.	Positive trend compared to baseline (further 24% of SANTE legislation will be evaluated)	Positive trend compared to baseline	Value of the indicator for 2017- 40%

SANTE performance for 2017

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 within the last five years; (*idem)*
c) implementing acts.

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.

At that time, 30% of the acquis had been subject to a "recent" evaluation.

In 2017 the DG completed the planned evaluations of four other acts. In 2016 it evaluated another two acts. Therefore since 2015 when the baseline was set, the DG evaluated in total 17 acts including the 11 acts already evaluated at the time of setting the baseline. Meanwhile the acts referred to in a) and b) above have been adopted and are part of DG SANTE acquis (now totalling 41 major acts). As a result the current value of the indicator is at around 40% ((11+2+4)/41).

The cancellation of eight evaluations foreseen in the 2017 MP initially planned to start after 2020 does not affect the indicator because all the cancelled items were supposed to start from 2019 onwards.

The positive trend of this indicator is therefore confirmed.

Indicator 3: Percentage of evaluations planned and finalised in the last year (2015)

Explanation: Evaluations might cover not only regulatory acquis but also soft policies 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. **Relevance of Indicator 3:** This indicator assesses planning performance of the evaluated areas.

Source of data: Planning of evaluations and Studies 2015

Baseline	Interim Milestone 2016	Target 2020	Latest known results 2017
Number of evaluations planned in the next 5 years (until 2020) Planned: 26[2]	Percentage of evaluations with final report 27% (7 evaluations - please see 2016 MP Annex 3)	100% of evaluations planned are finalised (final report)	42%

SANTE performance for 2017

DG SANTE started 2017 with 8 (eight) on-going evaluations from previous years. Of these ongoing ,four evaluations were completed in 2017 as planned. In addition, *all 5 new evaluations (listed in section 2.2.2) planned to start in 2017 were on time. Two evaluations have already been finalised in 2016.*

The indicator value is equal to 42% ((4+2+5)/26)

In short , SANTE delivered according to the plan.

[2] Number taken from the Strategic Plan: https://ec.europa.eu/info/publications/strategic-plan- 2016-2020-health-and-food-safety_en

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 2017, although the percentage in 2017 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.

Indicator 1 shows a good improvement compared to 2016 (1.28%). In 2017 DMO reports on registered documents that are not filed were sent very regularly and followed-up closely. Documents that are still not filed for 2017 are expected to be filed soon. It is likely that statistics will show in March 2018 that the target of 0% is reached also for 2017.

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[3] (ratio) **Source of data:** *Hermes-Ares-Nomcom (HAN)[4] statistics*			
Baseline 2015	Target (2020)	Latest known results 2016	**Latest known results 2017**
1.24%	0%	1,28%	**0,51%**
Indicator 2: Number of HAN files readable/accessible by all units in the DG **Source of data:** *HAN statistics*			
Baseline 2015	Target (2020)	Latest known results 2016	**Latest known results 2017**
98%	75%	98,33%	**97,98%**
Indicator 3: Number of HAN files shared with other DGs **Source of data:** *HAN statistics*			
Baseline 2015	Target (2020)	Latest known results 2016	**Latest known results 2017**
98%	75%	98,33%	**97,98%**
Indicator 4: Percentage of units using collaborative tools to manage their activities			
Baseline (2015)	Interim Milestone (2018)	Target (2020)	Latest known results (2017)
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)
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)	Latest known results (2017)
100%	100% (in total 512 requests)	100%	100% (in total 732 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)	Latest known results (2017)
20%	60%	90%	50%

**) A new version of the collaborative platform, scheduled for mid 2018, will allow all Units to have a new uniform way of managing their activities and projects.*

[3] 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.

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

Annex 2.4 External Communication

Tables (3A – 3G) on the objectives contributing to SANTE Strategic Plan 2016/2020 with the presentation of the main outputs are included here below.

Table 3.A

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 2017: Specific communication actions in the four main areas: Antimicrobial Resistance (AMR), Country knowledge in Health care systems, European Reference Networks (ERN), Food Waste and crisis preparedness/management, notably in Plant Health and the EU as a global health and food safety player.			
Output	**Indicator**	**Target 2020**	**Latest known results**
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 graphic material	*Number of DG SANTE unique visitors, social media impressions, participants at events, reach of media buying, reach of media seminars and info session, page views of press material, subscribers to e-news, print runs, online views of graphic material*	50 000[5] *(Baseline 2015: 222 710 099)*	✓ 33 824 283 contacts in 2017[6] ✓ 21 043 125[7] contacts in 2016
Output	**Indicator**	**Target 2017**	**Latest known results**
Debate with Commissioner on the occasion of 7 Citizens' Dialogues organised during 2017[8]	*Number of participants*	*1 260 participants in Citizens' Dialogues in 2017.*	✓ 1 770 participants in the events ✓ Media outreach 3 239 647 (viewers, listeners, readers) ✓ Social media and viewers of the webstreaming 2 742 159 ✓ Total contacts: 5 983 576

[5] This figure, coming from the Strategic Plan 2016-2019, did not take into account web visitors and Twitter impressions figures, which alone amount for more than 13 million views/year.

[6] Reach of communication activities in 2017 includes Citizens' Dialogues (5 983 576), DG SANTE Web unique page views (9.658,615), Twitter (12 635 800 impressions over the year – 1 735 800 for @Food_EU and 10 900 000 for @EU_Health according to Twitter Analytics), LinkedIn (94 225 impressions (paid campaign for State of Health 2017 via the European Commission central account); visitors to stands JPO (4 500), AMR (928 623 including Press release and 48.497 web visits and impressions Action Plan); European Reference Networks (1 076 042 including 77 133 page views, and social media impressions); State of Health in the EU (1 127 415 including 77 606 page views, social media sponsored posts and video views); Press Releases and Memos (91 020 page views), e-news (28 531 subscribers and 355 741 emails opened), newsletters (50 165 subscribers and 1 077 537 emails opened), publications (32 020 printed copies distributed and 6 353 online views*); Info-graphs & Factsheets (10 816 page views)

* Extrapolation: due to a technical migration, we can only gather the exact numbers from July to December).

[7] The big difference with 2015 baseline figures lays on the termination of the Ex-Smokers campaign which ended in 2016, which alone represents around 90% of 2015 reach.

[8] Citizen Dialogues are organised by DG COMM and the Commissioner's Cabinet

Table 3.B

Objective: The role of the EU as a global best practice region in the 'One Health' EU Action Plan to combat AMR This objective contributes to specific objective 1.4. Effective, accessible and resilient healthcare systems in the EU			
Main outputs in 2017: Press event, animated clip and promotion plan, web updates, social media promotion			
Description	**Indicator**	**Target**	**Latest known results**
Press Event- Journalist invited	- *Number of journalists attending Press Conference (November 2017)* - *Percentage of journalists who write a follow-up article* - *Number of follow up articles*	- *Up to 30 journalists attending* - *70% journalists write a follow up article or publish a news item in the next 3 months* - *24 articles published*	– 25 journalists attended ✓ 80% of journalists produced at least one article and/or radio and/or TV spot within 3 months ✓ 44 articles and TV spots)
Animated 90" clip and promotion plan (including through a broadcasting campaign by Euronews between 29 June and 19 July)	- *Number of views*	- *20.000 views in 6 months*	✓ 29.165 views EC AV Portal ✓ 375.000 ad impressions on Euronews online, with a CTR of 4.16% ✓ 367.000 impacts on Euronews TV
Web	- *number of visits to DG SANTE Website section on AMR*	- *10% increase of visits to DG SANTE Website section on AMR (baseline 2016: 35.400 visits)*	✓ 48 497 page views representing over 50% increase
Social media	- *number of social media posts* - *social media reach (regular and paid)*	- *At least 30 dedicated social media posts (at least 5 paid)* - *35.000 Twitter accounts reached* - *500 000 impressions*	✓ 94 social media posts (7 paid) ✓ More than 1 million accounts reached at the launch of the action plan ✓ 654 263 impressions (organic, throughout 2017, via @EU_Health and @Food_EU) ✓ 2 733 206 impressions (paid campaigns)

Table 3.C

Objective: Increased awareness and stakeholder engagement on the "State of the Health in the EU" cycle **This objective contributes to 1.4. Effective, accessible and resilient healthcare systems in the EU**			
Main outputs in 2017: Press event, animated clip and promotion plan, web updates, social media promotion on the delivery of 28 country health profiles and a Companion Report, on the basis of the analytical work by the OECD and the European Observatory of Health Systems and Policies			
Description	**Indicator**	**Target**	**Latest known results**
Press Conference and five national media briefings organised (ES, FR, PL, AT, LU	– *number of journalists attending the press events (November 2017)* – *number of articles covering the event*	– *15 journalists attending* – *70% journalists write an article on the report or publish a news item in the next 3 months*	✓ 20 journalists attended the Press Conference in Brussels ✓ 40 journalists attended one of the national briefings ✓ 100% of journalists attending the Press Conference wrote an article or publish a news item ✓ Press released downloaded over 5 300 times ✓ 185 press articles and radio/TV mentions collected ✓ the media coverage reached a potential audience of as much as 40 to 50 million people
Web	– *number of views of the report/summary on SANTE website*	– *5 000 web visits in the 6 months after the publication*	✓ 16 294 web visits and 31 772 page views[9]
Social media	- *number of social media posts* - *social media reach (regular and paid)*	– *20 tweets (at least 4 paid)* – *35 000 Twitter accounts reached* – *300 000 impressions*	✓ 51 tweets (18 paid) ✓ more than 1 million Twitter accounts reached in the days after the launch ✓ 165 558 impressions November 2017 onwards (organic via @EU_Health) ✓ Targeted promotion campaign: 1.4 million impressions on Twitter; 94 225 on Linkedin
Animated video-clip	- *Number of views*	- *5 000 views in 6 months*	✓ over 12 000 views EC AV Portal ✓ 887.599 views on Twitter (paid campaign)

[9] Between 23 November 2017 and 17 January 2018

Table 3.D

Objective: Increased awareness and stakeholder engagement on the European Reference Networks (ERNs) **This objective contributes to specific objective 1.5. Increased access to medical expertise and information for specific conditions**			
Main outputs in 2017: ERN 3rd conference, promotion (web, social media, media) and organisation 4th conference			
Description	**Indicator**	**Target**	**Latest known results**
3rd ERN conference in Vilnius in March 2017 and organisation of the 4th conference in 2018	– *number of journalists attending the conference* – *number of articles covering the topic of ERNs following the conference*	– *5 journalists attending ERN conference* – *5 articles on ERN topic following the conference*	– 4 attending journalists – 4 news items (articles / TV reportage)
Web	– *number of views on ERN web page on SANTE website*	– *5% increase in ERN page views (baseline 2016: 64 617)*	✓ 77 133 page views representing nearly 20% increase
Social media	- *number of social media posts* - *social media reach (regular and paid)*	- *10 regular & 2 sponsored tweets* - *30 000 accounts reached* - *450 000 impressions (baseline 2016: 637 666 impressions)*	✓ 39 tweets (5 paid) ✓ More than 127 000 accounts reached ✓ 209 258 impressions throughout the year 2017 (organic via @EU_Health) ✓ 1 420 147 impressions (paid campaigns)
Media Info session (28 February 2017 at the occasion of the Rare Disease Day. Organised at the Leuven University Hospital	- *Number of journalists attending media info session* - *Percentage of journalists who write a follow-up article* - *Number of follow up articles*	- *Up to 15 journalists attending media info session* - *70% journalists write a follow up article or publish a news item in the next 3 months* - *10 articles published*	✓ 18 journalists attended ✓ 78% journalists produced at least one article or news item within 3 months ✓ Financial Times – remote coverage of the event (Facebook live) ✓ 28 articles, blogs or TV spots in total

Table 3.E

Objective: Increased interaction with Food Waste stakeholders and relevant national authorities in the area of Food Waste and the Circular Economy Package. **This objective contributes to specific objective 1.2. Safe and sustainable food and feed production systems**			
Main outputs in 2017: Social media action on Food Waste			
Description	**Indicator**	**Target**	**Latest known results**
Social media	– *number of social media posts* – *social media reach (regular and paid)*	- *15 tweets (at least 4 paid)* – *20 000 accounts reached* – *200 000 impressions*	✓ 34 tweets ✓ 1 Facebook post (central account) ✓ 50 000 accounts reached – 169 716 impressions (organic, throughout 2017 via @Food_EU)
Web	– *number of views on Food Waste web page on SANTE website*	– *Food Waste page views (no baseline)*	✓ 82 523 page views

Table 3.F

Objective: Increased confidence in the EU control systems and recognition of the added value of action at EU level, thus contributing to facilitate trade. This objective contributes to specific objective 1.6. Effective, efficient and reliable official controls			
Main outputs in 2017: multimedia material to be promoted on web, stakeholder events and social media			
Description	**Indicator**	**Target**	**Latest known results**
Series of videos explaining the role of the DG SANTE's Directorate on Health and Food Audits and Analysis in the EU control systems and the identification and dissemination of best practices.	– *Number of views in DG SANTE Website*	– *2 000 views (videos to be released mid-2017)*	✓ 21 715 views
Social media	– *number of social media posts* – *social media reach (regular and paid)*	– *At least 4 regular tweets* – *15 000 accounts reached* – *100 000 impressions*	✓ 35 tweets ✓ 40 000 accounts reached ✓ 138 484 impressions (organic, throughout 2017 via @Food_EU)

Table 3.G

Objective: Trade partners' understanding of Sanitary and Phytosanitary (SPS) requirements is facilitated in the fields of Plant Health, Animal Health and Food Safety This objective contributes to specific objectives 1.6. Effective, efficient and reliable official controls, 1.4. Effective, accessible and resilient EU healthcare systems, 1.7. Increased EU influence in international fora and 3.1. A balanced agreement with the US on pharmaceutical products and in SPS area.			
Main outputs in 2017: Three animated clips and factsheets on Food Safety, Plant Health and Animal Health			
Description	**Indicator**	**Target**	**Latest known results**
3 animated clips on Food Safety, Plant Health and Animal Health	- *Number of views online*	- *2 000 views in 6 months*	– The video clips have not been done*
3 Factsheets on Food Safety, Plant Health and Animal Health	- *Number of clicks online* - *Number of factsheets printed and distributed*	- *2 000 clicks* - *1 500 factsheets printed*	✓ 5 507 clicks

* The production of these videos has been cancelled by the policy unit in order to deliver on other policy priorities. Social media activities to promote these videos have not been therefore carried out.

Annex 3 Financial Reports - DG SANTE - Financial Year 2017

Additional comments

TABLE 1: OUTTURN ON COMMITMENT APPROPRIATIONS IN 2017 (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	2,50000	2,50000	100,00 %
Total Title 05			2,50000	2,50000	100,00%
Title 07 Environment					
07	07 02	Environmental policy at Union and international level	0,50000	0,50000	100,00 %
Total Title 07			0,50000	0,50000	100,00%
Title 09 Communications networks, content and technology					
09	09 03	Connecting Europe Facility (CEF) - Telecommunications networks	2,73800	2,73800	100,00 %
Total Title 09			2,73800	2,73800	100,00%
Title 17 Health and food safety					
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	20,27917	20,21264	99,67 %
	17 03	Public health	190,02091	176,45284	92,86 %
	17 04	Food and feed safety, animal health, animal welfare and plant health	246,89110	245,39314	99,39 %
Total Title 17			457,19119	442,05863	96,69%
Title 26 Commission's administration					
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,66290	0,53574	80,82 %
Total Title 26			0,66290	0,53574	80,82%
Title 33 Justice and consumers					
33	33 01	Administrative expenditure of the 'Justice and consumers' policy area	1,73226	1,73226	100,00 %
	33 04	Consumer programme	0,02349	0,02349	100,00 %
Total Title 33			1,75575	1,75575	100,00%
Total DG SANTE			465,34783	450,08811	96,72 %

** 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*

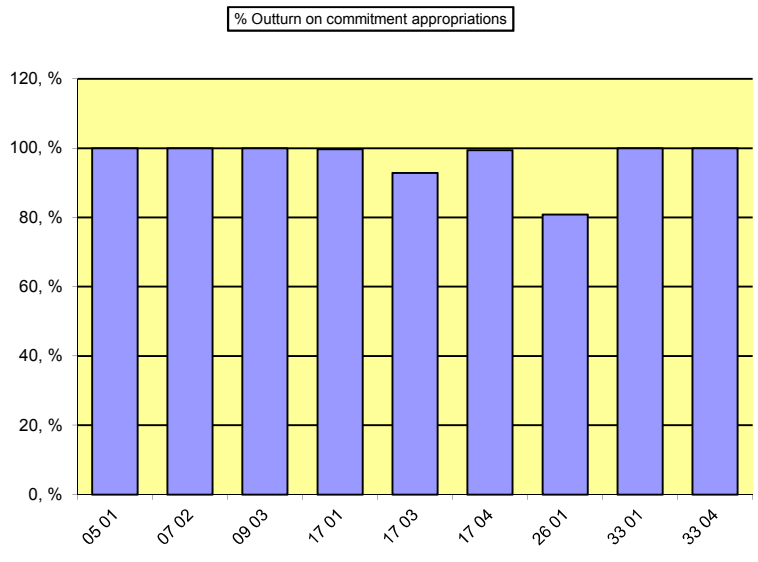

TABLE 2: OUTTURN ON PAYMENT APPROPRIATIONS IN 2017 (in Mio€)					
Chapter			Payment appropriations authorised *	Payments made	%
			1	2	3=2/1
Title 05 Agriculture and rural development					
05	05 01	Administrative expenditure of the 'Agriculture and rural development' policy area	2,50000	2,50000	100,00 %
	05 04	Rural development	0,25000	0,24853	99,41 %
Total Title 05			2,75000	2,74853	99,95%
Title 07 Environment					
07	07 01	Administrative expenditure of the 'Environment' policy area	0,09084	0,08984	98,90 %
Total Title 07			0,09084	0,08984	98,90%
Title 09 Communications networks, content and technology					
09	09 03	Connecting Europe Facility (CEF) - Telecommunications networks	1,87351	1,87351	100,00 %
Total Title 09			1,87351	1,87351	100,00%
Title 17 Health and food safety					
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	16,00911	12,11111	75,65 %
	17 03	Public health	193,48564	179,07393	92,55 %
	17 04	Food and feed safety, animal health, animal welfare and plant health	230,47449	227,14797	98,56 %
Total Title 17			439,96924	418,33301	95,08%
Title 26 Commission's administration					
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,87665	0,54262	61,90 %
Total Title 26			0,87665	0,54262	61,90%
Title 33 Justice and consumers					
33	33 01	Administrative expenditure of the 'Justice and consumers' policy area	1,73226	1,73226	100,00 %
Total Title 33			1,73226	1,73226	100,00%
	Total DG SANTE		447,29249	425,31977	95,09 %

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

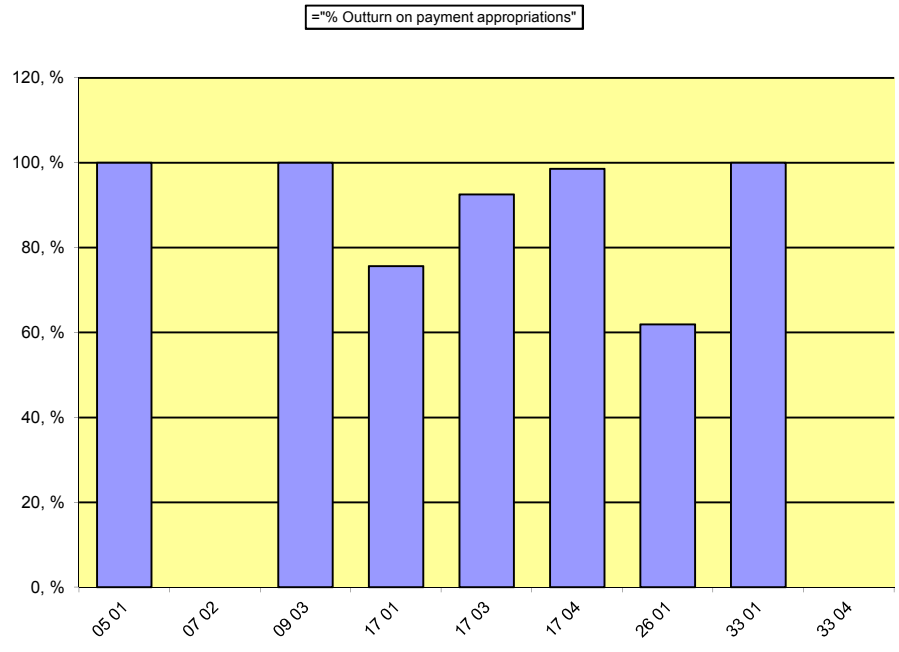

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2017 (in Mio€)									
Chapter			2017 Commitments to be settled				Commitments to be settled from financial years previous to 2017	Total of commitments to be settled at end of financial year 2017	Total of commitments to be settled at end of financial year 2016
			Commitments 2017	Payments 2017	RAL 2017	% 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	2,50000	2,50000	-	0,00 %	-	-	-
	05 04	Rural development	-	-	-	0,00 %	0,18882	0,18882	0,4374
Total Title 05			2,50000	2,50000	-	0,00%	0,18882	0,18882	0,4374
Title 07 : Environment									
07	07 01	Administrative expenditure of the 'Environment' policy area	-	-	-	0,00 %	-	-	0,0908
	07 02	Environmental policy at Union and international level	0,50000	-	0,50000	100,00 %	-	0,50000	-
Total Title 07			0,50000	-	0,50000	100,00%	-	0,50000	0,0908
Title 09 : Communications networks, content and technology									
09	09 03	Connecting Europe Facility (CEF) - Telecommunications networks	2,73800	-	2,73800	100,00 %	3,76803	6,50603	5,6415
Total Title 09			2,73800	-	2,73800	100,00%	3,76803	6,50603	5,6415
Title 17 : Health and food safety									
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	20,21264	14,07763	6,13501	30,35 %	-	6,13501	5,1730
	17 03	Public health	176,45284	164,01115	12,44169	7,05 %	14,14444	26,58613	31,5606
	17 04	Food and feed safety, animal health, animal welfare and plant health	245,39314	54,81663	190,57651	77,66 %	91,53639	282,11290	290,3831
Total Title 17			442,05863	232,90541	209,15322	47,31%	105,68082	314,83404	327,1167
Title 26 : Commission's administration									
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,53574	0,34101	0,19473	36,35 %	-	0,19473	0,2137
Total Title 26			0,53574	0,34101	0,19473	36,35%	-	0,19473	0,2137
Title 33 : Justice and consumers									
33	33 01	Administrative expenditure of the 'Justice and consumers' policy area	1,73226	1,73226	-	0,00 %	-	-	-
	33 04	Consumer programme	0,02349	-	0,02349	100,00 %	-	0,02349	0,02986
Total Title 33			1,75575	1,73226	0,02349	1,34%	-	0,02349	0,02986
	Total DG SANTE		450,08811	237,47868	212,60943	47,24 %	109,63768	322,24711	333,53002

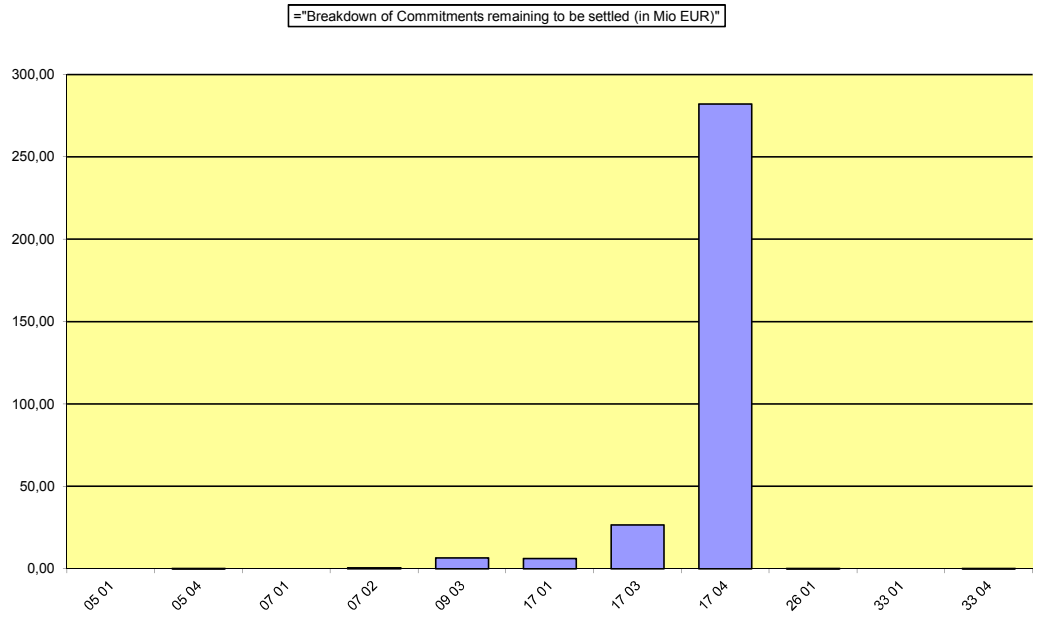

TABLE 4 : BALANCE SHEET SANTE

BALANCE SHEET	2017	2016
A.I. NON CURRENT ASSETS	17.123.583,50	16.121.519,76
A.I.1. Intangible Assets	2.902.780,63	1.349.643,55
A.I.2. Property, Plant and Equipment	13.315.413,02	14.771.876,21
A.I.5. Non-Current Pre-Financing	905.389,85	-
A.II. CURRENT ASSETS	29.813.758,55	28.387.889,48
A.II.2. Current Pre-Financing	17.929.766,82	14.769.914,58
A.II.3. Curr Exch Receiv &Non-Ex Recoverables	2.194.709,66	1.558.083,71
A.II.4. Inventories	9.683.858,70	12.052.523,59
A.II.6. Cash and Cash Equivalents	5.423,37	7.367,60
ASSETS	**46.937.342,05**	**44.509.409,24**
P.I. NON CURRENT LIABILITIES	(6.163.396,71)	(8.210.999,88)
P.I.3. Non-Current Financial Liabilities	(6.163.396,71)	(8.210.999,88)
P.II. CURRENT LIABILITIES	(276.266.464,90)	(182.524.165,02)
P.II.2. Current Provisions	(86.601.166,45)	(14.448.890,53)
P.II.3. Current Financial Liabilities	(2.047.603,09)	(2.045.664,07)
P.II.4. Current Payables	(17.249.976,52)	(6.938.020,53)
P.II.5. Current Accrued Charges &Defrd Income	(170.367.718,84)	(159.091.589,89)
LIABILITIES	**(282.429.861,61)**	**(190.735.164,90)**
NET ASSETS (ASSETS less LIABILITIES)	**(235.492.519,56)**	**(146.225.755,66)**

P.III.2. Accumulated Surplus/Deficit	1.497.128.587,53	1.133.462.551,07

Non-allocated central (surplus)/deficit*	(1.261.636.067,97)	(987.236.795,41)

TOTAL	**0,00**	**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 5 : STATEMENT OF FINANCIAL PERFORMANCE SANTE

STATEMENT OF FINANCIAL PERFORMANCE	2017	2016
II.1 REVENUES	283.241,19	(2.057.491,99)
II.1.1. NON-EXCHANGE REVENUES	(3.765.463,18)	(6.188.701,97)
II.1.1.5. RECOVERY OF EXPENSES	(2.406.012,25)	(200.218,42)
II.1.1.6. OTHER NON-EXCHANGE REVENUES	(1.359.450,93)	(5.988.483,55)
II.1.2. EXCHANGE REVENUES	4.048.704,37	4.131.209,98
II.1.2.1. FINANCIAL INCOME	(2,35)	
II.1.2.2. OTHER EXCHANGE REVENUE	4.048.706,72	4.131.209,98
II.2. EXPENSES	498.022.094,61	365.680.915,85
II.2. EXPENSES	498.022.094,61	365.680.915,85
II.2.10.OTHER EXPENSES	102.694.898,45	32.875.192,96
II.2.2. EXP IMPLEM BY COMMISS&EX.AGENC. (DM)	241.380.674,69	187.023.522,80
II.2.3. EXP IMPL BY OTH EU AGENC&BODIES (IM)	153.938.044,27	141.012.276,39
II.2.4. EXP IMPL BY 3RD CNTR & INT ORG (IM)	(134.125,20)	4.459.602,12
II.2.5. EXP IMPLEM BY OTHER ENTITIES (IM)	203.315,88	301.077,90
II.2.6. STAFF AND PENSION COSTS	(74.920,28)	(92.128,15)
II.2.8. FINANCE COSTS	14.206,80	101.371,83
STATEMENT OF FINANCIAL PERFORMANCE	**498.305.335,80**	**363.623.423,86**

Explanatory Notes (facultative):
Please enter the text directly (no copy/paste of formatted text which would then disappear when saving the document in pdf), use \\\"ctrl+enter\\\" to go to the next line and \\\"enter\\\" to validate your typing.

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

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

TABLE 5bis : OFF BALANCE SHEET SANTE		
OFF BALANCE	**2017**	**2016**
OB.1. Contingent Assets	-	-
GR for pre-financing	-	-
OB.2. Contingent Liabilities	(362.327.252,56)	(356.785.817,92)
OB.2.6. CL Other	(7.327.252,56)	(1.785.817,92)
OB.2.7. CL Amounts relating to legal cases	(355.000.000,00)	(355.000.000,00)
OB.3. Other Significant Disclosures	(129.759.455,12)	(163.676.272,11)
OB.3.2. Comm against app. not yet consumed	(129.759.455,12)	(163.676.272,11)
OB.4. Balancing Accounts	492.086.707,68	520.462.090,03
OB.4. Balancing Accounts	492.086.707,68	520.462.090,03
OFF BALANCE	**(0,00)**	**-**

Explanatory Notes (facultative):
Please enter the text directly (no copy/paste of formatted text which would then disappear when saving the document in pdf), use \\\"ctrl+enter\\\" to go to the next line and \\\"enter\\\" to validate your typing.

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 2017 - 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)
13	1				1	100,00 %	15,00
20	1	1	100,00 %	18,00			
30	1554	1484	95,50 %	16,86	70	4,50 %	46,36
45	6	6	100,00 %	19,00			
60	80	79	98,75 %	24,03	1	1,25 %	63,00
90	227	217	95,59 %	62,38	10	4,41 %	125,10
211	1	1	100,00 %	204,00			
212	1	1	100,00 %	197,00			

Total Number of Payments	**1871**	**1789**	**95,62 %**		**82**	**4,38 %**	
Average Net Payment Time	**24,35**			**22,91**			**55,78**
Average Gross Payment Time	**35,06**			**33,15**			**76,71**

Suspensions

Average Report Approval Suspension Days	Average Payment Suspension Days	Number of Suspended Payments	% of Total Number	Total Number of Payments	Amount of Suspended Payments	% of Total Amount	Total Paid Amount
0	54	370	19,78 %	1871	143.589.296,78	34,98 %	410.464.451,62

Late Interest paid in 2017			
DG	**GL Account**	**Description**	**Amount (Eur)**
SANTE	65010000	Interest expense on late payment of charges	0,00
			0,00

TABLE 7 : SITUATION ON REVENUE AND INCOME IN 2017								
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
52	REVENUE FROM INVESTMENTS OR LOANS GRANTED, BANK AND OTHER INTEREST	2,35	-	2,35	2,35	-	2,35	-
57	OTHER CONTRIBUTIONS AND REFUNDS IN CONNECTION WITH THE ADMINISTRATIVE OPERATION OF THE INSTITUTION	950.387,59	69.169,18	1.019.556,77	560.561,20	69.169,18	629.730,38	389.826,39
59	OTHER REVENUE ARISING FROM ADMINISTRATIVE MANAGEMENT	347.909,96	-	347.909,96	347.909,96	-	347.909,96	-
60	CONTRIBUTIONS TO UNION PROGRAMMES	203.820,00	23.662,00	227.482,00	203.820,00	23.662,00	227.482,00	-
66	OTHER CONTRIBUTIONS AND REFUNDS	15.567.456,27	145.254,51	15.712.710,78	15.435.307,39	-	15.435.307,39	277.403,39
Total DG SANTE		**17.069.576,17**	**238.085,69**	**17.307.661,86**	**16.547.600,90**	**92.831,18**	**16.640.432,08**	**667.229,78**

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

INCOME BUDGET RECOVERY ORDERS ISSUED IN 2017	Error		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	Nbr	RO Amount
2010							2	1.753.632,00		
2013			6	122.259,56	**6**	**122.259,56**	6	122.259,56	100,00%	100,00%
2014	1	14.173,53	8	519.396,35	**9**	**533.569,88**	9	533.569,88	100,00%	100,00%
2015	1	14.642,83	1	164.399,19	**2**	**179.042,02**	3	279.915,32	66,67%	63,96%
2016	1	14.642,83	1	132.148,88	**2**	**146.791,71**	16	14.175.529,35	12,50%	1,04%
Sub-Total	**3**	**43.459,19**	**16**	**938.203,98**	**19**	**981.663,17**	**36**	**16.864.906,11**	**52,78%**	**5,82%**

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	11	48.640,96	98	2.659.096,29			**109**	**2.707.737,25**	154	19.162.505,91	70,78%	14,13%
CREDIT NOTES	21	828.684,26	42	290.133,25			**63**	**1.118.817,51**	96	1.237.351,95	65,63%	90,42%
Sub-Total	**32**	**877.325,22**	**140**	**2.949.229,54**			**172**	**3.826.554,76**	**250**	**20.399.857,86**	**68,80%**	**18,76%**

GRAND TOTAL	**35**	**920.784,41**	**156**	**3.887.433,52**			**191**	**4.808.217,93**	**286**	**37.264.763,97**	**66,78%**	**12,90%**

TABLE 9: AGEING BALANCE OF RECOVERY ORDERS AT 31/12/2017 FOR SANTE						
	Number at 01/01/2017	**Number at 31/12/2017**	**Evolution**	**Open Amount (Eur) at 01/01/2017**	**Open Amount (Eur) at 31/12/2017**	**Evolution**
2011	1	1	0,00 %	145.254,51	145.254,51	0,00 %
2016	4		-100,00 %	92.831,18		-100,00 %
2017		4			521.975,27	
	5	5	0,00 %	238.085,69	667.229,78	180,25 %

TABLE 10 : RECOVERY ORDER WAIVERS IN 2017 >= EUR 100.000						
	Waiver Central Key	**Linked RO Central Key**	**RO Accepted Amount (Eur)**	**LE Account Group**	**Commission Decision**	**Comments**

Total DG SANTE	

Number of RO waivers	

Justifications:
Please enter the text directly (no copy/paste of formatted text which would then disappear when saving the document in pdf), use "ctrl+enter" to go to the next line and "enter" to validate your typing.

TABLE 11 : CENSUS OF NEGOTIATED PROCEDURES - DG SANTE - 2017

Internal Procedures > € 60,000

Negotiated Procedure Legal base	Number of Procedures	Amount (€)
Art. 134.1(b) (Without prior publication) Work of art, technical reasons or protection of exclusive rights	3	9.306.071,00
Total	**3**	**9.306.071,00**

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

Internal Procedures > € 60,000

Procedure Legal base	Number of Procedures	Amount (€)
Exceptional Negotiated Procedure without publication of a contract notice (Art. 134 RAP)	3	9.306.071,00
Open Procedure (Art. 104(1) (a) FR)	4	24.794.140,00
Open Procedure (Art. 127.2 RAP)	2	591.501,00
Restricted Procedure (Art. 104(1) (b) FR)	3	1.230.934,00
Total	**12**	**35.922.646,00**

Additional Comments:

TABLE 13 : BUILDING CONTRACTS

Legal base	Contract Number	Contractor Name	Description	Amount (€)

TABLE 14 : CONTRACTS DECLARED SECRET

Legal base	Contract Number	Contractor Name	Description	Amount (€)

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.

ANNEX 5: Internal Control Templates for budget implementation (ICTs)

Annex 5.1 Internal Control Template 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

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**	**Control indicators**
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	**Effectiveness and efficiency indicators**: - 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**	**Control indicators**
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.	**Effectiveness indicators:** - Ratio of modified programmes to total programmes retained after evaluation ⇨ Target: qualitative analysis of reasons for rejections and modifications **Efficiency Indicators**: - 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**	**Control indicators**
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	**Effectiveness and efficiency indicator:** - 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**	**Control indicators**
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	**Effectiveness indicators**: - 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% **Efficiency indicators**: - 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**	**Control indicators**
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	**Effectiveness indicators**: - Detected error rate ⇨ Target: decreasing trend - Residual error rate in ABB activity ⇨ Target: < 2% - Number of files referred to OLAF. ⇨ Target: 0 **Efficiency indicators**: - 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**	**Control indicators**
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	**Effectiveness indicators:** - Audit results related to DG SANTE implemented ⇨ Target: 100% **Efficiency Indicators**: - "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.	**Effectiveness and efficiency indicator:** - 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

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**	**Control indicators**
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.	**Effectiveness indicators**: - 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 **Efficiency indicators**: - 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**	**Control indicators**
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.	**Effectiveness indicators**: - 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) **Efficiency indicators**: --Timeliness of procurement procedures relative to Commission Work Programmes

Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Control indicators**
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.	**Effectiveness indicators**: - 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% **Efficiency indicators**: --Ratio of average cost of control to budget spent on procurement

Procurement				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs and benefits of controls**	**Control indicators**
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.	**Effectiveness indicators**: - Estimated value of the financial corrections made during ex-ante controls of the final payment ⇨ Target: < 2% **Efficiency indicators**: - 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**	**Control indicators**
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	**Effectiveness indicators**: - 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% **Efficiency indicators**: - 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 Internal Control Template 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 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 2017, 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 63,1 million which amounts to about 20% of the 2017 operational budget (without subsidy payments to agencies). Cross-sub-delegations were given to authorising officers of other DGs for a total of EUR 0,7 million of commitment credits and EUR 0,2 million of payment credits.

DG SANTE finances part of the running costs of CHAF-EA through the payment of a subsidy of EUR 5,5 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**	**Control indicators**
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	**Effectiveness and efficiency indicators**: 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 2017

1. Budget implementation tasks delegated to the executive agency				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Control indicators**
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 2017, 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	**Effectiveness indicators:** Granting budget autonomy without significant delay ⇨ Target: Not applicable in 2017 (agency gained full autonomy in 2007) **Efficiency Indicators:** - 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**	**Control indicators**
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	**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	**Effectiveness indicators**: --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**	**Control indicators**
	general EU budget by the budgetary 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).			**Efficiency indicators**: - 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; COVO is fully fee-financed].

- **European Centre for Disease Prevention and Control (ECDC)** located in Stockholm, Sweden[1] *(Budget 2017: total sum of human resources 287; EU funding 100%: EUR 58,0 million)*
  ECDC works to prevent disease outbreaks and to react quickly and effectively to minimise their impact. To this end, ECDC operates dedicated surveillance networks, provides scientific opinions, operates the early warning and response system (*EWRS*) and provides scientific and technical assistance and training.
- **European Food Safety Authority (EFSA)** in Parma, Italy[2] *(Budget 2017: total sum of human resources 463; EU funding 100%: EUR 79,2 million)*
  EFSA provides independent scientific opinions and scientific and technical advice on food and feed safety, animal and plant health.
- **European Medicines Agency (EMA)** in London, UK[3] *(Budget 2017: total sum of human resources 799; EU funding 9%: EUR 29,3 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 2017 budget amounted to EUR 322,1 million which is to a large extent fee-financed.
- **Community Plant Variety Office (CPVO)** in Angers, France[4] *(Budget 2017: total sum of human resources 45; 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 2017 budget amounted to EUR 18,8 million (fully fee-financed).
- **European Chemicals Agency (ECHA)** located in Helsinki[5] - relevant for DG SANTE are ECHA's biocides activities *(Budget 2017 for biocides: total sum of human resources 59; EU funding 37,5%: EUR 3,9 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 budget for biocides in 2017 amounted to EUR 10,4 million.

---

1 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.

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

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

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

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

2. Subsidy payments to EU decentralised agencies				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Control indicators**
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"[6] 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.	**Effectiveness and efficiency indicators**: 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%

[6] 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**	**Control indicators**
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 2013/2014, due to the new FFR and staff regulations; 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	**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 (see footnote above)	**Effectiveness and efficiency indicators:** - 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**	**Control indicators**
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 (see footnote above).	**Effectiveness and efficiency indicators**: - 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**	**Control indicators**
	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**	**Control indicators**
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 (next in 2019); - EFSA every 6 years (next in 2017); - ECDC every 5 years (next in 2020). 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 (see footnote above)	**Effectiveness indicators**: - 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 **Efficiency indicators**: - 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**	**Control indicators**
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).	**Effectiveness indicators**: - 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% **Efficiency indicators**: - Time-to-pay (target: maximum 30 days) ⇨ Target: 100% on time

Annex 9: EVALUATIONS AND OTHER STUDIES FINALISED OR CANCELLED DURING THE YEAR

		Title	Reason [1]	Scope [2]	Type [3]	Associated DGs	Costs (EUR)	Comments [4]	Reference [5] (publication in the Interinstitutional DB)
	I. Evaluations finalised or cancelled in 2017								
	a. Evaluations finalised in 2017								
		Mid-term Evaluation of the Health Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020.	**L**	The evaluation will cover the first three years of the 3rd Health Programme implementation and will mainly examine the relevance of the choices made in the Work Programmes 2014, 2015 and 2016 and proposals submitted and awarded for EU funding under the subsequent calls. It will cover also the efficiency of the use of resources, the Union added value of the Programme, the internal and external coherence of the Programme, and simplification measures, assessing the need for change and alignment of the Programme's priorities in view of new challenges or to deliver better results.	E	none	€ 228.200		http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation?studyProjectId=3527
		Mid-term evaluation report on the achievement of the objectives set out in the frame of the Common Financial Framework (CFF) for food and feed.	**L**	Measure the achievement of objectives, the added value of the measures implemented and the efficiency of the use of resources, also taking into account evaluation results on the long-term impact of the predecessor measures. Proposal for a regulation establishing a CFF for food and feed. Regulation adopted in 2013. To be evaluated according to article 42 of REGULATION (EU) No 652/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 15 May 2014 EC.	E	AGRI, SG, BUDG	€ 180.000		https://webgate.ec.testa.eu/publications/studiesdb/Consultation.action?studyProjectId=3548
		General Food Law Fitness Check Evaluation of the Rapid Alert System for Food and Feed and of crisis management procedures		The overall aim of the Fitness Check is to analyse the effectiveness, efficiency, coherence, relevance and EU added value of the legislative framework introduced by Regulation (EC) No 178/2002 on general food law. In doing so, the Fitness Check should take into account previous evaluations already performed in this policy area as well as the results of the two external evaluations that have been commissioned to support the Fitness check: one on the RASSF and management of emergencies/crisis and the other on the General Food Law. Broad stakeholder consultations should be performed during the whole Fitness Check exercise to collect the views of relevant actors in the Food chain and to gather information and evidence.	REFIT	AGRI; SJ; COMP; SG; GROW; TRADE; ENV	€ 259.960		http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3525
	b. Evaluations cancelled in 2017								
		Evaluation of Fight against Food Fraud	O	The aim of this evaluation will be to assess EU initiatives aimed at fighting food fraud.	E	Tbd	Tbd	abandoned by Management Board decision	http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation?studyProjectId=6515
		Evaluation of State of health	O	(Country Knowledge: Country profiles, health reporting, Dialogue on health profiles and information initiative with the Member States, Coordination on country knowledge and information with other DGs and WHO and OECD,Input to European Semester, Suport to financial assistance programme countries: CY, EL)	E	none	n/a	abandoned by Management Board decision	6530
		Evaluation of the initiatives on Nutrition, Physical Activity, Overweight and Obesity	O	Activities of the High Level Group on Nutrition and Physical Activity, of the EU platform for action on diet, physical activity and health, of the EU Framework for National Initiatives on Selected Nutrients, of the Action Plan on Childhood Obesity and other relevant EU initiatives on the topic. Monitoring of the activities of the EU Platform for Action on Diet, Physical Activity and Health is foreseen between 01/2018-12/2020	E	EAC	€ 250.000	abandoned by Management Board decision	6535
		Evaluation of the Joint procurement Agreement/Mechanism for joint procurement for medical countermeasures (linked to health threats)	O	the benefits and impact of their past decisions and of options for future ECDC's role and functioning	E	ECDC - EMA - GROW - CNECT - RTD	tbd	abandoned by Management Board decision	6532

Annex 9: EVALUATIONS AND OTHER STUDIES FINALISED OR CANCELLED DURING THE YEAR

		Title	Reason [1]	Scope [2]	Type[3]	Associated DGs	Costs (EUR)	Comments[4]	Reference[5] (publication in the Interinstitutional DB)
		Evaluation of the Action to reduce the burden of chronic diseases (neurodegenearative diseases and mental health; Communication on the Cancer Partnership)	O	Evaluation on the chronic disease approach to address issues common to all chronic diseases, including mental health and cancer); evaluation whether implementation and scaling up of best practice by Member States is effective.	E	JRC, RTD, EMPL, SG; CNECT, SANTE (incl. CHAFEA)	€ 300.000	abandoned by Management Board decision	6526
		Evaluation of rare diseases (development of rare cancer work; EU strategy on rare diseases; liaison with European Reference Network)	O	Evaluation of the different actions undertaken by different services (SANTE, RTD, JRC, EMA) related to rare diseases and their cooperation.	E			abandoned by Management Board decision	6503
		Evaluation of EU initiatives on alcohol related harm	O	Activities of the Committee on National Alcohol Policy and Action, of the EU Alcohol and Health Forum, of the Action Plan on Youth Drinking and on Heavy Episodic Drinking and other relevant EU initiatives on the topic.	E	tbd	€ 250.000	abandoned by Management Board decision	6617
		Evaluation of the EU policy on serious cross-border health threats to health. Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC.	L	The aim of the evaluation would be to assess whether the objectives of Decision No 1082/2013 of the European Parliament and of the Council of 22 October 2013 on serious cross-border threads to health have been achieved and that the EU health security framework under that Decision has been proven effective towards combating serious cross-border threats to health. This will include an assessment of the effectiveness and efficiency of the mechanisms established under the Decision in particular regarding the early warning and coordination of responses to serious cross-border threats to health. RO: The Commission shall submit to the European Parliament and the Council by 7 November 2015, and every three years **thereafter a report on the implementation of this Decision.**	E	ECDC, SJ, ECHO	tbd	abandoned by Management Board decision	6531
		Evaluation of the Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on solidartiy in health: reducing health inequalities in the EU.	O	Activities of the Social Determinants and Health Inequaliteis expert group and of other relevant EU initiatives on the topic.	E	EMP	€ 500.000	abandoned by Management Board decision	6620
	II. Other studies finalised or cancelled in 2017								
	a. Other studies finalised in 2017								
		Study on Cross-border health services.	O	Review of potential obstacles for healthcare providers in the EU; Public Health Programme WP 2014-2020	S	none	€ 200.000		https://webgate.ec.testa.eu/publications/studiesdb/Consultation.action?studyProjectId=3555
		Study on the transposition measures of Member States in relation to the pharmaceutical legislation (Directive 2001/83/EC) on the rules on penalties applicable to infringements of the national provisions adopted pursuant to the Falsified Medicines Directive	L	Art. 118a of Directive 2001/83/EC requires the Commission to submit a report to the EP and the Council giving and overview of the transposition measures on the rules on penalties which are applicable to infringements of the national provisions adopted pursuant to the Falsified Medicines Directive.	S	none	€ 200.000		http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=6498

Annex 9: EVALUATIONS AND OTHER STUDIES FINALISED OR CANCELLED DURING THE YEAR

		Title	Reason [1]	Scope [2]	Type[3]	Associated DGs	Costs (EUR)	Comments[4]	Reference[5] (publication in the Interinstitutional DB)
		Study on the economic impact of the Paediatric Regulation, including its rewards and incentives	L	Required by legal basis Article 50(3) of Regulation 1901/2006 - study should feed in the Commission report to EP and Council due in 2017. The general objective of this request is to assess the economic impact of the Paediatric Regulation with specific focus on the rewards and incentives established under it. This includes an assessment of the extent to which the rewards and incentives are capable of offsetting the costs that private companies have to bear in order to comply with the obligations under the Paediatric Regulation or to engage in voluntary research and development projects for paediatric medicines.	S	BUDG; GROW; JUST; RTD; SJ(LS); SG	€ 180.000		http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3556
		Study on the preparation of best practices on the protection of animals at the time of killing.	O	The study will contribute to complete one action of the EU animal welfare strategy 2012-2015 (guidelines on the protection of animals at the time of killing). The purpose of the study is to collect information on best practices on the protection of animals at the time of killing. Based on the outcomes of the study, the Commission will consider if such information could be used for EU guidance documents under appropriate formats depending on the subject matter considered. The Commission audits have indicated that information on best practices is particularly needed in certain areas such as the slaughter of animals in small slaughterhouses, the stunning of poultry using the electrical waterbath method, the slaughter of animals without stunning in the context of ritual slaughter and the killing of animals on farm.	S	AGRI	€ 230.275		https://webgate.ec.testa.eu/publications/studiesdb/Consultation.xhtml?studyProjectId=3567
		Welfare of farmed fish: Common practices during transport and at slaughter	O	The study will contribute to complete the three actions of the EU animal welfare strategy 2012-2015 (two studies + a report on fish killing). Farmed fish are covered by Regulation (EC) No 1099/2009 on the protection of animals at the time of killing[1] which requires that the Commission submit a report on the possibility of introducing certain requirements regarding the protection of fish at the time of killing taking into account animal welfare aspects as well as the socio-economic and environmental impacts. With regard to transport the rules laid down in Regulation (EC) No 1/2005[2] apply also to farmed fish. The EU strategy for the protection and welfare of animals 2012-2015[3] foresees a study both on the welfare of farmed fish during transport and at the time of killing. The aim of the study thus is to gather information on current animal welfare practices prevailing in European aquaculture as regards the transport and slaughter of farmed fish. Information will also be gathered on national rules and on the use of international standards, best practices or voluntary assurance schemes. In addition factors which may influence the use of animal welfare principles such as the economic situation of the aquaculture industry, trade issues and available knowledge will be assessed.	S	MARE	€ 250.000		http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation?studyProjectId=3570
		Cost/benefit analysis of a sustainable EU Health Information System	O	The purpose of this Study is to review the costs and the benefits for Member States (MS) counterparts and beneficiaries of the EU health information system and to compare the current set-up with a possible system built on a sustainable ground. The dimensions of the analysis regard in particular: (1) indicator development and implementation; (2) data analysis and reporting to the competent entity.	S		€ 120.000		http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation?studyProjectId=3559
		Study on the impact of animal welfare international activities on the competitiveness of European livestock producers in a globalised world.	O	The study will constitute the main supporting element of the "Report on the impact of animal welfare international activities on the competitiveness of European livestock producers in a globalised world" foreseen by the EU AW Strategy 2012-2015.	S	AGRI	€ 350.000		http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3572

Annex 9: EVALUATIONS AND OTHER STUDIES FINALISED OR CANCELLED DURING THE YEAR

		Title	Reason [1]	Scope [2]	Type [3]	Associated DGs	Costs (EUR)	Comments [4]	Reference [5] (publication in the Interinstitutional DB)
		Study on intra-EU animal health certification of certain live animals and commodities.	O	The purpose of the study is to support the Commission in the decision making process for the delegated acts to be adopted under the future Regulation on transmissible animal diseases (Animal Health Law). The study should assess the current situation as regards the animal health certification of certain live animals for the movements between Member States and the economic impacts (positive aspects and burdens and costs) of such certification procedures (i.e. the baseline scenario). Furthermore, it would estimate changes and shifts in financial costs and benefits associated with providing derogations from animal health certification requirements for certain intra-EU movements.	S	none	€ 90.000		https://webgate.ec.testa.eu/publications/studiesdb/Consultation.xhtml?studyProjectId=3569
		Mapping of Health Technology Assessment national organisations and processes. Study to support the Health Technology Assessment Impact Assessment	R	Study to support the Health Technology Assessment Impact Assessment	S	GROW,RTD	€ 15.000		http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=6494
		Mapping of HTA methodologies in EU and Norway Study to support the Health Technology Assessment Impact Assessment	O	The main objective of the study is to provide a concise overview of the scientific methodologies implemented by the Member States' HTA bodies.	S	GROW,RTD	€ 15.000		http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=6494
		Study on impact analysis of policy options for Strengthened EU cooperation on Health Technology Assessment . Study to support the Health Technology Assessment Impact Assessment	R	Study to support the Health Technology Assessment Impact Assessment	S	none	€ 400.000		http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=6496
		Cost benefit study on the current and future operation of the commission's Better Training for Safer Food (BTSF) programme	O	The study should provide a cost/benefit analyses of the various technical and financial aspects of the current and future operation of the Better Training for Safer Food (BTSF) programme in order to inform the decision making process on how BTSF will develop its organisational structure (incl development of a model to measure training impact and quantify benefits in monetary terms, a CBA of the current training model, identify future needs and SWOT analysis of different training models)	S	none	€ 180.000		https://webgate.ec.testa.eu/publications/studiesdb/Consultation.xhtml?studyProjectId=3558
		Market study on date marking and other information provided on food labels and food waste prevention	O	Circular Economy Action Plan requires COM to explore options for more effective use and understanding of date marking (by 2017). Study would map current practices related to use of date marking in food supply chain (FBOs and control authorities) to help inform COM's work on date marking in relation to food waste prevention . Outcome will support COM's dialogue with FBOs to streamline date marking practices as well as discussion with MS/stakeholders on possible developments in date marking (Regulation N° 1169/2011)	S	GROW	€ 300.000		http://studiesdb.opoce.cec.eu.int/studiesdb/Consultation.xhtml?studyProjectId=3571
	b. Other studies cancelled in 2017								
		Study on background and options for new actions advancing telemedicine and eHealth in the EU	O	The study will map options for the sustainable implementation of the cross-border exchange of health data, make suggestions for new use cases beyond e-prescriptions and patient summaries, proposals for technical standards and systems necessary in telemedicine and electronic access to own health data, map the main health platforms and make a recommendation for policy actions, as well as provide information on the public opinion on eHealth and on the uptake of the eHealth services.	O	CNECT	€ 400.000	abandoned by Management Board decision	6527

Annex 9: EVALUATIONS AND OTHER STUDIES FINALISED OR CANCELLED DURING THE YEAR

		Title	Reason [1]	Scope [2]	Type[3]	Associated DGs	Costs (EUR)	Comments[4]	Reference[5] (publication in the Interinstitutional DB)
		Study on the conduct of a comprehensive analysis of vaccination schedules and on the development of technical guidance on financial planning of national vaccination programmes	O	Study aiming at reviewing existing evidence and analysing reasons for diverging national vaccination schedules with a view to assisting countries on optimal programmatic vaccine decision-making	O	none	€ 800.000	abandoned by Management Board decision	6505
		Monitor the activities of the European Alcohol and Health Forum	O	To monitor and evaluate the work of the members of the European Alcohol and Health Forum. This is part of the preparatory work for the Evaluation on Alcohol related harm initiatives.	O	none	€ 160.000	all monitoring activities merged in one study of the European Alcohol and health Forum and Monitor the activities of the EU Platform for Action on Diet, Physical Activity and Health	6507
		Access to healthcare in rural areas. Pilot Project of the European Parliament	O	This European pilot project shall increase our understanding of how best to improve the health of people who are living in isolated situations across Europe. The project will assess their particular health needs and challenges, as well as identify best practices to support them and ultimately improve their health.	O	none	€ 1.000.000	cancelled. E-mail from B1 on 30.03.2017	6533
		Study of the health and economic impact of public health measures to address HIV/AIDS, viral hepatitis and tuberculosis.	O	The aim of this study is to provide evidence reviews, and develop further evidence through scenario development and modelling on the basis of existing survey data and models. This will include assessment of the cost-effectiveness of screening and treatment and its economic impact on health systems taking also into account existing EU level instruments such as the Joint Procurement Agreement and actions under the EU Health Programme.	O	none	€ 200.000	abandoned by Management Board decision	3589
		Support to the design and implementation of public procurement guidelines for food	O	Report compiling the related guidance documents at EU and national level, a summary of their commonalities, a draft of a consensus text between Member States' authorities on this topic, and an analysis of the implications and potential (including public health impact) of wide implementation of such voluntary guidelines in Europe.	O	none	€ 250.000	abandoned by Management Board decision	6525

[1] Reason why the evaluation/other study was carried out. The individual symbols used have the following meaning: L - legal act, LMFF - legal base of MFF instrument, FR - financial regulation, REFIT, REFIT/L, CWP - 'evaluate first', O - other (please specify in Comments)

[2] Specify what programme/regulatory measure/initiative/policy area etc. has been covered

[3] FC – fitness check, E – expenditure programme/measure, R – regulatory measure (not recognised as a FC), C – communication activity, I – internal Commission activity, O – other – please specify in the Comments

[4] Comments related to the item (in particular changes compared to the planning). When relevant, the reasons for cancelling evaluations/ other studies are explained in this column.

[5] For evaluations the references are 1) number of its Evaluation Staff Working Document and number of the SWD's executive summary; 2) link to the supportive study of the SWD in EU bookshop. For other studies the references are the link to EU bookshop or other reference where the 'other study' is published,

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** (2016)	**Target** (2020) Europe 2020 target
69.2%	71.1%	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** (2016)	**Target** (2020) Europe 2020 target
122.7 million	118.0 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** 2015 (reporting analysis of data to be conducted in Q1 2018)
0	14	28	0

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** 2015 (reporting analysis of data to be conducted in Q1 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): 18 1.2.B. (ii): 22 1.2.B. (iii): 16

Managing and isolating outbreaks of major animal disease

Specific objective 1.1: Effective preparedness, prevention , reaction and eradication of human, animal and plant diseases		Related to Food and feed expenditure Regulation (EU) No. 652/2014
Result indicator 1.1C: Reduction of restrictions in the EU caused by outbreaks of major epidemic animal diseases (foot and mouth disease, classical swine fever, African swine fever, avian influenza and lumpy skin disease) **Source of data:** Commission internal from several sources: safeguard and regionalisation decisions, eradication and monitoring programmes against these diseases, Animal Disease Notification System (ADNS), other information by MS		
Baseline 2014	**Interim Milestone** 2018	**Target** 2020	**Latest known results** 2017
168[1]/7800[2]	Decreasing value	Decreasing value (internal target)	529/7800
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 Newcastle 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** (2017)
19/25[3]	Increasing	Increasing (internal target)	18/25

[1] 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

[2] 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

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

Preventing plant disease

Specific objective 1.1: Effective preparedness, prevention , reaction and eradication of human, animal and plant diseases (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme)			Related to Food and feed expenditure Regulation (EU) No. 652/2014
Result indicator 1.1E: Percentage of the EU territory covered by surveys for plant pests, in particular for pests not known to occur in the Union territory **Source of data:** Data can be procured using the Survey programs submitted by MS			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	2017	2020 (agreed in Commission proposal COM(2013)327 final)	(2017)
50%	70%	100%	85.71%
Result indicator 1.1F: Percentage of the EU territory covered by surveys for plant pests considered to be most dangerous, as defined under Directive 2000/29/EC **Source of data:** Monitoring results for pests subject to EU measures is completed by Member States and reported to the Commission on an annual basis.			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	2017	2020 (agreed in Commission proposal COM(2013)327 final)	(2017)
100%	100%	100%	100%
Result indicator 1.1G: Time between finding and notification for plant pests not known to occur in the Union **Source of data:** Data can be procured using notification of outbreaks by MS (electronic system Europhyt-Outbreaks)			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	2017	2020	(2017)
42 days	20 days	8 days	19 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)	(2017)
0%	60%	95%	No data available[4]

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

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 programme(s) - 3rd EU Health Programme - CFF for the Food Chain 2014-2020	
Main outputs in 2017:			
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
Human diseases			
Long term impact and sustainability of the Health Programmes	*Impact study launched*	*Q3/2017*	*Impact study replaced by data-gathering study due to MFF timelines; results foreseen in Q2 2018*
Two studies related to vaccination (on the added-value of the strategic and life-course approach to vaccination & a study on shortcomings related to low vaccination coverage in health care workers)	*Final reports with recommendations*	*December 2017*	*The studies were not implemented, tasks were partly reallocated to the Joint Action on vaccination, as well as addressed by ECDC.*
Joint Action on vaccination	*Launch of the Joint Action*	*Q2 2017*	*Expected Q2 2018. Additional time required for the submission of the revised proposal and collection of documentations from 20 partners*
Joint Action on preparedness and action at points of entry (air, maritime and ground crossing	*Launch of the Joint Action*	*Q2 2017*	*Expected Q2 2018 due to delay with the nomination process and submission of revised proposal*
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*	*14*	*15*
Swine diseases	*No. of programmes which received co-financing*	*13*	*14*
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*	*13*	*12*
National survey programmes for organisms harmful to plants	*No. of programmes which received co-financing*	*24*	*24*
Emergency measures (animal and plant)	*Adoption*	*Emergency measures (animal and plant)*	*47 (only for animal)*
Other			
Commission Report to the European Parliament and the Council on mid-term evaluation of the Common Financial Framework (CFF) 2014-2020 (2015/SANTE/462)(CFF also contributes to objectives 1.2 and 1.6)	*Adoption*	*Q2 2017*	*26/09/2017*
Commission Report to the European Parliament and the Council on mid-term evaluation of the Health Programme, the third multi-annual programme of EU action in the field of health for the period 2014-2020 (2015/SANTE/680) (Health Programme also contributes to specific objectives: 1.3, 1.4, 1.5, 1.6, 2.1, 2.2, 2.3)	*Adoption*	*Q2 2017*	*11/10/2017*
Public procurement on purchase and supply of foot-and-mouth disease (FMD) antigens and lumpy skin disease (LSD) vaccine to the Union bank	*FMD antigens and LSD vaccine doses purchased and supplied to the Union bank*	*Throughout the year*	*Total LSD vaccine grants to countries in 2017: 325.000 doses*
Other important outputs			
Human diseases			
Commission implementing Decision with regard to procedures for the functioning of the early warning and response system for notifying alerts, and for the information exchange, consultation and coordination of response under Decision 1082/2013/EU on serious cross-border health threats (2015/SANTE/172)	*Adoption*	*Q1 2017*	*13/02/2017*
Commission implementing Decision to adapt the list of communicable diseases under surveillance and to amend case definitions for diseases under Decision 1082/2013/EU (2015/SANTE/021)	*Adoption*	*Q4 2017*	*Expected Q1 2018 due to number of comments received from Member States*

Output	Indicator	Target	Latest known results
Animal diseases			
Commission decisions on handling evolving epidemiological situations	*Adoption of emergency Decisions as necessary, according to the epidemiological situation*	*In course of 2017*	*47*
Commission rules on safe imports, trade and related aspects	*Adoption of Commission implementing rules.*	*In course of 2017*	*13*
Commission implementing Decision for updating the current Decision 2014/709/EU that relates to the regionalisation for African swine fever (PLAN/2016/68)	*Adoption*	*Q1 2017*	*07/12/2016*
Safeguard measure on Chronic Wasting Disease in Norway (2016/SANTE/163)	*Adoption*	*Q3 2017*	*28/10/2016*
***Implementation of the Animal Breeding Regulation**:* *1) implementing Regulation laying down model forms for the zootechnical certificates (2016/SANTE/205)* *2) implementing Regulation laying down the model forms for the presentation by Member States to the public of the information to be included in the list of recognised breed societies and breeding operations (2016/SANTE/206)* *3) implementing Regulation on the designation of the EU reference centre contributing to the harmonisation or improvement of the methods of performance testing and genetic evaluation of purebred breeding animals of the bovine species (2016/SANTE/207)* *4) delegated Regulation as regards the content and format of zootechnical certificates issued for purebred breeding animals of the equine species contained in a single lifetime identification document for equidae (2016/SANTE/250)*	*Adoption*	*1) Q2 2017* *2) Q2 2017* *3) Q2 2017* *4) Q2 2017*	*10/04/2017* *10/04/2017* *04/08/2017* *13/07/2017*
Plant diseases			
Commission Decisions on emergency measures against some specific pests	*Adoption of Decisions as necessary according to (new) outbreak situations*	*In course of 2017*	*3*
Commission Decisions with specific import requirements for trade lines where there are too many import interceptions	*Adoption of Decisions as necessary according to import interception notifications from Member States*	*In course of 2017*	*2*
Commission decisions on derogations for import from non-EU countries	*Adoption*	*In the course of 2017*	*3*
Commission implementing Directive updating the Annexes of the Council Directive 2000/29/EC on protective measures against harmful organisms (2015/SANTE/153)	*Adoption*	*Q2 2017*	*14/07/2017*

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

Specific objective 1.2: Safe and sustainable food and food production systems			Related to spending programmes : **No**
Result indicator 1.2.A: The number of cases of diseases in humans in the EU linked to food safety or zoonoses **Source of data:** ECDC surveillance data on human cases, Annual joint EFSA/ECDC report on zoonoses			
Baseline (2012)	**Milestone (2018)**	**Target (2020[18])**	**Latest known results (2016)**
94,278 confirmed cases of human salmonellosis	67000 cases	60000 (sustained negative trend in incidence cases)	94,530

Result indicator 1.2.B[5]: Compliance rate with legal deadlines for presentation of a draft Review Report and regulatory decision on approval/non-approval or renewal/non-renewal of approval for pesticides to the Standing Committee on Plants, Animals, Food and Feed (PAFF) within 6 months after an EFSA conclusion
Source of data: Operational Units to provide data on the compliance rate.

Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	**2017**	**2020**	**2017**
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%[6]**	80%	85%	25/30=83%

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

Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	**2017**	**2020**	**2017**
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%	87,5%

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** 2017
0/0	5/5	4/5

[5] 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.

[6] 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 Comission 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.

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 2017:			
All new initiatives and REFIT initiatives from the Commission Work Programme			
Output	**Indicator**	**Target**	**Latest known results**
Commission Regulation on plant protection products to specify criteria to identify endocrine disruptors (2015/SANTE/001) Reference in the text of CWP 2016	*Adoption*	*Q1 2017*	*Planned for Q2 2018 Scrutiny started on 8 January 2018 (PRAC). A part of the act proposed earlier to MS was split during the negotiations and is on-hold until after adoption of the criteria*
Commission delegated Regulation on endocrine disruptors (biocides) (2016/SANTE/045) Reference in the text of CWP 2016	*Adoption*	*Q1 2017*	*04/09/2017*
Commission Regulation establishing a legal limit for the industrial trans fats content in foods (2016/SANTE/143) Reference in the text of CWP 2016	*Adoption*	*Q3 2017*	*Planned for Q1 2019 Delay due to complex preparations for the launch of the impact assessment*
Fitness check of General Food Law, Regulation EC 178/2002 (2015/SANTE/427) Annex II of the CWP 2016	*Publication of the SWD*	*Q2 2017*	*15/01/2018*
Study supporting REFIT evaluation of Nutrition Health Claims Regulation (2015/SANTE/595) Annex II of the CWP 2016	*Study to be completed*	*Q2 2017*	*Delay due to the controversy of the subject and the political context. The study will be completed in the first quarter of 2018 and the final report in a form of a Staff Working Document is planned for Q2 2018.*
Study supporting REFIT evaluation of plant protection products and maximum residue levels legislation (2016/SANTE/197) Annex II of the CWP 2016	*Start of the study*	*Q2 2017*	*Q2 2018 Study delayed due to extensive internal consultation process at the onset*
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*	*24*	*86 individual programmes in 24 member States*
Study to support the preparation of delegated Regulation on processed-cereal based food and baby food	*Study to be Completed*	*Q4 2017*	*Q1 2018 Slight delay due to more extensive preparatory consultations than originally planned*
EU Platform on Animal Welfare (PLAN/2016/12)	*Adoption of the Commission Decision*	*Q1 2017*	*24/01/2017*

Output	Indicator	Target	Latest known results
Food labelling database	*Completion of the database*	*Q4 2017*	*Public website is expected in Q4 2018.* *Admin IT tool for the collection of data is developed.* *Delay due to complexity of the project which involves collection of national legislation of all Member States*
Operational support services for the EU Platform on Food Losses and Food Waste	*Establishment of digital platform and user activity*	*Q4 2017*	*Digital Platform established, user activity ongoing*
Innovation in food processing technologies	*Start of the work on a Portal for e-authorisations*	*Q4 2017*	*The work on the Portal has started and by the end of 2017 was operational for new novel food applications. The work for other areas for which e-authorisation shall be introduced will continue in 2018.*
Conference on Modern Biotechnologies and Innovation in Sustainable Agriculture	*Completion*	*Q3 2017*	*Conference took place on 28/9/2017*
Study on date marking	*Completion*	*Q4 2017*	*Study completed – final report will be published by end of January 2018.*
Other important outputs			
Plant protection products and biocides			
Renewal/non-renewal of active substances for plant protection products	*Adoption*	*Ongoing regular activity in 2017*	*Regulations concerning the renewal/non-renewal of existing approvals were adopted for 19 substances, 15 were renewals and 4 were non-renewals.*
Commission Report to Parliament and Council on the Directive on sustainable use of pesticides (2015/SANTE/024)	*Adoption*	*Q3 2017*	*10/10/2017*
Guidance Document on the risk assessment of plant protection products on bees (2016/SANTE/036)	*Adoption*	*Q2 2017*	*Postponed to 2018 due to ongoing internal discussions*
Commission Regulation on uniform principles for evaluation and authorisation of plant protection products (2016/SANTE/039)	*Adoption*	*Q2 2017*	*Its adoption is linked to the guidelines document on bees - 2016/SANTE/036*
Commission Implementing Regulation renewing approval of active substance glyphosate for use in plant protection products (2016/SANTE/007)	*Adoption*	*Q4 2017*	*12/12/2017*
Establishing maximum residues levels (MRL) for pesticides	*Adoption*	*Ongoing regular activity in 2017*	*1) Regulations adopted setting MRLs for 80 substances based on applications and/or implementing Codex MRLs.* *2) Regulations adopted with a complete review of all existing MRLs for 14 substances.*

Output	Indicator	Target	Latest known results
Establishing list of non-acceptable co-formulants in plant protection products	*Adoption*	*In course of 2017*	*Postponed to Q4 2018. The involvement of two scientific agencies and 3 DGs into the project resulted in more complex discussions than anticipated and to a complete restructuring of the decision process compared to the one initially foreseen.*
Commission implementing Regulations renewing the approval of biocidal active substances	*Adoption*	*Ongoing regular activity in 2017*	*8 Regulations (a Regulation can cover the use of the active substance for one or more biocidal product-types)*
Commission implementing Regulations/Decisions for approval or non-approval of biocidal active substances included in the review programme	*Adoption*	*Ongoing regular activity in 2017*	*16 approval Regulations and 2 non-approval Decisions (a Regulation/ Decision can cover the use of the active substance for one or more biocidal product-types)*
Genetically Modified Organisms (GMOs)			
Commission Directive aiming to update of the Environmental Risk Assessment requirements in Directive 2001/18 concerning GMO (2015/SANTE/428)	*Adoption*	*Q3 2017*	*Q1 2018* *The vote in the committee took place on 13 October. After this 3 months PRAC period is required.*
Authorisations of GMO's food and feed uses, and for cultivation	*Adoption*	*In course of 2017*	*33 authorisations for food and feed*
Authorisations of substances			
Commission Regulation on Bisphenol A as food contact material (2015/SANTE/534)	*Adoption*	*Q1 2017*	*12/02/2018* *Delay due to discussions on endocrine disruptors*
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 2017*	*Through several regulations* *-Food additives: 1 authorisation and 9 amendments to uses* *- Food flavourings: 20 amendments* *- Novel Food: 12 authorisations (+6 authorisations by Member States and 58 notifications)* *- Food Contacty materials: 6 substances autorised*
Authorisations of recycling processes for plastics used in food contact materials	*Adoption*	*In course of 2017*	*Delayed to 2018 due to the discussion on recycling of plastic waste.*
Regulatory measures on contaminants in feed and food following EFSA opinions	*Adoption*	*In course of 2017*	*3 Regulations and 1 Recommendation*
Withdrawal of certain substances (flavourings)	*Adoption*	*In course of 2017*	*1 Regulation (EU) 2017/1250*
Authorisations and re-authorisations of feed additives and new uses of feed additives.	*Adoption*	*In course of 2017*	*56 implementing regulations approving some 243 feed additives, one additive authorisation denied, 385 additives withdrawn and one additive authorisation suspended*
Withdrawal of certain already authorised additives for which no applications were submitted	*Adoption*	*In course of 2017*	*1 Regulation (2018/98 of 22/01/2018)*

Output	Indicator	Target	Latest known results
Implementation of the new Novel Food Regulation			
Implementing act on procedural steps of the consultation process regarding determination of novel food status (PLAN/2016/265)	*Adoption*	*Q4 2017*	*Expected Q1 2018* *During the feedback mechanism stakeholders raised concerns about the lack of confidentiality requirements in the proposal. The Commission is working on addressing this issue.*
Implementing act on initial establishment of the Union list (transfer of existing authorisations to the Union list) (PLAN/2016/266)	*Adoption*	*Q4 2017*	*20/12/2017*
Implementing act on administrative and scientific requirements for traditional foods from a Third Country in relation to transitional measures (PLAN/2016/264)	*Adoption*	*Q3 2017*	*20/12/2017*
Implementing act on administrative and scientific requirements for novel food applications (PLAN/2016/263)	*Adoption*	*Q3 2017*	*20/12/2017*
Delegated act on updating and adjusting the definition of "engineered nanomaterials" to technical and scientific progress (PLAN/2016/269)	*Adoption*	*Q4 2017*	*Expected Q1 2019* *This act depends of the ongoing revision of the Commission Recommendation 2011/696/EU on the definition of a nanomaterial which is expected to be completed at the end of Q2 2018*
Implementation of the legislation on plant reproductive material			
Implementing acts amending the annexes as regards the certification marketing requirements of the 12 basic Directives	*Adoption*	*2017*	*5*
Decision(s) on EU equivalence for seed certification and field inspection	*Adoption*	*2017*	*1*
Implementation of the legislation on Community Plant Variety Rights			
To support new innovative plant varieties by updating the rules on variety denominations	*Adoption*	*2017*	*Rules not yet adopted by CPVO*
Food hygiene			
Adapt rules for Specified Risk Materials in small ruminants (2016/SANTE/241)	*Adoption*	*Q2 2017*	*On hold* *Discussions with the Member States in the PAFF Committee*
Review export rules for the export of Processed Animal Proteins (2016/SANTE/240)	*Adoption*	*Q3 2017*	*24/05/2017*
Commission Regulation on processed animal protein derived from insects (2016/SANTE/095)	*Adoption*	*Q1 2017*	*24/05/2017*
Process hygiene criterion for Campylobacter at slaughterhouse (2016/SANTE/035)	*Adoption*	*Q2 2017*	*23/08/2017*
Creation of a new EU Reference Laboratory on viruses (PLAN/2016/228)	*Adoption*	*Q3 2017*	*26/07/2017*

Output	Indicator	Target	Latest known results
Implementation of Animal Welfare Strategy 2012-2015			
Report to the European Parliament and the Council on the application of broilers Directive (2016/SANTE/114)	*Adoption*	*Q4 2017*	*Expected Q1 2018* *• There was much more material to consider for this report (an external study, BTSF courses, SANTE audits, etc) and the unit needed time to review them properly.* *• Many comments received during internal SANTE consultation which required more time to process.*
Report to the European Parliament and the Council on protection of fish at the time of killing (2016/SANTE/138)	*Adoption*	*Q4 2017*	*Expected Q1 2018* *• The study on fish was finalised with a delay.* *• The mentioned study lacked certain data so other sources had to be consulted.*
Report to the European Parliament and the Council on impact of animal welfare international activities (PLAN/2016/499)	*Adoption*	*Q4 2017*	*Adoption foreseen on 26/01/2018*
Pilot project on best practices in protection of animals during transport	*Publication*	*Q3 2017*	*Best practices published in September 2017*
Study on best practices on the protection of animals at the time of killing	*Publication*	*Q4 2017*	*Published in October 2017*
Study on transport and killing of farmed fish	*Publication*	*Q4 2017*	*Published in October 2017*
Others			
Implementing Regulation on voluntary food origin labelling (2015/SANTE/670)	*Adoption*	*Q2 2017*	*Expected Q2 2018* *Delay due to complex internal COmmission discussions to clarify the application of the measure on Trademarks and protected geographical indication (PGI) products.*
EU guidelines on food donation (2016/SANTE/072)	*Adoption*	*Q4 2017*	*16/10/2017*
Report to the European Parliament and the Council on labelling of alcoholic beverages (2015/SANTE/681)	*Adoption*	*Q1 2017*	*13/03/2017*
Guidelines for use of former foodstuff as feed (2016/SANTE/073)	*Adoption*	*Q2 2017*	*Expected 2018 Q2* *Postponed due to the ongoing discussions with the Member States*

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[7]

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** 2017
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) 22 2) 26 3) 24 4) 22

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 spending programme(s) 3rd EU Health Programme
Main outputs in 2017:			
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
Report from the project on the implementation of the Action Plan on Childhood Obesity	*Completion*	*Q4 2017*	*Q1 2018* *delay due to additional time for consultations with stakeholders*

[7] 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.

Output	Indicator	Target	Latest known results
Support to the preparation of voluntary guidelines for public procurement of food	*Launch tender*	*Q4 2017*	*Launched*
Support and piloting of adequate monitoring systems for reformulation initiatives	*Launch tender*	*Q4 2017*	*Completed*
Preparatory work for a collection of best practice on physical inactivity	*Launch tender*	*Q4 2017*	*Cancelled (not deemed in line with Commission priorities)*
Report from the project on exposure of children to marketing of foods high in fat, sugar or salt	*Launch tender*	*Q4 2017*	*Launched*
Compass conference on mental health	*Conference*	*Q3 2017*	*Forum/Conference on 8/9 June*
Guidance on mental health at the workplace	*Guidance documents available*	*Q4 2017*	*To be reconsidered in light of guidance from various stakeholders*
Organise meetings of the EU Health Policy Forum	*1-2*	*Q4 2017*	*Completed (November 207)*
Completion of the First Joint Action on chronic diseases	*Final conference in January*	*Q1 2017*	*Held February 2017*
Dissemination of project results in the area of chronic diseases	*Cluster meeting with European journalist*	*Q2 2017*	*Held October 2017*
Collection of best practices in health promotion and prevention	*Call for proposal launched*	*Q3 2017*	*IT platform to be launched in Q2 2018, call for proposal to follow; delay due to prolonged pilot testing of methodology*
Strengthen evidence base for chronic diseases	*Administrative agreement with JRC signed*	*Q4 2017*	*Signed December 2017*
Develop support for rare diseases registries interoperability	*Administrative agreement with JRC signed*	*Q2 2017*	*Signed December 2017*
Launch of Joint Actions with Member States	*- on chronic diseases* *- on rare cancers* *- on frailty* *- on innovative partnership on action against cancer* *- on health inequalities*	*Q2 2017* *Q1 2017* *Q1 2017* *Q1 2017* *Q4 2017*	*Q3/2017* *Q4/2016* *Q1/2017* *Q2/2018; delayed due to late adoption of AWP 2017* *Q2/2018; delayed due to late adoption of AWP 2017*
Cancer control	*- Implementation report on EU cancer screening published* *- pilot action on the initiative on breast cancer launched* *- updated guidelines on screening of breast cancer published*	*Q1 2017* *Q2 2017* *Q1 2017*	*Completed* *Completed* *Completed*
Characterising flavours in tobacco products	*-establishment of an advisory panel to assist Member States and the Commission in determining tobacco products with characterising flavour*	*Q1 2017* *Q4 2017*	*Established Q1 2017* *Q1 2018 (due to complex tender procedure)*

Output	Indicator	Target	Latest known results
	-establishment of a technical group to assist the advisory panel with sensory and chemical analysis		
Reporting on tobacco and electronic cigarettes	*-ensure a well-functioning electronic reporting tool (EU Common Entry Gate) for reporting in accordance with TPD from industry to national regulators*	*Q2 2017*	*Functional Q2 2017*
Supporting the transition towards a sustainable EU Health Information System	*Completion of BRIDGE-Health project*	*Q4 2017*	*Final report submitted end of 2017.*
Other important outputs			
Output	**Indicator**	**Target**	**Latest known results**
Guidelines on allergen labelling, on Quantitative Ingredients Declaration (QUID) and Q&A on Food Information to Consumers (2015/SANTE/647)	*Adoption*	*Q1 2017*	• *Commission Notice on allergen labelling (PLAN/2017/1073) adopted on 13/07/2017,* • *Commission Notice on QUID (PLAN/2017/1078) adopted on 21/11/2017* • *Q&A (2015/SANTE/647) adoption planned for Q1 2018 (delay due to overall increased workload in the labelling sector and unforeseen resource issues)*
Commission delegated Regulation on total diet replacement for weight control (2015/SANTE/146)	*Adoption*	*Q2 2017*	*02/06/2017*
Delegated act authorising new sources of iron and calcium for process cereal-based food, baby food and food for special (2016/SANTE/239)	*Adoption*	*Q1 2017*	*10/04/2017*
Commission Decisions on tracking and tracing under the Tobacco Products Directive (201440/EC): *1) tracking and tracing system for tobacco products (2015/SANTE/694)* *2) data storage contracts between manufacturers and importers of tobacco products and an independent third party (2015/SANTE/695)* *3) technical specifications for the security feature for tobacco products (2015/SANTE/696)*	*Adoption*	*Q4 2017*	*15/12/2017* *15/12/2017* *15/12/2017*

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		2017
4	8	12	18	9

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** 2016
24.33[8] 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	**23.96** defined daily doses/1000 inhabitants/day consumed in the Community and hospital sectors combined (21.9 in the Community and 2.06 in the hospital sector)

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 spending programme 3rd EU Health Programme
Main outputs in 2017:			
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
State of Health in the EU: 28 Country health profiles and accompanying Commission Staff Working Document	*Health profiles and Staff Working Document published*	*Q4 2017*	*Country Health Profiles and Staff Working Document launched on 23 November 2017.*
Study on Antimicrobial Resistance and causes of non-prudent use of antibiotics in human medicine.	*Completion*	*Q2 2017*	*Completed Q2 2017 Published Q3 2017*
Joint Action (JA) between EU and EU Member States on AMR (2017-2020)	*Launch of the Joint Action*	*Q1 2017*	*Launched Q3 2017*

[8] 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).

Output	Indicator	Target	Latest known results
Direct grant agreement with WHO EURO for cooperation on AMR	*Establishment of the grant*	*Q3 2017*	*The grant was established and work was extended to 2018 at European Observatory request. Work under the grant agreement to start 2018.*
Direct grant agreement with OECD	*Publication of a model assessing the health and economic burden caused by AMR and estimating the cost-effectiveness of policies aimed at tackling AMR*	*Q4 2017*	*Work extended to June 2018 at OECD request; modelling work was more extensive than originally foreseen.*
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 2017*	*Grant establishment delayed due to late receipt of proposal and need for revisions. Work under the grant agreement to start 2018.*
Study on cooperation in cross-border regions and toolbox for National Contact points	*Completion*	*Q4 2017*	*Draft final report received in December 2017, finalization in early 2018.*
Study on cross-border health services: enhancing information provision to patients	*Completion*	*Q4 2017*	*Work extended to June 2018 due to delay at the start.*
eHealth Digital Service Infrastructure: building core services and national access, the eHealth Member State Expert Group	*8 national access points set up*	*Q4 2017*	*9 Member States and Switzerland report readiness to join the exchange as soon as possible (Wave 1 2018)*
Study on regulatory aspects of cross-border telemedicine	*Completion*	*Q4 2017*	*Q4 2018 due to delay in signing the contract*
Direct grant to OECD and European Observatory on Health Systems and Policies	*Contract*	*Q4 2017*	*Direct grant agreements completed in December 2017.*
Workshop on "New forms of investment for new forms of care"	*Organisation of event*	*Q1 2017*	*Held February 2017*
Other important outputs			
New Commission's Communication on Action Plan against Antimicrobial Resistance (2016/SANTE/176)	*Adoption*	*Q2 2017*	*29/06/2017*
Guidelines on prudent use of antimicrobials in human medicines	*Publication*	*Q2 2017*	*27/06/2017*
Commission Report to the European Parliament and the Council on the implementation of the organ legislation (2015/SANTE/504)	*Publication*	*Q1 2017*	*04/01/2017*
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 2017*	*3 new pilots were initialised and 2 closed. Discussion continues with 4 Member States.*

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

Specific objective 1.5: Increased access to medical expertise and information for specific conditions			Related to **Health Programme; CEF financing programme**
Result indicator 1.5.A: Number of established European Reference Networks **Source of data:** Information system on ERN, minutes of the Board of Member States on ERN meetings, licences of the ERN trademark licensed			
Baseline (2015)	**Interim Milestone**: 2016	2018	**Target** 2020 (forecast as the establishment of ERNs dependent on the no. of proposals received to the Call for ERN and the no. of approvals decided by the competent body (ERN Board of MS)	**Latest known results** 2017
0	10	20	30	24

Result indicator 1.5B: Number of data requests from the database **Source of data:** Orphanet database			
Baseline 2015	**Interim Milestone** 2018	**Target** 2020	**Latest known results** 2017
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[9]	1) On average around 82,000 pages viewed per day[10] 2) 5,822 diseases annotated with prevalence or incidence data

Result indicator 1.5C: Number of stakeholders included in the European Platform on Rare Diseases Registration and the size of the EU population covered by surveillance networks **Source of data:** The European Platform on Rare Diseases Registration			
Baseline 2015	**Interim Milestone** 2018	**Target** 2020	**Latest known results** 2017
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: 82; EU birth population covered: approx. 43% (approx. 2,2 million)

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 spending programme 3rd EU Health Programme
Main outputs in 2017:			
All new initiatives and REFIT initiatives from the Commission Work Programme			
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
Kick-off conference for the European Reference Networks (ERNs)	*Organisation of the conference*	*March 2017*	*Conference held 9-10 March 2017, with 24 ERNs established*
Virtual patient handling IT system for ERNs	*Operational*	*Q2 2017*	*After testing in the summer, the Clinical Platform Management System (CPMS) started assisting real patients on 20/11/2017*

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

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

Output	Indicator	Target	Latest known results
Establishment and effective coordination of approved ERNs	*All annual grants signed and operational*	*Q2 2017*	*Accomplished*
Coordination support contract for ERNs' functioning (training, communication, standard templates)	*Contract(s) signed*	*Q2 2017*	*Delayed due to further analysis of Networks' needs during their first year of operation*
Other important outputs			
Revision of Commission Regulation 847/2000 on orphan medicinal products (2016/SANTE/043)	*Adoption*	*Q2 2017*	*Expected Q1 2018* *Scientific comments received during the feedback mechanism which need to be consulted with the European Medicines Agency experts*
Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products ("ATMPs") (2015/SANTE/573)	*Adoption*	*Q2 2017*	*22/11/2017*
Link between ERNs and the Rare Disease Registration Platform	*Cooperation established*	*Q3 2017*	*Working relationship established*

Specific objective 1.6: Effective, efficient and reliable controls

Specific objective 1.6: Effective, efficient and reliable official controls		Related to **Food and feed expenditure Regulation (EU) No. 652/2014**
Result indicator 1.6.A: Percentage of DG SANTE's recommendations following its audits that Member States (MS) have satisfactorily addressed with corrective action. **Source of data:** Commission internal (DG SANTE)		
Baseline (2014)	**Target** (2017) (agreed on the basis of available data to DG SANTE)	**Latest known results**
60% for recommendations from reporting cycles 2011 - 2013	70% for recommendations from reporting cycles 2013-2015	74% for recommendations from reporting cycles 2013-2015

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 2017:			
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
EU Reference Laboratories	*No. of laboratories funded*	*43*	*46*
Better Training for Safer Food	*No. of trainings organised*	*175*	*170*
Computerised systems + IT (e.g. TRACES, ADIS, ADNS, EUROPHYT)	*No. of computer systems funded*	*7*	*7*
Other important outputs			
Commission Report to the European Parliament and the Council on the overall operation of official controls performed in Member States (2014-2016) to ensure the verification of compliance with food and feed law, animal health and welfare rules (2014/SANTE/011)	*Adoption*	*Q2 2017*	*Q2 2018* *SANTE is preparing a combined report covering the three past years (2014, 2015 and 2016) to give a comprehensive overview of Member State and Commission activities.)*
Health and Food Safety audits	*80% of programmed audits completed* *90% of the number of programmed and new audits completed*	*end 2017*	*80%* *95%*
Other SANTE activities to improve the performance of control systems:			
Organisation of regular meetings of networks of Member State officials 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 2017*	• *7 plenary meetings of the Networks for Multi-annual national control plans and national audit systems*

Output	Indicator	Target	Latest known results
Organisation of meetings with Member State (MS) experts in a number of areas such as animal welfare, slaughter hygiene or live bivalve molluscs to discuss common problems and exchange best practices identified	*Number of meetings:* *as per published SANTE audit and analysis work programme 2017*	*end 2017*	• *6 meetings with MS experts under the BTSF umbrella* • *1 meeting on cross-sectoral emergency preparedness* • *3 meetings in the area of animal welfare* • *12 meetings in the areas of pesticides/plant protection products, biocides, Europhyt*
Evaluation of facilities of Border Inspection Posts (BIPs)	*Number of evaluations:* *on average 50*	*end 2017*	• *21 applications from Member States and one from a non-EU country;* • *One audit performed in Denmark to assess a new BIP;* • *Correspondence sent to Member States requesting clarification: 32;* • *Layouts approved: 11.*
Evaluation of Member States' (MS) and non-EU countries' residue monitoring plans	*Number of evaluations:* *28 Member States plans and up to 50 non-EU country plans*	*end 2017*	• *28 MS plans and results fully evaluated;* • *274 plans from 87 non-EU countries reviewed for completeness and clarity;* • *38 non-EU country plans evaluated, incl. replys to competent authorities' questions;* • *5 recommendations to list new plans and 3 recommendations to delist plans provided.*
Management of lists of approved non-EU country establishments for the production of food of animal origin	*127 lists by country (27 lists by sector)*	*end 2017*	• *500 requests received to list, de-list or modify establishment lists from non-EU countries (relating to 15 different food sectors).* *All requests processed within the applicable time-limits.*
Operation of the notification system for plant health interceptions, EUROPHYT and reporting on plant pests	*Europhyt annual report*	*end 2017*	*Annual report on interceptions published July 2017.* *Annual report on outbreaks published November 2017*

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** (2016)	**Target** (2020)
17.1%	17.4 %	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)
20.4%	20.3 %	Increase
Bookmark		

SANTE specific data[11]

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

	2009	2010	2011	2012	2013	2014	2015	2016
EU28	4.65	4.66	4.63	4.66	4.65	4.67	4.64	4.64

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
	1.61	1.66	1.76	1.81	1.89	1.86	1.85	1.89

Source: Eurostat

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

	Jan.-Dec. 2012	Jan.-Dec. 2013	Jan.-Dec. 2014	Jan.-Dec. 2015	Jan.-Dec. 2016
IMPORT	85,521,430,550	86,042,115,489	90,748,071,584	100,106,566,653	100,876,733,723
growth (%)	1.3	0.6	5.5	10.3	0.8
EXPORT	70,093,343,859	75,419,779,783	78,793,204,577	81,931,187,052	83,961,191,029
growth (%)	10.6	7.6	4.5	4.0	2.5

Source: Eurostat

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

	Jan.-Dec. 2012	Jan.-Dec. 2013	Jan.-Dec. 2014	Jan.-Dec. 2015	Jan.-Dec. 2016
IMPORT	241,886,171,824	254,229,181,113	258,647,197,217	271,342,059,323	280,029,882,265
growth (%)	5.4	5.1	1.7	4.9	3.2
EXPORT	245,872,401,931	259,079,357,059	263,751,007,730	275,026,043,649	283,623,734,860
growth (%)	5.0	5.4	1.8	4.3	3.1

Source: Eurostat

[11] The data may differ slightly from the data included in the SANTE Strategic Plan 2016-2020 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	2017
2	12	22	29	14

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 spending programme: 3rd EU Health Programme
Main outputs in 2017:			
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*	*Q4 2017*	*Adoption delayed until Q1 2018 due to extensive work with the opinion of the impact assessment*
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
Health Technology Assessment reports under EUnetHTA Joint Action	*Reports prepared Implementation and uptake of joint work*	*In course of 2017*	*5 joint assessment reports (on medicinal products and medical devices); 7 early dialogues; 2 assessments of registries; Report presenting key implementation challenges in 59 HTA bodies in 31 countries was finalised in December 2017*

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** 2017
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	87 % All new centrally authorised MA decisions 100 % new MA Commission decisions for which there was an accelerated assessment by EMA[12]

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 spending programme: 3rd EU Health Programme
Main outputs in 2017:			
Important items from work programmes/financing decisions/operational programmes			
Output	**Indicator**	**Target**	**Latest known results**
On-site audit/assessment by DG SANTE for listing of non-EU countries	*Assessment finalised*	*1*	*Assessment of Korea - negative outcome, reassessment needed*
Study to support reporting requirement on centralised and decentralised procedures for pharmaceutical products	*Launch*	*2017*	*Procurement procedure to select contractor launched on 22/12/2017*
Other important outputs			
Report to the European Parliament and the Council on the performance of the EU's paediatric Regulation(2015/SANTE/530)	*Adoption*	*Q4 2017*	*26/10/2017*
Commission implementing Directive laying down the principles and guidelines of good manufacturing practices for medicinal products for human use (2015/SANTE/141)	*Adoption*	*Q1 2017*	*15/09/2017*
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	*Recognition of authorities of non-EU countries*	*In course of 2017*	*No Decision adopted due to the negative assessment of Korea*

[12] 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.

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** 2017
0	5	15	4

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 spending programme(s): NO
Main outputs in 2017:			
Other important outputs			
Output	**Indicator**	**Target**	**Latest known results (situation on 31/12/2017)**
Report to the Council Working Party on Public Health at Senior Level on Integrated Care	*Publication*	*Q1 2017*	*Published*
Report to the Council Working Party on Public Health at Senior Level on Primary Care	*Publication*	*Q4 2017*	*Published*

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 and DG Trade for the list of countries covered by trade and investments agreements*			
Baseline Goods average for 2014-2016, Services and FDI average for 2013-2015	**Latest known value** (2017) Goods, Services and FDI average for 2014-2016	**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 27% Exports 32% Total 30% Services: Imports 10% Exports 10% Total 10% FDI stocks: Imports 4% Exports 7% Total 6%	Goods: Imports 32% Exports 37% Total 34% Services: Imports 15% Exports 15% Total 15% FDI stocks: Imports 9% Exports 13% Total 11%	Goods: Imports 51% Exports 61% Total 56% Services: Imports 54% Exports 52% Total 53% FDI stocks: Imports 55% Exports 59% Total 57%
Goods Bookmark to the denominator			
Services bookmark to the denominator			
FDI stocks bookmark to the denominator			
* 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
SHARE	4.8	4.4	4.5	4.5	4.7	5.0	5.2	5.3

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
SHARE	5.3	4.9	4.8	4.9	5.0	5.3	6.1	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 2017**
WHO Executive Board: 85% resolutions negotiated	90%	95%	87%
World Health Assembly: 60% resolutions negotiated	75%	90%	80%
WHO Regional Committee for Europe: 50% resolutions negotiated	70%	90%	90%

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 (2017)**
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	4
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 60% 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**[13]	15 new or revised ICH guidelines	25 new or revised ICH guidelines	8

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

Result indicator 3.1.C: WTO cases[14] brought against the EU **Source of data:** WTO			
Baseline (2014)	**Interim Milestone** 2017	**Target** 2020 A diminishing number of cases brought against the EU by other WTO Members is in line with our policy to align EU legislation to international standards.	**Latest known results** (2017)
8	7	5	6

Outputs table:

Specific objective 3.1: Increased EU influence in international fora			Related to spending programme(s): NO
Main outputs in 2017:			
Other important outputs			
Output	**Indicator**	**Target**	**Latest known results**
Coordinated EU positions on WHO resolutions	*Delivered*	*20*	*36*
EU co-sponsored WHO resolution	*Delivered*	*1*	*0*
EU statements for WHO meetings	*Delivered*	*9*	*34*
Common positions coordinated with EU Member States to facilitate the alignment of existing and planned EU legislation and initiatives with Codex standards	*Delivered*	*120*	*101*
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	*Delivered*	*In the course of 2017*	*3*
Coordinated EU position for the OIE's aquatic and terrestrial Code and Manual	*Deliveredin writing*	*4*	*153*
Coordinated EU Statements for the OIE General Assembly	*Delivered orally*	*In course of 2017*	*29*
Coordinated EU positions in Organisation for Economic Co-operation and Development (OECD) meetings	*Delivered*	*In course of 2017*	*0 (health)* *90 coordinated EU positions at 3 meetings of Coordination Working Party (plant and seeds)*
Coordinated EU positions in documents and guidelines of the International Union for the Protection of New Varieties of Plants (UPOV)	*Delivered*	*In course of 2017*	*83 coordinated EU positions at 2 meetings of Coordination Working Party*
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 2017*	*19 coordinated EU positions at 1 meeting of Coordination Working Party*

[14] 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
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*	*Agreement on Sanitary-phytosanitary (SPS) were concluded with Japan in the context of the Free Trade Agreement (FTA) negotiations.* *Opening of FTA negotiations with Indonesia and Philippines. Good results under SANTE (SPS) perspectives until now.* *Very good progress on the negotiation of the SPS Chapter in view of a AA EU-MERCOSUR.* *Incorporation of Ecuador to the Multiparty Agreement EU-Colombia and Peru* *On-going negotiations of the EU-Azerbaijan Comprehensive Agreement*

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	2017
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	2017
4	3	1	4

Outputs table:

Specific objective 3.2: A balanced agreement with the US on pharmaceutical products and in SPS area			Related to spending programme(s) 3rd EU Health Programme
Main outputs in 2017:			
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 Programme; implementation of the agreement	*Submission of 12 audit reports to US; Recognition of around 10 EU authorities as equivalent*	*Q4 2017*	*20 audit reports submitted to US* *8 Member States recognised*