ANNEXES

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, 30 March 2017

[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

2.1 Human Resources

Objective 1: The DG deploys effectively its resources in support of the delivery of the Commission's priorities and core business, has a competent and engaged workforce, which is driven by an effective and gender-balanced management and which can deploy its full potential within supportive and healthy working conditions.		
Indicator 1: Percentage of female representation in middle management **Source of data:** Sysper		
Baseline: 27% at end 2015	**Target:** 35% by 2019 in accordance with the specific targets in SEC(2015)336, "Targets for female representations in management functions in the European Commission for the years 2015-2019". Milestone 1: 30% by 2017	**Latest known results** (2016) In 2016 SANTE recruited three new female Head of Units. The SANTE ratio of female middle managers increased by the end of 2016 to 31%.
Indicator 2: Percentage of staff who feel that the Commission cares about their well-being[2] **Source of data: Commission staff survey**		
Baseline: 42% in 2014 Staff survey	**Target**: gradual increase every year reaching above 50% by 2019	**Latest known results** (2016) 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.
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) 65% in 2016 Staff Survey which is place 29 out of 54 DGs and services. This indicator declined slightly in 2016 Staff Survey, but stays still above the Commission average. Factors contributing to this include the changes listed above and the cummulation 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.

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

Main outputs in 2016:			
Description	**Indicator**	**Target**	**Latest known results**
DG SANTE organisational structure is adapted in line with the operational needs of the SP.	New DG organigramme in place	01/02/2016	Organigramme implemented on 1/2/2016
Organisational culture: Define the 'Health(y)' DG we want to be. Organisation of a DG SANTE Management seminar to set the tone and ensure alignment of all SANTE managers to the overall strategic 'organisational excellence' objective	SM identifies and communicates on vision and expectations (organisational identity) to Staff.	15/03/2016	Extended management seminar took place on 2nd and 3rd March 2016
Redeployment: Staff is allocated in line with the priorities and operational needs identified in the SP taking carefully account of the balance between the interest of the service and the interest of the individual staff member	Reinforcements of priorities have been organised.	01/04/2016	Efficiency savings amounting to 17 FTEs were identified and 30 internal redeployments were implemented.
Recruitment of female managers: fill vacant management posts.	Recruit minimum two female HoUs and one female Senior Manager.	01/09/2016	Three new female HoUs and one female Director were recruited
Organisational change: Building effective teams and ensure staff engagement	At least all entities with new managers and/or significant change of staff members will participate into a team building exercise	31/12/2016	13 teambuilding events were organised involving 270 staff of which, 11 concerned Units with new HoU and/or significant change in the mission statement. Several team-buildings are planned in the beginning of 2017 to ensure 100% coverage.
Organise staff development actions to improve engagement and empowerment: to assist staff in taking a more active role in making things better.	Organise learning events for all staff on key skills Implement DG SANTE's Internal coaching initiative	31/12/2016	On average SANTE internal coachers received two requests for internal coaching per month. Three specific personal wellbeing SANTE wide trainings were organised.

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 2016

In 2016 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 the last 3 years, which does not make a representative sample nor 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. 11 legal acts are covered by evaluation/assessment/review and have already been evaluated in the last 5 year period. Soft policies or evaluations under FR rules are not 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) For more specific information on planned evaluations, please see Annex 3	Positive trend compared to baseline	30% based on the 2016MP; 28% based on 2017 MP

SANTE performance for 2016

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);
b) acts adopted within the last five years;
c) implementing acts;

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

For the 2017 MP, DG SANTE broadened the acquis covered by the screening of ex-post evaluation needs, so that all its policy areas were considered as potential candidates. The result of the mapping exercise yielded 25 evaluations (between 2017 and 2025), of which 6 are to start in 2017. This makes comparison with the baseline difficult (as the acquis is much broader than the list considered in 2015).

Also, other criteria (apart from the "age" of the last evaluation) influenced the decisions to evaluate or not in a certain area (policy priorities, resource constraints) which may lead to give precedence to evaluating certain areas as opposed to others with "older" evaluations.

All in all, DG SANTE considers that the trend of this indicator is positive.

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
Number of evaluations planned in the next 5 years (until 2020) Planned: 26[3]	Percentage of evaluations with final report 27% (7 evaluations - please see Annex 3)	100% of evaluations planned are finalised (final report)	50% (2 of 4 planned to be finalised in 2016)

SANTE performance for 2016

DG SANTE started 2016 with 7 (seven) on-going evaluations from previous years. Of them 4 (four) evaluations were planned to be completed, but only 2 were actually finalised in 2016.

From the 12 (twelve) evaluations planned to start in 2016-2022, 4 (four) evaluations were to start in 2016. However, only one of them started in 2016. Thus, DG SANTE finished the year with 6 (six) ongoing evaluations (5 (five) started before 2016 and 1 (one) started in 2016) which will continue in 2017, as indicated in the MP 2017.

The planning cycle is still affected by the new requirements brought about by the Better Regulation guidelines in 2015, which have extended the average time needed to perform an evaluation. As a result 4 of the 6 ongoing evaluations are planned to be completed in 2017, and one in 2018. *Indicator 3 – "Percentage of evaluations planned and finalised in the last year"* is expected to improve in subsequent years as this effect will phase out.

Other factors which affect the duration of the evaluation are the complexity of the legislation and its political visibility. Indeed, the three ongoing evaluations, included in the Commission's REFIT programme will continue longer than the average.

[3] Annex 3 MP 2016 gives us only 12 planned evaluations till 2020, not 26 as stated in the baseline of the Indicator 3 in the SP. In comparison, Annex 3 MP 2017 lists 25 items

2.3 Information Management

According to information gathered by the Document Management Officer (DMO), in 2016 DG SANTE already exceeded the target set for 2020 for indicators 2 and 3.

However, final official statistics partly differ from the data gathered by the DMO. This is particular true for indicator 2. The reason is that files opened to the visibility of the entire Commission were not taken into account at the moment in which calculations for this indicator were done. Therefore, it was decided to quote the official statistics used for indicator 3 also for indicator 2, as all SANTE files with normal visibility are shared with at least one other service (Internal Audit Service, Unit B.2).

Regarding indicator 1, the table reflects official statistics. The DMO report shows that all documents for 2015 are filed. All SANCO documents (2010-2014) had been also filed on the basis of DIGIT reports. Based on further information by the DMO, it is likely that statistics will show in March that the target of 0% is reached also for 2016.

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[4] (ratio) **Source of data:** *Hermes-Ares-Nomcom (HAN)[5] statistics*			
Baseline 2015		Target (2020)	Latest known results (2016)
1.24%		0%	1,28%
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)
98%		75%	98.33%
Indicator 3: Number of HAN files shared with other DGs **Source of data:** *HAN statistics*			
Baseline 2015		Target (2020)	Latest known results (2016)
98%		75%	98.33%
Indicator 4: Percentage of units using collaborative tools to manage their activities			
Baseline (2015)	Interim Milestone (2018)	Target (2020)	Latest known results (2016)
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

[4] 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.

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

			results (2016)
100%	100% (in total 512 requests)	100%	100% (in total 512 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 (2016)
20%	60%	90%	50%

2.4 External Communication

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.

Indicator 1: Percentage of EU citizens having a positive image of the EU

Definition: Eurobarometer measures the state of public opinion in the EU Member States. This global indicator is influenced by many factors, including the work of other EU institutions and national governments, as well as political and economic factors, not just the communication actions of the Commission. It is relevant as a proxy for the overall perception of the EU citizens. Positive visibility for the EU is the desirable corporate outcome of Commission communication, even if individual DGs' actions may only make a small contribution

Source of data: Standard Eurobarometer (2016)

Baseline: November 2014	Target: 2020	Latest known results[6]
Total "Positive": 39%; Neutral: 37 %; Total "Negative": 22%	Positive image of the EU ≥ 50%	Total "Positive": 35%; Neutral: 38 %; Total "Negative": 25%

Specific objective: To improve the image of the Commission by building on the benefits and savings of competitive protective systems in the Health and Food Safety Sectors for the EU citizens[7]

Indicator 2: Percentage of EU citizens who are informed about antimicrobial resistance and awareness raising campaigns

Source of data: Eurobarometer on AMR (2016)

Baseline: 2013[8]	Target[9]	Latest known results[10]
- 33% received information about unnecessary use of antibiotics - 36% changed behaviour after receiving information	- 40% respondents receive information about unnecessary use of antibiotics - 40% changed behaviour after receiving information	- 33% received information about unnecessary use of antibiotics (same than in 2013) - 34% changed behaviour after receiving information (36% in 2013).

Indicator 3: Number of contacts made as a result of communication actions supporting SANTE's policy priorities

Source of data: Collated monitoring data collected by SANTE from website visitors, social media reach, events participants and visitors their actions, from monitoring and evaluation contractors; from opinion pools

Baseline: 2015	Target	Latest known results[11]
222.710.099	50.000[12]	21.043.125[13]

[6] http://ec.europa.eu/COMMFrontOffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/STANDARD/surveyKy/2137

[7] This will be achieved through communication around the priorities mentioned in the narrative (Antimicrobial Resistance, modernisation of Health systems, crisis preparedness/management, notably in Plant Health and the EU as a global health and food safety player)

[8] 2013 AMR EB Results

[9] Trends are based on previous EB results on AMR 2009-2013 and targets are an indicative extrapolation based on the joint policy effort to be made in the period 2016-2020 (new Action Plan, increased coordination with MS including communication)

[10] http://ec.europa.eu/COMMFrontOffice/publicopinion/index.cfm/Survey/getSurveyDetail/instruments/SPECIAL/surveyKy/2107

[11] Reach of communication activities in 2016 includes DG SANTE Web unique visitors (8,993,127), Twitter (8,153,700 impressions over the year – 2.411.000 for @Food_EU and 5.742.700 for @EU_Health according to Twitter Analytics), visitors to stands at IGW, SIA (357.000) and JPO (3.200), AMR (928,623 including Press release launch Eurobarometer , visits website and impressions Action Plan); European Reference Networks (1,076,042 including visits website, and social media impressions); Ex-Smokers campaign (81,212 including page views and social media impressions);State of Health in the EU (1,127,415 including visits website, social media sponsored posts and video views); Press Releases and Memos (227.543 page views), e-news (35.326 subscribers), publications (24.220 printed copies distributed and 6.353 online views); Infographs & Factsheets (27.277 page views) and Web brochures (2,087 downloads)

Table 3.A

Objective: Informed policy decisions and better targeted communication campaigns on Antimicrobial Resistance at national, EU and international level, based on updated data and trends of knowledge by the general public on antimicrobial resistance. This objective contributes to specific objective 1.4. Effective, accessible and resilient healthcare systems in the EU and 1.8. Increased EU influence in international fora **Main outputs in 2016:** Antimicrobial Resistance Eurobarometer (2016): summary, national factsheets, press material, web updates, social media promotion, to be presented at media seminar (tbc).			
Description	**Indicator**	**Target**	**Latest known results**
Eurobarometer on Antimicrobial Resistance in the 28 MS and non-EU countries, promotion of results	- number of respondents who have taken antibiotics - number who took antibiotics for a flu - respondents who are aware that antibiotics do not kill viruses	Maintain, at least, same trends as between 2009 and 2013 EB - 5% decrease in citizens who have taken antibiotics - 2% fewer people who take antibiotics for a flu - 4% decrease in citizens who are aware that antibiotics do not kill viruses	EB published on 16 June 2016[14] : - 1% decrease in citizens who have taken antibiotics ✓2% decrease people who take antibiotics for a flu - 3% decrease in citizens who are aware that antibiotics do not kill viruses
Web	- number of page views on DG SANTE Website section on AMR	- 5% increase of visits to DG SANTE Website section on AMR (baseline 2015: 31.200 visits)	✓ Visits: 54 628 Unique visitors: 49 367
Social media	- number of social media posts - social media reach (organic and paid)	- At least 10 dedicated social media posts (at least 2 paid) - 30.000 Twitter accounts reached	✓ 62 tweets: 431.371 impressions (organic) 2 sponsored posts Eurobarometer ✓ 252.449 impressions: AMR Action Plan: 871.507 impressions

[12] 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.

[13] 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. This together with the absence of media seminars in 2016, explains why the figures are lower, even the overall reach on all the other comparable indicators increased in 2016.

[14] http://ec.europa.eu/dgs/health_food-safety/amr/docs/eb445_amr_generalfactsheet_en.pdf

The media seminar on AMR, initially foreseen for 2016, has been postponed by the final launch of the new Action Plan in June 2017. Media coverage, increased media attention and journalist engagement would benefit if media seminar is coordinated with this important policy deliverable.

Table 3.B

Objective: Relevant stakeholders engagement (NGOs) tackling the problem of Antimicrobial Resistance is encouraged and rewarded. This objective contributes to specific objectives 1.4. Effective, accessible and resilient healthcare systems in the EU **Main outputs in 2016:** EU Health Award for NGOs 2016 on AMR, promotion includes media relations, social media and web			
Description	**Indicator**	**Target**	**Latest known results**
Health Award for Good practices of European or national non-governmental bodies which have made a significant contribution to tackle Antimicrobial-Resistance: media relations	- number of journalists attending the award ceremony - number of articles following the award ceremony	- 10 journalists attending the award ceremony - 70 articles on the award	Action postponed to February 2017
Web	- Web visits to corresponding section/page	- 5% increase of web visits (baseline: 16.500)	Action postponed to February 2017
Social media	- number of social media posts & respective reach	- 5 unpaid & 1 sponsored tweets - 22.000 accounts for organic reach tweets & 30.000 accounts for sponsored tweets	Action postponed to February 2017

The award ceremony has been postponed to 2017 due to need to coordinate two Commissioners (RTD and SANTE) agendas. The 8 shortlisted initiatives for the EU Health Award for NGOs fighting AMR were announced during the European Antibiotic Day on 18 November 2016.

Table 3.C

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 2016:** ERN call for proposals, technical platform, ERN 3rd conference, promotion (web, social media, media)			
Description	**Indicator**	**Target**	**Latest known results**
Communication activities on the ERNs process –promotion for February 2016 call for proposals -, 3rd ERN conference: media relations	– number of journalists attending the conference in autumn 2016 – number of articles covering the topic of ERNs following the conference in autumn 2016	– 5 journalists attending ERN conference in autumn 2016 – 70% journalists write an article on ERN topic following the conference	3rd ERN conference will take place in March 2017, together with the formal launch of the networks (postponed).

Web	– number of views on ERN web page on SANTE website	– 5% increase in ERN page views	✓ Page Views: 438.376 – visits: 72.095; unique visitors: 43.098
Social media	- number of organic & sponsored @EU_Health tweets to promote the ERN call for proposals - reach of organic & sponsored @EU_Health tweets promoting ERN call for proposals	- 3 unpaid & 2 sponsored tweets - 22.000 accounts for organic reach tweets & 30.000 accounts for sponsored tweets	✓ 15 unpaid tweets published so far on the call for proposals ✓ 637.666 impressions ✓ Sponsored tweets postponed to 2017 (at the occasion of the launch and the conference)

24 ERNs applied in response to the first call for proposals in March-July 2016, including more than 900 highly specialised healthcare units of 350 hospitals located in 26 Member States and covering almost all possible diseases groups. Following an independent technical assessment, on 15 December 2016 the European Reference Network Board of Member States approved 23 ERNs; the 24th network is to be approved early 2017. The ERNs will become operational in March 2017. The 3rd conference together with the formal launch of the networks has been postponed as result of the time needed for the screening and approval process of the first wave of networks, which could only be finalised by the Board of Member States in December 2016.

Table 3.D

Objective: Increased awareness and stakeholder engagement on the "State of the Health in the EU" cycle This objective contributes to specific objective 2.3 Common Member States' tools and methodologies used for EU health systems performance assessments **Main outputs in 2016:** joint Commission-OECD report Health at a Glance: Europe (descriptive, horizontal starting point for the State of Health in the EU cycle, adjusted to the 2014 Commission Communication on effective, accessible and resilient health systems) NOTE: communication to be developed in cooperation with the OECD (channels, indicators and targets will be fine-tuned following the further negotiations on this action)			
Description	**Indicator**	**Target**	**Latest known results**
Communication on the publication of the HaG report: media relations	– number of journalists attending the publication press conference (23 November 2016) – number of articles covering the report	– 15 journalists attending the presentation of the report – 70 articles on the report	✓ approx. 30 journalists attended the presentation of the report ✓ approx. 100 articles on the report
Web	– number of views of the report/summary on SANTE website	– 5,000 web visits in the 6 months after the publication	- Health at a Glance: Europe 2014 Report page (23 Nov. 2016 – 31 Dec. 2016) - Visits: 846 and Page views: 870 (ongoing)
Social media	- number of @EU_Health tweets to promote the report - reach of @EU_Health tweets promoting the report	- 10 tweets - 22.000 accounts for organic reach tweets	✓ 18 tweets (organic) – 161.240 impressions ✓ 1 sponsored posts: 818.569 impressions ✓ 308.000 video views (paid & unpaid)

As a first step in the Commission's State of Health in the EU cycle, the Health at a Glance: Europe 2016 report was published on 23 November 2016. Published by the OECD with cooperation from the Commission, this report provides updated analysis of the health status of EU citizens and the performance of health systems.

Apart from various chapters with statistical indicators of 35 European countries, the 2016 report includes two cross-cutting chapters on political priorities: the labour market impacts of behavioural risk factors and related chronic diseases, and the strengthening of primary care systems.

Table 3.E

Objective: The advantages of a smoke-free life are promoted and smokers are encouraged to quit. This objective contributes to specific objective 1.3. Cost effective health promotion and disease prevention **Main outputs in 2016**: Finalisation of Ex-Smokers Campaign – phase-out & follow-up			
Description	**Indicator**	**Target**	**Latest known results**
Final phase of Ex-Smokers Campaign: media relations, stakeholder engagement	– number of media clippings – number of stakeholder accounts involved in the campaign	– 250 media clippings – 100 stakeholder accounts involved in the campaign	✓ 315 media clippings ✓ 200 stakeholder accounts involved
online activities (web, social media) aimed at promoting the online tool iCoach	– number of views on Ex-Smokers web page – number of iCoach downloads – number of tweets & Instagram posts – number of engagements on Twitter & Instagram – organic social media reach	– maintain the same number of page views – 5% increase in iCoach downloads – 5 tweets & 5 Instagram posts / week – 200 Twitter engagements & 100 Instagram engagements	✓ 21.300 page views iCoach went offline on 31 July 2016.

The last edition of 'Ex-Smokers are Unstoppable' was more determined than ever to help 25 to 34 year old smokers abandon tobacco by making them realise the many benefits of a smoke-free lifestyle and providing the tool to get them there. Better health and well-being, more disposable income and ultimately a better quality of life await those who decide to quit smoking. iCoach went offline on 31 July 2016.

Table 3.F

Objective: Information on regulation of e-cigarettes, public health & single market benefits of Tobacco Products Directive are communicated to stakeholders and general public This objective contributes to specific objective 1.3. Cost effective health promotion and disease prevention **Main outputs in 2016**: Tobacco Products Directive (entry into force May 2016): awareness event –tbc-, press material, web, social media			
Description	**Indicator**	**Target**	**Latest known results**
Media, digital & visual communication on new binding tobacco legislation – possibly using World No Tobacco Day 2016 as a hook,	– number of views on dedicated policy page	– 10% increase in web page views (Baseline: 15,600 visits -page on tobacco products. Whole tobacco section – 422,900 visits)	- Tobacco Policy page: Visits: 1 487 + Page views: 2 035 - Tobacco Products Regulation page :

			Visits: 1 512 + Page views: 1 783
Social media	– number of social media posts – social media reach (organic and paid)	– 5 unpaid & 2 sponsored tweets – 22.000 accounts for organic reach tweets & – 30.000 accounts for sponsored tweets	✓ 11 unpaid tweets published ✓ Overall reach 59,912 impressions - (no sponsored posts)

20 May 2016 was the Transposition deadline for Member States for the Tobacco Products Directive. In that same period the European Court of Justice confirmed that the Directive was valid. This triggered a lot of interest of the media in the Member States, to which the Commission responded with proactive information tools (Commissioner statement, memo, infographic, etc.).

Table 3.G

Objective: Increased confidence in a strong and efficient EU preparedness, prevention and response to crises in plant health. This objective contributes to specific objective 1.6. Effective, efficient and reliable official controls **Main outputs in 2016: Plant Health study trip for journalists**			
Description	**Indicator**	**Target**	**Latest known results**
One study trip in the first semester on Plant Health	– Number of attending journalists – Percentage of journalists who write a follow-up article – Number of follow-up articles	– 15 attending journalists – 70% journalists write a follow up article in the next 3 months – 24 articles published	– 14 attending journalists ✓ 86% journalists write a follow up article in the next 3 months – 12 articles published

The study trip lasted 3 days from 6 to 8 June 2016 and was focused on Plant Health and Pesticides. When the Study trip scheme was launched, it was decided that it shall focus on a "priority" of the portfolio. "Plant health" was therefore chosen (autumn 2015) and, since it appeared that media interest in this particular topic could be limited (topic hardly tackled in general media – with some exceptions (Xylella)), it was decided to modify the theme to be covered by "Pesticides", as this theme was the one preferred by the journalists (which at least triggered the most questions), because of its newsworthiness.

Table 3.H

Objective (definition): 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 2016:** series of four videos to be promoted on web, stakeholder events and social media			
Description	**Indicator**	**Target**	**Latest known results**
Series of four 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. The videos will primarily target stakeholders and competent authorities.	– Number of views in DG SANTE Website – Number of videos distributed in stakeholders meetings	– 400 video files distributed – 2.000 views (video to be released mid-2016)	Action postponed to 2017
Social media	– Number of dedicated social media posts – Reach of dedicated social media posts	– At least 4 dedicated social media posts – At least 20 000 accounts reached	Action postponed to 2017

The production of four videos will be successfully completed within the foreseen contract deadline of January 2017. The completion date of July 2016 had to be changed due to a delay in the procurement/contract process and the need to focus the available video communication resources at the beginning of 2016, in order to quickly reflect the DG SANTE re-organisation and change of the FVO name in all existing DG SANTE-Directorate F video/publication/web page content. This was successfully achieved. Upon completion, the new video series will be made available on-line and announced through social media, electronic newsletter and targeted mailing.

Table 3.I

Objective: EU added value on Antimicrobial Resistance and 'One Health'/'From Farm to Fork' policies are raised in stakeholders' agenda and made known to visitors in key events This objective links to specific objectives 1.2 Safe and sustainable food and food production systems and 1.4 Effective, accessible and resilient healthcare systems in the EU **Main outputs in 2016:** Stand at International Green Week, Salon International de l'Agriculture, Salone del Gusto and JPO (in cooperation with DG AGRI and DG MARE), promotion and media relation activities, stakeholder events			
Description	**Indicator**	**Target**	**Latest known results**
Promotional stand and stakeholder/media events at 2016 International Green Week in Berlin, Salon International de l'Agriculture, Salone del Gusto and JPO	– number of visitors to the stand – number of participants who declare the event met their expectations (survey)	International Green Week/SIA/Salone del Gusto: – 100.000 visitors/Fair – 75 % satisfaction – 15 participants in stakeholder events/Fair JPO: – 4.000 visitors at the stand	International Green Week/SIA/Salone del Gusto[15] ✓ 296 visitors/5 min at SIA, 194 visitors/5 min at IGW ✓ 99.8% at SIA and 100 % satisfaction rate at IGW

[15] Figures provided by DG AGRI

	– number of participants at stakeholders' events – satisfaction rate with the stand	– satisfaction rate 85%	✓ 19 participants JPO[16] - 3.200 visitors at the stand[17] ✓ satisfaction rate 86%.
Media relations	– number of articles	– 2 articles	- 2 articles
Social media	– number of dedicated social media posts – reach of dedicated social media posts	International Green Week/SIA/Salone del Gusto: – At least 10 dedicated social media posts (per event) – At least 30 000 accounts reached (Twitter) JPO – at least 5 dedicated social media posts with at least 15 000 accounts reached	International Green Week/SIA/Salone del Gusto: ✓ 14 tweets in Greek Week ✓ 11 tweets in SIA ✓ Overall reach: 140.554 impressions JPO - 2 tweets - 5 390 impressions

Annual communication spending (based on estimated commitments):			
Baseline (2015):	Target (2016):	Total amount spent	Total FTEs working on external communication
€2 677 000	**€2 543 000**	**€ 1 683 887**[18]	**8.5**[19] **FTE**

[16] Figures provided by DG COMM

[17] The overall visitors for the JPO decreased compared to 2015 (3.200 visitors in 2016 compared to 4.200 visitors of the stand in 2015; overall visitors 9.423 compared to 13.000 in 2015)

[18] The total amount spent in 2016 corresponds to activities for external communication, excluding stakeholder relations or other activities that are only policy related. Also, some of the activities initially included in the MP estimates have been carried out in-house, resulting in some savings. Finally, some activities (i.e. media seminars) have been postponed to 2017 to coincide with policy deliverables and thus ensuring increased impact.

[19] Staff carrying out communication activities strictly speaking. Other FTEs within the communication unit, contributing to policy development and other tasks (management and administrative support), are excluded.

Annex 3 Financial Reports - DG SANTE - Financial Year 2016

Additional comments

TABLE 1: OUTTURN ON COMMITMENT APPROPRIATIONS IN 2016 (in Mio €)					
			Commitment appropriations authorised	Commitments made	%
			1	2	3=2/1
Title 05 Agriculture and rural development					
05	05 04	Rural development	0,37	0,37	100,00 %
Total Title 05			0,37	0,37	100,00%
Title 07 Environment					
07	07 01	Administrative expenditure of the 'Environment' policy area	0,12	0,12	100,00 %
Total Title 07			0,12	0,12	100,00%
Title 17 Health and food safety					
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	18,98	18,98	99,96 %
	17 03	Public health	184,40	165,74	89,88 %
	17 04	Food and feed safety, animal health, animal welfare and plant health	240,50	236,58	98,37 %
Total Title 17			443,88	421,29	94,91%
Title 26 Commission's administration					
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,64	0,53	82,63 %
Total Title 26			0,64	0,53	82,63%
Total DG SANTE			445,01	422,31	94,90 %

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

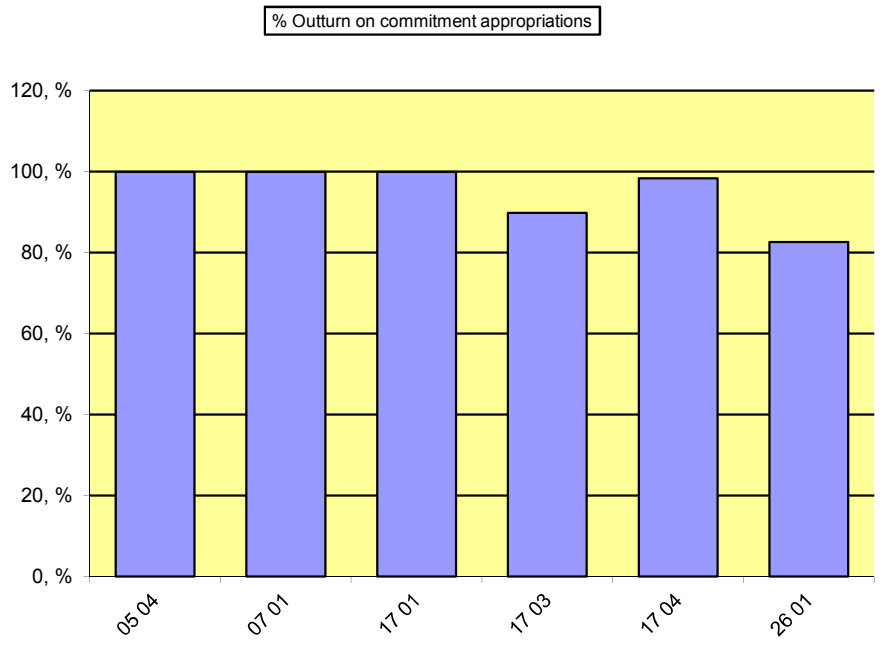

TABLE 2: OUTTURN ON PAYMENT APPROPRIATIONS IN 2016 (in Mio€)					
Chapter			Payment appropriations authorised *	Payments made	%
			1	2	3=2/1
Title 05 Agriculture and rural development					
05	05 04	Rural development	0,3	0,14	46,24 %
Total Title 05			0,3	0,14	46,24%
Title 07 Environment					
07	07 01	Administrative expenditure of the 'Environment' policy area	0,12	0,03	23,77 %
Total Title 07			0,12	0,03	23,77%
Title 09					
09	09 03		2,02	2,02	100,00 %
Total Title 09			2,02	2,02	100,00%
Title 17 Health and food safety					
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	24,34	17,92	73,60 %
	17 03	Public health	184,65	165,93	89,86 %
	17 04	Food and feed safety, animal health, animal welfare and plant health	227,26	222,71	98,00 %
Total Title 17			436,25	406,56	93,19%
Title 26 Commission's administration					
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,83	0,47	57,07 %
Total Title 26			0,83	0,47	57,07%
Title 33					
33	33 04		0,48	0,48	100,00 %
Total Title 33			0,48	0,48	100,00%
	Total DG SANTE		440,00	409,70	93,11 %

** 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).*

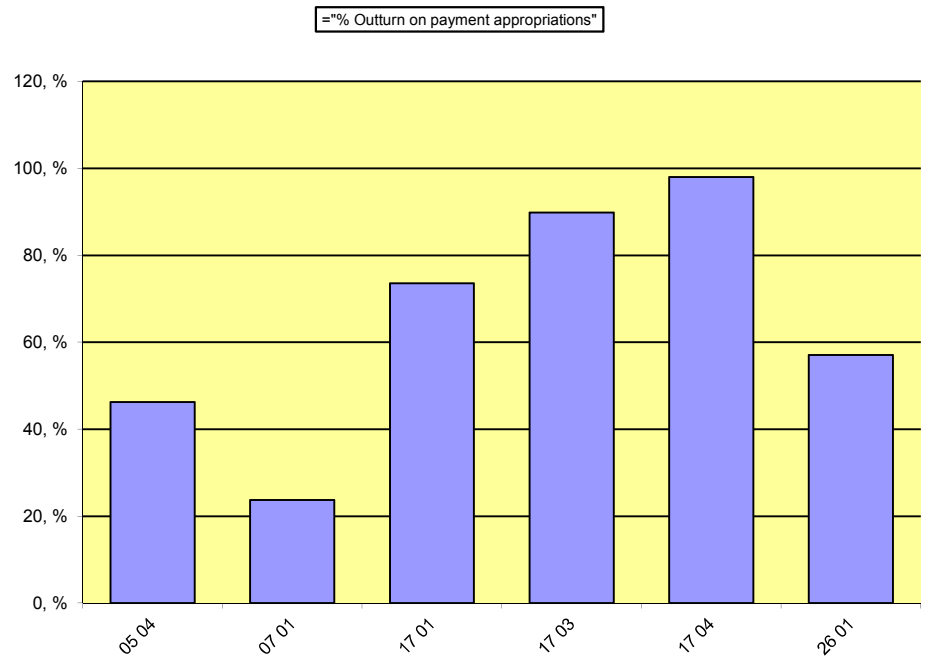

TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2016 (in Mio €)									
Chapter			2016 Commitments to be settled				Commitments to be settled from financial years previous to 2016	Total of commitments to be settled at end of financial year 2016(incl corrections)	Total of commitments to be settled at end of financial year 2015 (incl. corrections)
			Commitments 2016	Payments 2016	RAL 2016	% 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 04	Rural development	0,37	0,02	0,3491	94,35 %	0,09	0,44	0,21
Total Title 05			0,37	0,02	0,3491	94,35%	0,09	0,44	0,21
Title 07 : Environment									
07	07 01	Administrative expenditure of the 'Environment' policy area	0,12	0,03	0,09	0,76	-	0,09	-
Total Title 07			0,12	0,03	0,09	0,76	-	0,09	-
Title 09 :									
09	09 03		0	0,00	0	0,00 %	5,64	5,64	10,50
Total Title 09			0	0,00	0	0,00%	5,6415384	5,6415384	10,50306082
Title 17 : Health and food safety									
17	17 01	Administrative expenditure of the 'Health and food safety' policy area	18,98	13,80	5,17	0,27	-	5,17	5,36
	17 03	Public health	165,74	151,66	14,08	0,08	17,48	31,56	33,03
	17 04	Food and feed safety, animal health, animal welfare and plant health	236,58	33,46	203,11	0,86	87,27	290,38	317,63
Total Title 17			421,29	198,92	222,37	0,53	104,75	327,12	356,02
Title 26 : Commission's administration									
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,53	0,32	0,21	40,22 %	-	0,21	0,18
Total Title 26			0,53	0,32	0,21	40,22%	0	0,21374889	0,18234091
Title 33 :									
33	33 04		-	-	-	0,00 %	0,11	0,11	0,98
Total Title 33			-	-	-	0,00%	0,11	0,11	0,98
	Total DG SANTE		422,31	199,29	223,02	52,81 %	110,58	333,61	367,90

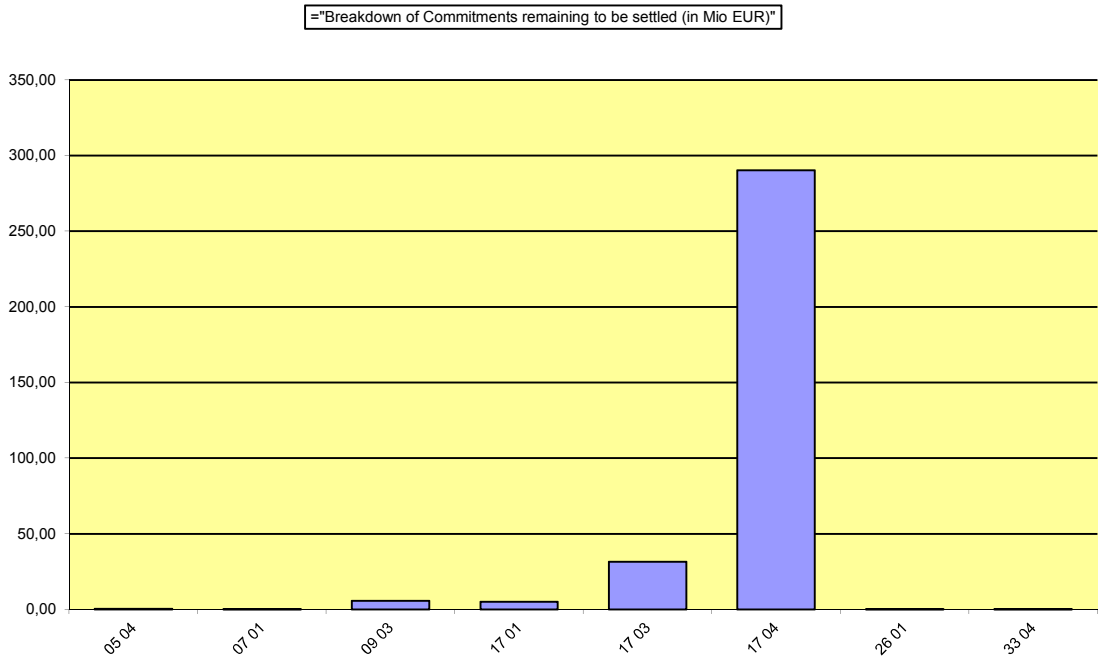

TABLE 4 : BALANCE SHEET SANTE

BALANCE SHEET	2016	2015
A.I. NON CURRENT ASSETS	16.121.519,76	17.734.851,09
A.I.1. Intangible Assets	1.349.643,55	914.154,22
A.I.2. Property, Plant and Equipment	14.771.876,21	16.205.990,37
A.I.5. Non-Current Pre-Financing	-	614.706,50
A.II. CURRENT ASSETS	28.387.889,48	35.981.937,82
A.II.2. Current Pre-Financing	14.769.914,58	21.698.743,40
A.II.3. Curr Exch Receiv &Non-Ex Recoverables	1.558.083,71	3.042.849,64
A.II.4. Inventories	12.052.523,59	11.232.100,00
A.II.6. Cash and Cash Equivalents	7.367,60	8.244,78
ASSETS	**44.509.409,24**	**53.716.788,91**
P.I. NON CURRENT LIABILITIES	(8.210.999,88)	(10.256.663,30)
P.I.3. Non-Current Financial Liabilities	(8.210.999,88)	(10.256.663,30)
P.II. CURRENT LIABILITIES	(182.524.165,02)	(206.857.679,32)
P.II.2. Current Provisions	(14.448.890,53)	(14.224.936,35)
P.II.3. Current Financial Liabilities	(2.045.664,07)	(2.001.381,30)
P.II.4. Current Payables	(6.938.020,53)	(9.121.608,24)
P.II.5. Current Accrued Charges &Defrd Income	(159.091.589,89)	(181.509.753,43)
LIABILITIES	**(190.735.164,90)**	**(217.114.342,62)**
NET ASSETS (ASSETS less LIABILITIES)	**(146.225.755,66)**	**(163.397.553,71)**

P.III.2. Accumulated Surplus / Deficit	1.133.462.551,07	764.443.912,25

Non-allocated central (surplus)/deficit*	(987.236.795,41)	(601.046.358,54)

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	2016	2015
II.1 REVENUES	-2057491,99	-1985050,88
II.1.1. NON-EXCHANGE REVENUES	-6188701,97	-4859688,26
II.1.1.5. RECOVERY OF EXPENSES	-200.218,42	-2.628.626,38
II.1.1.6. OTHER NON-EXCHANGE REVENUES	-5.988.483,55	-2.231.061,88
II.1.2. EXCHANGE REVENUES	4131209,98	2874637,38
II.1.2.1. FINANCIAL INCOME		-451,93
II.1.2.2. OTHER EXCHANGE REVENUE	4.131.209,98	2.875.089,31
II.2. EXPENSES	365680915,9	370648239,9
II.2. EXPENSES	365680915,9	370648239,9
II.2.10.OTHER EXPENSES	32.875.192,96	32.754.989,46
II.2.2. EXP IMPLEM BY COMMISS&EX.AGENC. (DM)	187.023.522,80	185.346.702,55
II.2.3. EXP IMPL BY OTH EU AGENC&BODIES (IM)	141.012.276,39	155.078.886,50
II.2.4. EXP IMPL BY 3RD CNTR & INT ORG (IM)	4.459.602,12	-2.475.458,95
II.2.5. EXP IMPLEM BY OTHER ENTITIES (IM)	301.077,90	
II.2.6. STAFF AND PENSION COSTS	-92.128,15	-175.410,50
II.2.8. FINANCE COSTS	101.371,83	118.530,86
STATEMENT OF FINANCIAL PERFORMANCE	**363.623.423,86**	**368.663.189,04**

Explanatory Notes (facultative):
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TABLE 5bis : OFF BALANCE SHEET SANTE		
OFF BALANCE	**2016**	**2015**
OB.1. Contingent Assets	0	299528
GR for pre-financing	0,00	299.528,00
OB.2. Contingent Liabilities	-356785817,9	-387150770,5
OB.2.6. CL Other	-1.785.817,92	-2.150.770,53
OB.2.7. CL Amounts relating to legal cases	-355.000.000,00	-385.000.000,00
OB.3. Other Significant Disclosures	-163676272,1	-156617515
OB.3.2. Comm against app. not yet consumed	-163.676.272,11	-156.617.514,96
OB.4. Balancing Accounts	520462090	543468757,5
OB.4. Balancing Accounts	520.462.090,03	543.468.757,49
OFF BALANCE	**0,00**	**0,00**

Explanatory Notes (facultative):
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TABLE 6: AVERAGE PAYMENT TIMES FOR 2016 - 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)
20	1	1	100,00 %	15			
30	1592	1483	93,15 %	17,45	109	6,85 %	38,83
42	1	1	100,00 %	40			
44	4	4	100,00 %	41			
45	23	21	91,30 %	25,10	2	8,70 %	648
60	73	72	98,63 %	26,89	1	1,37 %	61
90	301	291	96,68 %	62,32	10	3,32 %	100,6
198	1	1	100,00 %	185			
211	5	5	100,00 %	183,8			
212	4	4	100,00 %	177			
214	1	1	100,00 %	198			
217	1	1	100,00 %	48			
221	1	1	100,00 %	185			
227	1	1	100,00 %	26			

Total Number of Payments	**2009**	**1887**	**93,93 %**		**122**	**6,07 %**	
Average Net Payment Time	**27,65**			**25,95**			**54,06**
Average Gross Payment Time	**45**			**43,91**			**61,81**

Target Times

Target Payment Time (Days)	Total Number of Payments	Nbr of Payments within Target Time	Percentage	Average Payment Times (Days)	Nbr of Late Payments	Percentage	Average Payment Times (Days)
20	37	28	75,68 %	14,43	9	24,32 %	25,67
30	63	50	79,37 %	16,42	13	20,63 %	129,54

Total Number of Payments	**100**	**78**	**78,00 %**		**22**	**22,00 %**	
Average Net Payment Time	**31,4**			**15,71**			**87,05**
Average Gross Payment Time	**111,08**			**102,28**			**142,27**

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	78	445	22,15 %	2009	143.714.852,73	36,34 %	395.451.712,22

Late Interest paid in 2016

DG	GL Account	Description	Amount (Eur)
SANTE	65010000	Interest expense on late payment of charges	0,00
SANTE	65010100	Interest on late payment of charges New FR	459,25
			459,25

TABLE 7 : SITUATION ON REVENUE AND INCOME IN 2016								
Chapter		Revenue and income recognized			Revenue and income cashed from			Outstanding balance
		Current year RO	Carried over RO	Total	Current Year RO	Carried over RO	Total	
		1	2	3=1+2	4	5	6=4+5	7=3-6
57	OTHER CONTRIBUTIONS AND REFUNDS IN CONNECTION WITH THE ADMINISTRATIVE OPERATION OF THE INSTITUTION	871.138,95	283.652,00	1.154.790,95	801.969,77	283.652,00	1.085.621,77	69.169,18
59	OTHER REVENUE ARISING FROM ADMINISTRATIVE MANAGEMENT	256.496,87	-	256.496,87	256.496,87	-	256.496,87	-
60	CONTRIBUTIONS TO UNION PROGRAMMES	148.877,00	-	148.877,00	125.215,00	-	125.215,00	23.662,00
66	OTHER CONTRIBUTIONS AND REFUNDS	22.583.354,09	182.865,32	22.766.219,41	22.583.354,09	37.610,81	22.620.964,90	145.254,51
Total DG SANTE		**23.859.866,91**	**466.517,32**	**24.326.384,23**	**23.767.035,73**	**321.262,81**	**24.088.298,54**	**238.085,69**

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

INCOME BUDGET RECOVERY ORDERS ISSUED IN 2016	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			1	160.852,80	**1**	**160.852,80**	2	1.181.858,15	50,00%	13,61%
2011			5	177.636,08	**5**	**177.636,08**	5	177.636,08	100,00%	100,00%
2012	1	12.611,85	9	110.566,96	**10**	**123.178,81**	10	123.178,81	100,00%	100,00%
2013			6	77.175,69	**6**	**77.175,69**	6	77.175,69	100,00%	100,00%
2014			2	46.655,06	**2**	**46.655,06**	2	46.655,06	100,00%	100,00%
2015	1	285.640,51			**1**	**285.640,51**	10	22.104.486,12	10,00%	1,29%
Sub-Total	**2**	**298.252,36**	**23**	**572.886,59**	**25**	**871.138,95**	**35**	**23.710.989,91**	**71,43%**	**3,67%**

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	59	9.056.129,10	117	4.955.376,06			**176**	**14.011.505,16**	261	29.159.453,52	67,43%	48,05%
CREDIT NOTES	15	165.218,00	28	202.040,30			**43**	**367.258,30**	70	2.375.052,82	61,43%	15,46%
Sub-Total	**74**	**9.221.347,10**	**145**	**5.157.416,36**			**219**	**14.378.763,46**	**331**	**31.534.506,34**	**66,16%**	**45,60%**

GRAND TOTAL	**76**	**9.519.599,46**	**168**	**5.952.645,33**			**244**	**15.472.244,79**	**366**	**55.245.496,25**	**66,67%**	**25,92%**

TABLE 9: AGEING BALANCE OF RECOVERY ORDERS AT 31/12/2016 FOR SANTE						
	Number at 01/01/2016	**Number at 31/12/2016**	**Evolution**	**Open Amount (Eur) at 01/01/2016**	**Open Amount (Eur) at 31/12/2016**	**Evolution**
2011	1	1	0,00 %	145.254,51	145.254,51	0,00 %
2015	4		-100,00 %	321.262,81		-100,00 %
2016		4			92.831,18	
	5	5	0,00 %	466.517,32	238.085,69	-48,97 %

TABLE 10 : RECOVERY ORDER WAIVERS IN 2016 >= EUR 100.000						
	Waiver Central Key	**Linked RO Central Key**	**RO Accepted Amount (Eur)**	**LE Account Group**	**Commission Decision**	**Comments**

Total DG	

Number of RO waivers	

Justifications:
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TABLE 11 : CENSUS OF NEGOTIATED PROCEDURES - DG SANTE - 2016

Procurement > EUR 60,000

Negotiated Procedure Legal base	Number of Procedures	Amount (€)
Art. 134.1(a)	1	299.150,00
Art. 134.1(b)	1	80.000,00
Art. 134.1(c)	1	675.530,00
Total	**3,**	**1.054.680,00**

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

External Procedures > € 20,000		
Procedure Type	**Count**	**Amount (€)**
Competitive Dialogue (104(1) (e) FR)	1	5.000.000,00
TOTAL	**1**	**5.000.000,00**

Internal Procedures > € 60,000		
Procedure Type	**Count**	**Amount (€)**
Exceptional Negotiated Procedure without publication of a contract notice (Art. 134 RAP)	3	1.054.680,00
Open Procedure (Art. 104(1) (a) FR)	3	1.317.212,50
Open Procedure (Art. 127.2 RAP)	2	2.172.080,40
Restricted Procedure (Art. 104(1) (b) FR)	2	2.410.592,00
Restricted Procedure (Art. 127.2 RAP)	1	345.496,00
TOTAL	**11**	**7.300.060,90**

Additional comments

TABLE 13 : BUILDING CONTRACTS

Total number of contracts :	
Total amount :	

Legal base	Contract Number	Contractor Name	Description	Amount (€)

No data to be reported

TABLE 14 : CONTRACTS DECLARED SECRET

Total Number of Contracts :	
Total amount :	

Legal base	Contract Number	Contractor Name	Type of contract	Description	Amount (€)

No data to be reported

ANNEX 4: Materiality criteria

The criteria used in DG SANTE for making reservations are based on the standing instructions for the preparation of Annual Activity Reports. 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.

Thus, 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.

⇨ 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 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 or 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[1].

2.3 Non-representative sampling:

When 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.

[1] https://myintracomm.ec.europa.eu/budgweb/EN/rep/aar/Pages/guidance.aspx

ANNEX 5: Internal Control Template(s) for budget implementation (ICTs)

*The table below shows **DG SANTE's 2016 commitment implementation** without credits managed by cross-delegations (none in 2016), the Executive Agency for Consumers, Health, Agriculture and Food (CHAF-EA, EUR 65,1 million).*

Type of budget implementation - direct management Commitments executed by DG SANTE		**2016 M€**		**%**	**Number**		**Average M€**	**Control strategy**
Grants to Member States in the Food and Feed Safety policy area (Co-financing based on Regulation (EU) No 652/2014)	Animal disease eradication programmes	156,9			28 Member States	130 Programmes 2016	1,2	Annex 5.1.1
	Veterinary emergency fund	20,0			7 Member States	21 "Emergency files"	1,0	
	Phytosanitary measures (mostly "Solidarity" and "pest survey")	17,1			22 Member States 17 Member States	22 "pest survey" 17 "Solidarity"	0,5 0,3	
	Subtotal		**194,0**	**47%**				
Grants, direct management (Heterogeneous types of grants not following the typical grant procedure of an open call for proposal)	Subsidies to Reference Laboratories	15,7			43 Reference Laboratories		0,4	./.
	Other "grants" to Member States	2,0			28 Member States	58 Commitments	0,0	
	Direct grants to international organisations (OIE, UPOV, FAO)	1,0			3 Organisations		0,3	
	Subtotal		**18,7**	**5%**				
	Direct grants to WHO and other grants	3,4	**3,4**	**1%**	5 Beneficiaries		0,7	
Public procurement (According to Title V of the Financial Regulation)	Feed and Food	22,6				111	0,2	Annex 5.1.2
	Public Health	8,0				100	0,1	
	Support credits and other	3,0						
	Subtotal		**33,6**	**8%**				
Subsidies to the operating budgets of the executive agency and the three EU agencies	CHAF-EA (former EAHC)	5,5						Annex 5.2.1 5.2.2
	EFSA	79,4						
	ECDC	58,2						
	EMA	17,2						
	ECHA-biocides	0,9						
	Subtotal		**161,2**	**39%**		5 Agencies		
TOTAL commitments			**410,9**	**100%**				

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 the Food and Feed policy area and secondly, DG SANTE's control strategy for public procurement procedures.

a) 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. In 2016, the Common Financial Framework (CFF, Regulation (EU) No 652/2014) was the main basis for the corresponding expenditure in 2016.

The following descriptions focus on the national programmes for animal disease eradication and control as these account for about 74% 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.	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.	- 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

b) 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 table above).

By far most of the procurement procedures are based on framework contracts of DG SANTE or another DG, in particular DG DIGIT. 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.	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.	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.

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

In 2016, 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 65,1 million which amounts to 20% of the 2016 operational budget (without subsidy payments to agencies). Cross-delegations were given to authorising officers of other DGs for EUR 1,5 million of payment credits; none for commitment 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 2016

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 2016, 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 2016 (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. Guidelines for the day-to-day co-ordination between DG SANTE and the agency are established; where necessary, they are 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 quarterly 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.			**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)

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

In 2016, DG SANTE was 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].

- **European Centre for Disease Prevention and Control (ECDC)** located in Stockholm, Sweden[2] *(Budget 2016: total sum of human resources 291; EU funding 100%: EUR 58,2 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[3] *(Budget 2016: total sum of human resources 470; EU funding 100%: EUR 79,4 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[4] *(Budget 2016: total sum of human resources 811; EU funding 5%: EUR 17,2 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 2016 budget amounted to EUR 324,7 million which is to a large extent fee-financed.

- **Community Plant Variety Office (CPVO)** in Angers, France[5] *(Budget 2016: total sum of human resources 46; 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 2016 budget amounted to EUR 15,5 million (fully fee-financed).

- **European Chemicals Agency (ECHA)** located in Helsinki[6] - relevant for DG SANTE are ECHA's biocides activities *(Budget 2016 for biocides: total sum of human resources 55; EU funding 11%: EUR 0,9 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 2016 amounted to EUR 7,9 million.

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2 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.

3 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.

4 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).

5 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.

6 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 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"[7] 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.	**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 assessment or cost-benefit analysis, etc. **Benefits:** The total annual budget amount paid as subsidy to the agency's running costs possibly at 100% if significant legal errors occurred[8].	**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%

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

[8] Not all agencies are 100% financed by the EU budget, notably, CPVO is fee-financed to 100% and EMA to 5% in 2016 (see the introduction above).

2. Subsidy payments to EU 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, an agency worked on its whistleblowing procedure (SANTE co-operated with OLAF)	**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 7 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 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 "common vision paper on monitoring and supervision of decentralised agencies"; the Commission guidelines for the programming document and from 2015, the template for the activity report 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"	**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 7 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 agencies				
Main inherent risks	**Mitigating controls**	**Control coverage**	**Costs/benefits of controls**	**Control indicators**
	for decentralised agencies foresees that the agencies report on the "Assessment of the effectiveness of the internal control systems". All SANTE agencies that receive a Union subsidy adhere to this template. DG SANTE monitors that the information is provided and assesses. 6. After adoption by the MB, the agency publishes its annual report, final accounts and report on financial management. 7. If need be, DG SANTE informs the Internal Audit Service (IAS), refers issues to OLAF or as member of the MB triggers the "warning system" (SG note to all DGs Ref. Ares(2013)231088 - 21/02/2013).			

2. Subsidy payments to EU 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 7 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 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 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-financings until the agency's accounts have been audited by the Court of Auditors; DG SANTE recovers - if applicable – the 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 6 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 8: Decentralised agencies

DG SANTE included information in Annex 5

Annex 9 Evaluations and other studies finalised or cancelled during the year

No used in Annex	Title	Reason 1	Scope 2	Type3	Associated DGs	Costs (EUR)	Comments4	Reference5
I. Evaluations finalised or cancelled in 2016								
a. Evaluations finalised in 2016								
I.2	Evaluation of the functioning of the non-food scientific committees.	FR	Financial Regulation Art. 30, RAP. 18. The functioning of these scientific committees is to be evaluated in order to assess the value of their advice in the Commission decision-making process. This evaluation will also guide the services for the renewal of the mandate of the Scientific Committees in 2016 in support of the update of the Commission Decision.	O	SG, GROW, SANTE, ENV, EMPL	€ 79.100,00		https://bookshop.europa.eu/en/second-intermediate-evaluation-of-the-functioning-of-the-sante-non-food-scientific-committees-pbEW0616018/
I.4	Evaluation of the EU Action Plan against the rising threats from antimicrobial resistance	L	In line with the 5-year Action Plan on Antimicrobial Resistance (AMR), implementing the legislative framework for the harmonised monitoring of AMR in food and animals and the launch of the tender for an evaluation report, to be published in 2016, on the impact and effectiveness of the measures taken and the goals achieved by the Action Plan.	R	SG,AGRI, GROW, RTD	€ 199.812,59		https://bookshop.europa.eu/en/evaluation-of-the-ec-action-plan-against-the-rising-threats-from-antimicrobial-resistance-pbEW0116632/
b. Evaluations cancelled in 2016								
II. Other studies finalised or cancelled in 2016								
a. Other studies finalised in 2016								
III.1	Economic landscapes of human tissues and cells for clinical application in the EU	O	It aims to build an economic picture of importance and drivers/opportunities of (innovative) tissue and cell sectors in the EU. The main objective of the reports that shall be prepared under the present specific contract is to get detailed information, in-depth analysis and forecast on the global and EU market of tissues and cells for transplantation. The report shall provide insight into the following aspects:1. The characteristics of the EU tissues and cells market, such as market size, prices, actors, the extend and ratio of VUD, concerns and conflicts, supply and demand volumes and other elements in order to better understand these markets.2. The main actors involved in the tissues and cells markets, for each of the EU27 MS and overall on the EU level.3. Regulations on reimbursement and financing in the EU MS as well as countries outside the EU 4. A forecast for the EU market on tissue transplantation for the next 10 years, with respect to economic, medical, social, political and ethical evolutions in the different sectors within the field of tissues and cells' markets.	R	CHAFEA	€ 300.000,00	ISBN 978-92-9200-666-2	https://bookshop.europa.eu/en/economic-landscapes-of-human-tissues-and-cells-for-clinical-application-in-the-eu-pbEB0215343/

No used in Annex	Title	Reason 1	Scope 2	Type3	Associated DGs	Costs (EUR)	Comments4	Reference5
III.2	Review and map of education and training capacities in the EU (OECD study).	O	The study will map the structure and capacity of national education and training programmes for health professionals in the EU, particularly in medical universities and nursing schools. (Commission support to OECD study).	O	OECD	n/a		DOI:10.1787/9789264239517-en
III.3	FCM Foresight Project: baseline of the current situation concerning food contact materials for which there are no specific EU harmonised measures	O	To map the current industry supply chain and collect and organise information on the current national measures or other measures in place for these materials in order to assess the efficiency and effectiveness of the current situation, including the benefits as well as the administrative burdens and costs of the existing situation on businesses.	O	JRC	€ 111.144,00	JRC Study.	https://ec.europa.eu/jrc/en/news/mapping-industry-and-regulatory-frameworks-food-contact-materials-support-better-regulation.
III.4	Mapping of best practices and development of testing methods and procedures for identification of characterising flavours in tobacco products.	L	To contribute towards setting of uniform rules for the procedures for determining characterizing flavours (as set out under Article 7(3) of the Tobacco Products Directive) and to developing procedures for the operation and establishment for the independent advisory panel (as set out under Article 7(4)of the Tobacco Products Directive) [both implementing acts]	R	CHAFEA	€ 220.000,00	ISBN 978-92-9200-681-5 Doi:10.2818/08983	http://bookshop.europa.eu/en/mapping-of-best-practices-and-development-of-testing-methods-and-procedures-for-identification-of-characterising-flavours-in-tobacco-products-pbEB0415422/
III.6	Assessment of Citizens' exposure to tobacco marketing (Chafea/2014/Health/18)	L	Project to understand how, and through which channels, citizens (in particular young people) are exposed to tobacco and e-cigarette marketing in the EU. [Evaluation of Tobacco Advertising Directive 2003/33/EC]	E	CHAFEA	€ 200.000,00	ISBN 978-92-9200-684-6 doi:10.2818/7898	https://bookshop.europa.eu/en/an-assessment-of-citizens-exposure-to-tobacco-marketing-pbEB0215577/
III.7	Study on the identification of potential risks to public health associated with the use of refillable electronic cigarettes and development of technical specifications for refill mechanisms.	L	Study to assist the identification of potential risks to public health associated with the use of refillable electronic cigarettes, as set out in Article 20(10) of the Tobacco Products Directive [obligation to report to Council and Parliament], and the development of technical specifications for refill mechanisms, as set out in Article 20(13) of the Tobacco Products Directive [implementing act].	R	B2	€ 180.000,00	Not published in EUBookshop. ISBN 978-92-9200-715-7 doi: 10.2818/422906	http://ec.europa.eu/health/tobacco/docs/potentialrisks_specs_refillableecigarettes.pdf
III.8	Study on better cross-border coordination for high-cost capital investments in health.	O	Commission Agenda on Sustainable Health Systems; Public Health Programme WP 2014-2020. The study analyses the policy options of 'external price referencing' (EPR) and 'differential pricing' (DP) in terms of technical, economic and legal considerations, in order to investigate possible benefits from improved cross-country policy coordination in the area of pharmaceutical pricing.	O	None	€ 120.000,00	ISBN: 978-92-79-62108-6 DOI: 10.2875/36129 EW-06-16-024-EN-N	Executive summary: https://bookshop.europa.eu/en/study-on-better-cross-border-cooperation-for-high-cost-capital-investments-in-health-pbEW0616023/ Final report: https://bookshop.europa.eu/en/study-on-better-cross-border-cooperation-for-high-cost-capital-investments-in-health-pbEW0616024/

No used in Annex	Title	Reason 1	Scope 2	Type3	Associated DGs	Costs (EUR)	Comments4	Reference5
III.9	Study on enhanced cross-country coordination in the area of pharmaceutical product pricing.	O	The study analyses the policy options of 'external price referencing' (EPR) and 'differential pricing' (DP) in terms of technical, economic and legal considerations, in order to investigate possible benefits from improved cross-country policy coordination in the area of pharmaceutical pricing.	O	GROW	€ 80.000,00	ISBN 978-92-79-53462-1 EW-01-15-894-EN-N	Executive summary: https://bookshop.europa.eu/en/study-on-enhanced-cross-country-coordination-in-the-area-of-pharmaceutical-product-pricing-pbEW0415861/ Final report: https://bookshop.europa.eu/en/study-on-enhanced-cross-country-coordination-in-the-area-of-pharmaceutical-product-pricing-pbEW0115894/
III.10	Study on cost benefit analysis of reference laboratories for human pathogens	O	Mapping of existing sources of information	I	None	€ 196.000,00	ISBN 978-92-9200-721-8 doi:10.2818/959846 EB-02-16-620-EN-N	https://bookshop.europa.eu/en/study-on-cost-benefit-analysis-of-reference-laboratories-for-human-pathogens-pbEB0216620/
III.11	Third assessment of implementation of the Council Recommendation 77/2002/EC on the prudent use of antibiotic agents in human medicine on the basis of the reports from Member States.	L	Carry out an evaluation to determine the level of implementation of the measures proposed in the Recommendation and to assess the need for further action.	R	None	€ 15.000,00	Evaluation study	http://ec.europa.eu/dgs/health_food-safety/amr/docs/amr_projects_3rd-report-councilrecprudent.pdf
III.13	Monitor the activities of the EU Platform for Action on Diet, Physical Activity and Health	CWP	To monitor and evaluate the work of the members of the EU Platform for Action on Diet, Physical Activity and Health.	O	None	€ 97.410,00	Report not suitable for publication on EU bookshop or Sharepoint.	http://ec.europa.eu/health/nutrition_physical_activity/docs/2016_report_en.pdf
III.14	Monitor the activities of the European Alcohol and Health Forum.	CWP	To monitor and evaluate the work of the members of the European Alcohol and Health Forum.	O	None	€ 100.000,00	Report not suitable for publication on EU bookshop or Sharepoint.	http://ec.europa.eu/health/alcohol/docs/monitoring_progress7_en.pdf
III.15	Support for the definition of core competences of healthcare assistants	O	The development of a common training framework according to the moderised professional qualification directive for healthcare assistants should be prepared by setting up a network to build consensus on common knowledge, core competences and skills for healthcare assistance.	O	None	€ 190.665,00	To be soon published.	no
III.16	Assessment of available evidence on toxicity, addictiveness and attractiveness of ingredients contained in tobacco and related products on the basis of information submitted by the industry in the context of reporting obligations introduced by Directive 2001/37/EC and their utility for further regulatory action.	L	This study aims to ensure that existinfg legislation is well implemented and delivers concrete results on the ground, promote public health including as a factor for growth. Project to assist in the development of a 'Priority list of additives' as set out in Article 6(1) of the Tobacco Products Directive [Implemeting act]	R	CHAFEA	€ 250.000,00	To be soon published. ISBN 978-92-9200-743-0 doi: 10.2818/65608	no

No used in Annex	Title	Reason 1	Scope 2	Type3	Associated DGs	Costs (EUR)	Comments4	Reference5
III.17	Study on the regulation of advanced therapies in selected jurisdictions	O	To assess regulatory approached for advanced therapies in other jurisdictions outside the EU.	O	None	€ 170.000,00	Num Projet: 2016.5123 Catalog number : EB-04-16-602-EN-N ISBN : 978-92-9200-731-7 DOI : 10.2818/74841	https://bookshop.europa.eu/en/study-on-the-regulation-of-advanced-therapies-in-selected-jurisdictions-pbEB0416602/
III.18	Study on costs of unsafe care.	O	To gather evidence on costs of poor patient safety in orde to help political prioritisation in Member States. Report from the Commission COM(2012) 658 final	R	None	€ 200.000,00	To be soon published.	no
III.20	Study on off-label use of medicinal products in the EU.	O	The general objective for this request is to produce a study on the off-label use in the EU. The study intends to cover the public health aspects related to the off-label use of medicinal products, and in particular the balance between its benefits and risks for patients, and the regulatory framework for the off-label use of medicines. The conclusions of the study will be further assessed by Commission services and discussed with the Member States in order to identify if there is a need for coordination at EU level.	O	None	€ 230.000,00	To be soon published.	no
III.21	Studies on the impact of the establishment of criteria for endocrine disruptor (Reg. 1107/2009 and possibly cosmetics)	L	To investigate the impact of the criteria. Reg. 1107/2009, annex II. 3.6.5.	O	JRC	€ 336.750,00	ISBN: 978-92-79-59005-4 DOI: 10.2875/328498 Catalogue number: EW-02-16-567-EN-N	https://bookshop.europa.eu/en/screening-of-available-evidence-on-chemical-substances-for-the-identification-of-endocrine-disruptors-according-to-different-options-in-the-context-of-an-impact-assessment-pbEW0216567/
III.22	Background study for the assessment of the appropriateness and impact of the existing fee model for the Biocidal Products Regulation	L	Review the fee system establised by Regulation (EU) No 564/2013 on the fees and charges payable to the Europan Chemicals Agency pursuant to Regulation (EU) No 528/2012. Investigate what changes would be needed to ensure that fees constitute a sustainable source of income to complement the EU subsidy to support the biocides-related activities of the European Chemicals Agency. Legal base: Art. 17 of Regulation (EU) No 564/2013	E	None	€ 80.000,00	Catalogue number EW-04-17-143-EN-N DOI: 978-92-79-65683-5 ISBN: 10.2875/512528 To be soon published.	no
III.23	Study on the services to be provided by the European Reference Networks and its Members.	O	The purpose of this contract is to provide a conceptual framework, catalogue and analysis on the typology, characteristics and cost of services to be provided by the European Reference Networks and its Members.	O	None	€ 163.900,00	To be soon published.	no

No used in Annex	Title	Reason 1	Scope 2	Type3	Associated DGs	Costs (EUR)	Comments4	Reference5
III.24	Big Data in Healthcare Policy and Research	O	The study should provide an overview about the most promising trends of implementation of Big Data initiatives in EU health care sector. This study relates to Commission priority on the Digital Single Market where Big Data together with cloud computing is recognised as maximising the growth potential.	O	CNECT informed	€ 80.000,00	ISBN: 978-92-79-63285-3 DOI: 10.2875/734795	https://bookshop.europa.eu/en/study-on-big-data-in-public-health-telemedicine-and-healthcare-pbEW0616218/
III.25	Two assessments of Review of good practices in addressing selected health threats.	O	Assessments on serious cross-border threats to health caused by the Middle-East Respiratory Syndrome (MERS), by the declaration of poliomyelitis as a public health emergency of international concern, and by the recurrent measles outbreaks in a number of EU Member States.	O		€ 370.000,00	To be soon published.	no
III.26	Two case studies on environmental and biological threats incidents other than the ones caused by communicable diseases	O	The case studies are intended to allow understand potential challenges of a specific scenario, being used as lessons learned from real events, show good practices and bottlenecks and gaps in the response and monitoring of events, identify innovative developments in the risk management of threats to health.	R		€ 150.000,00	To be soon published.	no
III.27	Study on the availability/supply capacities of critical medical countermeasures against serious cross-border threats to health as defined by Decision 1082/2013 EU at Member states level and in the industry producing such countermeasures	CWP	The overall objective of this study is to identify MS needs for medical countermeasures against serious cross-border threats to health as defined by Decision 1082/2013/EU considered critical.	O		€ 110.000,00	To be soon published.	no
III.28	Study on the Public Health law network supporting the implementation of Decision 1082/2013/EU	O	Study aiming at getting a better understanding of national legislation in place in MS to make preparadness possible and underlining the differences between legality of measures in the various countries.	R	None	€ 302.000,00	To be soon published.	no
IV.9	Eurobarometer on Antimicrobial Resistance		This survey intends - to identify the use of antibiotics among the EU public: the frequency with which they take antibiotics, how they obtained them, and for what reason they took them; - to measure the levels of public knowledge about the nature and effectiveness of antibiotics and the risks associated with their unnecessary use; - to determine the impact of antibiotic awareness campaigns on the knowledge and actions of Europeans			€ 400.000,00	Eurobarometer Member States has been completed.	http://ec.europa.eu/dgs/health_food-safety/amr/docs/eb445_amr_generalreport_en.pdf
IV.26	EU Health Report 2016	O	The report provides the latest comparable data on the health status of Europeans and various aspects of health system performance in the EU Member States and EU candidate countries as well as in the EFTA/EEA.		None	€ 375.000,00	This report is the 4th edition of "Health at a Glance: Europe". OECD Publication.	http://ec.europa.eu/health/state/summary_en
	b. Other studies cancelled in 2016							

No used in Annex	Title	Reason 1	Scope 2	Type3	Associated DGs	Costs (EUR)	Comments4	Reference5
IV. 11	Study on economic scenarios related to the introduction of EU welfare requirements for farming of pigs (group housing of sows) in third countries and their impact on EU trade.	O	The study has been agreed by both parties during the 2nd technical meeting of the parties in the framework of the "Administrative Memorandum of Understanding on technical cooperation on animal welfare between DG SANTE and the Brazilian Ministry of Agriculture, Livestock and Food Supply". The meeting was held in Brasilia on 24 November 2014 and the actions for 2015 formally agreed. The actions included the performing of a feasibility study conducted by both parties with independent resources. One part of the study performed by SANTE will assess the economic scenarios for the introduction of EU welfare requirements for farming of pigs (group housing of pregnant sows) in Brazil, and their impact for EU trade. The complementary study carried out by the Brazilian authorities aims at characterizing pig production in Brazil and developing a Brazilian strategy to implement the EU requirements on group housing of sows. This action reflects one of the main objectives of the MoU with Brazil that is: *"to coordinate activities and projects (…) and facilitate the good understanding and the future negotiations on farm animal welfare matters between both parties"*	O	None	€ 100.000,00	STUDY CANCELLED FOLLOWING MANAGEMENT DECISION	N/A
IV. 12	Baseline Study on MS data needs	O	The study aims to identify a comprehensive set of implementation indicators for baseline data from 28 Member States (MS) from various existing sources and specific to the main policy areas within the remit of DG SANTE. The purpose is to develop a comprehensive policy baseline as the basis of further monitoring and assessment tools that can inform continuously on the level of implementation and impact of DG SANTE legislation in the EU Member States.	I	None	€ 400.000,00	STUDY CANCELLED FOLLOWING MANAGEMENT DECISION	N/A
IV. 25	Baseline Study on neurodegenerative diseases in EU Member States. **WP 2016**	O	Provide an overview of neurodegenerative diseases in EU Member States and EEA/candidate country and good practices. It should support countries in the planning of their policies and the exchange at European level. It contributes to the follow-up to the First WHO Ministerial Conference on Dementia.		None	€ 100.000,00	STUDY CANCELLED	N/A

1 Reason why the evaluation/other study was carried out, please align with Annex 3 of the MP 2016. The individual symbols used have the following meaning: L - legal act, LMFF - legal base of MFF instrument, FR - financial regulation, REFI
2 specify what programme/regulatory measure/initiative/policy area etc. has been covered
3FC – 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
4Allows to provide any comments related to the item (in particular changes compared to the planning). When relevant, the reasons for cancelling evaluations/ other studies also needs to be explained in this column.
5For evaluations the references should be 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 sho

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)	**Target** (2020) Europe 2020 target	**Latest known results** (2015)
69.2%	at least 75%	70,1%
Bookmark [1]		
Impact indicator 1.2: People at risk of poverty or social exclusion **Source of the data**: Eurostat		
Baseline (2013)	**Target** (2020) Europe 2020 target	**Latest known results** (2015 - estimated)
121.6 million	At least 20 million people fewer: 96.6 million	118.8 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 (no change to baseline, the next reporting exercise will be completed in November 2017)
0	14	28	0

[1] Please note that Eurostat periodically revises its published data to reflect new or improved information, also for previous years. The latest published data is available by clicking on "bookmark". The "latest known value" column reflects the data that was available at the time of the preparation of the AARs 2016 and it is the reference point for the AARs of Commission services.

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 The first report has been developed by SANTE C3 in June 2015 and has been presented to the Health Security Committee. The targets have been agreed internally within the Health threats Unit. Under Article 4 of Decision 1082/2013/EU Member States are obliged to consult each other with the aim to address the inter-sectoral dimension of preparedness and response planning at Union level.	**Latest known results** 2015 (no change to baseline, the next reporting exercise will be completed in November 2017)
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	**Interim Milestone**	**Target**	**Latest known results**
2014	2018	2020	2016
152/7800[2]	Decreasing value	Decreasing value (internal target)	217/7800
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	**Interim Milestone**	**Target**	**Latest known results**
2014	2018	2020	(2016)
19/25[3]	Increasing	Increasing (internal target)	21/25

[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			Related to Food and feed expenditure Regulation (EU) No. 652/2014
Result indicator 1.1E: Percentage of the EU territory covered by surveys for pests, in particular for pests not known to occur in the Union territory (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme) **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)	(2016)
50%	70%	100%	90%
Result indicator 1.1F: Percentage of the EU territory covered by surveys for pests considered to be most dangerous, as defined under Directive 2000/29/EC (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme) **Source of data:** Monitoring results for pests subject to EU measures.			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	2017	2020 (agreed in Commission proposal COM(2013)327 final)	(2016)
100%	100%	100%	100%
Result indicator 1.1G: Time between finding and notification for pests not known to occur in the Union (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programmes) **Source of data:** Data can be procured using notification of outbreaks by MS (electronic system planned to be put in place)			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2015	2017	2020	(2016)
42 days	20 days	8 days	49 days Expalnation included under chapter 1.1.1, point 3
Result indicator 1.1H: Success rate in eradicating pests not known to occur in the Union (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme) **Source of data:** Data can be procured using notification of outbreaks by MS (electronic system planned to be put in place)			
Baseline	**Interim Milestone**	**Target**	**Latest known results**
2013	2017	2020 (agreed Commission proposal COM(2013)327 final)	(2016)
0%	60%	95%	8,4%

Outputs table:

Specific objective 1.1: Effective preparedness, prevention , reaction and eradication of human, animal and plant diseases			Related to Health Programme; Food and feed expenditure Regulation (EU) No. 652/2014
Main outputs in 2016:			
Policy–related outputs			
Description	**Indicator**	**Target date**	**Latest known results (situation on 31/12/2016)**
Human diseases			

Commission Implementing Decision on coordination of health threats coordination under Decision 1082/2013/EU on serious cross-border health threats (2015/SANTE/171)	Adoption in (comitology) committee for serious cross-border health threats by April 2016	April 2016	Merged with 2015/SANTE/172 Adopted on 13/02/2017
Commission Implementing Decision on procedures of Early Warning and Response under Decision 1082/2013/EU on serious cross-border health threats (2015/SANTE/172)	Adoption in (comitology) committee for serious cross-border health threats by April 2016	April 2016	Merged with 2015/SANTE/171 Adopted on 13/02/2017
Commission implementing Decision to adapt the list of communicable diseases under surveillance under Decision 1082/2013/EU (2015/SANTE/021)	Adoption in (comitology) committee for serious cross-border health threats by December 2016	December 2016	Foreseen for 4Q 2017 Explanation for the delay included in point 1.1.1
Commission implementing Decision to amend case definitions for diseases under Decision 1082/2013/EU (2015/SANTE/022)	Adoption in (comitology) committee for serious cross-border health threats by December 2016	December 2016	Merged with 2015/SANTE/021 (above)
Animal diseases			
New legal framework for animal health in a form of the EP and Council Regulation	Adoption by the EP and the Council	May 2016	Published in OJ on 31/03/2016
Commission Decisions on handling evolving epidemiological situations	Adopted emergency Decisions as necessary, according to the epidemiological situation.	In course of 2016	24 decisions adopted in the course of the year
Commission rules on safe imports, trade and related aspects	Adopted Commission implementing rules.	In course of 2016	2 Decisions relating to trade facilitation following an outbreak of an animal disease in a third country 9 Decisions relating to trade facilitation adding countries or regions to the list of countries allowed to export
Plant diseases			
Commission Decisions on emergency measures against some specific pests	Adoption of Decisions as necessary according to (new) outbreak situations	31 December 2016	3 Commission Decisions
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	31 December 2016	1 Commission Decision
Adoption of Commission implementing	Adoption	1) 2nd	1) published on

legislation/guidance recognising innovative developments in seed production (1. fodder plants (2015/SANTE/698), 2.true potato seeds (2015/SANTE/568)		quarter 2016 2) 4th quarter 2016	02/12/2016 2) adopted on 21/03/2017 (delay due to continued discussions with the Member States)
Adoption of Commission proposals to recognise EU equivalence with Ukraine and to move decision making to Commission level to meet increasing import requests due to globalisation of trade (2015/SANTE/669 and 2015/SANTE/668)	Adoption of two co-decision proposals	3rd quarter 2016	4Q 2017 (delay due to internal procedures still ongoing)
To support new innovative plant varieties by revising the proceeding before CPVO, (2015/SANTE/014)	Adoption	2nd quarter 2016	Adopted on 01/09/2016
Main expenditure outputs			
Description	Indicator	Target	**Latest known results (situation on 31/12/2016)**
Human diseases			
Study on the added value of a strategic and life course approach to vaccination)	Final report with recommendations	July 2016	cancelled (as a tenderer did not provide documentation to meet exclusion criteria))
Study on shortcomings related to low vaccination coverage in health care workers (education and training of health care workers)	Final report with recommendations	July 2016	cancelled (reason as above)
2 Case studies on environment and biological threats other than the ones caused by communicable diseases and making assessments of existing good practices in addressing health threats	Report and identification of good practices	July 2016	Delivered in July 2016
Study on the Public Health law network supporting the implementation of Decision 1082/2013/EU	Identification of gaps in national laws that could jeopardise the implementation of coherent preparedness planning in EU Member States	October 2016	A workshop and exercise delivered in 2016. Report to be finalised in Q1 2017
Workshop targeting media, civil society and health professionals relating to the implementation of the Decision 1082/2013 on serious cross-border threats to health	Final report with concrete recommendations for future steps	July 2016	Delivered in July 2016
Study on the availability / supply	Final report with concrete	July 2016	Delivered in 2016

capacities of critical medical countermeasures at Member States level and in the industry	recommendations for future steps		
Intersectoral table top exercise on outbreak coordination and response involving public health and other sectors", mainly on climate change	Final report with concrete recommendations for future steps	July 2016	Delivered in April 2016
Animal diseases			
Reduction in the number of cases in wildlife in Member States where a programme is co-funded	Annual report	Less than 150 cases in 2017	31 in 2016 (latest available data)
Reduction in the number of classical BSE cases in Member States where a programme is co-funded	Annual report	Less than 5 cases in 2017	2 in 2015 (latest available data)
Reduction of herd prevalence of bovine tuberculosis in Member States where a programme is co-funded	Annual report	Reduction of 10% per year	Reduction of 3,57% in 2015 (latest available data)

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 (2015)**
90000 confirmed cases of human salmonellosis	67000 cases	60000 (sustained negative trend in incidence cases)	94625

Result indicator 1.2.B[4]: 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**	**2016**
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%[5]**	80%	85%	81.5%

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**	**Target**	**Latest known**

[4] 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.

[5] The number of outputs may have been influenced partially by the introduction of new, more time consuming administrative procedures.

	Milestone		results
2015	**2017**	**2020**	**2016**
Number of draft Review reports which were actually submitted to PAFF Committee / Number of draft review reports which should have been submitted to SCPAF **8/9= 89%**	90%	100%	89%

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 DG 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** 2016
0/0	5/5	0/0

Outputs table:

Specific objective 1.2: Safe and sustainable food and food production systems	Related to spending programme: Food and feed expenditure Regulation (EU) No. 652/2014		
Main outputs in 2016:			
Policy–related outputs			
Description	**Indicator**	**Target date**	**Latest known results (situation on 31/12/2016)**
Commission Report to Parliament and Council on National Action Plans under the Directive on Sustainable Use of pesticides (2015/SANTE/024)	Adoption	2nd quarter 2016	Q3 2017 (explanation for the delay included in point 1.1.2)
Report on food intended for sports people (2015/SANTE/057)	Adoption	2nd quarter 2016	Adopted on 15/06/2016
Report on young-child formulae (2015/SANTE/059)	Adoption	1st quarter 2016	Adopted on 31/03/2016
Report on the implementation of Directive 2009/41 on the contained use of genetically modified micro-organisms (2015/SANTE/429)	Adoption	3rd quarter 2016	Adopted on 20/12/2016
Report on alcoholic beverages (2015/SANTE/681)	Adoption	3rd quarter 2016	Adopted on 13/03/2017 (delay due to the Commission's internal discussions)
Guidelines on allergen labelling and on Quantitative Ingredients Declaration (QUID) (2015/SANTE/647)	Adoption	2nd quarter 2016	1Q 2017 (explanation for the delay included in point 1.1.2)
Report on the exercise on the delegated powers under Regulation (EU) No 1169/2011 (2015/SANTE/677)	Adoption	11 March 2016	Adopted on 11/03/16
Commission Implementing Regulation on the provision of voluntary indication of origin or place of provenance of foods - Article 26(3) of Regulation (EU) No 1169/2011 (2015/SANTE/670)	Adoption	4th quarter 2016	Q2 2017 (delay due to consultations with Member States and

			stakeholders)
Report to the European Parliament and the Council on systems restraining bovine animals (2015/SANTE/548)	Adopted	8 February 2016	Adopted on 08/02/2016
EU Guidelines on protection of pigs (2015/SANTE/387)	Adoption	8 March 2016	Adopted on 08/03/2016
Report on the application of EU animal welfare rules at farm level (2015/SANTE/610)	Adoption	2nd quarter 2016	Adopted on 08/09/2016
Report to the European Parliament and the Council on broilers' genetic selection (2015/SANTE/555)	Adoption	2nd quarter 2016	Adopted on 07/04/2016
Market access for safe substances			
Authorisations for new substances and new uses of already authorised substances used as food additives, food flavourings, novel foods, substances used in plastic food contact materials	Adoption	Throughout the year	39 authorisation adopted
Authorisations for new active substances , new uses of already authorised active substances, modifications and re-evaluations of feed additives	Adoption	Throughout the year	289 additives authorised
Individual authorisation of 106 recycling processes for plastic materials coming into contact with food (2015/SANTE/203-332)	Adoption	4th quarter 2016	Q3 2017 (delay due to legal issues to be solved and workload because of unexpected priorities)
Approvals and renewal of previously approved active substances in plant protection products (PPP) and biocidal products	Adoption	Throughout the year	Biocides: 30 approvals of active substances for one or more biocidal-product types Pesticides: 16 approvals and renewals for active substances for PPP
Establishing maximum residues levels (MRL) for pesticides	Adoption	Throughout the year	MRLs established for 86 substances based on applications or implementing Codex maximum residue limits for certain commodities Complete MRL review (all commodities) was performed for 39 substances.
Withdrawal of certain substances (flavourings, pesticides)	Adoption	Throughout the year	Flavouring substances : 9 Biocides: 46 active substances not approved for use in one or more biocidal product-types due to unacceptable risk or lack of support by the manufacturer Pesticides: 6 active substances for PPP not

			approved/not renewed
Authorisations of GMO's food and feed uses, and for cultivation	Adoption	Throughout the year	11 authorisations
Report on the sustainable use of biocides (2015/SANTE/180)	Adoption	1st quarter 2016	Adopted on 17/03/2016
Guidance Document on the risk assessment of plant protection products on bees (2016/SANTE/036)	Adoption	3rd quarter 2016	Q2 2017 (explanation for the delay included in point 1.1.2)
Implementation of food legislation			
Commission Delegated Regulation on total diet replacement for weight control (2015/SANTE/146)	Adoption	3rd quarter 2016	2Q 2017 (explanation for the delay included in point 1.1.2)
Commission Delegated Regulation on food for special medical purposes (2015/SANTE/144)	Adoption	1st quarter 2016	Published in OJ on 25/09/2015
Commission Delegated Regulation on infant formula and follow-on formula (2015/SANTE/145)	Adoption	1st quarter 2016	Published in OJ on 25/09/2015
Commission Regulation for the meal replacements (2015/SANTE/666)	Adoption	3rd quarter 2016	Adopted on 24/08/ 2016
Commission implementing Regulation on plant protection products to specify criteria to identify endocrine disruptors (2015/SANTE/001)	Adoption	3rd quarter 2016	2Q 2017 (discussions in respective Committee took longer than expected)
Commission Delegated Regulation on endocrine disruptors (biocides) (2016/SANTE/045)	Adoption	3rd quarter 2016	2Q 2017 (discussions in respective expert group took longer than expected)
Main expenditure outputs			
Description	Indicator	Target	**Latest known results (2015)**
Reduction in the number of confirmed cases of brucellosis in humans in Member States where a programme is co-funded	Annual report	Reduction of 2% per year	Increase of 17.3% in 2015 compared to 2014
Reduction in the number of confirmed cases of *salmonella* in humans in Member States where a programme is co-funded	Annual report	Reduction of 2% per year	Increase of 6.8% in 2015 compared to 2014 (2016 report will be published after the summer 2017)

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** (based on the Global Capacity Survey in 2015)
2015	2017	2019	2015
12	19	28	12 (next Global Capacity Survey to be carried out in 2017)

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			
Baseline 2015	**Interim Milestone** 2017	**Target** 2020 Gradual coverage of all MS as final target	**Latest known results** 2016
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) 21 2) 23 3) 20 (added sugars) and 15 (total sugars) 4) 23

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 State reporting on implementing the European Commission Initiative on Breast Cancer			
Baseline (2017: guidelines under development until 2017)	**Interim Milestone** 2018	**Target** 2019 "Communication from the commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on action against cancer: European partnership"	**Latest known results** (data will be available in 2017)
0	18	24	0

Outputs table:

Specific objective 1.3 : Cost effective health promotion and disease prevention		Related to spending programme: Health Programme	
Main outputs in 2016:			
Policy–related outputs			
Description	**Indicator**	**Target date**	**Latest known results (situation on 31/12/2016)**
Commission implementing decision on a priority list of additives (2015/SANTE/487)	Adoption	2nd quarter 2016	Adopted on 18/05/2016

Commission implementing decision on technical standards for refillable cigarettes and Report on health risks of refillable electronic cigarettes (2015/SANTE/486)	Adoption	2nd quarter 2016	Adopted on 14/04/2016
Commission Implementing acts on determining characterising flavour and setting up of an advisory Panel (originally scheduled for Q4 2015) (2015/SANTE/134 and 2015/SANTE/547)	Adoption	2nd quarter 2016	Adopted on 18/05/2016
Main expenditure outputs			
Description	**Indicator**	**Target**	**Latest known results (situation on 31/12/2016)**
Health at a Glance: Europe 2016 report on the health situation in the EU Member States	Report published	4th quarter 2016	Moved to specific objective 1.4
Joint Action on reducing alcohol related harm: guidance for policy makers on low risk drinking guidelines, survey methodology on consumption patterns and harmful use and a tool kit on best practises to reduce alcohol related harm.	Completion	4th quarter 2016	October 2016
Policy brief and international conference by the project "Innovating care for people with multiple chronic conditions in Europe" (ICARE4EU)	Policy brief produced International conference held	February 2016	22 March 2016
Platform on Knowledge Exchange of the Joint Action CHRODIS - an online help-desk for policy makers and a repository of best practices on chronic care	Platform operational	May 2016	February 2017 (it took longer than expected to develop the criteria for evaluation of best practices)

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		2016
4	8	12	18	10

Result indicator 1.4.B: Level of average EU consumption of antibiotics in human **Source of the data**: ECDC			
Baseline 2013	**Interim Milestone** 2017	**Target** 2021	**Latest known results (2015)**[6]
23.9 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 23.9 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	24.9 Defined daily doses/1000 inhabitants/day consumed in the Community and hospital sectors combined (22.4 in the Community and 2.5 in the hospital sector)

Outputs table:

Specific objective 1.4: Effective, accessible and resilient healthcare systems in the EU			Related to spending programme(s) N/A
Main outputs in 2016:			
Policy–related outputs			
Description	**Indicator**	**Target date**	**Latest known results (situation on 31/12/2016)**
Evaluation of EU Action Plan against rising threats from antimicrobial resistance. (2015/SANTE/521)	Evaluation report published	First half 2016	Published on 24/10/ 2016
Report on the implementation of the blood legislation (2015/SANTE/501)	Implementation report published	2nd quarter 2016	Published on 21/04/2016
Report on the implementation of the organ legislation (2015/SANTE/504)	Implementation report published	3rd quarter 2016	Published on 10/01/2017
Report on the implementation of the tissue legislation (2015/SANTE/505)	Implementation report published	2nd quarter 2016	Published on 21/04/2016

[6] Data for 2016 will be available only in November 2017

Main expenditure outputs			
Description	**Indicator**	**Target**	**Latest known results (situation on 31/12/2016)**
Health at a Glance: Europe 2016 report on the health situation in the EU Member States	Report published	4th quarter 2016	Published on 23/11/2016
Preparatory action: Antimicrobial resistance and causes of non-prudent use of antibiotics in human medicine (ARNA)	Publication of report of study with recommendations Conference	4th quarter 2016 2nd quarter 2016	Report to be published in Q2 2017 (further work is required by DG SANTE on a study prepared by the external contractor) The conference took place in June 2016 in Utrecht, NL.
Implementation of Council Recommendation on prudent use of antimicrobials in human medicine.	Report on implementation of recommendation by EU Member States published	2nd quarter 2016	Published September 2016
Meeting of ministers of health and agriculture on antimicrobial resistance.	Ministerial conference and outcome statement	February 2016	Took place in February 2016

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**:		**Target**	**Latest known results**
	2016	2018	2020 (forecast as the establishment of ERNs dependent on the no. of proposals received to the Call for ERN and the no. of approvals decided by the competent body (ERN Board of MS)	2016
0	10	20	30	23

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** 2016
On average around 90,000 pages viewed per day 4,726 diseases annotated with prevalence or incidence data	Maintain number of the website requests To increase number of annotated diseases	To increase number of website requests To increase number of annotated diseases[7]	On average around 130,000 pages viewed per day 5,329 diseases annotated with prevalence or incidence data

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

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	**Interim Milestone**	**Target**	**Latest known results**
2015	2018	2020	2016
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: 56; EU birth population covered: approx. 34% (approx. 1.8 million)

Outputs table:

Specific objective 1.5: Increased access to medical expertise and information for specific conditions			Related to spending programme(s): N/A
Main outputs in 2016:			
Policy–related outputs			
Description	**Indicator**	**Target date**	**Latest known results (situation on 31/12/2016**
Assessment report on the package leaflet and the summary of product characteristics of medicinal products for human use (2015/SANTE/701)	Adoption	2nd quarter 2016	Adopted on 22/03/2017 (delay du to revision of the draft dollowing stakeholders' comments)
Revision of the Commission notice on orphan medicinal products (2015/SANTE/139)	Adoption	2nd quarter 2016	Adopted on 17/11/2016
Revision of Commission Regulation 847/2000 on orphan medicinal products (2016/SANTE/043)	Adoption	4th quarter 2016	Q2 2017 (more time was needed than expected to carry out consultations)
Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products ("ATMPs") (2015/SANTE/573)	Adoption	4th quarter 2016	Q2 2017 (explanation for the delay included in point 1.1.5)

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** (2016) (agreed on the basis of available data to DG SANTE)	**Situation end of 2016**
60% for recommendations from reporting cycles 2011 - 2013	70% for recommendations from reporting cycles 2012-2014	79% for recommendations from reporting cycles 2012-2014

Outputs table:

Specific objective 1.6: Effective, efficient and reliable official controls			Related to Food and feed expenditure Regulation (EU) No. 652/2014
Main outputs in 2016:			
Policy–related outputs			
Description	**Indicator**	**Target date**	**Latest known results (situation on 31/12/2016)**
Report on the operation of official controls in the Member States on food safety, animal health and animal welfare, and plant health (2014/SANTE/011)	Adoption	2nd quarter 2016	2Q 2017 (explanation for the delay included in point 1.1.5)
Main expenditure outputs			
Description	**Indicator**	**Target**	**Latest known results (2015-2016)**
BTSF: success rate of the tests performed by the participants after the training	Tests of participants	Success rate for more than 70 % of the total number of participants	88 % (2015)
BTSF: overall satisfaction rate of participants attending the training	Satisfaction survey	Satisfaction rate of over 80%	90 % (2016)
EURLs: Percentage of success rate of proficiency tests organised by EURL for the NRL	Results of proficiency tests	Success rate of over 80%	85 % (2015)
EURLs: Satisfaction rate of participants at the annual workshop organised by the EUIRL, according to a standard survey	Satisfaction survey	Satisfaction rate of over 80%	87 % (2015)

Specific objective 1.7: Increased EU influence in international fora

Specific objective 1.7: Increased EU influence in international fora			Related to spending programme(s) **No**
Result indicator 1.7.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 2016**
WHO Executive Board: 85% resolutions negotiated	90%	95%	80%
World Health Assembly: 60% resolutions negotiated	75%	90%	77%
WHO Regional Committee for Europe: 50% resolutions negotiated	70%	90%	90%
Result indicator 1.7.B: Number of countries which recognise ICH guidelines			

Source of data: ICH			
Baseline 2015	**Interim Milestone** 2018	**Target** 2020 The new ICH Association was established in 2015. Implementation of guidelines take time and a 5-year implementation plan will be requested from new ICH members for guidelines that are considered to be a priority	**Latest known results** **(2016)**
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	5 new ICH members (2 regulatory and 3 industry members)
Implementation of ICH guidelines by new members ICH members will have to gradually implement the corpus of ICH guidelines and associated harmonisation documents. **ICH has until now (since 1990) developed more than 60 guidelines**.	70 % of guidelines implemented by new ICH members	85 % of guidelines implemented by new ICH members	The information from the 2 new regulatory members is not yet available(they only joined ICH in November 2016)
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**[8]	15 new or revised ICH guidelines	25 new or revised ICH guidelines	6 revised ICH guidelines 5 Q&As

Result indicator 1.7.C: WTO cases[9] 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** (2016)
8	7	5	8

Outputs table: None

[8] 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)

[9] 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.

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)	**Target** (2020) Europe 2020 target	**Latest known results** (2015)
17.1%	20%	17.3%
Bookmark		
Impact indicator 2.2: Intra-EU trade in goods (% of GDP) **Source of the data**: Eurostat		
Baseline (2014)	**Target** (2020) Europe 2020 target	**Latest known results** (2015)
20.4%	Increase	20.4%
Bookmark		

SANTE specific data[10]

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

	2008	2009	2010	2011	2012	2013	2014
EU28	4,35	4,68	4,68	4,65	4,68	4,68	4,70

Source: Eurostat

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

PERIOD	2008	2009	2010	2011	2012	2013	2014	2015
	1,59	1,61	1,66	1,76	1,81	1,89	1,87	1,86

Source: Eurostat

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

	Jan.-Dec. 2011	Jan.-Dec. 2012	Jan.-Dec. 2013	Jan.-Dec. 2014	Jan.-Dec. 2015
IMPORT	84.397.197.463	85.521.420.515	86.042.335.807	90.748.311.791	100.106.202.407
growth (%)	14,2	1,3	0,6	5,5	10,3
EXPORT	63.353.940.050	70.081.347.209	75.419.757.878	78.793.914.233	81.934.856.414
growth (%)	16,7	10,6	7,6	4,5	4,0

Source: Eurostat

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

	Jan.-Dec. 2011	Jan.-Dec. 2012	Jan.-Dec. 2013	Jan.-Dec. 2014	Jan.-Dec. 2015
IMPORT	229.581.048.744	241.880.239.497	254.129.571.806	258.606.144.232	271.520.329.824
growth (%)	8,9	5,4	5,1	1,8	5,0
EXPORT	234.165.567.966	245.856.815.509	259.081.326.857	263.847.808.360	275.459.047.827
growth (%)	8,9	5,0	5,4	1,8	4,4

Source: Eurostat

[10] 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 assessments 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	2015
2	12	22	29	15

Outputs table: None

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** 2016
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	89% All new centrally authorised MA decisions 87.5% new MA Commission decisions for which there was an accelerated assessment by EMA[11]

[11] 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.

Outputs table:

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
Main outputs in 2016:			
Policy–related outputs			
Description	**Indicator**	**Target date**	**Latest known results (situation on 31/12/2016**
Commission Delegated Regulation laying down principles of good manufacturing practice for investigational medicinal products for human use and associated Commission guidelines (2015/SANTE/142)	Adoption	4th quarter 2016	Planned early 2017
Commission Implementing Regulation on the details arrangements for the Good Clinical Practice inspection procedures including the qualifications of the inspectors (2015/SANTE/140)	Adoption	4th quarter 2016	Planned early 2017 Unexpected discussion on the interplay with the data protection Regulation
Commission Implementing Directive laying down the principles and guidelines of good manufacturing practices for medicinal products for human use (2015/SANTE/141)	Adoption	4th quarter 2016	Planned early 2017
Guideline on Guidelines on Good Manufacturing Practice for investigational medicinal products (2015/SANTE/532)	Adoption	4th quarter 2016	Completed but to be adopted jointly with the legal acts mentioned above
Report on EU pharmacovigilance activities (2012 - 2014) (2015/SANTE/589)	Adoption	2nd quarter 2016	Adopted on 08/08/2016

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** 2015
0	5	15	0

Outputs table: None

General objective 3: A reasonable and balanced free trade agreement with the US

General objective 3 : A Reasonable and Balanced Free Trade Agreement with the U.S.		
Impact indicator 3.1: Share US in total EU FDI stocks (US trade / extra trade) **Source of the data**: Eurostat		
Baseline (2014)	**Target** (2020) Europe 2020 target	**Latest known results** (2015)
Inwards 35.0% Outwards 32.4% Total 33.3% The figures were calculated subtracting "Special Purpose Entities" FDI from "Total" FDI in order to have "non-SPE" FDI figures that can be comparable with other international data.	Increase	Inwards 43.5% Outwards 35.0% Total 38.4%
Bookmark		

SANTE specific data[12]

Table 5 Share of US in total FDI for selected sectors (2013, 2014, EU 28)

		Direct investment abroad (DIA)	Direct investment in the reporting economy (DIRE)
		Net FDI outward	Net FDI inward
Extra EU-28	Manufacture of food products; beverages and tobacco products, 2013	233.787,1	92.830,3
Extra EU-28	Manufacture of basic pharmaceutical products and pharmaceutical preparations, 2013	111.957,0	35.902,3
Extra EU-28	**All FDI activities 2013**	**5.456.191,8**	**4.130.346,0**
Extra EU-28	Manufacture of food products; beverages and tobacco products, 2014	276.284,7	107.108,2
Extra EU-28	Manufacture of basic pharmaceutical products and pharmaceutical preparations, 2014	133.929,5	40.908,6
Extra EU-28	**All FDI activities 2014**	**6.000.193,6**	**4.758.479,3**
Extra EU-28	**All FDI activities 2015**	**6.894.053,7**	**5.841.913,7**
United States	Manufacture of food products; beverages and tobacco products, 2013	43.399,2	55.507,9
United States	Manufacture of basic pharmaceutical products and pharmaceutical preparations, 2013	55.386,7	27.977,4
United States	**All FDI activities 2013**	**1.835.582,0**	**1.675.978,9**
United States	Manufacture of food products; beverages and tobacco products, 2014	53.931,8	62.901,6
United States	Manufacture of basic pharmaceutical products and pharmaceutical preparations, 2014	75.926,9	27.634,5
United States	**All FDI activities 2014**	**2.059.388,6**	**1.784.865,9**
United States	**All FDI activities 2015**	**2.561.234,2**	**2.436.420,4**
Share US in total EU FDI in manufacture of food products;		18,6%	59,8%

[12] 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).

	Direct investment abroad (DIA)	Direct investment in the reporting economy (DIRE)
	Net FDI outward	Net FDI inward
beverages and tobacco products, 2013	**Average inward/outward: 39,2%**	
Share US in total EU FDI in manufacture of basic pharmaceutical products and pharmaceutical preparations, 2013	49,5%	77,9%
	Average inward/outward: 63,7%	
Share US in total EU FDI 2013	33,6%	40,6%
	Average inward/outward: 37,1%	
Share US in total EU FDI in manufacture of food products; beverages and tobacco products, 2014	19,5%	58,7%
	Average inward/outward: 39,1%	
Share US in total EU FDI in manufacture of basic pharmaceutical products and pharmaceutical preparations, 2014	56,7%	67,6%
	Average inward/outward: 62,1%	
Share US in total EU FDI 2014	34,3%	37,5%
	Average inward/outward: 35,9%	
Share US in total EU FDI 2015	37,2%	41,7%
	Average inward/outward: 39,4%	

Source: Eurostat – the data in the table includes "Special Purpose Entities" FDI

Table 6 Share (%) of US trade in food (food and live animals) in total of EU extra trade on food and live animals (EU28)

	2008	2009	2010	2011	2012	2013	2014	2015
SHARE US/EXTRA	7,3%	6,8%	7,1%	7,0%	6,9%	7,3%	7,7%	8,4%

Source: Eurostat

Specific objective 3.1: A balanced agreement with the US on pharmaceutical products and in SPS area

Specific objective 3.1: A balanced agreement with the US on pharmaceutical products and in SPS area			Related to spending programme(s) **No**
Result indicator 3.1.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	2016
Beef	2	8	20	3
Sheep/Goat meat	1	2	4	1
Grade A Dairy Products	0	3	9	0
Apples and Pears	0	8	8 (current number of applications)	0
Egg Products	1	3	9	2

Result indicator 3.1.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	2016
4	3	1	4

Outputs table: None