

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, 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 exhaustive.”

[Signed in ARES]

Matthew Hudson

Brussels, 30 March 2016

ANNEX 2: Human and financial resources

DG	Activity	Establishment Plan posts	External Personnel	Total
	Food and feed safety, animal health, animal welfare and Plant health	407	61	468
	Management of the Directorate-General for Health and Food Safety	72	16	88
	Policy strategy and coordination for the Directorate-General for Health and Food Safety	37	13	50
	Public health	158	49	207
SANTE	Total	674	139	813

General remark: the above data rely on the snapshot of Commission personnel actually employed in each DG/service as of 31 December of the reporting year. These data do not necessarily constitute full-time-equivalents throughout the year

Budget lines		FMC	Crédits	Engagement	Paiement	% EXECUTION
17	17.010211.00.01.10	SANTE	3.384.072	3.384.072	2.828.897	
17	17.010211.00.01.30	SANTE	25.000	25.000	17.186	
17	17.010211.00.02.20	SANTE	1.500.000	1.500.000	1.037.324	
17	17.010211.00.02.40	SANTE	417.928	417.928	4.592	
17	17.010211.00.03	SANTE	2.000.000	2.000.000	1.037.800	
17	17.010211.00.04	SANTE	-	-		
17	17.010211.00.05	SANTE	50.000	50.000		
17	17.010211.00.06	SANTE	218.196	218.196	119.191	
17 Total			7.595.196	7.595.196	5.044.990	100,00%

Annex 3 Financial Reports - DG SANTE - Financial Year 2015**Table 1 : Commitments****Table 2 : Payments****Table 3 : Commitments to be settled****Table 4 : Balance Sheet****Table 5 : Statement of Financial Performance****Table 6 : Average Payment Times****Table 7 : Income****Table 8 : Recovery of undue Payments****Table 9 : Ageing Balance of Recovery Orders****Table 10 : Waivers of Recovery Orders****Table 11 : Negotiated Procedures (excluding Building Contracts)****Table 12 : Summary of Procedures (excluding Building Contracts)****Table 13 : Building Contracts****Table 14 : Contracts declared Secret**

Additional comments

TABLE 1: OUTTURN ON COMMITMENT APPROPRIATIONS IN 2015 (in Mio €)					
			Commitment appropriations authorised	Commitments made	%
			1	2	3=2/1
Title 07 Environment					
07	07 02	Environmental policy at Union and international level	6,28195371	5,95158202	94,74 %
Total Title 07			6,28195371	5,95158202	94,74%
Title 17 Health and consumer protection					
17	17 01	Administrative expenditure of the 'Health and consumer protection' policy area	21,14427358	21,05683467	99,59 %
	17 03	Public health	188,9145279	182,684114	96,70 %
	17 04	Food and feed safety, animal health, animal welfare and plant health	237,238628	236,8760871	99,85 %
Total Title 17			447,2974295	440,6170358	98,51%
Title 26 Commission's administration					
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,60873084	0,495965	81,48 %
Total Title 26			0,60873084	0,495965	81,48%
Total DG SANTE			454,188114	447,0645829	98,43 %

* 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

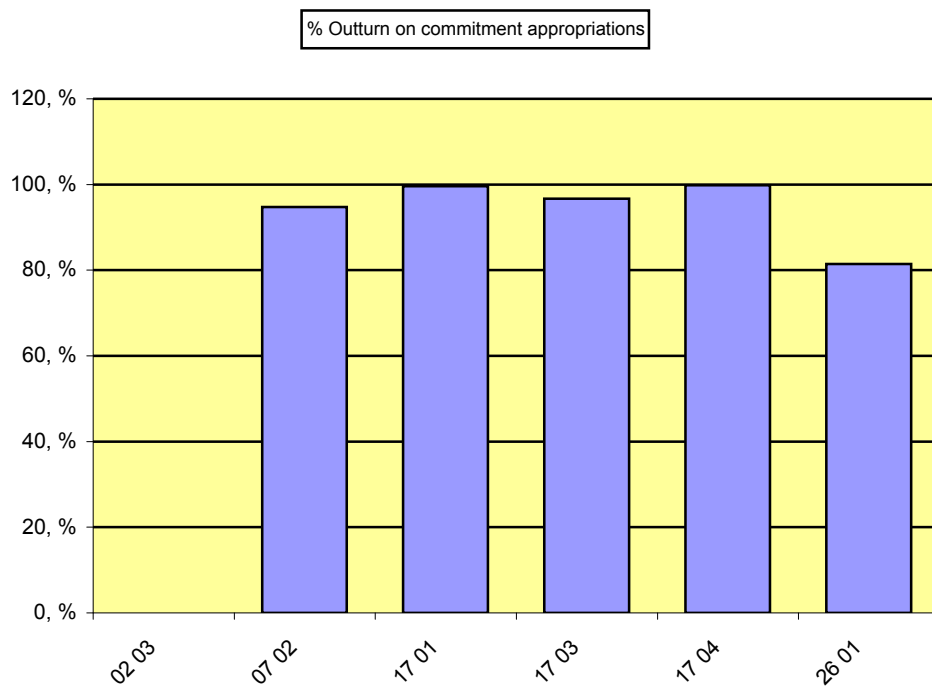


TABLE 2: OUTTURN ON PAYMENT APPROPRIATIONS IN 2015 (in Mio€)					
Chapter			Payment appropriations authorised *	Payments made	%
			1	2	3=2/1
Title 02 Enterprise and industry					
02	02 03	Internal market for goods and sectorial policies	0,086	0,08381976	97,46 %
Total Title 02			0,086	0,08381976	97,46%
Title 07 Environment					
07	07 02	Environmental policy at Union and international level	6,28195371	5,951582	94,74 %
Total Title 07			6,28195371	5,951582	94,74%
Title 17 Health and consumer protection					
17	17 01	Administrative expenditure of the 'Health and consumer protection' policy area	27,22442184	20,69551545	76,02 %
	17 03	Public health	187,8908499	181,6832696	96,70 %
	17 04	Food and feed safety, animal health, animal welfare and plant health	186,3633786	186,1913866	99,91 %
Total Title 17			401,4786504	388,5701717	96,78%
Title 26 Commission's administration					
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,81842943	0,51303642	62,69 %
Total Title 26			0,81842943	0,51303642	62,69%
Total DG SANTE			408,6650335	395,1186099	96,69 %

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

= "% Outturn on payment appropriations"

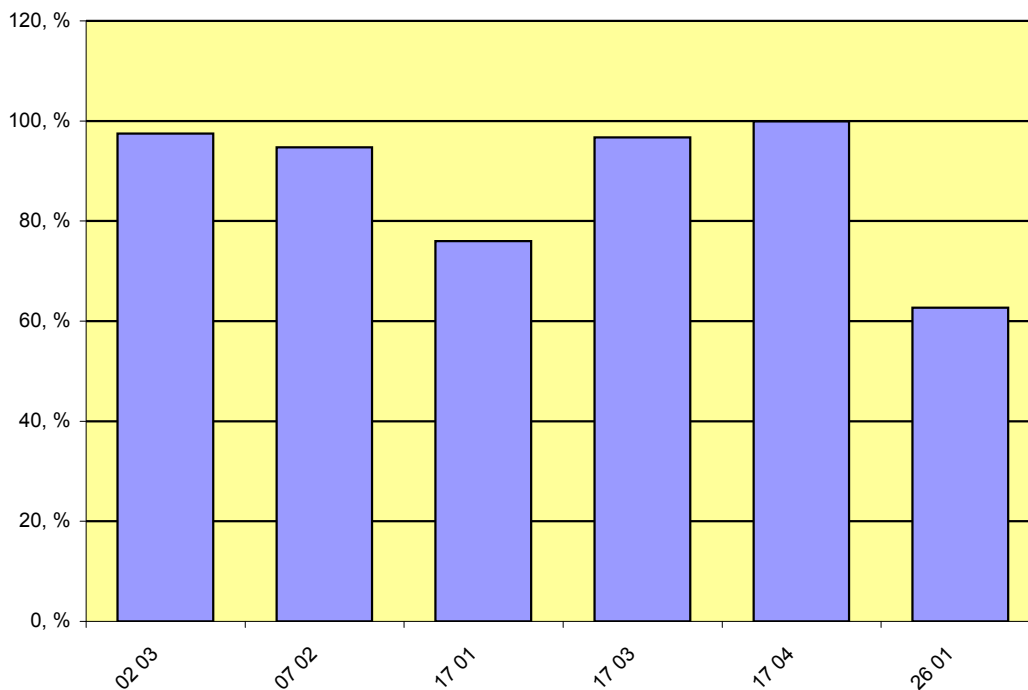


TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2015 (in Mio €)									
Chapter			2015 Commitments to be settled				Commitments to be settled from financial years previous to 2015	Total of commitments to be settled at end of financial year 2015 (incl. corrections)	Total of commitments to be settled at end of financial year 2014 (incl. corrections)
			Commitments 2015	Payments 2015	RAL 2015	% to be settled			
			1	2	3=1-2	4=1-2/1	5	6=3+5	7
Title 02 : Enterprise and industry									
02	02 03	Internal market for goods and sectorial policies	0	0,00	0	#DIV/0	0,00	0,00	0,27
Total Title 02			0	0,00	0	#DIV/0	0	0	0,27403
Title 07 : Environment									
07	07 02	Environmental policy at Union and international level	5,95158202	5,95	2E-08	0,00 %	0,00	0,00	0,00
Total Title 07			5,95158202	5,95	2E-08	0,00%	0	0,00000002	0
Title 17 : Health and consumer protection									
17	17 01	Administrative expenditure of the 'Health and consumer protection' policy area	21,05683467	15,22	5,83718537	27,72 %	0,01	5,84	6,08
	17 03	Public health	182,684114	166,56	16,12587979	8,83 %	18,09	34,21	36,71
	17 04	Food and feed safety, animal health, animal welfare and plant health	236,8760871	13,67	223,2095765	94,23 %	95,65	318,86	325,48
Total Title 17			440,6170358	195,44	245,1726416	55,64%	113,7404844	358,913126	368,2735386
Title 26 : Commission's administration									
26	26 01	Administrative expenditure of the 'Commission's administration' policy area	0,495965	0,32	0,17721091	35,73 %	0,00	0,18	0,21
Total Title 26			0,495965	0,32	0,17721091	35,73%	0	0,17721091	0,20969859
Total DG SANTE			447,0645829	201,71	245,3498526	54,88 %	113,7404844	359,0903369	368,7572672

"Breakdown of Commitments remaining to be settled (in Mio EUR)"

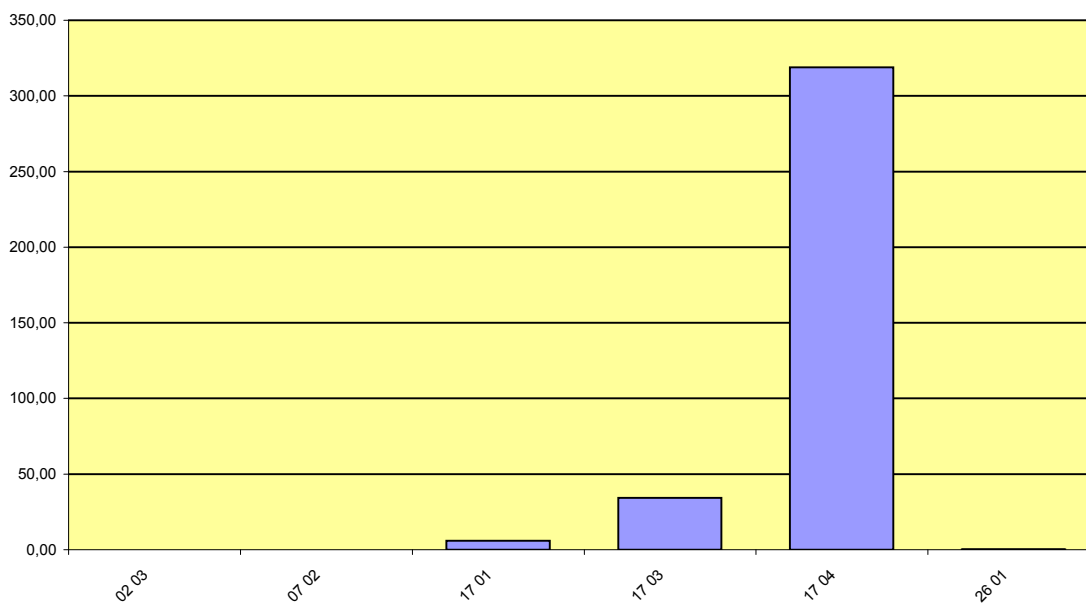


TABLE 4 : BALANCE SHEET

BALANCE SHEET	2015	2014
A.I. NON CURRENT ASSETS	17.734.851,09	19.225.335,64
A.I.1. Intangible Assets	914.154,22	806.129,00
A.I.2. Property, plant and equipment	16.205.990,37	17.649.385,84
A.I.6. Non-Current Pre-Financing	614.706,50	769.820,80
A.I.7. OLD LT Pre-Financing	-	-
A.II. CURRENT ASSETS	35.981.937,82	20.466.686,36
A.II.1. Inventories	11.232.100,00	11.232.100,00
A.II.2. Current Pre-Financing	21.698.743,40	8.264.217,73
A.II.4. Exchange Receivables	760.300,86	453.818,73
A.II.5. Non-Exchange Receivables	2.282.548,78	507.418,36
A.II.7. Cash and Cash Equivalents	8.244,78	9.131,54
ASSETS	53.716.788,91	39.692.022,00
P.II. NON CURRENT LIABILITIES	(10.256.663,30)	(12.258.044,58)
P.II.3. Long-term financial liabilities	(10.256.663,30)	(12.258.044,58)
P.III. CURRENT LIABILITIES	(206.857.679,32)	(199.694.208,66)
P.III.2. Short-term provisions	(14.224.936,35)	(16.249.401,22)
P.III.3. Short-term financial liabilities	(2.001.381,30)	(1.984.396,84)
P.III.4. Accounts Payable	(9.121.608,24)	(21.205.537,26)
P.III.5. Accrued charges and deferred income	(181.509.753,43)	(160.254.873,34)
LIABILITIES	(217.114.342,62)	(211.952.253,24)
NET ASSETS (ASSETS less LIABILITIES)	(163.397.553,71)	(172.260.231,24)
P.I.2. Accumulated Surplus / Deficit	764.443.912,25	384.217.389,68
Non-allocated central (surplus)/deficit*	(601.046.358,54)	(211.957.158,44)
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

TABLE 5 : STATEMENT OF FINANCIAL PERFORMANCE

STATEMENT OF FINANCIAL PERFORMANCE	2015	2014
II.1 REVENUES	(1.985.050,88)	2.383.026,45
II.1.1. NON-EXCHANGE REVENUES	(4.859.688,26)	(1.272.790,06)
II.1.1.5. RECOVERY OF EXPENSES	(2.628.626,38)	(529.534,90)
II.1.1.6. OTHER NON-EXCHANGE REVENUES	(2.231.061,88)	(743.255,16)
II.1.2. EXCHANGE REVENUES	2.874.637,38	3.655.816,51
II.1.2.1. FINANCIAL INCOME	(451,93)	(1,42)
II.1.2.2. OTHER EXCHANGE REVENUE	2.875.089,31	3.655.817,93
II.2. EXPENSES	370.648.239,92	377.365.443,38
II.2. EXPENSES	370.648.239,92	377.365.443,38
II.2.10. OTHER EXPENSES	32.754.989,46	38.124.579,37
II.2.2. EXP IMPL BY COMMISS&EX.AGENC. (DM)	185.346.702,55	169.788.932,05
II.2.3. EXP IMPL BY OTH EU AGENC&BODIES (IM)	155.078.886,50	166.187.333,06
II.2.4. EXP IMPL BY 3RD CNTR & INT ORG (IM)	(2.475.458,95)	3.215.696,38
II.2.6. STAFF AND PENSION COSTS	(175.410,50)	(94.839,78)
II.2.8. FINANCE COSTS	118.530,86	143.742,30
STATEMENT OF FINANCIAL PERFORMANCE	368.663.189,04	379.748.469,83

Explanatory Notes (facultative):

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

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

TABLE 6: AVERAGE PAYMENT TIMES FOR 2015 - 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 %	13			
30	1592	1495	93,91 %	17,57324415	97	6,09 %	37,12371134
45	44	38	86,36 %	21,21052632	6	13,64 %	67,66666667
60	73	73	100,00 %	28,79452055			
90	117	117	100,00 %	58,57264957			
194	1	1	100,00 %	184			
195	1	1	100,00 %	189			
198	25	25	100,00 %	190,08			
199	8	8	100,00 %	190,375			
200	6	6	100,00 %	191,1666667			
204	7	7	100,00 %	167,7142857			
205	7	7	100,00 %	194,7142857			
206	11	11	100,00 %	195			
207	6	6	100,00 %	193,6666667			
208	3	3	100,00 %	199,3333333			
211	22	22	100,00 %	206,5454545			
212	17	17	100,00 %	204,4705882			
213	5	5	100,00 %	210,4			
214	1	1	100,00 %	210			
215	2	2	100,00 %	203			
217	5	5	100,00 %	205,2			
219	1	1	100,00 %	201			
220	3	3	100,00 %	214			
221	1	1	100,00 %	216			
227	2	2	100,00 %	219			
228	1	1	100,00 %	219			
237	1	1	100,00 %	231			
240	1	1	100,00 %	229			
352	1	1	100,00 %	350			

Total Number of Payments	1965	1862	94,76 %		103	5,24 %	
Average Payment Time	34,36641221			34,11546724			38,90291262

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	35	28	80,00 %	16,32142857	7	20,00 %	22
30	324	257	79,32 %	19,42801556	67	20,68 %	38,8358209

Total Number of Payments	359	285	79,39 %		74	20,61 %	
Average Payment Time	22,85793872			19,12280702			37,24324324

Suspensions							
Average Report Approval Suspension	Average Payment Suspension Days	Number of Suspended Payments	% of Total Number	Total Number of Payments	Amount of Suspended Payments	% of Total Amount	Total Paid Amount
4	63	265	13,49 %	1965	#####	9,31 %	#####

Late Interest paid in 2015			
DG	GL Account	Description	Amount (Eur)
SANTE	65010000	Interest expense on late payment of charges	0,00
			0,00

TABLE 7 : SITUATION ON REVENUE AND INCOME IN 2015

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		
52	REVENUE FROM INVESTMENTS OR LOANS GRANTED, BANK AND OTHER INTEREST	454,26	0	454,26	454,26	0	454,26	0
57	OTHER CONTRIBUTIONS AND REFUNDS IN CONNECTION WITH THE ADMINISTRATIVE OPERATION OF THE INSTITUTION	1042098,28	0	1042098,28	758446,28	0	758446,28	283652
59	OTHER REVENUE ARISING FROM ADMINISTRATIVE MANAGEMENT	470485,26	0	470485,26	470485,26	0	470485,26	0
66	OTHER CONTRIBUTIONS AND REFUNDS	7195146,14	200632,13	7395778,27	7157535,33	55377,62	7212912,95	182865,32
Total DG SANTE		8708183,94	200632,13	8908816,07	8386921,13	55377,62	8442298,75	466517,32

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

INCOME BUDGET RECOVERY ORDERS ISSUED IN 2015	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
2011				3	9.640,45		
No Link				39	394.531.000,00		
Sub-Total				42	394.540.640,45		

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												
CREDIT NOTES	35	342768,11					35	342768,11	58	40.551.796,31	60,34%	0,85%
Sub-Total	35	342768,11					35	342768,11	58	40551796,31	60,34%	0,85%
GRAND TOTAL	35	342768,11					35	342768,11	100	435092436,8	35,00%	0,08%

TABLE 9: AGEING BALANCE OF RECOVERY ORDERS AT 31/12/2015 FOR SANTE

	Number at 01/01/2015	Number at 31/12/2015	Evolution	Open Amount (Eur) at 01/01/2015	Open Amount (Eur) at 31/12/2015	Evolution
2010	1		-100,00 %	55.377,62		-100,00 %
2011	1	1	0,00 %	145.254,51	145.254,51	0,00 %
2015		4			321.262,81	
	2	5	150,00 %	200.632,13	466.517,32	132,52 %

TABLE 10 : RECOVERY ORDER WAIVERS IN 2015 >= EUR 100.000

	Waiver Central Key	Linked RO Central Key	RO Accepted Amount (Eur)	LE Account Group	Commission Decision	Comments

Total DG	
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Number of RO waivers	
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Justifications:

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TABLE 11 : CENSUS OF NEGOTIATED PROCEDURES - DG SANTE - 2015

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

No data to be reported

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

Internal Procedures > € 60,000		
Procedure Type	Count	Amount (€)
Exceptional Negotiated Procedure without publication of a contract notice (Art. 134 RAP)	1	3.327.815,80
Open Procedure (Art. 104(1) (a) FR)	3	1.352.800,00
Open Procedure (Art. 127.2 RAP)	7	6.322.240,30
Restricted Procedure (Art. 127.2 RAP)	2	3.010.000,00
TOTAL	13	14.012.856,10

Additional comments

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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" approach¹.

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 for budget implementation

The table below shows **DG SANTE's 2015 commitment implementation** without credits managed by cross-delegations (EUR 0,2 million), the Executive Agency for Consumers, Health and Food (CHAF-EA, former EAHC, EUR 63,2 million).

Type of budget implementation - direct management Commitments executed by DG SANTE		2015 € million		%	Number		Average € million	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	165,3			28 Member States	140 Programmes for 2015	1,2	Annex 5.1.1
	Veterinary emergency fund	16,4			12 Member States	15 "Emergency files"	1,1	
	Phytosanitary measures ("Solidarity fund")	7,6			17 Member States	17 "Solidarity files"	0,4	
	Subtotal		189,3	44%				
Grants, direct management (Heterogeneous types of grants not following the typical grant procedure of an open call for proposal)	Subsidies to Reference Laboratories	16,0			43 Reference Laboratories		0,4	./.
	Other "grants" to Member States	3,4			28 Member States	58 Commitments	0,0	
	Direct grants to international organisations (OIE, UPOV, FAO)	8,8			3 Organisations		2,9	
	Subtotal		28,2	6%				
	Direct grants to international organisations (WHO) and others	0,3	0,3		4 Beneficiaries		0,1	
Public procurement (According to Title V of the Financial Regulation)	Feed and Food	19,3				154	0,1	Annex 5.1.2
	Public Health	10,3				105	0,1	
	Administrative support credits	3,1						
	Subtotal		32,7	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	79,6						
	ECDC	58,4						
	EMA	33,9						
	ECHA-biocides	6,0						
	Subtotal		183,4	72%		5 Agencies	36,7	
TOTAL commitments			433,9	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.

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 2015, the Common Financial Framework (CFF, Regulation (EU) No 652/2014) was the main basis for the corresponding expenditure in 2015.

The following descriptions focus on the national programmes for animal disease eradication and control as these account for about 70% of the EU funds in the Food and Feed policy area. The controls described below are implemented as far as applicable for other kinds of grants or cost reimbursements 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 <i>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)</i>				
<p>a) Eligibility, selection and award criteria should be adequate to evaluate the proposed national programmes and to ensure that the policy objectives are achieved.</p>	<ol style="list-style-type: none"> 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 standard 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. 	<p>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.</p> <p>Thus, at the programming stage the controls on an annual basis are quite low. They are embedded in stages 1b), 3) and 4) below.</p>	<p>Cost of control:</p> <ul style="list-style-type: none"> - Included in general estimate of DG SANTE's staff costs for programming, evaluation and grant decision <p>Benefits of control:</p> <p>As no significant errors are to be expected, the benefits are mainly administrative in nature and thus non-quantifiable in budgetary terms</p>	<p>Effectiveness and efficiency indicators:</p> <ul style="list-style-type: none"> - Ratio of rejected national programmes to total programmes submitted <ul style="list-style-type: none"> ⇒ Target: qualitative analysis of reasons for rejections and adjustments in relation to priority diseases - Timeliness of Commission work programmes <ul style="list-style-type: none"> ⇒ 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
<p>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.</p>	<ol style="list-style-type: none"> 1. To ensure a high level of expertise in the evaluation exercise <ul style="list-style-type: none"> - 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. 	<ol style="list-style-type: none"> 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 	<p>Cost of control:</p> <ul style="list-style-type: none"> - 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 <p>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.</p>	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> - Ratio of modified programmes to total programmes retained after evaluation ⇒ Target: qualitative analysis of reasons for rejections and modifications <p>Efficiency Indicators:</p> <ul style="list-style-type: none"> - 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 <i>Main control objectives: ensuring that the actions and funds allocation is optimal (best value for public money; effectiveness, economy, efficiency) and compliant (legality & regularity).</i>				
<p>The national programmes for which a grant decision is taken by the authorising officer by delegation (AOSD) should correspond to</p> <p>(a) the programmes and amounts communicated to the PAFF and/or</p> <p>(b) the budgetary commitment.</p>	<ol style="list-style-type: none"> DG SANTE approves the annual national programmes and associated funding by 31 January each year (awarding decision by the AOSD; communication to the PAFF). 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. 	<ol style="list-style-type: none"> 100% of programmes to be technically approved prior to preparing the grant decision 100% of grant decisions checked prior to approval (depth of checks depends on risk criteria) 	<p>Cost of control:</p> <ul style="list-style-type: none"> Included in general estimate of DG SANTE’s staff costs for programming, evaluation and grant decision; <p>Benefits of control: Compliance</p>	<p>Effectiveness and efficiency indicator:</p> <ul style="list-style-type: none"> 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 <i>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).</i>				
<p>Controls have to prevent that the national programmes' objectives are only partially achieved or not at all and/or that ineligible amounts are paid.</p>	<ol style="list-style-type: none"> 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. 	<ol style="list-style-type: none"> 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 	<p>Cost of control:</p> <ul style="list-style-type: none"> - 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 <p>Benefits of control:</p> <ul style="list-style-type: none"> - Estimated value of corrections made during 2nd level financial controls 	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> - 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% <p>Efficiency indicators:</p> <ul style="list-style-type: none"> - 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
<p>Stage 4: Ex-post controls: on-the-spot controls and evaluation</p> <p><i>Main control objectives:</i></p> <p>a) <i>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);</i></p> <p>b) <i>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);</i></p> <p>c) <i>Monitoring disease eradication activities in Member States to improve the cost-benefit ratio of animal eradication programmes.</i></p>				
<p>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.</p>	<p>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.</p> <p>1b. The ex-post control strategy and the work plan are adopted annually by DG SANTE's Directors' Steering Committee.</p> <p>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.</p> <p>3. All audit reports undergo a contradictory procedure within DG SANTE and with the auditees (i.e. Member States).</p> <p>4. If deemed necessary, the file is referred to OLAF.</p>	<ul style="list-style-type: none"> - Risk based audit sample - 20% minimum audit coverage to maximise audit correction 	<p>Cost of control:</p> <ul style="list-style-type: none"> - Estimated staff costs for ex-post controls - Estimated mission costs for ex-post controls - Cost of external audit services. <p>Benefits of control:</p> <ul style="list-style-type: none"> - Value of the financial corrections made during ex-post controls 	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> - Detected error rate ⇒ Target: decreasing trend - Residual error rate in ABB activity ⇒ Target: < 2% - Number of files referred to OLAF. ⇒ Target: 0 <p>Efficiency indicators:</p> <ul style="list-style-type: none"> - 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.	<ol style="list-style-type: none"> 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. 	<ol style="list-style-type: none"> 1. 100% of final control results 2. 100% 2nd level financial control of recovery orders 	<p>Cost of control:</p> <ul style="list-style-type: none"> - Estimated staff costs for technical and financial monitoring of the Member States' programmes <p>Benefits of control:</p> <ul style="list-style-type: none"> - Amount of actually corrected errors 	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> - Audit results related to DG SANTE implemented ⇒ Target: 100% <p>Efficiency Indicators:</p> <ul style="list-style-type: none"> - "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.	<ol style="list-style-type: none"> 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 . 	<ol style="list-style-type: none"> 1. All national programmes covered 2. Depending on the disease 	<p>Cost of control:</p> <ul style="list-style-type: none"> - Estimated staff costs for monitoring <p>Benefits of control:</p> <p>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.</p>	<p>Effectiveness and efficiency indicator:</p> <ul style="list-style-type: none"> - Percentage of recommendations of the task force implemented by Member States ⇒ Target: 100% - Evolution of the progress measured by DG SANTE staff: achievement of the objectives of the programmes (for eradication, control and monitoring) in relation to the evolution of the disease in previous years ⇒ Target: positive trend

2. Type of expenditure: procurement

Following the transfer of implementation tasks to the Executive Agency for Consumers, Health and Food (CHAF-EA, former EAHC), 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: In 2015,

- EUR 3,1 million were committed in 2015 for 4 Pilot Projects;
- A total of 13 new contracts awarded in 2015 above EUR 60.000.
- 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 <i>Main control objectives: ensuring sound financial management (i.e. effectiveness, efficiency and economy); compliance (legality & regularity); prevention of fraud (anti-fraud strategy)</i>				
<p>a) Needs have to be well defined (operationally and economically) and decision to procure have to be appropriate to meet the operational objectives.</p> <p>Poor planning or inadequate organisation of the procurement procedure could entail delays or interruptions of services leading to an underachievement of the policy objectives.</p>	<ol style="list-style-type: none"> 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. Planned external studies are listed in a register kept by Secretariat General. Each call for tenders fixes either a maximum value or a price range for the contract based on a pricing methodology. The timing and organisation of a procurement procedure is supervised by the Authorising Officer responsible. 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. 	<ol style="list-style-type: none"> 100% of calls for tender are covered by a Commission financing decision. 100% of external studies are listed in a special register at the level of the Secretariat General. All calls for tender are based on a pricing methodology (depth depending on feasibility). -5. All public procurements in the annual work programmes are approved by the Management 	<p>Cost of control:</p> <ul style="list-style-type: none"> Estimated staff costs for programming and planning and execution of the procurement procedures. <p>Benefits of control:</p> <ul style="list-style-type: none"> Amount of rejection of unjustified purchases or services discontinued. 	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> 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 <p>Efficiency indicators:</p> <ul style="list-style-type: none"> 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
<p>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.</p>	<ol style="list-style-type: none"> 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. 	<ol style="list-style-type: none"> 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 	<p>Cost of control:</p> <ul style="list-style-type: none"> - Estimated staff costs for drafting tender specifications <p>Benefits of control:</p> <ul style="list-style-type: none"> - 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. 	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> - 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) <p>Efficiency indicators:</p> <ul style="list-style-type: none"> --Timeliness of procurement procedures relative to Commission Work Programmes

Procurement				
Main inherent risks	Mitigating controls	Control coverage	Costs and benefits of controls	Control indicators
<p>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.</p>	<ol style="list-style-type: none"> 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. Persons involved in the formal procedures sign declarations of absence of conflict of interest. Bidders are checked against exclusion and selection criteria published with the tender specifications. The central procurement committee examines open call tender procedures > €130.000 and gives an independent opinion to the Authorising Officer responsible. The Authorising Officer responsible validates the evaluation results and takes the award decision. After the award decision, a standstill period of two weeks applies in certain procedures before the contract is signed to give unsuccessful tenderers the opportunity to raise concerns. 	<ol style="list-style-type: none"> 100% of tender procedures are documented; for 100% of tender procedures > €60.000 committees are formally appointed 100% of evaluators 100% of bidders checked For 100% of open call tender procedures above the threshold the CMP gives an opinion 100% validated 100% when conditions are fulfilled 	<p>Cost of control:</p> <ul style="list-style-type: none"> Estimated staff costs in the evaluation process <p>Benefits of control:</p> <ul style="list-style-type: none"> 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. 	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> 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% <p>Efficiency indicators:</p> <ul style="list-style-type: none"> --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 <i>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).</i>				
<p>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.</p>	<ol style="list-style-type: none"> 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. 	<p>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);</p> <p>5. 100% if conditions are fulfilled</p>	<p>Cost of control:</p> <ul style="list-style-type: none"> - Estimated staff costs for monitoring and financial transactions - Mission costs for monitoring activities <p>Benefits of control:</p> <ul style="list-style-type: none"> - 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. 	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> - Estimated value of the financial corrections made during ex-ante controls of the final payment ⇒ Target: < 2% <p>Efficiency indicators:</p> <ul style="list-style-type: none"> - 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 <i>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);</i>				
<p>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.</p>	<ol style="list-style-type: none"> 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. 	<ol style="list-style-type: none"> 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 	<p>Cost of control:</p> <ul style="list-style-type: none"> - 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 <p>Benefits of control:</p> <ul style="list-style-type: none"> - Value of the financial corrections made during ex-post audits or controls 	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> - 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% <p>Efficiency indicators:</p> <ul style="list-style-type: none"> - Implementation of the annual work plans of audit and ex-post control on procurement ⇒ Target: 100% - Average cost per audit to average amount of audit correction ⇒ Target: > 100%

ANNEX 5.2: Internal Control Template for budget implementation through entrusted entities

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

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

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

In 2015, DG SANTE managed financial operations under the following two policy areas: Public Health and Food and Feed Safety. DG SANTE entrusted the Consumers, Health and Food Executive Agency (CHAF-EA, former EAHC) with the implementation of about EUR 63,2 million which amounts to 20% of the 2015 operational budget (without subsidy payments to agencies). Cross-delegations were given to authorising officers of other DGs for about 0,06% of the total 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
<p>Stage 1. "Mandate of the entrusted entity": establishment, prolongation or adjustment of the delegation act of the executive agency</p> <p><i>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)</i></p>				
<p>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.</p>	<p>The legal framework ("statute") for executive agencies is laid down by Council Regulation (EC) 58/2003.</p> <ol style="list-style-type: none"> 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. 	<p>100% in-depth controls at each stage on DG SANTE's and DG BUDG's side</p> <p>Frequency:</p> <ul style="list-style-type: none"> - Once in 2004-2005 when the agency was established - 2013 when the mandate of the agency was prolonged from 2014 to 2020 	<p>Cost of control:</p> <p>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</p> <p>Benefits of control:</p> <p>The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred</p>	<p>Effectiveness and efficiency indicators:</p> <ul style="list-style-type: none"> 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 2015

1. Budget implementation tasks delegated to the executive agency

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Control indicators
<p>Stage 2. Readiness assessment of the executive agency's control framework towards autonomy</p> <p><i>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.</i></p>				
<p>The financial and control framework deployed by the executive agency should be fully mature to guarantee that the control objectives are met.</p>	<ol style="list-style-type: none"> 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. 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. 	<ol style="list-style-type: none"> 100% in-depth control once when the agency was set up Each request for substantial change is examined in-depth <p>Frequency:</p> <ul style="list-style-type: none"> Once in 2005-2006 when the agency gained autonomy 	<p>Cost of control:</p> <p>Not applicable per year and not in 2015, as estimated staff costs for ex-ante assessment only once when agency is established</p> <p>Benefits of control:</p> <p>The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred</p>	<p>Effectiveness indicators:</p> <p>Granting budget autonomy without significant delay</p> <p>⇒ Target: Not applicable in 2015 (agency gained full autonomy in 2007)</p> <p>Efficiency Indicators:</p> <ul style="list-style-type: none"> Time between establishment of the agency and granting of autonomy ⇒ Target: 100% on time according to internal planning <i>(comment: not applicable after 2007 when the agency gained full autonomy)</i>

1. Budget implementation tasks delegated to the executive agency

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Control indicators
<p>Stage 3: Operations: DG SANTE's monitoring and supervision (“control <i>with</i> the executive agency”) <i>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;</i></p>				
<p>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.</p>	<p>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.</p> <p>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.</p> <ol style="list-style-type: none"> 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. 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. The Steering Committee, chaired by DG SANTE, meets four times a year and adopts (i) the agency's annual work programme, after approval by the Commission, and (ii) the draft administrative budget, including the establishment plan, after adoption of the general EU budget by the budgetary authority. 	<p>Coverage: 100% of the tasks delegated to the agency monitored and supervised</p> <p>Depth of control: risk based; DG SANTE has full access to the agency's internal control information, if need be</p> <p>Frequency: quarterly, annually and in day-to-day contacts as deemed necessary</p>	<p>Cost of control:</p> <ul style="list-style-type: none"> Estimated SANTE staff costs for monitoring and supervising the agency's activities Mission costs for monitoring activities <p>Benefits of control: The total budget amount delegated to the agency per year possibly at 100% if significant legal errors occurred</p>	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> 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
	<p>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.</p> <p>5. DG SANTE's central financial Unit reports quarterly on the implementation of the budget delegated to the agency.</p> <p>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.</p> <p>7. If deemed necessary, issues are referred to OLAF.</p>			<p>Efficiency indicators:</p> <ul style="list-style-type: none"> - Timely endorsement by the Steering Committee of the agency's annual work programme and administrative budget (target: December N-1 at the latest) ⇒ Target: 100% on time - Ratio of annual supervision costs to annual operational budget delegated and subsidy paid to the annual administrative budget of the agency ⇒ Target: Commission benchmark (not yet available)

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

In 2015, DG SANTE was responsible for four EU agencies of which three received an annual subsidy from the EU budget. DG SANTE also 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, Sweden¹ (*Budget 2015: total sum of human resources 295; EU funding 100%: EUR 58,4 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, Italy² (*Budget 2015: total sum of human resources 477; EU funding 100%: EUR 79,6 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, UK³ (*Budget 2015: total sum of human resources 803; EU funding 11%: EUR 33,9 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 2015 budget amounted to EUR 308,1 million which is to a large extent fee-financed.

- **Community Plant Variety Office (CPVO)** in Angers, France⁴ (*Budget 2015: 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 2015 budget amounted to EUR 14,7 million (fully fee-financed).

- **European Chemicals Agency (ECHA)** located in Helsinki⁵ - relevant for DG SANTE are ECHA's biocides activities (*Budget 2015 for biocides: total sum of human resources 48; EU funding 66%: EUR 6,0 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 2015 amounted to EUR 9,1 million.

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

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

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

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

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

2. Subsidy payments to EU agencies

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Control indicators
Stage 1. “Mandate of the agency”: founding regulation <i>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)</i>				
<p>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.</p>	<p>The legal framework of the EU agency is laid down in its founding regulation (see above) without expiry date. Amendments follow the Commission’s legislative procedures and, since July 2012 the “Common Approach”⁶ laid down by the Interinstitutional working group on EU agencies, e.g.</p> <ul style="list-style-type: none"> - An impact assessment is carried out prior to establishing an EU agency; - 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. <ol style="list-style-type: none"> 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. 	<p>100% in-depth once in establishment phase</p> <p>100% in-depth case by case if amendment or review is foreseen</p>	<p>Cost of control:</p> <ul style="list-style-type: none"> - 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. <p>Benefits:</p> <p>The total annual budget amount paid as subsidy to the agency’s running costs possibly at 100% if significant legal errors occurred⁷.</p>	<p>Effectiveness and efficiency indicators:</p> <ul style="list-style-type: none"> Number of legal issues a/o negative opinions during interservice consultations ⇒ Target: 0 Quality of the legal work not challenged by auditors or OLAF ⇒ Target: 100%

⁶ http://europa.eu/about-eu/agencies/overhaul/index_en.htm

⁷ Not all agencies are 100% financed by the EU budget, notably, CPVO is fee-financed to 100% and EMA to 11% in 2015 (see the introduction above).

2. Subsidy payments to EU agencies

Main inherent risks	Mitigating controls	Control coverage	Costs/benefits of controls	Control indicators
<p>Stage 2. Assessment of the agency's control framework and financial rules</p> <p><i>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.</i></p>				
<p>The financial and control framework deployed by the EU agency should be fully mature to guarantee that the control objectives are met.</p>	<ol style="list-style-type: none"> 1. The agency's Management Board adopts provisions implementing the Staff Regulations based on the Commission's Staff Regulations. 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. 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. <p>In addition to monitoring compliance, DG SANTE identifies and disseminates good practices in collaboration with the agencies.</p>	<p>100% in-depth per agency as need be, e.g. if amendments are to be made</p> <p>Frequency: In 2013/2014, due to the new FFR and staff regulations; In 2015, due to the agencies' development of anti-fraud strategies</p>	<p>Cost of control: Included in general estimate of SANTE's staff costs for monitoring and supervising the agency's activities</p> <p>Benefits of control: The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred (see footnote 7 above)</p>	<p>Effectiveness and efficiency indicators:</p> <ul style="list-style-type: none"> - 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") <i>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;</i>				
<p>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.</p>	<ol style="list-style-type: none"> 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"; from 2015, the Commission guidelines for the programming document and the template for the activity report are applicable. 2. Regular bilateral meetings 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 annual budget and work programme as well as "strategy documents", e.g. on independence. 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. After adoption by the MB, the agency publishes its annual report, final accounts and report on financial management. 6. 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). 	<p>Coverage: all of the agency's activities are monitored and supervised</p> <p>Depth of control: risk based; if need be, DG SANTE has access to the agency's internal control information</p> <p>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</p>	<p>Cost of control:</p> <ul style="list-style-type: none"> - Included in the general estimate of DG SANTE's staff costs for monitoring and supervising the agency's activities; - Mission costs for monitoring activities. <p>Benefits of control: The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred (see footnote 7 above).</p>	<p>Effectiveness and efficiency indicators:</p> <ul style="list-style-type: none"> - 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
Stage 4: Audit and evaluation, discharge <i>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.</i>				
<p>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.</p>	<ol style="list-style-type: none"> 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 audits the accounts and transactions of the agency and issues a declaration of assurance; 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: <ul style="list-style-type: none"> - EMA every 10 years (next in 2019); - EFSA every 6 years (next in 2017); - ECDC every 5 years (next in 2020). 	<p>Coverage: 100% of the agency's activities audited and evaluated</p> <p>Depth of control: risk based; auditors have full access to the agency's internal control information</p> <p>Frequency:</p> <ul style="list-style-type: none"> - Regularly by the IAS - Annually by the Court of Auditors - Frequency of external evaluations varies with the agencies 	<p>Cost of control:</p> <ul style="list-style-type: none"> - Included in the general estimate of SANTE's staff costs for monitoring and supervising the agency's activities <p>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)</p>	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> - 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: 100% of Court's recommendations implemented - Discharge authorities grant discharge to the agency ⇒ Target: discharge granted ⇒ Target: 100% of recommendations of the discharge authorities implemented <p>Efficiency indicators:</p> <ul style="list-style-type: none"> - 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
<p>Stage 5: DG SANTE's payments of the subsidy</p> <p><i>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)</i></p>				
<p>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.</p>	<ol style="list-style-type: none"> 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: <ul style="list-style-type: none"> - 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. 	<p>Coverage: 100% of DG SANTE's subsidy payments through the established financial circuits</p> <p>Depth of control: risk based</p> <p>Frequency: Administrative budget of the agency annually audited by the Court of Auditors</p>	<p>Cost of control:</p> <ul style="list-style-type: none"> - Estimated staff costs for budget and finance in central financial Unit; <p>Benefits of control:</p> <p>The total subsidy paid to the agency per year possibly at 100% if significant legal errors occurred (see footnote 6 above).</p>	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> - 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 <ul style="list-style-type: none"> ⇒ 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 <ul style="list-style-type: none"> ⇒ Target: 100% <p>Efficiency indicators:</p> <ul style="list-style-type: none"> - Time-to-pay (target: maximum 30 days) <ul style="list-style-type: none"> ⇒ Target: 100% on time

ANNEX 9: Evaluations and other studies finalised or cancelled in 2015

Reference No of Annex 4 MP2015	Title	Reason ¹	Scope ²	Type of evaluation or other study			Associated DGs	Costs (EUR)	Comments	Reference	Cancelled
				Focus ³	Author ⁴	Type ⁵					
I. Evaluations finalised or cancelled in 2015											
a. evaluations finalised in 2015											
I.2	Evaluation of ECDC.	L	Every 5 years. Regulation (EC) No 851/2004 of the EP and of the Council establishing a European centre for disease prevention and control.	R	E	O	ECDC	€ 210.100,00		http://ecdc.europa.eu/en/aboutus/Key%20Documents/ECDC-external-evaluation-2014.pdf	No
I.3	Evaluation of the implementation of the Commission Communication 'Combating HIV/AIDS in the European Union and the neighbouring countries, 2009–2013'	L	(i) IAB of the IA accompanying the Communication on combating HIV/AIDS asked to carry out an evaluation of the implementation of the new HIV action plan; (ii) the "independent evaluation of the overall EU intervention to combat HIV/AIDS in Europe" and the evaluation of the implementation of the HIV AP are commitments mentioned in the communication COM/2009/569 and in the HIV action plan. COM/2009/569: Commission communication on combating HIV/AIDS in the European Union and neighbouring countries, 2009-2013; chapter 6	R	E	O	CHAFEA	€ 119.850,00		http://bookshop.europa.eu/en/evaluation-of-the-implementation-of-the-commission-communication-pbEW0415448/	No
I.4	Evaluation of the Public Health Programme 2008-2013 (ex post).	LMFF	To provide the final assessment of the impact and effectiveness of the programme on the basis of the results obtained and, in particular, to assess the impact of measures on all countries. Council Decision 1350/2007	R	M	E	EMPL	€ 200.000,00		http://bookshop.europa.eu/en/ex-post-evaluation-of-the-health-programme-2008-2013--pbEW0115342/ http://bookshop.europa.eu/en/ex-post-evaluation-of-the-health-programme-2008-2013--pbEW0415298/	No

I.5	Evaluation Ex-Smokers Campaign.	FR	To assess the impact of the different Ex-Smokers communication campaign actions in terms of their cost-benefit analysis/efficiency rated against the actual results achieved and to use the results of the evaluation as a basis for the communication services of DG SANTE to shape potential further improved actions in the same field and in other fields seeking behavioural change and improved life expectancy/healthy life.	R	E	C	SG	€ 189.128,00		To be published in Ebookshop mid-February. SWD not applicable.	No
b. Evaluations cancelled in 2015											
II.3	Evaluation of EU Reference Laboratories.	FR	To assess the effectiveness and cost-benefit analysis of EU Reference Laboratories	R	n/a	E	None	N/A		To be integrated in the "Evaluation report on the achievement of the objectives set out in the frame of the Common Financial Framework (CFF) for food and feed" planned for 2017. (Annex 3 - 2016 AMP)	Yes.
II.6	Evaluation of Regulation N° 1394/2007 on advanced therapy medicinal products	L	To assess the impact of legislation.	R	n/a	R	None	N/A			Yes
II.8	Evaluation of 2009 Council recommendation on seasonal influenza vaccination.	O	The Commission is invited to report regularly to the Council on the implementation of this Recommendation (implementation report), together with an Evaluation on the basis of the data the Member States will make available.	R	n/a	O	None	N/A			Yes

II.9	Evaluation of 2011 Council conclusions on childhood immunisation.	O	The Commission is invited to report regularly to the Council on the implementation of this Recommendation, on the basis of the data the Member States will make available.	R	n/a	O	None	N/A		N/A	Yes
II.10	Evaluation of 2009 Commission Communication on reducing health inequalities and 2010 Council Conclusion on equity and health in all policies.	O	Follow up to the Commission Communication in 2009 to see developments in the field of health inequalities in Europe.	R	n/a	O	None	N/A		N/A	Yes
II. Other studies finalised or cancelled in 2015											
a. other studies finalised in 2015											
I.04	Scoping study on communication action addressing chronic diseases	O	The objective of this action is to conduct a scoping study to help test different tools and methods in order to better communicate and raise awareness of health determinants and EU action to prevent chronic diseases, making use of evidence from social and behavioural science.	P	E	C	None	€ 198.990,00		http://ec.europa.eu/health/major_chronic_diseases/docs/2015_chronic_scopingstudy_en.pdf	No
I.06	Comparative efficiency of health systems, corrected for selected lifestyle factors	O	The objective is to deepen understanding of how confounding factors (such as lifestyle behaviour) can skew population level assessment of health outcome efficiency of health systems.	R	E	I		€ 250,000.00		http://ec.europa.eu/health/systems_performance_assessment/docs/2015_maceli_report_en.pdf	No
I.07	Ad-hoc study on the trade of illegal and counterfeit pesticides in the EU	O	Support analysis for future regulation on control.	R	E	R	None			http://ec.europa.eu/food/plant/pesticides/docs/study_on_illegal_ppps_summary_en.pdf	No

I.11	Ad hoc study in preparation of the development of a common methodology for gathering of information by the Member States on the consumption and use of food additives and flavourings in the European Union	O	study carried out during 2014 on - the ways this is currently done by the different Member States, including a comparison among them - identifying the needs in this respect by EFSA (in particular regarding the reevaluation of additives or the evaluation of flavourings), and - considering several options on how this monitoring could be done in the future.	P	E	O	None	€ 139.370,00		https://webgate.ec.europa.eu/sanco_foods/main/?event=document.view&identifier=8543&documentTypeId=57	No
I.12	Study concerning the review and mapping of continuous professional development and lifelong learning for health professionals in the EU	O	Study to review and map national systems and practices to ensure the continuous professional development of health professionals with the aim to promote good practice.	R	E	O	CHAFEA	€ 200.000,00	This second literature review was part of the Consumers, Health and Food Executive Agency (CHAFEA) study concerning the review and mapping of CPD and LLL for health professionals in the EU-28 Member States and EEA/EFTA countries.	http://ec.europa.eu/health/workforce/docs/cpd_mapping_annex3b_en.pdf	No
I.13	Recruitment and retention rates of health workers in the EU by sharing good practice.	O	EU wide study to map innovative and effective recruitment and retention strategies for the health workforce with a view to exchanging good practices between Member States and to explore a future joint action with Member States.	P/R	E	O	CHAFEA	€ 400.000,00		http://ec.europa.eu/chafea/documents/health/2015_healthworkforce_recruitment_retention_rep_en.pdf	No

I.18	Evaluative Study of operation of Directive 2011/24/EU on application of patients' rights in cross-border healthcare to inform report to Parliament and Council due in 2015.	L	The Commission shall by 25 October 2015 (...) draw up a report on the operation of this Directive and submit it to the Parliament and the Council. The Commission shall by 25 October 2013 draw up a report on the financial consequences of the application of the directive in the MS that have opted for reimbursement on t the basis of fixed amounts as well as on the interaction of the Directive and the Regulation in relation to healthcare that is subject to prior authorization. Directive 2011/24/EU on the application of patients rights in cross-border healthcare	R	E	R	EMPL, ESTAT, MARKT, SG, LS.	€ 180.000,00	This study was clustered with another Study of operation of Commission Implementing Directive 2012/52/EU of 20 December 2012 laying down measures to facilitate the recognition of medical prescriptions issued in another Member State	http://bookshop.europa.eu/is-bin/INTERSHOP.enfinity/WFS/EU-Bookshop-Site/en_GB/-/EUR/ViewPublication-Start?PublicationKey=ND0614082	No
I.21	Study on sound evidence for a better understanding of health literacy in the European Union.	O	a study on sound evidence for a better understanding of health literacy in the European Union (HEALIT4EU) that would provide (1) a systematic analysis of existing knowledge regarding health literacy interventions in EU Member States; (2) a mapping of policies and actions aimed at improving health literacy in EU Member States and (3) establishing a model of determinants of health literacy using publicly available information sources.	P	E	O	CHAFEA	€ 100.000,00		http://ec.europa.eu/health/policies/docs/2015_health_literacy_en.pdf	No
I.23	A cost/benefit analysis of self-care systems in the European Union	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	P/R	E	R	None	€200,000.00		http://ec.europa.eu/health/patient_safety/docs/2015_selfcaresystems_study_en.pdf	No

I.27	Study on mapping of patients' rights in all Member States	O	Assessment of implementation of Patients' Rights Directive. This mapping exercise should give a general overview of the laws, structures, procedures and mechanisms in place in the different Member States guaranteeing patients' rights. Article 6 of Directive 2011/24/EU - Public Health Programme WP 2014-2020	P	E	E	None	€ 154.799,00		To be published in Eubookshop	No
I.33	Study on the monitoring of the implementation of Directive 2006/52/EC as regards the use of nitrites by industry in different categories of meat products	L		R	E	R	None	€ 500.000,00		https://webgate.ec.europa.eu/sanco_foods/main/?event=document.view&identifier=15282&documentTypeId=57	No
I.34	Study addressing new health risks due to the increased mobility in the context of globalisation (tourism, trade, travel, traffic) and global warming.	O	the objective is to improve preparedness in the context of the response to serious cross border threats to health, Implementation of Decision 1082/2013/EC	P	E	R	None	€103,171.00		Publication pending	No
I.35	Study on the state of play as regards the availability of plans in the area of preparedness plans in the field of health in the Member States, including a gap analysis of areas not covered by preparedness planning and the identification of incompatibilities between Member States plans, especially concerning cross border interaction.	O	the objective is to improve preparedness in the context of the response to serious cross border threats to health, Implementation of Decision 1082/2013/EC	P/R	E	R	None	€103,171.00		Publication pending	No

I.36	Study on intersectoral coordination focusing on the identification and prioritisation at European level of key sectors other than health that need to be prepared for emergencies.	O	the objective is to improve preparedness in the context of the response to serious cross border threats to health, Implementation of Decision 1082/2013/EC	P/R	E	R	None	€99,63		Publication pending	No
I.38	Technical study in the context of the assessment of the need for harmonisation of methods of sampling and analysis for GM material in food	O	Contribute to the assessment of the need and the feasibility for harmonisation of methods of sampling and analysis for official controls as regards the presence in food of GM material, in particular for which an authorisation procedure is pending or the authorisation of which has expired.	P	E	O	None	€ 100.000,00		To be published in Ebookshop	No
I.46	Eurobarometer for tissues and cells	O	Survey on the awareness/opinion of EU citizens concerning practices related to donation of human blood and tissues and the safety of transfusion and transplantation services. The study could be used as the input from general public for potential amendments of the current Directives and for supporting awareness campaigns within EU Member States.	R	E	I	None	€ 250.000,00	Eurobarometer	http://ec.europa.eu/COMMFrontOffice/PublicOpinion/index.cfm/ResultDoc/download/DocumentKy/67251	No
I.49	Eurobarometer on tobacco (Attitudes of Europeans towards tobacco and Electronic cigarettes)	O	Survey on the awareness/opinion of EU citizens concerning habits of consumption of tobacco and related products. The study will complement previous Eurobarometer studies carried out and provide a means of gauging changing/emerging trends. Importantly, it will ask a range of questions on the newly regulated product category of e-cigarettes.	R	E	I	None	€ 500.000,00		http://ec.europa.eu/public_opinion/archives/ebs/ebs_429_en.pdf	No

I.50	Study on the development of an EU common reporting format for submission of data on ingredients contained in tobacco and related products and disclosure of the collected data to the public.	O	Project to develop an EU common reporting format for submission of data on ingredients contained in tobacco and related products and disclosure of the collected data to the public (to be adopted by Implementing Act as set out in Art. 5(5) of Tobacco Products Directive)	P	E	O	CHAFEA	€ 180.680,00		http://ec.europa.eu/health/tobacco/docs/reportingformat_dataingredients_en.pdf	No
I.54	Analysis and feasibility assessment regarding EU systems for tracking and tracing of tobacco products and for security features		Project to assist in defining technical standards for the tracking and tracing systems, well as security features and their possible rotation, as set out under Articles 15(11)(a) and (b) and 16(2) of the Tobacco Products Directive [Implementing acts]	P	E	E	CHAFEA	€ 284.000,00		http://ec.europa.eu/health/tobacco/docs/2015_tpd_tracking_tracing_report_en.pdf	No
II.01	Report on food intended for sportspeople	L	Article 13 of Regulation (EU) No 609/2013 requires the Commission to present a report to the European Parliament and to the Council on the necessity, if any, of provisions for food intended for sportspeople. If necessary the report may be accompanied by an appropriate legislative proposal. The study shall collect data for the Commission to draft the mentioned report. If budget is available for 2014 an external study on the market of food intended for sportspeople could be considered - Art. 13 of Regulation (EU) No 609/2013	P	E	R	None	€ 127.815,00		To be published on Ebookshop	No
II.06	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	Project to assist in the development of a 'Priority list of additives' as set out in Article 6(1) of the Tobacco Products Directive [Implementing act]	P	E	R	None	€ 250.000,00			No
b. other studies cancelled in 2015											

I.05	Study on direct and indirect costs of animal disease including international standards perspective	O	Input to preparation of EXPO Milan 2015, also as input to provide more solid basis for policy makers in relation to economic consequences of animal diseases.	R	E	I	None	n/a	Study cancelled.	N/A	Yes
I.16	Reimbursement systems for medicinal products: building blocks and best practice sharing from cost-effectiveness viewpoint.	O	The objective is to assess which role market forces/government intervention should play for which subsegment of medicinal product market. To which extent could such a model be rolled out internationally?	P	E, I, M	O	None	n/a	Study cancelled.	N/A	Yes
I.17	Study on existing pricing and tariff systems in Member States in order to define cost-intensive healthcare.	O	The objective is to define cost-intensive healthcare. It seeks to identify possible and likely objective criteria for cost calculation in healthcare provision and to determine how to define cost-intensive healthcare based on such criteria as well as how best to define 'highly specialised' healthcare.	P/R	E, I, M	O	None	n/a	Study cancelled.	N/A	Yes
I.19	Additional study to previous OIE study on listing and categorisation of priority animal diseases, including its applicability for aquatic animals.		To support the forthcoming Regulation on animal health, especially listing and categorisation of animal diseases.	P	E	I	None	N/A	Study cancelled.	N/A	Yes

I.20	Application of IT based solutions to Animal Health.	O	Input to preparation of EXPO Milan 2015, on the use and importance of modern technology such as electronic identification of animals, electronic databases, interconnected systems and similar in combating animal diseases.	P/R	E	I	none	N/A	Study cancelled.	N/A	Yes
I.25	Report on milk-based drinks and similar products intended for young children.	O	Consider the necessity, if any, of special provisions for milk-based drinks and similar products intended for young children. The report will be based on two EFSA opinions that will be delivered between end 2013 and mid-2014 - Art. 12 of Regulation (EU) No 609/2013	P	I	R	None	N/A	Study cancelled.	N/A	Yes
I.29	An ad-hoc study on the impact on official controls and enforcement actions of the current legal framework applicable to "food fraud" (fraud along the agri-food chain)	L	Study on the impact on official controls and enforcement action of the current legal framework applicable to food fraud (fraud along the agri-food chain, Regulation 882/2004, Article 66 c)).	R	E	I	None	N/A	Study cancelled. Output replaced by internal commission activity.	N/A	Yes

¹ L - legal act, LMFF - legal base of MFF instrument, FR - financial regulation, REFIT, CWP - 'evaluate first', O - other (please specify in Comments)

² specify what programme/regulatory measure/initiative/policy area etc. has been covered

³ P - prospective, R - retrospective, P/R - prospective and retrospective

⁴ E - external, I - internal, M - mixed (internal with external support)

⁵ FC – fitness check, E – expenditure programme/measure, R – regulatory measure (not recognised as a FC), C – communication activity, I – internal Commission activity, O – other – please specify in the Comments

ANNEX 12: Performance tables

1.1 Achievement of general objectives

1.1.1 Health

General objective 1: Improve the health of EU citizens and reduce health inequalities

General objective 1 Complement, support and add value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.		<input checked="" type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending	
External factors: The health of EU citizens is not only driven by health care related determinants, but is also linked to individual lifestyles and behaviour (smoking, alcohol consumption, employment status, housing tenure and so on) as well as environmental factors.			
Impact indicator 1.A (KPI-1): Number of Healthy Life Years at birth (European Innovation Partnership on Active and Healthy Ageing)			
Definition and relevance: Healthy Life Years (HLY) also called disability-free life expectancy at birth is defined as the number of years that a person is expected to continue to live in a healthy condition at birth. We are looking at HLY instead of life expectancy because it's a crucial question whether extra years of life gained through increased longevity are spent in good or bad health. Moreover, HLY also monitor health as a productive or economic factor. An increase in HLY would lead to lower public healthcare expenditure and would likely increase the possibility that people continue to work later into life. (Source of data: Eurostat)			
Baseline 2010 (estimates 2011)	Milestone (2018)	Latest situation (2013 estimates)	Target 2020 (agreed in the EIP on Active and Healthy Ageing)
Males: 61.8 (61.5) Females: 62.6 (62.1)	Increase by 1 year	Males: 61.4 Females: 61.5	Increase by 2 years
Planned evaluations			
Ex-post evaluation of Health Programme 2008-2013 (March 2016)			
Evaluation of the implementation 2009 Commission Communication on reducing health inequalities and 2010 Council Conclusion on equity and health in all policies (30 June 2016)			
Mid- term evaluation report on the achievement of the objectives of the Health Programme 2014-2020 (30 June 2017)			

1.1.2 Food and feed safety, animal health and welfare, and plant health

General objective 2: High level of health for humans, animals and plants along the food chain and in related areas

<p>Impact indicator 2.B (KPI-3): Reduction of restrictions in the EU due to outbreaks of major epidemic animal diseases (foot and mouth disease, classical swine fever, African swine fever, avian influenza and Newcastle-disease)</p> <p>Definition and relevance: The indicator is <u>synthetic number</u>¹ composed of the sum of the number of regions² which are restricted for each of these diseases. This indicator measures the deviation from the ideal situation where there are no outbreaks hence no regions are restricted from normal domestic or intra-EU trade of live animals and their products due to any of these diseases. It captures spatial elements on a yearly basis relevant to the burden they cause to livestock competitiveness and unhindered movements.</p> <p>External factors: The Member States are responsible for the implementation of the EU rules to fight these diseases (i.e. import requirements and rules on eradication of the disease) in doing so they also rely on compliance by stakeholders and citizens. Moreover the management of the animal health situation outside of the EU is not bound by EU legislation and policies.</p> <p>Source of data: Commission internal from several sources: safeguard and regionalisation decisions, eradication and monitoring programmes against these diseases, Animal Disease Notification System (ADNS).</p>			
Baseline (2014)	Milestone (2018)	Current situation (2015)	Target (2020)
172/7800	Decreasing trend	Stable situation	Decreasing trend

<p>General objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs</p>		<input checked="" type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending	
<p>External factors: The EU status of animal/plant diseases can be jeopardised by the introduction of agents of animal/plant disease through illegal imports of commodities from third countries. In addition, implementation on the ground is done by the authorities in the Member States. For third countries neighbouring EU Member States we are dependent on their efforts, which are not always of the same level as in the Union.</p>			
<p>Impact indicator 2.A (KPI-2): Reduction in the incidence of main food-borne disease in the EU –BSE & Salmonella (Regulation (EC) No 652/2004 on expenditure in the field of the food chain, animal health and welfare and on plant health and plant reproductive material)</p> <p>Definition and relevance: Maintaining effective control measures on two of the major food-borne diseases, based on sound scientific evidence, ensures the continued reduction in the incidence of these diseases in animals and gives greater protection to the public.</p> <p>Source of data: EU BSE surveillance programme and ECDC surveillance data on human cases published in the annual joint EFSA/ECDC report on zoonoses</p>			
Baseline (2012)	Milestone (2018)	Current situation (2015)	Target (2020)
18 BSE cases	10 cases	2 cases	5 cases
90000 confirmed cases of human salmonellosis	67,000 confirmed cases of human salmonellosis	88,715 (2014) confirmed cases of human salmonellosis	(60,000 cases) continuous reduction / no eradication possible

¹ a number between 0 (no outbreaks anywhere, theoretical minimum: optimum scenario) and 7.800(the 1.560 EU regions in Member States restricted during the year for all five diseases) as an absolute high

² as defined in Directive 64/432/EEC

Impact indicator 2.C: Maintenance of EU territory free from Citrus Black Spot and Citrus Canker			
Definition and relevance: EU is one of the few areas free from these two severe pests of citrus fruit and having an important production of citrus. Maintaining the freedom of EU territory from this pest is a decisive factor for the competitiveness of this production and associated EU exports.			
External factors: Member States are responsible for timely implementation of the relevant EU legislation and swift co-operation in order to agree on the measures to be taken.			
Source of data: Notification of outbreaks by MS: EPPO data			
Baseline (2012)	Milestone (2018)	Latest situation (2015)	Target (2020)
No confirmed cases of outbreaks of Citrus Black Spot and Citrus Canker in the EU	Keep disease freedom	No confirmed cases of outbreaks of Citrus Black Spot and Citrus Canker in the EU	Keep disease freedom

1.1.3 Cross-cutting objectives

1.1.3.1 Crisis management

General objective 3: Respond rapidly and efficiently to any outbreak potentially endangering the health and safety of citizens, animals, or plants in Europe

General objective 3: Respond rapidly and efficiently to any outbreak potentially endangering the health and safety of citizens, animals, or plants in Europe, through adequate reaction capacities, appropriate preparedness and efficacious tools for quick alert and exchange of information.	<input type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending		
External factors: The degree of preparedness and the ability to identify rapidly a hazard are crucial and heavily rely on the structure and capacity in place in Member States and third countries			
Impact indicator 3.A: Ability to quickly react to any alert and isolate/circumvent any outbreak of a given disease			
Definition and relevance: EU safety and health status is among the highest in the world. Preserving it is crucial not only as a goal in itself but also for its side effect on our ability to trade products or on tourism activities.			
Source of data: WHO/OIE, EPPO-IPPC, EFSA, EWRS (Decision 1082/2013/EU)			
Baseline (2014)	Milestone (2016)	Latest situation (2015)	Target (2020)
African Swine Fever			
5 EU MSs affected	3 EU MSs affected	5 EU MSs affected	0 EU MS affected
Citrus black spot			
0 MS affected	0 MS affected	0 MS affected	0 MS affected

1.1.3.2 Better regulation

General objective 4: Maintaining a high level of health and safety on the EU territory while allowing competitiveness of the economic sectors under SANTE policies through proportionate, fit for purpose legislation

General objective 4: Maintaining a high level of health and safety on the EU territory while allowing competitiveness of the economic sectors under SANTE policies through proportionate, fit for purpose legislation	Spending programme <input checked="" type="checkbox"/> Non-spending
External factors: Co-legislators may affect during the policy making process the initial intentions of the Commission. Furthermore, at the time of implementation, the Member States can also impact this approach either through stricter national standards or by not using flexibility provisions.	
Impact indicator 4.A: Intra-EU trade of food products	
Definition and relevance: Globalisation requires finding the right balance between the need to keep the EU level of safety and the ability of our industry to compete on international markets, or of SMEs to simply grow on the EU or national/local markets. Both are not mutually exclusive and on the contrary are mutually reinforcing as high quality products contribute to economic sustainability. The challenge is to offer the right regulatory environment to achieve this goal.	
Source of data: COMEXT, 2012 data (CN codes: 2 – 8, 10, 15 – 21, 23, 35), 27 MSs (without Croatia)	

Baseline (2012)	Milestone (2017)	Current situation (2015)	Target (2020)
Intra-EU export Quantity: 239 million tonnes Value: 260 billion euro	260 million tonnes 270 billion euro	254 million tonnes 287 billion euro	280 million tonnes 290 billion euro

1.2 Achievement of specific objectives

1.2.1 Health

1.2.1.1 Health determinants

Relevant general objective 1: Complement, support and add value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.				
Specific objective 1.1: In order to promote health, prevent diseases, and foster supportive environments for healthy lifestyles: Identify, disseminate and promote the up-take of evidence-based and good practices for cost-effective health promotion and disease prevention measures by addressing in particular the key lifestyle related risk factors with a focus on the Union added value				<input checked="" type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending
External factors: The desired results and expected outcomes depend strongly on the cooperation of Member State authorities and stakeholders (including the relevant and large involvement of all Member States), and on the efficient and effective implementation of the Health Programme by the Consumers Health and Food Executive Agency (CHAFEA).				
Result indicator 1.1.A: Number of Member States involved in health promotion and disease prevention, using evidence-based and good practices through measures and actions taken at the appropriate level in Member States. (Health Programme 2014-2020)				
Definition and relevance: The health programme provides support to Member States and stakeholders for the identification, validation and dissemination of good practices, through Joint Actions and other means, linked to policy priorities to prevent chronic diseases – including cancer – and rare diseases, and to address health determinants and common risk factors. The number of Member States using the validated good practice measures represents a good proxy for effective coordination and contacts developed in order to take up the experiences across borders.				
Source of data: Health programme implementation statistics (CHAFEA)				
Baseline (2013)	Milestones		Current situation 2015	Target (2020) (agreed in Health Programme 2014-2020)
0	2015	2018	28 (breast cancer screening guidelines)	28
	7	23		
Result indicator 1.1.B. Number of MS involved in projects of promoting health and preventing diseases (as deriving from indicator 1.1.A from Health Programme 2014-2020)				
Definition and relevance: The health programme provides support to Member States and stakeholders for work on promoting health and preventing diseases, through projects and other means, linked to policy priorities to promote investment in prevention. The number of Member States and the degree of their involvement in projects and joint actions presents a good proxy for Member States coordination and contacts to develop and take up the experiences across borders.				
Source of data: Health programme implementation statistics (CHAFEA)				
Baseline	Milestones		Current situation	Target
2013	2017		2015	2020
0	14		23	28
Result indicator 1.1.C: Number of EU countries with a national initiative on the reduction of saturated fat (White Paper on a strategy for Europe on Nutrition, Overweight and Obesity related health issues – COM (2007)279 final)				
Definition and relevance: In Europe today, 6 of the 7 biggest risk factors for premature death – blood pressure, cholesterol, Body Mass Index, inadequate fruit and vegetable intake, physical inactivity and alcohol abuse – relate to how we eat, drink and move. Multi-stakeholder's approach within and between Member States in particular for food reformulation campaigns is core in the strategy for Europe on Nutrition, Overweight and Obesity related health issues and the Member States endorsed on 3 February				

2011 the High Level Group (HLG) agreed on the EU Framework for National Initiatives on Selected Nutrients with a first focus on saturated fat. Source of data: High Level Group on Nutrition and Physical Activity				
Baseline (2013)	Milestones		Current situation 2015	Target (2020) (target agreed in the programme statement)
	2015	2018		
12	18	24	24	28
Result indicator 1.1.D: Number of EU countries in which a European accreditation scheme for breast cancer services is implemented (Programme Statement attached to the Budget 2014) Definition and relevance: The European Accreditation system should be in place in 2016/2017 and will provide a good proxy for Member State uptake of guidance and good practice tools developed at EU level				
Baseline (2013)	Milestone (2017)	Current situation 2015	Target (2020) (target agreed in the programme statement)	
0	10	0	28	
Result indicator 1.1.E: Percentage respondents which currently smoke cigarettes, cigars or a pipe Definition and relevance: Tobacco consumption is the single largest avoidable health risk in the European Union. It is the most significant cause of premature death in the EU, responsible for nearly 700,000 deaths every year. Around 50% of smokers die prematurely (on average 14 years earlier). In addition, smokers have more life years in poor health. Many forms of cancer, cardiovascular and respiratory diseases are linked to tobacco use, which causes more problems than alcohol, drugs, high blood pressure, excess weight or high cholesterol. Source of data: Eurobarometer (latest data: Special Eurobarometer 385, 2012)				
Baseline (2012)	Milestones	Current situation	Target (2021) (according to the Impact assessment of the Tobacco Products Directive)	
	2018	2015	24%	
28%	25%	26%	24%	
Main outputs in 2015				
Description		Indicator	Target	
A well-functioning cooperative structure with Member States and stakeholders to realise actions with health impact on selected chronic diseases		A cooperative structure in place	Regular meeting and contacts are held with MS on tobacco control	
Follow-up to the adoption of Tobacco Products Directive: - support and monitor the transposition by the Members States (by 20 May 2016) - develop the implementation legislation concerning mainly the ingredients and labelling of tobacco e-cigarettes, such as a common reporting format and adaptation of the health warnings on tobacco packs (Commission output) - report on potential risks from electronic cigarettes and their refillables - conference on Mental Health in All Policies - contract for a second Joint Action on Dementia signed - launch of new Joint Action on rare diseases - contract concluded for the development of the EU Compass for Action on Mental Health and Well-being.		Transposition Implementing legislation Report Conference	Continuous support and monitoring 4 implementing acts adopted and 4 in preparation being prepared for Q2 2016 May 2015 December 2015 September 2015 April 2015	
Planned evaluations				
Evaluation Ex-Smokers communication campaign (March 2015)				
Ex-post evaluation of Health Programme 2008-2013 (March 2016)				
Mid- term evaluation report on the achievement of the objectives of the Health Programme 2014-2020 (30 June 2017)				

1.2.1.2 Cross-border health threats

Specific objective 1.2: Protect citizens from serious cross-border health threats

Relevant general objective 1: Complement, support and add value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.				
Specific objective 1.2: In order to protect citizens from serious cross-border health threats: Identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies. External factors: The desired results and expected outcomes depend strongly on the cooperation of Member State authorities and stakeholders (including the relevant and large involvement of all Member States), and on the efficient and effective implementation of the Health Programme by the Consumers Health and Food Executive Agency (CHAFAEA).				<input checked="" type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending
Result indicator 1.2.A: Number of Member States integrating the developed common approaches in the design of their preparedness plans (source: Commission Staff Working paper impact assessment, accompanying the Decision of the European Parliament and Council on serious cross-border threats to health) Definition and relevance: The number of Member States integrating the developed common approaches in the design of their preparedness plans is a clear indicator that directly allows for a proper assessment of the ways Member States identify and develop coherent approaches and promote their implementation for better preparedness and coordination in health emergencies. A Member State with a developed common approach can be defined as a Member State which has completed the implementation of the International Health Regulations, and arrangements for inter-sectoral cooperation and business continuity plans in place. The legal basis that defines how these data will be achieved is already laid down in Commission Implementing Decision 504/2014/EU adopted on 25 July 2014. Source of data: Report on the state of preparedness of Member States (by 7 November 2014 and then every three years afterwards, according to Article 4 of Decision 1082/2013/EU)				
Baseline (2013)	Milestones		Current situation	Target (2020)
	2015	2017	2015	(agreed in the programme statement attached to the Budget 2014)
0	4	14	16	28
Result indicator 1.2.B: Number of Member States ensuring all Tissue Establishments are enrolled in the EU traceability system of tissues and cells (Single European Code, SEC) Definition and relevance: MS will ensure traceability by implementing the Single European Coding system, and ensuring the compendium of tissue establishments is kept up to date. While the legal obligation only enters in 2016, all IT tools are available to implement the system earlier. Source of data: Utilisation logs of compendia (IT).				
Baseline (2013)	Milestones		Current situation	Target (2020)
	2015	2018	End 2015	(Source: Eurocet128)
0	5	28	8	28
Main outputs in 2015				
Description		Indicator		Target
Decision on serious cross-border threats to health		Implementing acts on (EWRS) and procedures for mutual information, consultation and coordination to coordinate responses to a health threat		Adoption foreseen for second quarter 2016 - delayed because a major overhaul is needed due to substantial comments made during the inter-service consultation
Pandemic preparedness		Joint procurement agreement		22 Member States have signed so far
Joint procurement for personal protective equipment		Framework contract		for signature by mid-2016 - delayed because of delays in the submission of the needs analysis
Joint procurement of pandemic vaccines		Framework contracts		Under preparation, target date 2017 - delayed because of the complexity of the specifications and because of the need for Member States to update

		previously submitted needs analysis
New three-year joint action on HIV and co-infection prevention and harm reduction	Deliverables of the JA	Launched on 14 January 2014 (official starting date was 1 October 2015 but the actual launch was delayed. Only the Steering Committee meeting took place in 2015 (8-9 December). However, this has no impact on the substantial deliverables (due as of 2016) and the partners have agreed to compensate for the initial delay.
Anti-Microbial Resistance roadmap	Deliverables	Implemented
Stakeholder consultation on reference laboratories for human pathogens	Report	Adoption foreseen for mid-2016 – delayed because originally not foreseen stakeholder consultation was included in the study to collect additional expert input from Member States and national reference laboratories.
National Competent Authorities who are actively updating the authorised Tissue Establishments in the Single European Coding system. (While the legal obligation only enters in 2016, all IT tools are available to implement the system earlier.)	Nr of up to date compendia of authorized tissue establishments	8
Planned evaluations		
Evaluation of the European Centre for Disease Prevention and Control (ECDC) (March 2015)		
Ex-post evaluation of Health Programme 2008-2013 (March 2016)		
Evaluation of the implementation 2009 Council recommendation on seasonal influenza vaccination (30 June 2016)		
Evaluation of 2011 Council conclusions on childhood immunisation (July 2016)		
Mid-term evaluation report on the achievement of the objectives of the Health Programme 2014-2020 (30 June 2017)		

1.2.1.3 Health systems

Specific objective 1.3: Support public health capacity building and contribute to innovative, efficient and sustainable health systems

Relevant general objective 1: Complement, support and add value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.	
<p>Specific objective 1.3: In order to support public health capacity building and contribute to innovative, efficient and sustainable health systems: Identify and develop common tools and mechanisms at EU level to address shortages of resources, both human and financial, and facilitate the voluntary uptake of innovation in public health intervention and prevention strategies</p> <p>External factors: The desired results and expected outcomes depend strongly on the cooperation of Member State authorities and stakeholders (including the relevant and large involvement of all Member States), and on the efficient and effective implementation of the Health Programme by the Consumers Health and Food Executive Agency (CHAFEA).</p>	<input checked="" type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending
<p>Result indicator 1.3.A NEW: Advice produced, in particular the number of Health Technology Assessments produced per year (Health Programme 2014-2020 and Report from the Commission to the EP and Council on the evaluation of the Union4s finances on the results achieved COM(2014)383 final and Overview of the Monitoring and Evaluation Frameworks for the MFF 2014-2020 pp. 186-189 SWD(2014) 201 final)</p> <p>Definition and relevance: The number of Health Technology Assessment reports produced as a consequence of EU collaboration indicates the degree of joint work done by the Member States. The assessments are</p>	

counted as any types of reports (early dialogues, full HTA reports etc.) produced.				
Source of data: Information from EUnetHTA and other EU funded projects.				
Baseline	Milestones		Current situation	Target
2012	2015	2017	2015	2020 (agreed in the programme statement)
2	6	10	9	50
Result indicator 1.3.B: Number of Member States using the tools and mechanisms identified in order to contribute to effective results in their health systems: patient summaries data/ ePrescription in line with the EU guidelines (Health Programme 2014-2020 and Report from the Commission to the EP and Council on the evaluation of the Union's finances on the results achieved COM(2014)383 final and Overview of the Monitoring and Evaluation Frameworks for the MFF 2014-2020 pp. 186-189 SWD(2014) 201 final)				
Definition and relevance: Patient summaries contain personal and health data for healthcare delivery. Patient summary data and ePrescription alignment is necessary to allow cross-border exchange. The uptake of eHealth instruments such as Electronic Health Records (EHR) and ePrescriptions (eP) contributes to better developing and monitoring of health technologies, better serving patients' needs and possibly reducing the costs of health care				
Source of data: eHealth network and joint action supporting the eHealth				
Baseline	Milestones		Current situation	Target
2013	2015	2017	2015	2020
0	5	12	0	28
			The 2015 call for Member States closes only in 2016.	
Main outputs in 2015				
Description		Indicator		Target
HTA reports		Number produced		9
Organisation for building the eHDSI (eHealth Digital Service Infrastructure) for the exchange of patient summaries and e-prescriptions under the Connecting Europe Facility		eHealth DSI Project		The necessary eHealth Network guidance adopted in November 2015; the set-up starts aided by the CEF financing in January 2016
Patient summary data/ePrescription in line with EU guidelines - Number of Member States		Number of Member States		0 - The CEF financing contracts are expected at the end of 2016, resulting in the first countries online in 2018
Expert Panel opinions		Number produced		6
Planned evaluations and studies				
Ex-post evaluation of Health Programme 2008-2013 (March 2016)				
Study on economic impact of the Paediatric Regulation (Regulation (EC) No 1901/2006) (2016)				
Study on the international regulation of advanced therapy medicinal products (Regulation No 1394/2007) (2016)				
Mid- term evaluation report on the achievement of the objectives of the Health Programme 2014-2020 (30 June 2017)				

1.2.1.4 Access to healthcare

Specific objective 1.4: Facilitate access to better and safer healthcare for EU citizens

Relevant general objective 1: Complement, support and add value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats.	
Specific objective 1.4: In order to facilitate access to better and safer healthcare for Union citizens: Increase access to medical expertise and information for specific conditions also beyond national borders, facilitate the application of the results of research and develop tools for the improvement of healthcare quality and patient safety through, inter alia, actions contributing to improve health literacy	<input checked="" type="checkbox"/> Spending programme <input type="checkbox"/> Non-spending
External factors: The desired results and expected outcomes depend strongly on the cooperation of Member State authorities and stakeholders (including the relevant and large involvement of all Member States), on the efficient and effective implementation of the	

Health Programme by the Consumers Health and Food Executive Agency (CHAFAEA) and on the available financial resources.				
<p>Result indicator 1.4.A: The number of approved and functioning European Reference Networks established in accordance with Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patient's rights in cross-border healthcare (Health Programme 2014-2020)</p> <p>Definition and relevance: The networks will be approved by the ERN Board of Member States and will need the Commission support for the development of the assessment procedures, IT platform for ERN, studies and project grants. ERNS will contribute to better and safer healthcare for Union citizens suffering from rare or low-prevalence and complex diseases by increasing access across the EU to medical expertise and information, which will be achieved by bringing together and pooling the knowledge of highly specialised healthcare providers from different Member States. They will help to provide affordable, high-quality and cost-effective healthcare (diagnosis and treatment) in case of need of a particular concentration of resources or expertise in medical domains where expertise is rare.</p> <p>Source of data: Information system on ERN, minutes of the Board of Member States on ERN meetings, licenses of the ERN trademark licensed.</p>				
Baseline	Milestones		Current situation	Target
2013	2015	2017	2015	2020 (Health Programme 2014-2020)
0	0	10	0	22
<p>Result indicator 1.4.B: Number of healthcare providers and centres of expertise joining European Reference Networks (Health Programme 2014-2020)</p> <p>Definition and relevance: ERNs will help Member States with insufficient number of patients to provide highly specialised care and therefore the greater number of members will maximise the speed and scale of diffusion of innovations in medical science and health technologies. ERN will also contribute to the objective acting as focal points in medical training and research, information dissemination and healthcare evaluation.</p> <p>Source of data: Information system on ERN, minutes of the Board of Member States on ERN meetings, licenses of the ERN trademark licensed.</p>				
Baseline	Milestones		Current situation	Target
2013	2015	2017	2015	2020
0	0	120	0	266
<p>Result indicator 1.4.C: Number of Member States using the developed tools such as, having adopted and implemented a national strategy for the prevention and control of health-care associated infections (Commission report (COM (2012) 658 final) on the implementation of the Council Recommendation 2009/C 151/01)</p> <p>Definition and relevance: The increase of Member States adopting and implementing national strategies for the prevention and control of health-care associated infections will reduce the risk of acquiring a healthcare-associated infection when seeking healthcare, hence facilitate access to better and safer healthcare for Union citizens.</p> <p>Source of data: ECDC country summary sheets on HAI</p>				
Baseline	Milestones		Current situation	Target
2013	2015	2018	2015	2020
9	15	20	18	28
Main outputs in 2015				
Description		Indicator		Target
Assessment manual		One manual		Manual published on the webpage.
Selection of assessment bodies		Number of assessment bodies selected		Two tenderers positively evaluated but pending signature of contracts foreseen for March 2016
Development of a pilot IT infrastructure		One IT platform		Platform to be finalised in 2016
Communication campaign		Number of medical journals with inserted ERN ads		30
Second ERN conference		One conference		Conference organised in October 2015
First call for ERN		One call for tender		To be launched in March 2016
Call for proposals to set up the National eHealth Contact Points				Published November 2015
EUneHTA (European Network		The coalition of Member States		

for Health Technology Assessment) Joint Action renewed for 2016-2019	put together that submitted its proposal for a Joint Action in January 2016.	
Planned evaluations		
Ex-post evaluation of Health Programme 2008-2013 (March 2016)		
Mid- term evaluation report on the achievement of the objectives of the Health Programme 2014-2020 (30 June 2017)		

1.2.1.5 Crisis management

Specific objective 3.1: Effective public health crisis preparedness and response planning

Relevant general objective 3: Respond rapidly and efficiently to any outbreak potentially endangering the health and safety of citizens, animals, or plants in Europe, through adequate reaction capacities, appropriate preparedness and efficacious tools for quick alert and exchange of information.			
Specific objective 3.1: In order to complement public health preparedness and response planning and contribute to innovative, efficient and sustainable health systems: identify and develop shared tools and mechanisms ³ for sharing best practices, promoting inter-operability and inter-sectoral dimension and supporting the implementation of core capacity requirements ⁴ .			<input type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending
External factors: The desired results and expected outcomes depend strongly by the Member State authorities, who are asked to timely share their preparedness and response plans and by non-forecasted events which will happen in the future.			
Result indicator 3.1.A: Notifications by MS of the following criteria: (a) core capacity standards for preparedness and response planning; (b) description of the measures or arrangements aimed at ensuring interoperability between the health sector and other sectors including the veterinary sector, that are identified as being critical in the case of an emergency, in particular: (i) coordination structures in place for cross-sectoral incidents; (ii) emergency operational centres (crisis centres); (c) description of the business continuity plans, measures or arrangements aimed at ensuring the continuous delivery of critical services and products. (d) implementation of the preparedness plans for blood and transplant services (where/as applicable)			
Definition and relevance: The above are essential elements for health preparedness which are enshrined in the Decision 1082/2013/EC.			
Source of data: Notification by MS under Art 4 of Decision 1082/2013/EU			
Baseline (2015)	Milestone (2017)	Current situation (2015)	Target (2021)
4 ⁵	14 ¹²	16	28
Main outputs in 2015			
Description	Indicator		Target
Implementation of Decision 1082/2013/EU	Report of the Commission to European Parliament and Council		Adopted on 7/12/2015

1.2.1.6 International relations

Specific objective 1.5: Increase the voice and influence of the EU in global health fora

Relevant general objective 1: Complement, support and add value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities by promoting health, encouraging innovation in health, increasing the sustainability of health systems and protecting Union citizens from serious cross-border health threats	
Specific objective 1.5: Increase the voice and influence of the EU in global health fora	<input type="checkbox"/> Spending
External factors: Agreeing coordinated EU inputs at WHO and other UN Bodies depends on a	

³ according to Article 4 of Decisions 1082/2013/EU

⁴ according to Art 5 and 13 of the International Health Regulations

⁵ To be noted that this parameter was determined before the findings of the preparedness report under Article 4 of Decision 1082/2013/EU became available

consensual willingness of the EU MS to coordinate their positions. Reasons used in the past by MS for refusing include: they consider the topic as exclusive MS competence, as being irrelevant, that they do not have the capacity to coordinate on a large number of items, that there is a red line issue in the text for them, that the text is already acceptable etc.			program me <input checked="" type="checkbox"/> Non-spending
<p>Result indicator 1.5.A: Percentage of the total number of WHO Governing Body Resolutions adopted annually which contain coordinated EU inputs.</p> <p>Definition and relevance: Historically, EU Member States have negotiated texts individually at WHO governing bodies. The above indicator will (i) indicate a growing move from EU MS individual action to coordinated EU action, and (ii) a real impact of EU inputs to the texts of agreed resolutions</p> <p>Source of data: reports of WHO governing body meetings</p>			
Baseline	Milestone	Current situation	Target
2014	2017	2015	2021 (internal decision based on the year coinciding with the end of the posting of the next SANCO official to be sent to the UN in Geneva).
WHO Executive Board: 85% resolutions negotiated	90%	21%	95%
World Health Assembly 60% resolutions negotiated	75%	59%	90%
WHO Regional Committee for Europe: 50% Resolutions negotiated	70%	63%	90%
Main outputs in 2015			
Description		Indicator	Target
EU-level Mapping exercises for topics on agendas of the three annual WHO governing body meetings		Percentage of EU-relevant issues mapped Number of mapping meetings	100% 9
Coordinated EU statements at WHO and UNGA on EU-relevant health topics		Percentage of total EU-relevant topics for which statements are agreed in coordination Number of coordination meetings	45% 50
EU positions on WHO governing body resolutions and health-related resolutions at the UN		Percentage of total EU-relevant topics for which EU negotiating inputs are prepared and agreed at EU level.	68%

1.2.2 Food and feed safety, animal health and welfare, and plant health

1.2.2.1 Official controls and enforcement along the food chain

Specific objective 2.1: Improve the effectiveness, efficiency and reliability of official controls

Relevant general objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs			
Specific objective 2.1: Contribute to improve the effectiveness, efficiency and reliability of official controls and other activities carried out in view of the effective implementation of, and compliance with, EU rules			<input checked="" type="checkbox"/> Spending programme
External factors: The desired results and expected outcomes depend strongly on the willingness and vigour of Member States and third country authorities to act.			<input checked="" type="checkbox"/> Non-spending
Result indicator 2.1.A: Percentage of recommendations following DG SANTE audits that Member States have satisfactorily addressed with corrective action			
Definition and relevance: DG SANTE's Directorate on Health and Food Audits carries out audits to verify (a) compliance with EU rules and (b) that official controls are carried out in line with EU law. DG SANTE makes recommendations to the country's competent authority aimed at ensuring that Member States address any shortcomings revealed during the audits. The competent authority is requested to present an action plan to DG SANTE on how it intends to address any shortcomings. DG SANTE evaluates this action plan and monitors its implementation through a number of follow-up activities. The indicator is therefore an indication of the effect that DG SANTE's recommendations have in promoting compliance with relevant single market rules.			
Source of data: Commission internal (DG SANTE – Directorate on Health and Food Audits and Analysis)			
Baseline (2013)	Current situation (2015)	Target (2015)	
60% for recommendations from reporting cycles 2010 - 2012	79% From reporting cycles 2011 – 2013	70% of all recommendations from these reporting years to be addressed	
Result indicator 2.1.B: Ratio of satisfaction of participants in BTSF training programmes (training quality) and steady state of annual participants (minimum training target)			
Definition and relevance: Satisfaction ratio is an important tool to measure the training quality from a technical and organisational point of view, the relevance of the training in terms of addressing participants' expectations and needs in the workplace. In order to ensure effective, efficient and reliable controls, high quality training contributes to the better understanding and harmonised enforcement of the rules in place. Taking into account the 'trainee-trainer principle', the participants will disseminate this knowledge in their respective Member States. Therefore the need to ensure and maintain a critical mass of participants to the BTSF trainings. The satisfaction rate as measurable indicator provides a tool to evaluate the appropriateness and relevance for the daily work of the officials attending the training.			
Source of data: BTSF Annual Report 2013			
Baseline (2014)	Milestone (2018)	Current situation (2015)	Target (2020)
85% satisfaction rate/6000 participants trained	85% satisfaction rate/ 6000 participants trained	?	87% satisfaction rate/ 6000 participants trained
Main outputs in 2015			
Description	Indicator	Target	
Report on the operation of official controls along the food chain	Report will be adopted at the beginning of 2016 due to longer consultation period	Adoption	
Overview reports on FVO audit series	Number of reports published in 2015: 14 (the remaining beginning 2016 due to longer consultation period)	22	

FVO audits in the fields of food and feed safety, animal health and welfare and plant health - audits on imports from third countries of active pharmaceutical ingredients for medicinal products for human use - audit on organic production and labelling of organic products - audits on geographical indication schemes (MoU with DG AGRI)	(1) Completion rate of programmed audits: 86% (2) Overall use of audit capacity: 95% Number of audits: no applications received Number of audits: 11 Number of audits: 3	(1) 80% (2) 90% 2 – 3 (depending on applications) 11 3
Cross-sector projects	Number of projects 10	8
Mandatory joint assessments (with designating authorities) of notified bodies in the medical devices sector in MS, EFTA and ESA countries	Number of assessments 26	Approx. 25
Series of study visits to exchange information and best practice between MS on strategies and actions to improve slaughter hygiene (mammals), including the establishment of an expert group.	Number of study visits: 8 Interim overview report: 2016* Organisation of expert group meetings: 2	6 By end 2015 2
Residue control plans from MS and from third countries exporting food of animal origin to the EU	Number of evaluations: All plans checked, with in-depth evaluation based on risk criteria and requests for new listing.	28 MS plans and 85 TC plans (currently 84 TC are listed with 261 plans)
Approved third country establishments for the production of food of animal origin	Management of establishment lists: as per target	127 lists by country (27 lists by sector)
Evaluation of Border Inspection Post plans	Number of evaluations: 26	On average 50
Harmful organisms outbreak annual report	Number of reports: 1	1
Plant pest surveys	Number of surveys: 2	3
EUROPHYT Annual report	Number of reports: 1	1
Network meetings with Member State experts to identify problem areas and exchange good practices (e.g. animal welfare, national audit systems and multi-annual national control plans and others)	Number of meetings organised: National audit systems: 5 Multi-annual national control plans: 5 Animal welfare contact points: 2 Slaughter hygiene: 2 BTSF following audit series: 10	up to 10
Robust impact indicators to measure BTSF participants' post-training performance not Dir. F	Study in progress	Completion in 2016
Management of BTSF programmes	Number of contracts, Evaluation of reports & offers Organisation of meetings with contractors	15 (currently 45 BTSF contracts in progress) 100% evaluated within required timescale 100% organised as required

1.2.2.2 Animal health and welfare

Specific objective 2.3: Higher animal health status in the Union and the improvement of the welfare of animals

Relevant general objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs					
Specific objective 2.3: To contribute to a higher animal health status in the Union and to support the improvement of the welfare of animals External factors: The EU status of animal diseases can be jeopardised by the introduction of agents of animal disease through illegal imports of commodities from third countries. For animal welfare, incorrect implementation by operators and not sufficient controls by the competent authorities on the animal welfare rules can influence negatively the welfare of animals in the EU.				<input checked="" type="checkbox"/> Spending programme <input type="checkbox"/> Non-spending	
Result indicator 2.3.A: the increase of the number of Member States or regions thereof which are free from Aujeszky disease or with an approved eradication programme Definition and relevance: This indicator represents results of significant, planned, long-term eradication efforts by Member States, to achieve higher animal status (and hence reduced direct losses from this disease) and more competitiveness of their swine sector both on the internal EU market and for exports to third countries. Source of data: Annual reports under Directive 64/432/EEC and Decision 2008/185/EC					
Baseline ⁶ (2011)		Current situation (2015) as described in Decision 2008/185/EC		Target 2015 (Commission internal target)	
12 MS and 96 regions free		15 MS and 96 regions free		Increase in the number of free regions	
Result indicator 2.3.B: Disease parameters such as number of outbreaks and number of Member States or regions thereof which are free from animal diseases for which a financial contribution is granted (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme) Definition and relevance: The indicators are fundamental to achieve the general and specific objectives as they indicate if the disease has been reduced or even no more present in the concerned animal population and region/Member States (free) Source of data: annual reports from the Member States under Directives 64/432/EE, 91/68/EEC and (EU) Regulation No. 999/2001 and Animal Disease Notification System (ADNS)					
Disease/programme	Baseline (2012)	Milestone 2015	Milestone 2017	Current situation 2015	Target 2020
ERADICATION PROGRAMMES					
Bovine brucellosis	4 MS with co-financed programmes	4 ⁷ MS with co-financed programmes 1 MS free ⁸	2 MS with co-financed programmes 2 additional MS free	5 MS with co-financed programme 0 additional MS free	1 MS with co-financed programmes 3 additional MS free
Bovine tuberculosis	5 MS with co-financed programmes	6 MS ³ with co-financed programmes 0 MS free	5 MS with co-financed programmes 1 MS free	6 MS with co-financed programmes 0 additional MS free	2 MS with co-financed programmes 4 additional MS free
Ovine and caprine brucellosis (<i>Brucella melitensis</i>)	5 MS with co-financed programmes	4 MSs with co-financed programmes 2 MSs free	4 MS with co-financed programmes	5 MS with co-financed programme 1 additional	1 MS with co-financed programme

⁶ Source: annual reports from the Member States under Directive 64/432/EEC

⁷ Croatia has joined the EU in July 2013

⁸ See NB2 at the end of this table

				MS free		
Rabies	No of cases in wild animals					
	527 ⁹	384 ¹⁰	246	126	100	
CONTROL AND ERADICATION PROGRAMMES						
Classical swine fever (domestic pig and wild boar)	3 outbreaks in 1 MSs in domestic pigs 17 cases in 1 MSs in wild boars	0 outbreak in domestic pigs	0 outbreak in domestic pigs	0 in domestic 5 in wild boar	0 outbreak in domestic pigs	
African swine fever (domestic pig and wild boar)	74 outbreaks in 1 MS in domestic pigs 17 cases in 1 MS in wild boars	Less than 25 outbreaks in domestic pigs in 5 MSs	Less than 10 outbreaks in domestic pigs in 4 MSs	58 in domestic 1686 in wild boar	Less than 10 outbreak in domestic pigs in 1 MS	
TSE	Classical BSE	11 cases	Less than 5 cases	Less than 5 cases	2	Less than 3 cases
	Classical scrapie Free MSs	16 MSs	16 MSs	At least 19 MSs	17 MS	At least 22 MSs
Bluetongue	23 MSs free	23 MSs free	24 MSs free	18 MSs free	26 MSs free	
Main outputs in 2015						
Description		Indicator		Target		
Framework Regulation on animal health ¹¹		Final rule by co-legislators		Adoption in 2016		
Detailed rules under the Regulation		implementing act on listing of diseases		Preparation ongoing, adoption foreseen for 2017		
Conferences on key building blocks of EU animal health policy (on animal health and wild life, emerging diseases/One health, international trade standards, information technology)		Number of conferences		4		
World Organisation for Animal Health		Representation of Commission		EU position for General Session of June 2015 prepared and agreed with Member States		
Communication targeted to EU livestock sector		Participation at several major EU agricultural fairs in Berlin, Paris and in the EXPO2015		4		
International cooperation with EuFMD		Participation at its General Session, new Agreement with EuFMD		DG SANTE participated at the General Session and a new agreement with the EuFMD is under discussion		
Supporting studies for delegated and implementing rules under the Regulation on animal health (aquaculture, on-farm biosecurity)		Number of studies started		2		

⁹ In MSs where a co-financed programme for the disease is implemented (12 MSs) - Bats not included (source EFSA/ECDC 2012 zoonoses report)

¹⁰ -10% per year from 2012 to 2015

¹¹ This is beyond the full control of the Commission

New EP/Council rules on zootechnics ¹²	Final rules by co-legislators	Adoption in 2016
Welfare at slaughter	Report on restraining bovine by inversion FVO overview report on welfare at slaughter produced third semester and published November 2015 BTSF on this Network meeting for welfare at slaughter	Adopted (Feb 2016) Published November 2015 October 2015 Carried out
Information to consumers on the stunning of animals	A study	Published 2015
Education of veterinary practitioners on animal welfare	Number of foreseen workshops	1 (Bulgaria)
Welfare of dogs and cats	A study + conference	Conference - November 2015. Study to be finalised and published in 2016
Protection of animals during transport	Pilot project on best practices	Project started 10/05/2015
Welfare of dogs and cats	A study + conference	Finalisation of the study and participation in conference on this subject
Education of persons keeping or handling farmed animals	Series of audits on animal welfare training programmes (farm transport and slaughter in MS)	8 carried out
Bovine tuberculosis eradication	Number of foreseen programmes	7
Bovine brucellosis eradication	Number of foreseen programmes	5
Sheep and goats brucellosis eradication	Number of foreseen programmes	5
Blue tongue control and eradication	Number of foreseen programmes	15
Salmonella control	Number of foreseen programmes	24
Swine diseases (classical and African swine fever control and eradication)	Number of foreseen programmes	16
TSE control and BSE/Scrapie eradication	Number of foreseen programmes	28
Rabies eradication	Number of foreseen programmes	13
Avian influenza survey	Number of foreseen programmes	25

1.2.2.3 Plant health

Specific objective 2.2: Timely detection of pests and their eradication, where they have entered the EU

Relevant general objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs	
Specific objective 2.2: Contribute to timely detection of pests and their eradication, where they have entered the EU	<input checked="" type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending
Result indicator 2.2.A: 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)	
Definition and relevance: Survey programmes are an essential tool for early detection of pests enabling early	

¹² This is beyond the full control of the Commission

actions for their control. Currently, Regulation (EU) No 652/2014 sets out an incentive for carrying out such programmes through the possible co-financing. Annual survey programmes will become compulsory only through the new Plant Health proposal.

External factors: MS financial and administrative capacity of introducing relevant survey programmes; adoption of the new PH Regulation by the EP and Council without any substantial changes to its provisions.

Source of data: Survey programmes submitted by MS

Baseline	Milestones		Current situation	Target
2012	2015	2017	2015	2020 (agreed in Commission proposal COM(2013)327 final)
5%	50%	70%	57%	100%

Result indicator 2.2.B: 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)

Definition and relevance: Pests considered most dangerous are usually subject to EU measures, including the obligation of monitoring their presence and reporting monitoring results. It gives the possibility of following on a regular basis the evolution of these pests in EU.

External factors: Compliance of MS with EU measures

Source of data: Monitoring results for pests subject to EU measures.

Baseline	Milestones		Current situation	Target
2012	2015	2017	2015	2020 (agreed in Commission proposal COM(2013)327 final)
100%	100%	100%	100%	100%

Result indicator 2.2.C (KPI-4): Time between finding and notification for pests not known to occur in the Union (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme)

Definition and relevance: The reduction of time between finding of pests and its notification is influencing the timely adoption of eradication measures. The current legal framework is not clearly defining the obligation of notification in terms of days. The new PH proposal is introducing a 3 days period.

External factors: adoption of the new PH Regulation by the EP and Council without any substantial changes to its provisions; agreement of MS on the new deadline proposed for 2015 in the draft Commission implementing decision; successful implementation of the electronic system of outbreak notifications.

Source of data: Notification of outbreaks by MS (electronic system planned to be put in place)

Baseline	Milestones		Current situation	Target
2012	2015	2017	2015	2020 (agreed in Commission proposal COM(2013)327 final)
10 days	8 days	4-8days	8	3 days

Result indicator 2.2.D: Success rate in eradicating such pests -for pests not known to occur in the Union, the success rate of eradication of pests - 2012 (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme)

Definition and relevance: Successful eradication of notified outbreaks is ensuring the protection of crops, forests and green landscapes from extensive damages (economic and environmental)

External factors: administrative capacity of MS for putting in place the necessary measures and finance/co-finance them as needed.

Source of data: Electronic system of outbreaks notification

Baseline	Milestones	Current situation	Target
2013	2017	2015	2020 (agreed Commission proposal COM(2013)327 final)
0 ¹³	60%	Data not available yet	95%

Main outputs in 2015

Description	Indicator	Target
Amendment of Council Directive 2000/29	1 amendment covering the necessary updates concerning the status of pests and associated	Postponed to mid-2016 due to additional work required by the various working group

¹³ So far no official figures available up to the entry into force of the future EU Regulation on protective measures against pests of plants (COM(2013)267 final)

Amended Proposal on Regulation on plant reproductive material	requirements in the Annexes Amended proposal prepared	Proposal withdrawn by the Commission on 7/3/2015 following its earlier rejection by the European Parliament in 2014
Draft ToRs for the Plant Reproductive Material EU Reference Centres Updates of the Common Catalogues of varieties of agricultural and vegetable species	Draft ToRs prepared 12 updates and 2 consolidated versions	Following exclusion of the Marketing Directives from the scope of the Official Control Regulation, there is no legal basis therefore work has been cancelled. Common Catalogues were updated/consolidated according to the plan.
Emergency measures for Plant Health as needed	100%	adopted: Asian longhorn beetle (new): June 2015; Xylella (new) May 2015
Planned evaluations		
Evaluation of Regulation 1107/2009 concerning the placing on the market of plant protection products		
Ex-post Evaluation on pesticides Maximum Residue Levels legislation (Regulation 396/2005) (2016)		

1.2.2.4 Food safety

Specific objective 2.4: Contribute to a high level of safety of food and food production systems and of other products which may affect the safety of food, while improving the sustainability of food production

Relevant general objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs			
Specific objective 2.4: Contribute to a high level of safety of food and food production systems and of other products which may affect the safety of food, while improving the sustainability of food production External factors: Safety of food can be jeopardised by the illegal imports of commodities from third countries.			<input checked="" type="checkbox"/> Spending programme <input type="checkbox"/> Non-spending
Result indicator 2.4.A (KPI-2): The number of cases of diseases in humans in the EU linked to food safety or zoonoses (Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme) Definition and relevance: Maintaining effective control measures on Salmonella, based on sound scientific evidence ensures the continued reduction in the incidence of it in animals and gives greater protection to the public. Source of data: ECDC surveillance data on human cases published in the annual joint EFSA/ECDC report on zoonoses			
Baseline (2012)	Milestone (2018)	Current situation (2015)	Target (2020 ¹⁸)
90.000 confirmed cases of human salmonellosis	67.000 cases	88,715	60.000 (sustained negative trend in incidence cases)
Result indicator 2.4.B: Bring new additives to the market faster, within the established timelines, ensuring fast market access Definition and relevance: New uses of food additives (i.e. new additives or extension of existing uses) need an authorisation. Product authorisations within established timelines (9months for EFSA, 9 months for Commission, 4 months for procedural time) provides legal certainty and predictability, resulting in better planning and faster return on investment and,. It can therefore reduce the total cost of product development. Moreover, competitiveness is increased and companies use the latest research in their improved or new generation of products for consumers. New developments will impact positively the safety of the food chain. Source of data: Commission food additives database			
Baseline (2013)		Current situation (2015)	Target (2015) (as

		foreseen by legislation)
27 months new additives (including risk assessment) 13 months for extension of use (no risk assessment)	29 (delay due to EFSA stop requests for additional information needed for evaluation of the substances) 7	22 months 13 months
Main outputs in 2015		
Description	Indicator	Target
Preparation of proposal on food hygiene.	Commission proposal to the EP and the Council	The preparation of the revision of the hygiene package was stopped further to the difficulties encountered during the impact assessment process. Solutions that will not require such a proposal will be explored prior to the end of the transitional measures that triggered the preparation of such proposal.
Preparation of proposal on feed hygiene.	Commission proposal to the EP and the Council	The proposal was not finalised since due to its limited scope it was decided to wait for it to be combined with other Commission measures to propose a wide-ranging package of measures in support of SMEs.
Preparation of proposal on ionising radiation	Commission proposal to the EP and the Council	This could not be achieved in 2015 as the subject requires more investigation before any proposal can be made.
Alignment of the TSE Regulation (EC) 999/2001	Commission proposal to the EP and the Council	Though changes were made to adapt technically the annexes to the TSE Regulation, 2015 proved too early to consider deeper changes – including alignment – to the founding text.
Medicated Feed Regulation	Council position (expected by the end of 2015)	The compromise text is well advanced but the Council is waiting for the proposal on veterinary medicines to reach the same level of maturity before finalisation as the proposals are linked
Authorisation of feed additives in the framework of Regulation (EC) No 1831/2003	Number of decisions on authorisations	44 legal acts corresponding to 56 individual feed additive authorisations
Improve legal framework for feed use of safe by-products from vegetable food and biofuel industries	Legislative proposal	Discussions have been more difficult than expected. Draft Regulation to be adopted

		in 2016.
Timely processing of applications by the Commission of new uses of food additives upon receipt of an application from EFSA opinion (when an opinion is needed)	Percentage of authorisations submitted in time to the regulatory committee	75% (due to EFSA requests for additional information needed to evaluate the substances.
Timely processing by the Commission of EFSA conclusion on active substances to be used as pesticides	Percentage of conclusions processed in time	90%
Proposal for a Directive of the EP and Council amending Directive 2001/18/EC as regards the possibility for Member States to restrict or prohibit the cultivation of GMOs on their territory (beyond the control of the Commission)	Amendment	Adopted in April 2015
Review of the decision-making process applied to GMOs	Proposal and Communication of the Commission	Both adopted in April 2015
Commission notice clarifying whether products resulting from some new breeding techniques fall under the GMO legislation	Commission notice	Planned for adoption in Q2 2016
Act by the Commission modifying the annexes of Directive 2001/18/EC regarding environmental risk assessment of GMOs	Draft to be discussed with MS and stakeholders	Updated annexes to Dir 2001/18 – adoption foreseen by April 2017 at the latest
Publication of the study on voluntary GM free labelling	Study	Published in July 2015
Technical study to assess the need for harmonisation of sampling and analysis methods for GM material in food	Study	Study finalised mid-December 2015

Specific objective 2.5: Strengthen a basis for consumers to make informed choices to make safe use of food

Relevant general objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs			
Specific objective 2.5: Strengthen a basis for consumers to make informed choices to make safe use of food		<input type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending	
External factors: Lack of appropriate consumer education with a significant negative impact on consumer behaviour, leading ultimately to consumers taking decisions without being knowledgeable about their impacts. Additionally, purchasing power plays an important role in consumer food choices.			
Result indicator 2.5.A: Change in consumer behaviour through increased health awareness reflected in their purchasing habits and consumption of food			
Definition and relevance: The change in consumer behaviour towards healthier choices can only be expected when information that allows them to take informed decisions and to understand how their food choices impact their lives is available. Mandatory nutrition labelling will provide factual information on the vast majority of pre-packed food.			
Source of data for baseline: Flabel EU funded project (2008-2012)			
Baseline (2012)	Milestone (2017)	Current situation (2015)	Target (2020)
85% of products with back-of-pack nutrition labelling or related information (from 70% in Slovenia to 97% in Ireland)	nutrition declaration on 100% products under the mandatory nutrition	Nutrition declaration on 70-97% of products (depending on Member States)	nutrition declaration on 100% products under the mandatory

	declaration regime		nutrition declaration regime
Main outputs in 2015			
Description	Indicator	Target	
Reporting on origin indication of: -meat other than beef, pig, poultry, sheep/goat -milk -milk used as ingredient in dairy products -unprocessed food -single ingredient products -ingredients representing more than 50% of a food	Report foreseen in Regulation (EU) 1169/2011 on the provision of Food Information to consumers – Art. 26 (5)	Adopted on 20 May 2015	
Reporting on Trans fatty acids	Report foreseen in Regulation (EU) 1169/2011 on the provision of Food Information to consumers – Art. 30 (7)	Adopted on 3 December 2015	
Report in alcoholic beverages	Report foreseen in Regulation (EU) 1169/2011 - Art. 16(4)	Adoption in 2016	
Providing guidance on the presence of certain contaminants Guidance document for competent authorities and food business operators on compliance of natural mineral water with the definition laid down by Directive 2009/54/EC on the exploitation and marketing of natural mineral waters.	Guidelines document as foreseen in Directive 2009/54/EC on the exploitation and marketing of natural mineral waters Guidance document to ensure common application enforcement and control of the compliance of a natural mineral water with the definition laid down by Directive 2009/54/EC.	Under preparation	
Authorisation and refusal of authorisation of health claims following authorisation procedures as foreseen by Regulation (EC) No 1924/2006.	Commission Decisions to be adopted in 2015	10 adopted in 2015, 14 expected in 2016	
Exemption of generic descriptors (denominations) from the scope of Regulation (EC) No 1924/2006.	Commission Decisions to be adopted by 2015	no decision adopted yet	
Infant formula and follow-on formula, cereal based foods and other baby foods, foods for special medical purposes, total diet replacement for weight control	delegated acts foreseen by Regulation (EU) No 609/2013	In 2015, the Commission adopted Delegated Regulations on infant formula and follow-on formula; processed cereal-based food and baby food and food for special medical purposes. The ones on infant formula and follow-on formula and food for special medical purposes successfully passed the EP and Council scrutiny and were published in the OJ on 2 February.	

1.2.2.5 Crisis management

Specific objective 3.3: Provide fast and user-friendly information on food and feed and public health alerts through RASFF notifications

Specific objective 3.3: Provide fast and user-friendly information on food and feed and public health alerts through RASFF notifications External factors: Reliance on Member States Contact Points to inform and transmit information on potential risks		<input checked="" type="checkbox"/> Spending programme <input type="checkbox"/> Non-spending	
Result indicator 3.3.A NEW: Follow-up given by the Competent Authorities in the Member States on RASFF Alert notifications within 24 hours of receipt Definition and relevance: Alert notifications are sent when food, feed or food contact materials presenting a serious risk are on the market and rapid action is required in other countries than the notifying country. Source of data: RASFF			
Baseline (2012)	Milestone (2018)	Current situation (2015)	Target (2020)
100%	100%	100%	100%
Main outputs in 2015			
Description	Indicator	Target	
Timely reaction to an alert	Measures (including safeguard measures adopted on time)	100%	
Management of RASFF	All notifications dealt with	100%	

Specific objective 3.2: React swiftly to and isolate/circumvent any outbreak of a given disease with appropriate budget support

Relevant general objective 3: Respond rapidly and efficiently to any outbreak potentially endangering the health and safety of citizens, animals, or plants in Europe, through adequate reaction capacities, appropriate preparedness and efficacious tools for quick alert and exchange of information.			
Specific objective 3.2: Develop the ability to react swiftly to and isolate/circumvent any outbreak of a given disease with appropriate budget support External factors: The degree of preparedness and the ability to identify rapidly a hazard are crucial and heavily rely on the structure and capacity in place in Member States and third countries		<input type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending	
Result indicator 3.2.A (KPI-3) 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) Definition and relevance: The indicator shows a <u>synthetic number</u> ¹⁴ composed according to a matrix and is indicative of how containment of those diseases functioned during the year. This indicator is related to the effectiveness of the Member States with the coordination and technical and financial assistance of the Commission to halt the spread of these major diseases once they occur. While occasional outbreaks are almost inevitable, their swift containment is key priority of the veterinary services of the Member States and the EU. Source of data: Commission internal from several sources: Animal Disease Notification System (ADNS), safeguard decisions, other information by the Member States			
Baseline (2014)	Milestone (2018)	Current situation (2015)	Target (2020)
The baseline for 2014 was 172/7800	Decreasing trend	Mainly due to the outbreaks of African swine fever and avian influenza the number of affected regions has not diminished in 2015. For both diseases efforts are underway to limit the area affected but because of the important role of wildlife in the spread of both diseases	Decreasing trend

¹⁴ A number between 25 (successful containment, no disease spread, theoretical maximum: optimum scenario) and 5 (all 5 diseases spread vastly across EU borders affecting large areas: an absolute low).

		this is a longer term objective.	
Main outputs in 2015			
Description	Indicator	Target	
Safeguard cell	Organisation of meetings	100% when shortcomings with severe effects on human health are identified (eg by FVO)	
BTSF Training	Cross-sectoral training on Foodborne outbreak investigations	100% implementation of courses planned	

1.2.2.1 Better regulation

Specific objective 4.1 Proportionate legal framework that aims at achieving a high level of food safety while maintaining the competitiveness of the second employer of Europe, the food sector

Relevant general objective 4: Maintaining a high level of health and safety on the EU territory while allowing competitiveness of the economic sectors under SANTE policies through proportionate, fit for purpose legislation			
Specific objective 4.1 Provide a proportionate legal framework that aims at achieving a high level of food safety while maintaining the competitiveness of the second employer of Europe, the food sector External factors: The proposals made by the Commission are ultimately amended and adopted by the Council of Ministers and the European Parliament and the Commission cannot stay fully in control of the measures taken			<input type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending
Result indicator 4.1.A: Food safety legislation is not identified by SMEs among the Top 10 most burdensome legislation Definition and relevance: Safety rules can be perceived as burdensome, but are on the contrary a way to promote the competitiveness of the food industry through the recognition worldwide of the European standards, which can compensate for disadvantages such as labour costs and make EU products competitive on the international market. Source of data: TOP10 list of most burdensome EU legislative acts for SMEs			
Baseline (2013)	Milestone (2017)	Current situation (2015)	Target (2020)
Food safety legislation is not included in the TOP10 most burdensome EU legislative acts for SMEs	Food safety legislation is not included in the TOP10 most burdensome EU legislative acts for SMEs	<i>OBSOLETE</i> The list of TOP10 most burdensome EU legislative acts for SMEs does not exist anymore	Food safety legislation is not included in the TOP10 most burdensome EU legislative acts for SMEs
Main outputs in 2015			
Description	Indicator	Target	
Proposal for a Regulation of the European Parliament and of the Council on Animal Health	Legislative proposal	Political agreement in 2015, adoption by co-legislators in 2016	
Proposal for a Regulation of the EP and of the Council on protective measures against pests of plants.	Legislative proposal	Political agreement in 2015, adoption by co-legislators in 2016	
Codification of 11 Union acts regulating zootechnics in the EU amending Directives 89/608/EEC, 90/425/EEC and 91/496/EEC as regards references to zootechnical legislation	Codification of 11 acts	Political agreement in 2015, adoption by co-legislators in 2016	
Evaluations on-going in 2015 (to be finalised in 2016)			
Two external evaluations have been commissioned to support the Fitness check of the General Food Law: Evaluation on the definitions, general principles and requirements of the EU Food Law Evaluation on the functioning of the RASSF and management of emergencies/crisis			

1.2.2.2 International relations

Specific objective 2.6: Promote EU standards at the international and multilateral levels and to assist safe, predictable and uninterrupted trade between the EU and third countries and to avoid SPS measures being used as unjustified barriers to trade

Relevant general objective 2: Contribute to a high level of health for humans, animals and plants along the food chain and in related areas, by preventing and eradicating disease and pests, ensuring a high level of protection for consumers and the environment, while enhancing the Union food and feed industry competitiveness and favouring the creation of jobs			
Specific objective 2.6: Promote EU standards at the international and multilateral levels and to assist safe, predictable and uninterrupted trade between the EU and third countries and to avoid SPS measures being used as unjustified barriers to trade External factors: The achievement of the objective relies on negotiations which are held with up to 185 countries at any one time. Therefore we are dependent on these countries' approach to discussions.			<input type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending
Result indicator 2.6.A NEW: Increase of the number of actions having export facilitating effect in the Sanitary and Phytosanitary area Definition and relevance: Actions on which we have a documented role (be it a lifting of a trade barrier or the conclusion of a harmonised export certificate) with an export (and therefore growth and jobs creating) effect. Source of data: Commission internal			
Baseline (2014)	Milestone (2017)	Current situation (2015)	Target (2020)
5	20 (+5/year)	8	35 (+5/year)
Main outputs in 2015			
Description	Indicator	Target	
Opening of new markets in third countries for EU products of animal/plant origin	Number of countries lifting protectionists measures against EU products	2	
Active participation at all Codex Committees – international standards adopted in line with EU legislation	Meetings in 2015	18	
Regular attendance at WTO SPS Committee – rebuttal of attacks on EU measures, attack of third country measures hindering market access for EU business	Meetings in 2015	3	
Actions with trade (export) facilitating effect in the Sanitary and Phytosanitary area	Market access EU export health certificates	5	