



2014

Annual Activity Report

**Directorate
General for Health
and Consumers**

Table of Contents

INTRODUCTION	4
DG SANCO in brief	4
2014 in brief	5
EXECUTIVE SUMMARY.....	7
Key Performance Indicators (5 most relevant)	7
Policy highlights of the year (executive summary of part 1)	8
Key conclusions on resource management and internal control effectiveness (executive summary on part 2 and 3)	13
Information to the Commissioner(s).....	13
1. POLICY ACHIEVEMENTS.....	14
1.1 Achievement of general and specific objectives.....	14
1.1.1. CONSUMERS: general objective 1 - Ensure a high level of consumer protection, empower consumers and to place the consumer at the heart of the internal market.....	14
1.1.2. HEALTH: general objective 2 – Improve the health of EU citizens and reduce health inequalities.....	16
1.1.3. FOOD AND FEED SAFETY: general objective 3 –Contribute to a high level of health for humans, animals and plants along the food chain and in related areas.....	18
1.1.4. CONSUMERS: specific objective 1.1 - Reinforcing consumer safety.....	21
1.1.5. CONSUMERS: specific objective 1.2 - Enhancing knowledge.....	24
1.1.6. CONSUMERS: specific objective 1.3 - Strengthening rights and redress	27
1.1.7. CONSUMERS: specific objective 1.4 - Enforcement	29
1.1.8. CONSUMERS: specific objective 1.5 - Making markets work for consumers	31
1.1.9. HEALTH: specific objective 2.1 - Promote health, prevent diseases, and foster supportive environments for healthy lifestyles.....	35
1.1.10. HEALTH: specific objective 2.2 - Protect citizens from serious cross-border health threats	39
1.1.11. HEALTH: specific objective 2.3 - Support public health capacity building and contribute to innovative, efficient and sustainable health systems	42
1.1.12. HEALTH: specific objective 2.4 - Facilitate access to better and safer healthcare for Union citizens	45
1.1.13. FOOD AND FEED SAFETY: specific objective 3.1 - Contribute to improve the effectiveness, efficiency and reliability of official controls and other activities.....	49
1.1.14. FOOD AND FEED SAFETY: specific objective 3.2 - Contribute to timely detection of pests and their eradication.....	52
1.1.15. FOOD AND FEED SAFETY: specific objective 3.3 - Contribute to higher animal health status and support the improvement of the welfare of animals	55

1.1.16. FOOD AND FEED SAFETY: specific objective 3.4 - 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	59
1.1.17. FOOD AND FEED SAFETY: specific objective 3.5 - Strengthen a basis for consumers to make informed choices to make safe use of food.....	63
1.1.18. FOOD AND FEED SAFETY: specific objective 3.6 - Promote EU standards at the international and multilateral levels and to assist safe and smooth trade between the EU and third countries and to avoid that SPS measures could constitute unjustified barriers to trade	66
1.2 EU added value of spending programmes	68
1.3 Economy and efficiency of spending and non-spending activities	69
2. MANAGEMENT OF RESOURCES	71
2.1. Management of human and financial resources by DG Health and Consumers (DG SANCO)	73
2.1.1. Cost reimbursements to Member States in the policy area Food and Feed Safety	73
2.1.2. Procurement in all policy areas	80
2.1.3. Fraud prevention and detection	87
2.2. Budget implementation tasks entrusted to other services and entities.....	88
2.3. Assessment of audit results and follow-up of audit recommendations	94
2.3.1. DG SANCO's Internal Audit Capability (IAC)	94
2.3.2. Internal Audit Services of the Commission (IAS).....	97
2.3.3. European Court of Auditors	98
3. ASSESSMENT OF THE EFFECTIVENESS OF THE INTERNAL CONTROL SYSTEMS.....	101
4. MANAGEMENT ASSURANCE	107
4.1. Review of the elements supporting assurance	107
4.2. Reservations and overall conclusion on assurance (if applicable).....	108
DECLARATION OF ASSURANCE.....	109

ANNEXES

ANNEX 1: Statement of the Resources Director

ANNEX 2: Human and Financial resources

ANNEX 3: Draft annual accounts and financial reports

ANNEX 4: Materiality criteria

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

ANNEX 6: Implementation through national or international public-sector bodies and bodies governed by private law with a public sector mission (if applicable)

ANNEX 7: EAMR of the Union Delegations (DG DEVCO only, not applicable to DG SANCO)

ANNEX 8: Decentralised agencies (if applicable)

ANNEX 9: Performance information included in evaluations

INTRODUCTION

DG SANCO in brief

DG Health and Consumers' (DG SANCO) objective is to contribute to healthier, safer and more confident EU citizens via three main policy areas: consumer policy, public health, and food safety.

Under the political leadership of the EU Commissioners for "Health" and "Consumer Policy", DG Health and Consumers develops and proposes new legislation and monitors and ensures the proper implementation of existing legislation. It also coordinates actions and knowledge-sharing between EU countries where this is judged to add value.

We work primarily on the basis of multi-annual policies and finance frameworks; all of our work is based on the best available data, objective scientific advice and the widest possible consultation. We work in close cooperation with the Executive Agency for Consumers, Health and Food (CHAF-EA) – which helps to implement the Consumer Programme, the EU Health Programme and the Better Training for Safer Food initiative – the European Medicines Agency (EMA), the European Food Safety Authority (EFSA), the European Centre for Disease Protection and Control (ECDC), and the Community Plant Variety Office (CPVO).

DG SANCO plans and reviews its main priorities and objectives annually in the framework of the Management Plan (MP). The plan builds on the resources available and the risks identified which may have an impact on the achievement of objectives. Monitoring follows a specific process through bilateral meetings between the Director-General, individual Directorates and Unit Managers, as well as weekly management meetings involving the Director-General and the Management Team.

DG SANCO pursues its policies with a focus on prudent management and protection of the related EU financial resources. All financial transactions are carried out under direct centralised management. The Director-General is the authorising officer by delegation who sub-delegates at the level of Deputy Director-Generals, Directors and Heads of Units. Risk management facilitates the establishment of specific internal control strategies focussing on activities and domains representing the highest risks.

Our aim is to deliver on core European values and to help the EU meet its 2020 objectives of smart, sustainable and inclusive growth, notably by supporting growth and jobs in the food sector – the EU's second most important economic sector - and other crucial industrial sectors such as pharmaceutical, medical devices and cosmetics. We also contribute to a better health status of the population and more sustainable health systems, while EU consumer policy helps to promote the best possible use of the Single Market by driving consumers' involvement in the economy.

2014 in brief

The year 2014 was characterised by the new College of Commissioners taking office, which brought about a new way of working within the Commission. In an attempt to better prioritise and streamline work, a limited set of priority areas were given for the Directorates-General to focus on and Vice-Presidents were appointed to coordinate at a higher political level.

There were several changes that affected DG SANCO in terms of the policy areas under its responsibility:

- consumer policy was transferred from DG SANCO to DG JUST
- health technology and cosmetics policies were transferred from DG SANCO to DG GROW
- biocides and parts of food waste policies were transferred from DG ENV to DG SANCO

Although these changes were fully implemented only in the beginning of 2015, the end of the year was characterised by a transition period. Therefore, the 2014 AAR covers the year 2014 in its entirety under the arrangements prior to the reorganisation of the Commission services¹; thus, it mirrors DG SANCO's 2014 Management Plan with its three policy areas. The acronym "DG SANCO" is used throughout the report although DG Health and Consumers (DG SANCO) became DG Health and Food Safety (DG SANTE) on 1 January 2015.

Moreover, the appointment of Vice-Presidents also required a change in the working methods, not only at political level, but also at operational level as new internal and inter-institutional procedures were needed.

In 2014, DG SANCO initially allocated its resources² as follows (2014 budget adopted on 20 November 2013 by the budgetary authority):

	Operational Expenditure	Administrative expenditure (DG managed)	Total Financial Resources (€)	Human resources (by activity)
Horizontal Administration	0	21 115 840	21 115 840	157
CHAF-EA	0	7 070 000	7 070 000	
Consumer Policy	21 262 000	1 100 000	22 362 000	100
Public Health	53 070 000	1 500 000	54 570 000	233
European Medicines Agency (EMA)	37 333 000 ³	0	37 333 000	
European Food Safety Authority (EFSA)	76 545 000	0	76 545 000	

¹ Standing Instructions for the 2014 AAR (SEC(2014)553 of 10 November 2014) and reorganisation of the Commission services Ares(2014)3020173 of 15 September 2014

² Financial resources: commitment appropriations; human resources: establishment posts and external personnel in FTEs

³ The EU contribution to EMA is a balancing grant; EMA's total 2014 budget amounted to EUR 282,5 million, mainly financed by fees.

European Centre for Disease Prevention and Control (ECDC)	56 766 000	0	56 766 000	
Food and Feed Safety, Animal Health, Animal Welfare and Plant Health	251 000 000	1 500 000	252 500 000	453
Total	495 976 000⁴	32 285 840	528 261 840	943

In 2014, DG SANCO faced a change of Director-General who was authorising officer by delegation for four and a half years. The previous Director-General left the Commission on 31 October 2014 and handed over all tasks and responsibilities to one of DG SANCO's Deputy Directors General who became acting Director-General on 1 November 2014. He also ensured continuity of operations as Deputy Director-General for the policy area Food and Feed Safety.

In the handover note, the outgoing Director-General provided reasonable assurance that the resources assigned to the activities of the DG have been used for their intended purpose, in accordance with the principles of sound financial management, and under the control procedures put in place to offer the necessary guarantees concerning the legality and regularity of the underlying transactions.

As in previous years, DG SANCO's centralised on-the-spot controls played a prominent role in the financial control environment, verifying – where applicable – the eligibility of the costs claimed at beneficiary level and going to Member States. In 2014, DG SANCO's residual error rate did not exceed the materiality threshold of 2%. In the context of the animal disease eradication programmes in the policy area Food and Feed this confirms the downward trend observed since 2011: residual error rate 4,3% (2011); 3,4% (2012); 2,3% (2013) and 0,8% in 2014.

In the past few years, DG SANCO has taken a series of mitigating actions to reduce the error rate; it seems that their cumulative effect has continuously reduced the error rate which is now at an acceptable level. Therefore, DG SANCO can lift the reservation that was introduced in the Annual Activity Reports of 2011, 2012 and 2013.

⁴ In addition, DG SANCO is parent to the Community Plant Variety Office (CPVO). The office does not receive any EU subsidies; its 2014 budget amounted to EUR 14,7 million.

EXECUTIVE SUMMARY

Key Performance Indicators (5 most relevant)

Result/Impact indicator (description)	Trend	Target (or milestones)	Latest known results as per Annual Activity Report	
KPI 1 Consumer conditions index ¹	😊	2017: 65 2020: 67	2013 not available ⁵ 2012: 62 2011: 62	2010: 61 2009: 55 2008: 57
(see also Graph in section 1.1.1)				
KPI 2 Number of Healthy Life Years at birth	😞	2 years increase by 2020	EU-28 Female Male 2013 not available ⁶ 2012 (e) 61.9 61.3 2011 62.2 61.7 2010 62.7 61.9	EU-27 Female Male 2009 62.0 61.3 2008 62.2 61.1 2007 62.6 61.7
(see also Graph in section 1.1.2)				
KPI 3 Reduction in the incidence of main food-borne disease in the EU (BSE & Salmonella)	😊	Classical BSE: Progressive reduction to maximum 10 cases by 2018 and 5 by 2020 Salmonella: sustained negative trend to reach <67 000 cases in humans by 2018 and <60 000 cases by 2020	Classical BSE 2014: 8 cases 2013: 7 cases 2012: 18 cases 2011: 28 cases 2010: 45 cases 2009: 67 cases 2008: 125 cases	Salmonella: 2014: not available ⁷ 2013: 82,694 2012: 90,883 2011: 96,682 2010: 101,589 2009: 110,179 2008: 134,580
(see also Graphs in section 1.1.3)				
KPI 4 Reduction in the incidence of foot and mouth disease in the EU	😊	Keep disease freedom	2014: no cases 2013: no cases 2012: no cases	
KPI 5 Ex-post control residual error-rate split by ABB-activity	😊	< 2%	<u>2012:</u> Consumers: n/a Public Health: around 0% Food & Feed: 3,4% <u>2013:</u> Consumers: n/a Public Health: around 0% Food & Feed: 2,3% <u>2014:</u> Consumers: n/a Public Health: around 0% Feed & Food: 0,8%	

⁵ There is no CCI for 2013 as the relevant surveys were not carried out that year (as a consequence of Scoreboards' restructuring). The data for 2014 will be available in the 2015 Consumer Conditions Scoreboard, with some methodological modifications.

⁶ The data will be realised in April 2015.

⁷ See footnote 12

Policy highlights of the year (executive summary of part 1)

In 2014, no changes occurred to DG SANCO's main priorities and objectives as set out in the 2014 Management Plan.

DG SANCO contributed with its policy responses to five out of the seven flagship initiatives of the Europe 2020 Strategy, notably:

- Innovation Union – through the European Innovation Partnership on Active and Healthy Ageing and work with scientific committees ensuring safety and public trust for innovative products and services;
- Digital Agenda – through policies empowering digital consumers, enhancing digital literacy and work on eHealth;
- Industrial Policy – through policies creating better market conditions for food and consumer products, as well as better product safety and healthier products available for the consumer;
- Agenda for New Skills and Jobs – through work on health workforce and support to healthy lifestyles, including prevention initiatives addressing chronic diseases, that lead to a healthy workforce;
- European platform against poverty and social exclusion – through initiatives on investing in health, mental health, health inequalities, as well as work on healthcare systems' reforms enhancing efficiency, access and equity.

Consumers

DG SANCO activities in the area of consumer protection are cross-cutting in nature and aim at strengthening the Single Market; therefore they contribute to several flagship objectives of Europe 2020 Strategy.

DG SANCO continued development of the Online Dispute Resolution (ODR) platform which will become fully operational in 2016 and will allow consumers to submit disputes arising from online transactions online via the electronic Platform.

The Network of European Consumer Centres (ECC-Net), co-funded by the EU Consumer Programme and national authorities in the 28 EU Member States; provided the awareness and assistance to consumers on cases related to cross border e-commerce (more than 60% of cases dealt with by the ECC-Net and this proportion is constantly increasing).

Every year, under the coordination of SANCO, national enforcement authorities under the Consumer Protection Cooperation Network check hundreds of websites in a specific sector for their compliance with EU consumer rules and take corrective measures for websites considered problematic. In 2014, such check ("sweep") covered 550 websites in the online travel services sector and the owners of those not complying with EU consumer legislation were asked to correct them.

As evidenced by improved market assessments in the 10th Consumer Markets Scoreboard published in 2014, our actions contributed to increasing consumer trust in

the Single Market. The Scoreboard findings are reflected in the EU Semester documents and are used by consumer authorities in Member States to evaluate their policies and prioritise enforcement activities. The assessment demonstrates a better performance across all these markets, with the goods markets working considerably better than the services markets, but with a narrowing gap between the two.

Financial services remain the most problematic sector from a consumer perspective, but have seen a consistent improvement in performance over the past four years. On 18 September 2014, the Payment Accounts Directive entered into force which establishes a right of access to a basic bank account for EU citizens irrespectively of their financial situation, defines a simple and quick procedure for switching bank accounts, and enhances the transparency and comparability of payment account fees. Moreover, in May 2014, the Commission published a report on the functioning of the Consumer Credit Directive. In view of the shortcomings revealed, the Commission has worked with the enforcement authorities of the Member States to identify and share best supervisory practices.

In 2014, DG SANCO also carried out several activities aiming at enhancing product safety. DG SANCO continued negotiations with co-legislators on the major review of general consumer product safety and market surveillance rules, as well as of those governing medical devices. In 2014, the EU's Rapid Alert System for non-food dangerous products (RAPEX) reflected an improvement in Member States authorities' follow-up activities to notifications, putting a stop to the deterioration of the indicators registered in 2012 and 2013.

DG SANCO continued to work on better enforcement of consumer rights across the Single Market in order to ensure a level playing field to companies trading across borders and to reduce their compliance costs. Pulling resources among enforcers permit to reduce costs for administrations. In this context DG SANCO continued the review process of Consumer Protection Cooperation (CPC) Regulation, including the on-line public consultation which results were summarised in the Commission Report on the functioning of the CPC Regulation, adopted on 1 July 2014. Strengthening the mechanisms to ensure equal enforcement of consumer laws has been recognised as a priority by stakeholders.

In 2014, DG SANCO also adopted the Consumer Programme 2014-2020, which supports EU consumer policy in the years to come and aims to help the citizens fully enjoy their consumer rights and actively participate in the Single Market. To this end, SANCO also implemented the 2014 Annual Work Programme and adopted the Budget of the 2015 Work Programme which was fully supported by the Member States' in the Consumer financial programme committee.

Health

In 2014, DG SANCO pursued actions linked to the objectives of Europe 2020. The promotion of good health at EU level contributes to the Europe 2020 strategy for smart, sustainable and inclusive growth. Keeping people healthy and active longer and empowering them to take an active role in managing their health, has positive overall effects on health, including a reduction of health inequalities, and a positive impact on quality of life, on productivity and competitiveness, while reducing pressures on

national budgets.

As an example of this approach, DG SANCO has promoted innovative initiatives under the European Innovation Partnership on Active and Healthy Ageing and has supported Member States initiatives on health determinants which encourage the up-take of good practices for cost-effective disease prevention and health promotion and contributes to the improvement of the health status and quality of life of European citizens.

DG SANCO worked with other Commission services towards a consistent representation of health system reforms within the framework of the European Semester, building country-specific expertise and knowledge, contributing to the preparation of the Country Specific Recommendations (CSRs) and developing an EU agenda for health systems as described in the April 2014 Communication on health systems.

DG SANCO continued to address in 2014 the manifold challenges of globalisation and the movement of persons, health products and services and health threats across borders by fostering a high level of health protection healthier lifestyles and safety, and to support innovation for the benefits of the patients and the competitiveness of industry.

In 2014, DG SANCO also played its part in supporting the EU's capacity to address serious cross-border health threats, and notably to deal with crisis situations such as epidemics and pandemics. The Ebola outbreak demonstrated how the Commission can put in place appropriate systems to ensure that the Union citizens are protected from serious cross-border health threats. In the framework of Decision 1082/2013/EU on serious cross-border health threats the Commission brought together scientific expertise and the Member States to coordinate their preparedness and response activities and was able to mobilise political, financial and scientific resources to help contain, control, and treat the most complex Ebola epidemic on record. The EU was able to safely evacuate Ebola patients for treatment in the EU.

Moreover, the revised Tobacco Products Directive adopted in April 2014 and the updated Commission Directive on picture warnings to be used on tobacco products will make a significant contribution to reducing the incidence of chronic disease and premature mortality linked to tobacco consumption.

In March 2014, the Regulation establishing the third multiannual programme of EU action in the field of health for the period 2014–2020 entered into force. In May 2014, the Commission adopted the annual work programme for 2014 which promotes actions, in accordance with the principle of subsidiarity, where the EU added value can be demonstrated, e.g. exchanging good practices, knowledge sharing or mutual learning; addressing cross-border threats; addressing certain issues relating to the internal market; promoting innovation in health; or improving efficiency by avoiding duplication and optimising the use of financial resources.

The evaluation of the EU Health Programme 2008-2013 will be finalised in April 2015. Preliminary results show that the Programme is coherent with the Europe 2020 strategy, as the annual work programmes were oriented to emphasise objectives and priorities that could contribute more directly to the Europe 2020 flagship initiatives. It also seems that co-funded actions contributed to significant progress and results in a

number of key areas, mainly healthy ageing and helping to bridge health inequalities. However, the evaluators underline that almost any Programme action that contributes to improving the health status of the European population has the potential to contribute to growth and productivity in one way or another.

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

DG SANCO actions contribute to the EU Flagship initiative “Resource efficient Europe” and the Common Agricultural Policy, for example in keeping diseases and pests at bay and help production of agricultural goods in a safe, competitive and sustainable way. They also contribute to a smooth EU market of animals, plants and their products. The single market has been key to economic growth in the EU since decades and is a priority under the Flagship initiative “An industrial policy for the globalisation era”. Our policy actions ensure that important products such as food reach consumers safely and ensure their confidence in them. We also initiate actions to provide EU industry with possibilities for reductions in production and trading costs as long as food and feed safety is not compromised.

In 2014 the situation continued to improve as regards the number of bovine spongiform encephalopathy (BSE) cases detected in cattle and of Salmonella cases in humans, which reflects the successful implementation by Member States of the corresponding EU legislation. As regards Salmonella, the economic impact of the improving situation is beneficial as the costs associated to this food-borne illness for national public health systems can be huge (EUR 320 million was the estimated public health costs in the EU for year 2010 with number of human cases of salmonellosis at 101,589). Cases can also cause loss of productivity of several billion euros for the economies. The improving situation also helps rising confidence of consumers and fewer needs for product recalls.

During 2014 the EP and the Council agree on a common financial framework for food and feed, to support and complement EU Member States’ efforts to contribute to a high level of food safety and animal health. It provides for a single, clear financial framework that underpins the EU from the farm to fork policy objectives. It simplifies the regulatory environment and ensures a modern and more flexible financial tool that is better equipped to respond to environmental, demographic and social challenges. In all, it ensures that adequate financing will be available for the next years to support the policy actions on food and feed safety, animal health and welfare and plant health areas, with minimum administrative burden for the implementing Member States.

The Commission worked intensively to reach an agreement in December 2014 with the Council and the European Parliament on its proposal giving the possibility to Member States to have the final say on GMO cultivation on their territory. By applying the principle of subsidiarity for Member States on this sensitive issue, the compromise will provide more predictability for operators and enhance the credibility of the EU risk assessment.

Safety of the food chain is highly dependent on the effectiveness of controls and the exchange of information between Member States. These were enhanced in 2014 by the new interactive and high performance IT platform “iRASFF”. The increase in follow-up by the Member States of almost 15% compared to 2013 indicates an intensified use of the platform. Better Training for Safer Food (BTSF) continued to play a key role in

improving the efficiency and reliability of official controls by delivering high-value training courses to more than 6000 participants. Moreover, the audits and related control activities of DG SANCO's audit service Food and Veterinary Office (FVO), both in the EU and in third countries exporting animals, plants and products to the EU, provided a crucial contribution to ensure more uniform, objective and efficient controls throughout the EU and therefore effective enforcement.

To preserve the safety of food and sustainability of food production systems while at the same time providing certainty and a level playing field for food business operators, the Commission ensured that only substances with no harmful effect are allowed to be used at any step of the production chain. For example, 26% more reviews of maximum residue limits for pesticides were performed and 14 flavouring substances were removed from the Union list, as required data was not provided and the safe use of these substances could not be assessed.

To enable early detection and eradication of pests, several Commission Decisions have been adopted and are expected to offer a strong incentive to Member States to take proactive and comprehensive action towards surveying, and possible detecting, the presence of the most important pests in their territories. In addition, to tackle effectively the emergence and spread of plant diseases, several new pests have been added to the existing list of regulated pests and specific measures have been adopted. This defends the plant health status of those plants which may be affected by the newly regulated pests and can prevent in future the need to take costly curative measures.

On the animal health side the situation was relatively calm. There were several outbreaks of African swine fever reported close to the borders with Belorussia and the Russian Federation during 2014, but the outbreaks were successfully contained and limited to the border areas. For avian influenza a new strain was detected for the first time in the EU, infecting holdings in several Member States. EU rules and Commission actions are protecting these sectors and minimising damages such as the ultimate waste of dead or diseased animals. Thereby they contribute to a competitive European livestock sector under the EU Flagship initiative "Resource efficient Europe." Longer-term legislative work will lead to even better EU rules to help the livestock sector to become also resilient to other emerging diseases brought about e.g. by climate change.

In both cases the animal health framework established by the Commission in collaboration with Member States functioned properly, and the outbreaks were dealt with rapidly, the spread contained and the effects minimised. This ensured a high level of consumer protection, allowing the undisturbed functioning of the EU internal market of live animals and animal products.

On the international scene, DG SANCO contributed to the EU policy vis-à-vis third countries, maintaining its status as a reputable and reliable trading partner. DG SANCO technically concluded negotiations in 2014 for several agreements with six key partners, and continued bilateral negotiations with seven other countries, among them the US on the Transatlantic Trade and Investment Partnership (TTIP), and properly ensured the implementation of the 12 different existing agreements with an sanitary and phytosanitary (SPS) component. Several trade facilitations were achieved with key partners in 2014 with consequent positive effects for EU export and therefore for job creation and growth among which it is worth to mention: lifting of BSE related restrictions for the

export of EU beef to the USA, Chile and Brazil; extension of market access for EU dairy products to Chile; extension of market access for pork to Chile, Brazil and Canada; lifting of Schmallenberg virus related restrictions for semen and embryos to Chile and central America; resumption of export of live cattle to Turkey; establishment of harmonised EU export certificates for beef, pork, bovine semen, small ruminant embryos, equine semen, ovine/caprine semen, pet food, composite products, collagen and gelatine for several trade partners (Canada, Chile, Turkey).

Key conclusions on resource management and internal control effectiveness (executive summary on part 2 and 3)

In accordance with the governance statement of the European Commission, (the staff of) DG Health and Consumers conducts its operations in compliance with the applicable laws and regulations, working in an open and transparent manner and meeting the expected high level of professional and ethical standards.

The Commission has adopted a set of internal control standards, based on international good practice, aimed at ensuring the achievement of policy and operational objectives. As required by the Financial Regulation, the Director-General has put in place the organisational structure and the internal control systems suited to the achievement of the policy and control objectives, in accordance with the standards and having due regard to the risks associated with the environment in which it operates.

DG Health and Consumers has assessed the effectiveness of its key internal control systems during the reporting year and has concluded that the internal control standards are effectively implemented. Furthermore, DG Health and Consumers has taken measures to further improve the efficiency of its internal control systems in the areas of "ethics", "objectives and indicators" and "processes and procedures" as reported in Part 3.

In addition, DG Health and Consumers has systematically examined the available control results and indicators, including those aimed at supervising entities to which it has entrusted budget implementation tasks, as well as the observations and recommendations issued by internal auditors and the European Court of Auditors. These elements have been assessed to determine their impact on the management's assurance as regards the achievement of control objectives. Please refer to Part 2 for further details.

In conclusion, management has reasonable assurance that, overall, suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated; and necessary improvements and reinforcements are being implemented. The Acting Director-General, in his capacity as Authorising Officer by Delegation has signed the Declaration of Assurance.

Information to the Commissioner(s)

The main elements of this report and assurance declaration have been brought to the attention of Commissioner Andriukaitis, responsible for Health and Food Safety.

1. POLICY ACHIEVEMENTS

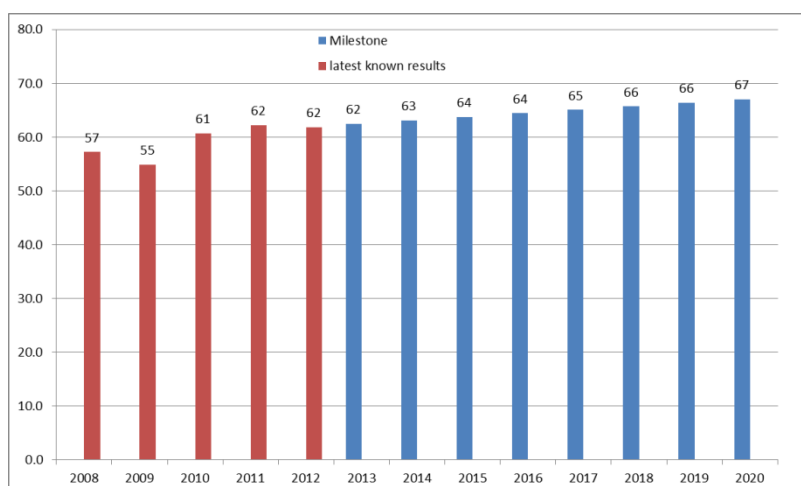
1.1 Achievement of general and specific objectives

1.1.1. CONSUMERS: general objective 1 - Ensure a high level of consumer protection, empower consumers and to place the consumer at the heart of the internal market

a) Performance tables

General objective 1: To ensure a high level of consumer protection, empower consumers and to place the consumer at the heart of the internal market, within the framework of an overall strategy for smart, sustainable and inclusive growth		<input checked="" type="checkbox"/> Spending programme for consumers ⁸
		<input checked="" type="checkbox"/> Non-spending
Impact indicator KPI-1: Consumer conditions index ⁹		
Baseline (2011)	Milestone (2017)	Target (2020)
62 (on a scale of 100)	65	67

Graph 1: Evolution of the Consumer Conditions Index



b) Narrative

Consumer trust is one of the key ingredients for economic recovery. Our actions contributed to increasing consumer trust, as evidenced by improved market assessments in the 10th Consumer Markets Scoreboard which tracks the performance of 52 consumer markets. The assessment demonstrates a better performance across all these markets, with the goods markets working considerably better than the services markets, but with a narrowing gap between the two. The increased confidence will help shifting the EU internal market into a higher gear, thus enabling the EU to reap the benefits of smart, sustainable and inclusive growth.

⁸ Consumer programme 2014-2020 – Regulation 254/2014 of the European Parliament and of the council of 26 February 2014 on a multiannual consumer programme for the years 2014-20 and repealing Decision No 1926/2006/EC

⁹ See footnote 5

The Consumer Conditions Index (CCI) remained stable from 2011 to 2012. There is no CCI for 2013 as the relevant surveys were not carried out that year (as a consequence of Scoreboards' restructuring). The data for 2014 will be available in the 2015 Consumer Conditions Scoreboard, with some methodological modifications.

In a world with increasing global production chains, ensuring a high level of consumer protection means that we must reach beyond EU borders and work with our international partners. We strengthened this cooperation for tracking, traceability and most importantly for seamless surveillance, especially with countries such as China, from which we receive the greatest number of problematic products.

Our efforts to ensure better and more equal enforcement of consumer rights across the Single Market and a level playing field for companies trading across borders, will help them to reduce their compliance costs. Additionally, by pulling resources among enforcers it also allows to reduce costs among administrations. The recent joint action of the Member States on in-app purchases is a model example in this respect.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, the Commission's actions related to EU consumer policy are well on track to meet the multiannual objectives and have achieved the annual performance indicators in the reporting year. The implementation of the multiannual European Consumer Agenda is well advanced, already reaching around 80% of its objectives.

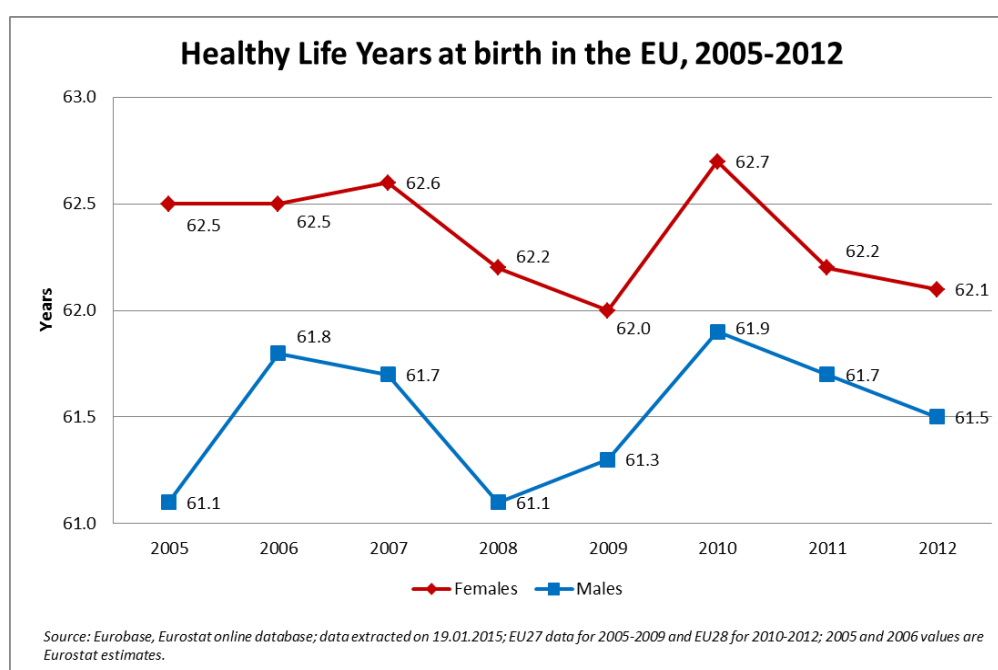
As regards the spending programme managed by the Directorate for Consumer Affairs, the 2014 Annual Work Programme was fully implemented and the corresponding budget allocated for this programme was consumed at a rate of nearly 100% in terms of commitment appropriation and at a rate of 100% in terms of payment appropriation. 76% of the total operational budget for consumers was delegated for implementation to the Consumers Health, Agriculture and Food Executive Agency (CHAFFEA).

1.1.2. HEALTH: general objective 2 – Improve the health of EU citizens and reduce health inequalities

a) Performance tables

General objective 2: 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 on health ¹⁰ <input checked="" type="checkbox"/> Non-spending
Impact indicator KPI-2: Number of Healthy Life Years at birth (Source: European Innovation Partnership on Active and Healthy Ageing)		
Baseline 2010 (2012) (Source: Eurostat)	Target 2020 (agreed in the EIP on Active and Healthy Ageing)	
Males: 61.9 (61.5) Females: 62.7 (62.1)	Increase by 2 years	

No data available for 2013 (will be released in April 2015).



b) Narrative

Good health is a pre-condition for smart, sustainable and inclusive growth and social cohesion in an ageing Europe, where resources are increasingly stretched. By investing in health promotion, health protection and disease prevention, the Commission helps to deliver better value for money and boost economic growth, limiting the costs linked to the treatment of preventable diseases.

In a context of increasing life expectancy and population ageing, healthy life years (HLY) has been endorsed as an important European indicator to monitor whether the extra years of life are lived in good health. The current main indicator of HLY is a measure which indicates how long people can expect to live without disability. On average across

¹⁰ Health Programme 2014-2020 - Regulation (EU) No 282/2014 of the European Parliament and of the Council of 11 March 2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020) and repealing Decision No 1350/2007/EC

EU Member States, HLY at birth in 2012 was 62.1 years for women and 61.5 years for men. This represents a reduction, for a second year in row, from the levels in 2010 as illustrated in Graph 2. In trying to understand this unwelcome trend, one needs to look at external factors.

The health of EU citizens is not only driven by healthcare related determinants, but is also linked to individual lifestyles and behaviour (smoking, alcohol consumption, nutrition, physical activity, employment status, housing tenure and so on) as well as environmental factors. Since the economic crisis might also influence lifestyle and behaviour as well as access to health, the apparent worsening of the health status (expressed by the reduction in HLY) might be partly explained by the economic crisis. Although Europe is emerging from it, the squeeze on health budgets continues in many European countries. Average health spending in the EU was 8.7% of GDP in 2012. Health spending per capita has decreased on average by 0.6% per year since 2009 (adjusted for inflation).

Furthermore, the demographic trend leading to an ageing population may have started to impact adversely on HLY, through an increase in chronic conditions.

In this context, and to help improve HLY in Europe, and among other measures, the Commission launched the European Innovation Partnership (EIP) on Active and Healthy Ageing (AHA), which aims to contribute to the increase in healthy life years by 2 years by 2020. DG SANCO, CNECT and JRC-IPTS are collaborating towards the development of a framework and a practical tool to capture the impact of the EIP on AHA actions on the quality of life and HLY. A first version of the tool, together with results of the impact of the most developed innovative practices on HLY, is expected in 2015. More information on the EIP on AHA is included under the objective 2.1.

Finding new tools and strategies to spearhead innovation in healthy ageing not only improves the quality of life of older people, but also reduces both the number and the length of hospitalisation and institutionalisation. The final results potentially will alleviate the budgetary pressure of our health and social care systems, allowing EU Member States to allocate more efficiently the resources for the health and care of their citizens.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, the SANCO policy which aims at complementing, supporting and adding value to the policies of the Member States to improve the health of EU citizens and reduce health inequalities is on course to meet its multiannual objectives for this objective. Nevertheless, an undesirable trend of reduction in the annual impact indicator – HLY – was observed in 2011 and 2012. While data for 2013 is still not available (it will be realised in April 2015) it is difficult to judge whether the trend continues or not. However, the available evidence from the innovative services implemented in the EIP on AHA suggests that a positive impact on HLY is to be expected from the actions of the EIP on AHA. A preliminary illustration of this is anticipated in 2015, on the basis of results from regions that have progressed with the implementation of such innovative services.

1.1.3. FOOD AND FEED SAFETY: general objective 3 –Contribute to a high level of health for humans, animals and plants along the food chain and in related areas

a) Performance tables

General objective 3: 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			<input checked="" type="checkbox"/> Spending programme – common financial framework for the food chain ¹¹ <input checked="" type="checkbox"/> Non-spending
Impact indicator KPI-3: Reduction in the incidence of main food-borne disease in the EU (BSE & Salmonella) Source: Regulation (EU) No 652/2014)			
Baseline (2012)	Milestone (2018)	Current situation	Target (2020)
18 BSE cases (including 11 classical BSE cases)	10 cases (less than 5 classical BSE cases)	8 cases of classical BSE	Less than 5 classical BSE cases
90000 confirmed cases of human salmonellosis	67,000 confirmed cases of human salmonellosis	2014 – not available ¹² 2013: 82,700 confirmed cases of human salmonellosis	(60,000 cases) continuous reduction / no eradication possible
Impact indicator KPI-4: Reduction in the incidence of foot and mouth disease in the EU (source: Commission internal)			
Baseline (2012)	Milestone (2018)	Target (2020)	
No confirmed cases of foot and mouth disease in the EU	Keep disease freedom	Keep disease freedom	

b) Narrative

The year 2014 did not see any major outbreak related to food safety, animal or plant health. This demonstrates that the food safety framework established by the Commission in collaboration with Member States functioned properly to prevent the occurrence of such events and to deal with them rapidly when they appeared.

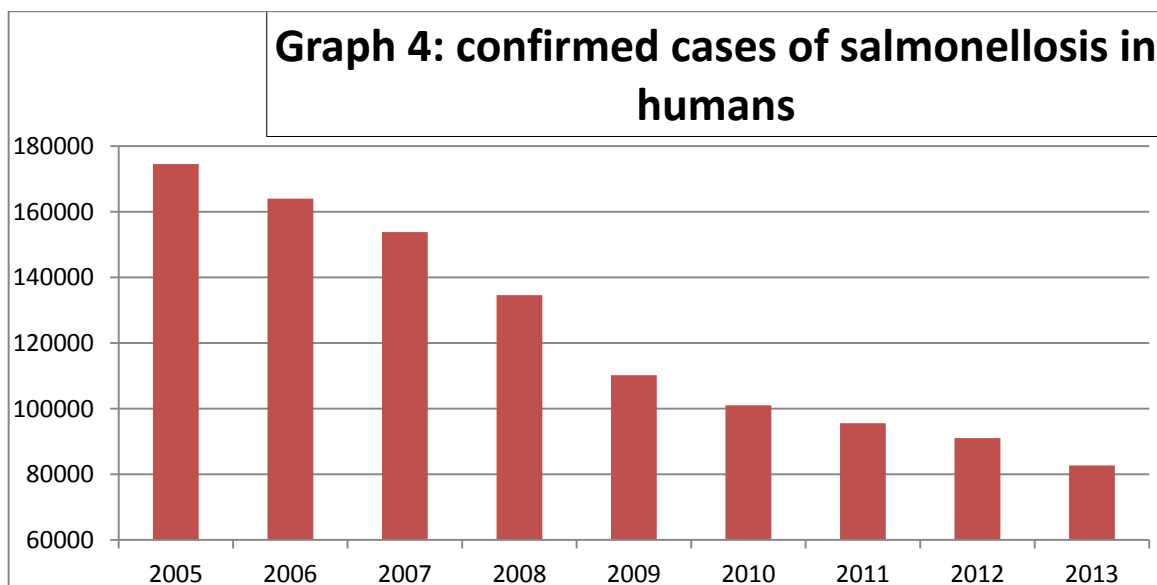
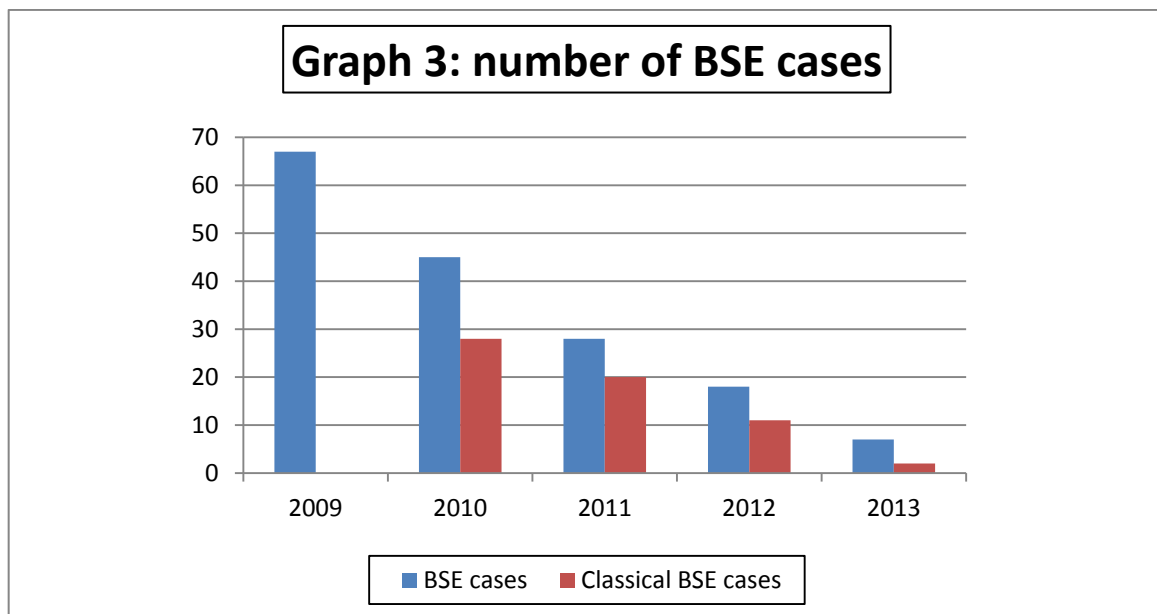
There was no big outbreak of food borne diseases in 2014 in the EU. The outbreaks of Avian Influenza (in Germany, the Netherlands, Italy and the United Kingdom) and African Swine Fever (in Lithuania, Latvia, Estonia and Poland) were properly and swiftly managed and contained. This ensured a high level of consumer protection, allowing the undisturbed functioning of the EU internal market of live animals and animal products and more generally speaking the agricultural sector.

Moreover there was no foot and mouth disease cases in the EU in 2014 and the

¹¹ Common financial framework for the food chain 2014-2020 - Regulation 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/EC and 2008/90/EC, Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC

¹² 2014 figures are reported by Member States to EFSA at the end of May 2015, with estimates established in conjunction with ECDC only in October 2015 and final publication in November 2015

situation continued to improve as regards the numbers of Bovine spongiform encephalopathy (BSE) cases detected in cattle and of Salmonella cases in humans. This reflects mainly the successful implementation by Member States of the corresponding EU legislation for those two diseases. Maintaining, at EU level, effective control measures on two of the major food-borne diseases, reflected by the impact indicators - BSE and Salmonella – will ensure the continued reduction in the incidence of these diseases and will give greater protection to the public.



The Commission worked intensively in order to reach an agreement end of 2014 with the Council and the European Parliament on its proposal giving the possibility to Member States to have the final say on GMO cultivation on their territory. Member States will be allowed to take into account their national circumstances in particular the views of their citizens, in line with the principle of subsidiarity. This alignment of the legislation to citizens' expectations should facilitate decision making on GMO cultivation in the EU which until now has proven to be extremely difficult. This new legal tool should limit the recourse to safeguard clauses not backed by EFSA. The existing EU authorisation system for GMOs is maintained, to secure uniform safety across the EU.

In order to further assist farmers and Member States, the Commission supported the development of best practice documents as regards the co-existence of conventional and organic genetically modified crops. The Commission supported also the development of documents helping those interested to perform assessments of the socio-economic impact of cultivation of GMOs. Such elements could be used by Member States when deciding on the cultivation of GMOs on their territory.

Actions for preventing the entry into, and the spread within EU territories of pests of plants have been undertaken through reinforcement of the legislative framework (new pests were added to the existing list of regulated pests and specific measures concerning the import of risk commodities from certain origins were adopted) and co-financing of measures taken by Member States for the control of pest outbreaks

As regards pesticides, the Commission discussed and published the National Action Plans of Member States for the sustainable use of pesticides and therewith confirmed its leading role in this sector. Moreover the Commission approved in 2014 the first two basic substances and prepared the adoption of the first low risk substance. This marks an important step towards sustainable food production by offering farmers sustainable plant protection tools.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, the animal health and food and feed safety policies managed by DG SANCO are on course to meet their multiannual targets for this objective and have achieved the performance indicators, outputs and milestones in the reporting year.

1.1.4. CONSUMERS: specific objective 1.1 - Reinforcing consumer safety

a) Performance tables

Relevant general objective 1: Ensure a high level of consumer protection, to empower consumers and to place the consumer at the heart of the internal market, within the framework of an overall strategy for smart, sustainable and inclusive growth			
Specific objective 1.1: Safety: to consolidate and enhance product safety through effective market surveillance throughout the Union		<input checked="" type="checkbox"/> Spending programme for consumers <input checked="" type="checkbox"/> Non-spending	
Result indicator 1.1.1: Percentage of RAPEX notifications (Rapid Alert System for Dangerous Consumer Products) entailing at least one reaction (by other Member States) (source: Consumers Programme 2014-2020)			
Baseline 2010 (as per Consumer Programme)	Milestone (2017)	Current situation	Target (2020)
43% (843 notifications) (source: RAPEX)	45%	42 % in 2014 37 % in 2013 34 % in 2012 46 % in 2011 43 % in 2010	Increase of 10 % to 47.5% (agreed in the Consumer Programme)
Result indicator 1.1.2: Ratio number of reactions/number of RAPEX notifications (serious risks) (source: Consumers Programme 2014-2020)			
Baseline 2010 (as per Consumer Programme)	Milestone (2017)	Current situation	Target (2020)
1.07 (source: RAPEX)	1.15	1.28 in 2014 0.90 in 2013 0.88 in 2012 1.32 in 2011 1.07 in 2010	Increase of 15 % to 1.23 (agreed in the Consumer Programme)
Main outputs in 2014			
Description	Indicator	Current situation	Target
Preparation of the future implementation of the Consumer Product Safety and Market Surveillance Regulations through guidance, implementing measures etc.	Guidance and, where necessary, implementing measures adopted; running of expert group	Adoption of EP 1 st reading resolutions and Commission position on EP amendments. No formal position of the Council yet. Negotiations with co-legislators to follow.	2015 (or date of application of new Regulations)
Implementation of actions (falling under the responsibility of DG Health and Consumers of the multi-annual action plan for market surveillance (with DG ENTR)	Establishment of a Member States working group on online sales	1 joint meeting of the Consumer Safety Network / Internal Market for Products-Market Surveillance Group (CSN/IMPMSG) expert group to discuss state of play of all actions 2 meetings of the new CSN subgroup on safety of products sold online which delivered input to the guidelines being developed in JUST (first consultation draft scheduled 1 st quarter 2015).	1 in 2014
Facilitation and co-financing of joint market surveillance actions by MS on consumer safety awarding of special indemnities for exchange of officials	Grant agreements for joint actions signed; Special indemnities for exchange of officials	Joint actions: focus on child safety barriers, acoustic toys, fireworks, power tools, CFL and LED lighting. EC contribution EUR 2M. Exchange of officials: 19 applications received from officials of 10 Member States.	2014

Close collaboration and regular information exchange with international stakeholders on consumer product safety	International Product Safety Week (IPSW) 2014	IPSW took place 16-20/06/2014 with 320 stakeholders	1 in 2014
Update of the definition of nanomaterials in the Cosmetics Regulation	Comitology or delegated act adopted	On hold. Awaiting review of Commission Recommendation 2011/696.	1 in 2014
Annual report on nanomaterials in cosmetics	Report adopted	On hold. Awaiting precise data to substantiate the report.	1 in 2014
Annual Report on Animal Testing	Report adopted	On hold. Awaiting input from some Member States.	1 in 2014
On-going technical adaptation of the Annexes to the Cosmetics Regulation	Several Commission Regulations adopted (on average five per year)	4	3 in 2014

b) Narrative

European legislation ensures a consistent, high level of protection for the health and safety of consumers by means of strict common safety rules and standards for products and services circulating within the internal market. In this respect, the Commission carried out several activities in 2014.

The EU's Rapid Alert System for non-food dangerous products (RAPEX) facilitates the rapid exchange of information between Member States and the Commission on measures taken against products posing a serious risk to the health and safety of consumers, and is a corner stone to strengthen product safety in the EU. The higher reaction rate per notification in the EU's RAPEX reflects an improvement in Member States authorities' follow-up activities to notifications, putting a stop to the deterioration of the indicators registered in 2012 and 2013.

In addition to the outputs listed in the MP 2014, product safety was further reinforced by the following activities.

A number of joint Member States actions co-financed by the Consumer Programme were continued to improve the effective application of the General Product Safety Directive (GPSD) through co-operation between national authorities responsible for the assessment, market surveillance and enforcement of the safety of non-food consumer products, in 2014, especially regarding carbon monoxide detectors, cosmetics, children's high chairs, textiles and ladders.

In order to maintain the high level of consumer safety, the Commission extended the ban on dangerous lighters and adopted safety requirements for consumer laser products. The Commission also issued a standardisation request¹³ for safety standards concerning certain children seats and adopted several implementing decisions to publish references to

¹³ Commission Implementing Decision C(2014)5058 of 22.7.2014.

European standards that provide presumption of safety (e.g. internal window blinds, gymnastic and training equipment). Even though European standards are voluntary, their application is considered as bringing benefits to consumers, notably in terms of improving safety.

The Commission continued its support to the implementation of the ban on animal testing for cosmetic products and to research of alternative methods with the aim of developing research and methods to better assess human safety.

With the objective to reduce allergic reactions to cosmetic products the Commission also launched a public consultation on fragrance allergens in cosmetic products (February-May 2014). Responses (over 200) have been analysed in view to preparing a report from the public consultation.

The European Commission has developed close cooperation with international partners to exchange information on emerging risks and unsafe products, to seek convergence in standardisation and to ensure that manufacturers worldwide are aware of the applicable safety requirements and comply with them. In 2014, the Commission pursued EU-US-China trilateral cooperation on consumer non-food product safety, where the three parties agreed to continue work towards seamless surveillance of consumer products for reinforced controls, improving information exchange and encouraging the adoption of safety culture through the supply chains. Considering that the greatest number of notified dangerous products come from China, tackling the problem at the source will ensure that safer products arrive on the EU market. Among other actions, during 2014, the multilateral co-operation in cosmetics regulations, continued among the EU, Canada, Japan and the US, in particular on alternative methods to animal testing and allergens.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, the part “Reinforcing consumer safety” of the 2014 spending programme managed by the DG under the Consumer Programme 2014-2020 is on track to meet its multiannual objectives for this objective and has achieved the annual performance indicators or outputs and milestones in the reporting year. The Percentage of RAPEX notifications entailing at least one reaction increased considerably from 2013 to 2014 being now close to the 2017 milestone, while the number of reactions/number of RAPEX notifications already achieved the 2020 target.

1.1.5. CONSUMERS: specific objective 1.2 - Enhancing knowledge

a) Performance tables

Relevant general objective 1: Ensure a high level of consumer protection, to empower consumers and to place the consumer at the heart of the internal market, within the framework of an overall strategy for smart, sustainable and inclusive growth			
Specific objective 1.2: Consumer information and education and support to consumer organisations: to improve consumers' education, information and awareness of their rights, to develop the evidence base for consumer policy and to provide support to consumer organisations, including taking into account the specific needs of vulnerable consumers			<input checked="" type="checkbox"/> Spending programme for consumers <input checked="" type="checkbox"/> Non-spending
Result indicator 1.2.1: Average percentage of consumers' correct answers to three questions about basic consumer rights (source: Consumer Conditions Scoreboard)			
Baseline (2012)	Milestone (2017)	Current situation	Target (2020)
52% (source: Consumer Scoreboard)	55%	43% ¹⁴ (2014)	57%
Result indicator 1.2.2: Number of complaint bodies and number of countries submitting complaints data to the European Consumer Complaints Registration System (ECCRS) (source: Consumer Programme 2014-2020)			
Baseline 2012 (Consumer Programme)	Milestone (2017)	Current situation (January 2014 – December 2014)	Target (2020)
33 complaint bodies from 7 countries in 2012 (source: ECCRS)	50 complaint bodies from 14 countries	37 complaint bodies from 13 countries	70 complaint bodies from 20 countries by 2020 (agreed in Consumer Programme)
Result indicator 1.2.3: Consumers' knowledge of basic consumer rights (Source: 9th Consumer Conditions Scoreboard)			
Baseline (2012)	Milestone (2017)	Current situation	Target (2020)
11.7% (source: Consumer Scoreboard)	12.5%)	9% ¹⁵ (2014)	15%
Main outputs in 2014			
Description	Indicator	Current situation	Target
Market studies	Finalisation of studies on second-hand cars, on the functioning of the electricity market for consumers, on online comparison tools and third-party verification schemes and on the feasibility of setting up a database of food labelling rules. Further study/studies to be launched based on the results of the 10 th Scoreboard	<p>Study on vehicle fuels and related Staff Working Document 2014 199 published in June 2014.</p> <p>Study on second hand cars finalised in November 2014 and scheduled for publication in the 1st quarter of 2015.</p> <p>The feasibility study for setting up a database of food labelling rules finalised in December 2014 (decision on publication is pending).</p> <p>Study on online comparison tools and third-party verification schemes, finalised in November 2014, for publication in the 1st quarter of 2015.</p> <p>The study on the functioning of the electricity market is launched and ongoing.</p>	4 to be finalised and 1 to be launched in 2014

¹⁴ The knowledge questions asked in 2014 were slightly different, and therefore comparison with previous years should be taken with caution. It should be noted, however, that for the question that is comparable with 2012 there was an increase of correct answers from 30.4% in 2012 to 32.5% in 2014. This data will be reported in the 2015 Consumer Conditions Scoreboard

¹⁵ The knowledge questions asked in 2014 were slightly different, and therefore comparison with previous years should be taken with caution. It should be noted, however, that for the question that is comparable with 2012 there was an increase of correct answers from 30.4% in 2012 to 32.5% in 2014. This data will be reported in the 2015 Consumer Conditions Scoreboard

Consumer vulnerability	Studies on the situation of vulnerable consumers across key markets in the EU and on the impact of marketing through social media, online games and mobile applications on children's behaviour	Studies ongoing, scheduled for finalisation in 2015.	2 in 2014
Follow-up to the Staff Working Document on the knowledge enhancing aspects of consumer empowerment 2012-2014	Staff Working Document	Document on hold. The previous version of this Document accompanied the 2012 European Consumer Agenda. In Spring 2014, it was finally decided to reserve the next version equally to the horizontal strategy on consumer policy to be decided by the new Commission college, rather than to issue it as self-standing document before the end of 2014 college	1 in 2014
Financial support to EU-level consumer organisations	Grant awarded	1 grant awarded to ensure that consumers are adequately represented in key EU policies and institutions.	1 in 2014
Consumer Classroom	Increase of the volume of pedagogical materials on the platform and of the number of registered users	Increased number of registered users from 2.326 in 2013 to 18.612 in 2014 Increased number of materials from 652 in 2013 to 970 in 2014.	Increase of pedagogical material and registered users in 2014
Capacity-building for consumer organisations	Implementation of an interactive and inclusive set of actions including the establishment of a web-based platform	Actions implemented: an interactive community website for best practice exchange, e-learning courses and the first (pilot) local training courses in Croatia.	Web platform established in 2014 and training actions implemented
Information campaign on consumer rights in Croatia	Preparation and launch of the campaign	Campaign launched on 17 October 2014 - ongoing	1 in 2014
Raise awareness of certain consumer rights in selected EU countries	Targeted materials produced and disseminated via intermediaries in the EU countries	DG SANCO contribution to campaign launches executed by DG JUST in 8 countries (BG, CY, EL, ES, IT, LV, PL, PT).	Materials produced in 2014

b) Narrative

In 2014, the Commission continued to build on modern consumer evidence to feed policy-making. The studies provided solid evidence for the development of better guidance for further specific policy actions, notably revised guidance to the Unfair Commercial Practices Directive (UCPD Directive). Consumer education related actions contributed to implement the new approach to consumers' education and capacity building of consumer organisations according to plan. Five studies directly influenced policy actions and our evidence base fed into policy actions, e.g. study on vehicle fuels, fed into the newly adopted Directive on Alternative Fuels Infrastructure, which envisages a colour coding scheme at the pump to make it easier for consumers to choose the right fuel.

The Commission (SANCO and GROW) is currently analysing the results of the feasibility study for setting up a database of food labelling rules (completed in December 2014) before deciding whether and how to proceed with the creation of a database on food labelling. While the main objective of such a database is to make it easier for businesses – in particular SMEs – to have precise information on labelling requirements in different Member States (thus facilitating intra-EU trade), it would also support consumer awareness and information with regard to food labelling.

To increase awareness on consumer rights among EU citizens, the Commission launched or continued a number of communication and education projects. The interactive education and community website – the “Consumer Classroom” – dedicated to help secondary school teachers find, build and exchange consumer education materials was further developed.

The Commission also launched an information campaign on consumer rights in Croatia which will continue until September 2015. In this framework, DG SANCO cooperated with DG JUST by providing consumer related information and advice for the launching of information campaigns in 8 countries.

In order to provide support to consumer organisation, the Commission established a new programme for consumer organisations on capacity building, called "Consumer Champion". It facilitated sharing of good practices among consumer organisations via an interactive community site with e-learning courses, supported by the courses organised locally in the Member States. The first local training courses in Croatia received very positive feedback.

Moreover, a new round of grants for national complaint handling bodies was launched in 2014 to support them in classifying and reporting consumer complaints and enquiries. As a result, 10 beneficiaries from 6 countries will provide harmonised data for at least 5 years to the Commission.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, the educational and information part of the policy and spending programme managed by the Directorate is on course to meet its multiannual objectives for this objective and has achieved the annual performance indicators in the reporting year. While the indicators on consumer knowledge of basic consumer rights (1.2.1 and 1.2.3) appear to show a decline from 2012 to 2014, it should be noted that the knowledge questions asked in 2014 were slightly different, and therefore comparison with previous years should be taken with caution. In fact, for the only question that is comparable with 2012 there was an increase of correct answers from 30.4% in 2012 to 32.5% in 2014.

1.1.6. CONSUMERS: specific objective 1.3 - Strengthening rights and redress

a) Performance tables

Relevant general objective 1: Ensure a high level of consumer protection, to empower consumers and to place the consumer at the heart of the internal market, within the framework of an overall strategy for smart, sustainable and inclusive growth			
Specific objective 1.3: Rights and redress: to develop and reinforce consumer rights in particular through smart regulatory action and improving access to simple, efficient, expedient and low-cost redress, including alternative dispute resolution			<input checked="" type="checkbox"/> Spending programme for consumers <input checked="" type="checkbox"/> Non-spending
Result indicator 1.3.1: Percentage of consumers who took action in response to a problem encountered in the past 12 months (source: Consumer Programme 2014-2020)			
Baseline (2010, Consumer Programme)	Milestone (2017)	Current situation (2014)	Target (2020)
83% (source: Consumer Scoreboard)	86%	76% ¹⁶ (source: FL 397 Eurobarometer, 2014)	90% (agreed in the Consumers Programme 2014-2020)
Main outputs in 2014			
Description	Indicator	Current situation	Target
ADR Directive	Publication of implementation guidelines for the ADR Directive	Internal consultation on ADR document - on-going	1 in 2014
ODR Regulation	Adoption of implementing acts in the context of the ODR Regulation	3 meetings of the ODR committee which discussed the draft implementing acts	4 committee meetings in 2014 in view of adopting the implementing acts
ODR platform	Pursue the technical development of ODR platform and running of the ODR expert group	4 ODR expert group meetings 1 test with expert group and 1 larger-scale test with 120 stakeholders Technical development of the production level of the ODR platform - on-going	9 ODR expert group meetings and testing of the platform in 2014
Studies, notably in the context of the CPC regulation and behavioural economics	Finalisation of behavioural studies on online gambling, food information and European Consumer Centres. Launch of market study on consumer guarantees and 2-3 behavioural studies in cooperation with other Commission services.	Behavioural studies on online gambling, food information, European Consumer Centres and energy labelling have been finalised. Study on consumer guarantees -ongoing. Behavioural studies on terms & conditions and on insurance market have been launched. Experiments on consumers' behaviours and attitudes related to food will be carried out in conjunction with the Milan Expo 2015.	3 to be finalised and 3-4 to be launched in 2014

¹⁶ The question was asked slightly different in 2014 and therefore comparison with previous years should be taken with caution. This data will be reported in the 2015 Consumer Conditions Scoreboard

b) Narrative

Activities at the European level concerning the Online Dispute Resolution (ODR) play an important role in the reinforcement of consumer rights. The ODR platform is a priority initiative for the Digital Agenda for Europe and its technical development continued in 2014. About 70% of participants taking part in testing of the platform had an overall positive impression of its functioning. The platform, which will become operational in January 2016, will allow consumers and traders to solve online their online disputes without going to court but via quality out-of-court procedures. They will therefore have access to fast and low-cost redress and will avoid litigation costs, while consumers would be encouraged to seek redress for lower value claims too.

The evidence from studies on consumer behaviour feeds into the policy development providing necessary data and ensures smart regulation and better reinforcement of consumer rights. For example, a behavioural study on the impact of the energy label and one on online gambling (carried out together with DG MARKT) were used in the Impact Assessments for the Commission proposals in these fields. The conclusions of the latter study were reflected in the Commission Recommendation on online gambling and were used to encourage Member States to pursue a high level of protection for consumers, players and minors through the adoption of principles for online gambling services and for responsible advertising and sponsorship of those services.

A behavioural study on how consumers look for assistance online in case of cross-border problems revealed that more consumers would use services such as the ones provided by European Consumer Centres (ECCs) if they had better information on success rates. This led the Commission to encourage ECCs to develop procedures to increase consumer information and feedback on the quality of their services.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, the part "redress" of the policy managed by the Commission is on course to meet its multiannual objectives for this objective and has achieved the outputs and milestones in the reporting year. While result indicator 1.3.1 appears to show a decrease in 2014 compared to 2012, the two figures are not directly comparable due to methodological changes in the 2014 survey (as part of Scoreboards' revision). The revised methodology will ensure a more meaningful monitoring of consumer use of redress mechanisms in the future through the Consumer Conditions Scoreboards, by taking into account additional aspects (e.g. satisfaction with complaint outcome).

1.1.7. CONSUMERS: specific objective 1.4 - Enforcement

a) Performance tables

Relevant general objective 1: Ensure a high level of consumer protection, to empower consumers and to place the consumer at the heart of the internal market, within the framework of an overall strategy for smart, sustainable and inclusive growth			
Specific objective 1.4: Enforcement: to support enforcement of consumer rights by strengthening cooperation between national enforcement bodies and by supporting consumers with advice			<input checked="" type="checkbox"/> Spending programme for consumers <input checked="" type="checkbox"/> Non-spending
Result indicator 1.4.1: Percentage of cases of enforcement requests handled in 12 months within the CPC network (Consumer Programme 2014-2020)			
Baseline (as per Consumer Programme)	Milestone (2017)	Current situation (2013/2014)	Target (2020)
50% (reference period 2007-2010) (Source: CPC network database)	55%	51%	Increase to 60% to be achieved (agreed in Consumer Programme)
Result indicator 1.4.2: Number of contacts with consumers handled by the ECC (Consumer Programme 2014-2020)			
Baseline 2010 (Consumer Programme)	Milestone (2017)	Current situation (2014)	Target (2020)
71 000 (source: ECC report)	88 750	93.741	106 500 (increase by 50%) (agreed in Consumer Programme)
Result indicator 1.4.3: Level of information flow and cooperation with the CPC Network (Consumer Programme 2014-2020)			
Baseline 2010 (Consumer Programme)	Milestone (2017)	Current situation (2014)	Target (2020) (agreed in Consumer Programme)
- 129 requests to exchange information between CPC authorities	156	132	167 Increase by 30%
- 142 requests for enforcement measures between CPC authorities	172	130 ¹⁷	184 Increase by 30%
- 63 alerts within the CPC network (source: CPC Network database)	76	35 ¹⁸	82 Increase by 30%
Result indicator 1.4.4: Percentage of information requests handled within 3 months within the CPC Network (Consumer Programme 2014-2020)			
Baseline (Consumer Programme)	Milestone (2017)	Current situation (2013/2014)	Target (2020) (agreed in Consumer Programme)
33% (reference period 2007-2010) (source: CPC Network database)	37%	34%	increase by 50%
Result indicator 1.4.5: Number of visits to the ECCs' websites (Consumer Programme 2014-2020)			
Baseline 2011 (Consumer Programme)	Milestone (2017)	Current situation	Target (2020)
1.670.000 (source: ECCNet evaluation report)	2.488.300	3 000 000 (2013)	2. 839.000 increase by 70% (agreed in Consumer Programme)
Main outputs in 2014			
Description	Indicator	Current situation	Target

¹⁷ The number of cases varies considerably from one year to the other. The trend has to be seen over several years.

¹⁸ Same observation as above applies.

CPC Regulation	Publication on a Report on the functioning of the Regulation (including the results of the public consultation)	Adopted in July 2014 – COM(2014) 439	1 in 2014
Joint enforcement actions in the framework of the CPC regulation	Publication of the results of the joint actions	A joint enforcement action regarding the marketing of in-app purchases in online games led to substantial changes in practices of major traders as communicated on DG JUST website on 22 December 2014	1 in 2014
Support to ECC and actions to increase the ECC visibility	Increased number of visitors to ECC websites	The number of visitors to ECCs website is increasing very fast, latest data from 2013 is showing that targets set for 2020 have already been met.	Increase of visitors in 2014

b) Narrative

The Consumer Protection Cooperation (CPC) framework for the enforcement of consumer rights generated concrete deliverables for consumers through mutual enforcement requests and joint enforcement activities at the EU level. In 2014, the Commission promoted several joint activities by ensuring a proactive facilitation role. Thanks to the sweep in the online travel services sector, more than 550 websites were screened and the owners of those not complying with EU consumer legislation were asked to correct them.

The Commission also implemented a new type of joint activity - enforcement authorities addressed, in a coordinated manner, major business players to find solutions to issues of common concern. This resulted in a better compliance to consumer rights in the sector of online games, with higher protection from unintended purchases made by children. This action also permitted to save enforcement resources in the Member States' administrations and reduce consumer detriment in a very efficient and rapid manner. The companies concerned also appreciated the possibility to work on enforcement of consumer rights at the EU level.

In line with the review clause of the CPC Regulation and in order to improve the enforcement of consumer rights, the Commission carried out an on-line public consultation (11 October 2013-13 February 2014) which attracted more than 200 responses. Its results, summarised in the Commission Report on the functioning of the CPC Regulation adopted on 1 July 2014, generated a lot of interest by stakeholders during the presentation at the Italian Presidency conference on enforcement cooperation. Strengthening the mechanisms to ensure equal enforcement of consumer laws has been recognised as a priority by stakeholders.

Under the European Consumer Programme 2014-2020, the co-financing of the European Consumer Centres Network (ECC-Net) has been improved so as to strengthen their sustainability. From 2015, (on 2014 credits), each ECC will start operating on the basis of a three years strategic partnerships. At the same time, the co-financing national authority ensured transparency of the designation of host structures for the next three years. This will allow for a more strategic approach in the management of ECCs, as well as clear medium term objectives and performance indicators.

In 2014, the Commission also assisted the ECCs in improving the visibility of the ECC-Net, increasing their online accessibility and developing quality standards. A branding strategy has been developed with a tool kit for communicating on basic consumer rights, especially on social media. The Commission also helped to establish a roadmap for developing quality procedures in the next years. Thanks to their increased visibility and efficiency, ECCs will be in position to deal with more cases and thus contribute to a better application of consumer rights and improved compliance of businesses.

c) *Risk assessment (not applicable)*

d) *Conclusion*

As evidenced above, the enforcement part of the policy and spending programme managed by the DG are on course to meet its multiannual objectives for this objective and has largely achieved the planned outputs and milestones in the reporting year.

1.1.8. CONSUMERS: specific objective 1.5 - Making markets work for consumers

a) *Performance tables*

Relevant general objective 1: Ensure a high level of consumer protection, to empower consumers and to place the consumer at the heart of the internal market, within the framework of an overall strategy for smart, sustainable and inclusive growth			
Specific objective 1.5: Making markets work for consumers			<input type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending
Result indicator 1.5.1: Consumer assessment of the functioning of energy services			
Baseline (2012) Consumer Markets Scoreboard (on a scale of 100)	Milestone (2017)	Current situation (2013)	Target (2020)
72.2	74	73	75
Result indicator 1.5.2: Consumer assessment of the functioning of financial services			
Baseline (2012)	Milestone (2017)	Current situation (2013)	Target (2020)
72.8	74.4	73.5	75.5
Result indicator 1.5.3: Consumer assessment of the functioning of transport services			
Baseline (2012)	Milestone (2017)	Current situation (2013)	Target (2020)
75.2	76.5	75.8	77.5
Result indicator 1.5.4: Consumer assessment of the functioning of telecom services			
Baseline (2012)	Milestone (2017)	Current situation (2013)	Target (2020)
73.3	74.8	73.5	76
Main outputs in 2014			
Description	Indicator	Current situation	Target
Consumer Markets Scoreboard 2014	Publication of the 10 th Scoreboard	Published in June 2014.	1 in 2014

2nd report on the implementation of the Consumer Agenda	Publication of the Report	1 in April 2014.	1 in 2014
2014 Consumer Summit on Digital	Organisation of the Summit	European Consumer Summit organised on 1-2 April.	1 in 2014
Citizens Energy Forum (CEF) 2014	Prepare Report to be submitted to the CEF with a focus on innovative ways for consumers to act as market agents.	Report prepared and will be presented at the 2014-2015 Citizens' Energy Forum in March 2015.	1 in 2014 (2014 Forum was postponed to March 2015 due to change of Commission)
Environmental claims	Study on "Consumer Market Study on environmental claims for non-food products" and review its conclusions and recommendations	Study finalised and will be published in 2015. The draft final report was circulated for comments to the stakeholders of the Multi-Stakeholder Group on Environmental Claims concerning possible next steps.	1 in 2014
Study on web comparison tools	Study containing an extensive mapping exercise of existing comparison tools, an analysis of the various business models, a consumer survey and possibly a behavioural component on consumers' perception of comparison tools and their influence on consumer choices.	Study finalised	1 in 2014
Payment Accounts Directive (with DG MARKT)	Negotiations between the co-legislators	Directive 2014/92/EU adopted in July 2014.	Conclusion of negotiations in 2014
Consumer Credit information campaign	Assessment of the campaign and possible extension	Campaign and evaluation exercise concluded. Campaign extended in another 3 Member States in 2015 (AT, CZ, EL).	Campaign and evaluation exercise concluded in 2014
Enforcement of the Consumer Credit Directive	Enforcement meetings with Member States	Two meetings took place which were devoted to sharing best practices on CCD enforcement.	3 in 2014

b) Narrative

The Consumer Markets Scoreboard is the Commission's flagship publication on consumer evidence. It flags underperforming markets from a consumer perspective. In addition to prompting for in-depth studies that recommend policy remedies in poorly functioning markets, the Scoreboard findings are reflected in the EU Semester documents and are used by consumer authorities in Member States to evaluate their policies and prioritise enforcement activities. In 2014, the Commission has initiated a methodological revision of the Scoreboard which aims at improving its quality and policy relevance, and in particular enabling more meaningful comparisons between different markets and countries.

The 10th Consumer Markets Scoreboard¹⁹ confirmed improvement between 2012 and 2013 in performance of 52 markets which were studied. Nevertheless, some key services markets continue to fail consumers. Financial services remain the most problematic sector from a consumer perspective, but have seen a consistent improvement in performance over the past four years. The electricity and gas markets continue to rank below average on comparability of offers, choice of providers and switching, despite considerable improvements in some countries. Telecoms markets have the highest incidence of problems and complaints of all the market clusters but score relatively better on comparability and switching. The market for train services has seen an important improvement in score between 2012 and 2013 (likely due to the emergence of competition in some countries).

In the field of financial services, the most problematic sector for consumers, the Commission concluded the negotiations on a legislative proposal on bank accounts, bank fees, transparency and switching. The Payment Accounts directive (2014/92/EU) entered into force on 18 September 2014. The Directive establishes a right of access to a basic bank account for EU citizens irrespectively of their financial situation, defines a simple and quick procedure for switching bank accounts, and enhances the transparency and comparability of payment account fees.

The Commission oversees and supports the transposition of EU law in financial services into national legislation in order to ensure the correct implementation at Member States' level. This will improve the functioning of the EU financial services market for consumers and provide for them a level playing field. The Report on implementation of the Consumer Credit Directive revealed shortcomings in the implementation by creditors and in the enforcement in Member States, as well as a low level of awareness among consumers about their rights. The Commission continue to work with Member States on the implementation and enforcement of the Directive and on the level of awareness among consumers about their rights by carrying out an information campaign for consumers on their rights as borrowers in Cyprus, Ireland, Malta and Spain. The campaign achieved overall positive results, as indicated by an external evaluation²⁰. A new campaign will therefore be launched in 2015 in another three Member States (Austria, Greece and Czech Republic).

In the field of the Digital Single Market, a high level policy event - "European Consumer Summit" - provided the Commission the opportunity to collect views from relevant stakeholders, especially in conjunction to e-commerce, to assess how consumers could fully benefit from the opportunities of the Digital Single Market. The aim of the Summit was to identify areas where consumer trust can be enhanced with a view to unleashing the demand side of the Digital Single Market, notably e-commerce. For example, in terms of concrete deliverables of the summit, the Commission has started to work with a view to establishing a specific digital competence framework for consumers.

The Commission continued its cooperation with stakeholders within the multi-stakeholder fora in order to consult them regularly. Outcome of discussions could feed into consumers' protection policy making aiming at an increased market transparency and efficiency, in order to make market work better for consumers.

¹⁹ http://ec.europa.eu/consumers/consumer_evidence/consumer_scoreboards/10_edition/index_en.htm
²⁰ <http://ec.europa.eu/smart-regulation/evaluation/search/download.do?documentId=11281094>

In this context, two studies were finalised in 2014. The Multi-Stakeholders Dialogue on Comparison Tools addressed the potential of these tools to increase market transparency and therefore increase market efficiency. The study on comparison tools found out that there were significant shortcomings with these comparison tools in terms of transparency and reliability, which could mislead consumers and erode their trust in the Digital Single Market. The evidence is useful in the follow-up work to the Multi-Stakeholders Dialogue on Comparison Tools with a view to establishing, together with stakeholders, principles for the transparency and reliability of comparison tools. The findings of this study are also contributing to the upcoming revision of the Commission's Guidance Document on the implementation of the Directive on Unfair Commercial Practices. Its findings are also relevant for the implementation of the Directive on Payment Accounts, as regards the provisions on comparison tools, aiming at making comparison tools in the banking sector as a reliable decision making tool for consumers.

Another multi-stakeholder group addresses the issue of misleading greens claims which distort competition to the detriment of law abiding firms, harming the creation of a legal playing field and inhibiting consumers taking informed sustainable consumption choices. In 2014 the Multi-Stakeholder Dialogue on Environmental Claims provided input to a dedicated Commission study on EU consumer markets and environmental claims for non-food products. The study findings show that consumers are confronted with many and different types of green claims and that they have a low level of understanding of such claims. The study also points to issues of non-compliance with EU legal requirements. The Commission will continue the work with stakeholders in 2015 on follow-up actions in this area, as this study and the work of the stakeholders' dialogue will also contribute to the upcoming revision of the Commission's Guidance document on the implementation of the Directive on Unfair Commercial Practices, which will aim at building a common understanding in this area to achieve a consistent enforcement throughout the EU.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, the integration part of the policy or spending programme managed by the DG is on course to meet its multiannual objectives for this objective and has achieved the annual performance indicators or outputs and milestones in the reporting year. The 10th Consumer Markets Scoreboard shows that some of the poorest performing markets have improved the most, while pointing to remaining problems that need to be addressed.

1.1.9. HEALTH: specific objective 2.1 - Promote health, prevent diseases, and foster supportive environments for healthy lifestyles

a) Performance tables

Relevant general objective 2: 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 2.1: 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 disease prevention and health promotion measures.				<input checked="" type="checkbox"/> Spending programme for health <input checked="" type="checkbox"/> Non-spending
Result indicator 2.1.1: Number of validated best practices for cost-effective prevention measures identified and disseminated (source: Health Programme 2014-2020)				
Baseline	Milestones		Current situation	Target
2013	2015	2018	2014	2020 (agreed in Health Programme 2014-2020)
0	7	23	n/a ²¹	28
Result indicator 2.1.2: Number of Member States involved in projects of promoting health and preventing diseases (source: Health Programme implementation statistics, CHAFAEA)				
Baseline	Milestones		Current situation	Target
2013	2015	2018	2014	2020
0	7	23	17 (provisional ²²)	28
Result indicator 2.1.3: Number of EU countries with a national initiative on the reduction of saturated fat (source: White Paper on a strategy for Europe on Nutrition, Overweight and Obesity related health issues – COM (2007)279 final)				
Baseline	Milestones		Current situation	Target
2013	2015	2018	2014	2020 (agreed in the programme statement)
12	18	24	21	28
Result indicator 2.1.4: Number of EU countries in which a European accreditation scheme for breast cancer services is implemented (source: Programme Statement attached to the Budget 2014)				
Baseline	Milestone	Current situation		Target
(2013)	(2017)	(2014)		2020 (agreed in the programme statement)
0	10	No data available		28
Main outputs in 2014				
Description		Indicator	Current situation	Target
Validated best practices for cost-effective prevention measures identified and disseminated		Number identified and disseminated	n/a ²³	2
First results from the European Innovation Partnership on Active and Healthy Ageing		Preparation of a communication	On hold	1
Council Recommendation on action in the field of rare diseases (moved from objective 2.4)		Implementation Report	July 2014	Adoption
Council Recommendation on smoke-free environments (moved from objective 2.4)		Implementation Report	Adopted	Adoption

²¹ Given that the statistical monitoring system is still being finalised, this indicator cannot be reported on in 2014. However, this indicator has been revised for the annual Management Plan 2015 to "the 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". It will be reported on in the annual activity report 2015.

²² There are organisations from 17 Member States participating in the relevant project proposals that have been proposed for co-funding by the evaluation committee. However, neither the award decision has been published nor the grant agreements signed.

²³ As above – indicator cannot be reported on. It has been changed for the annual work programme 2015.

Council Recommendations on cancer screening and the European Partnership for Action on Cancer (moved from objective 2.4)	Implementation Report	September 2014	Adoption
European initiative on Alzheimer's disease and other dementias (moved from objective 2.4)	Implementation Report	Adopted in October 2014	Adoption
Communication action addressing chronic diseases (moved from objective 2.4)	Scoping study	Ongoing	Preparation
Communicating nutrition and physical activity (moved from objective 2.4)	Promotional material	Ongoing	Preparation and dissemination

b) Narrative

Evidence-based and cost-effective prevention and health promotion actions play a key role in addressing the determinants of health and the risk factors for chronic diseases. Chronic diseases have negative impact on the sustainability of health systems and on the productivity of the workforce and can represent a major economic burden on health and social systems. The Commission supports Member States in the way they manage patients with chronic diseases in their health and social systems.

The outputs related to rare diseases, chronic diseases and healthy lifestyles which were included under the objective 2.4 on better access to healthcare in the DG SANCO Management Plan 2014 have been moved under this objective (2.1) as their results contribute better to the objective on disease prevention and health promotion.

The Joint Action on addressing chronic diseases and promoting healthy ageing started in 2014. It has been concentrating on the identification, compilation and exchange of good practices for prevention and treatment of major chronic diseases, and is the central tool to increase networking and cooperation among Member States to achieve better performance in addressing chronic diseases from prevention to treatment. More effective prevention and more efficient treatment and care pathways ultimately support the stability of and finally lead to better healthcare systems²⁴.

More specifically related to major chronic disease groups, the Commission published three implementation reports referring to policies on cancer²⁵, rare diseases²⁶ and Alzheimer's disease and other forms of dementia²⁷. The conclusions drawn from the reports and other actions will steer future EU action in these fields and eventually contribute to better performing healthcare systems in Member States. Actions were launched to improve coordination and cooperation among Member States in cancer prevention and treatment.

Moreover, the revised Tobacco Products Directive adopted by the Council and the European Parliament in April 2014 and the updated Commission Directive on picture

²⁴ <http://www.chrodis.eu/>

²⁵ Implementation of the Communication from the Commission, from 24 June 2009, on Action Against Cancer: European Partnership [COM (2009) 291 final] and Second Implementation Report on the Council Recommendation of 2 December 2003 on cancer screening (2003/878/EC)

²⁶ Implementation report on the Commission Communication on Rare Diseases: Europe's challenges [COM(2008) 679 final] and Council Recommendation of 8 June 2009 on an action in the field of rare diseases (2009/C 151/02)

²⁷ Implementation report on the Commission Communication on a European initiative on Alzheimer's disease and other dementias

warnings to be used on tobacco products will make a significant contribution to reducing the incidence of chronic disease and premature mortality linked to tobacco use. The impact assessment conducted before the adoption of the Commission proposal highlighted that the legislation would contribute to a reduction of tobacco consumption by 2% in five years. All implementing measures that are put in place as per the requirement of the Directive also contribute to this reduction.

The health of EU citizens is also linked to individual lifestyles and behaviour. Healthy lifestyle can contribute to decreased morbidity and mortality from chronic diseases. In this context, DG SANCO has supported the Member States' policies on health determinants with a focus on alcohol-related harm and overweight and obesity.

In particular, a Joint Action on alcohol-related harm was launched in January 2014 and it will be running until December 2016. It aims at building common methodology among the Member States to obtain comparable data for monitoring progress in reducing alcohol-related harm at national and EU level and to approximate national guidelines to communicate about alcohol-related harm. Support was also provided to Member States in the elaboration of a 2-years' Action Plan on Youth and Binge Drinking.

Responding to the call by the Irish Presidency in 2013, the High Level Group on Nutrition and Physical Activity²⁸ endorsed a 6-years' Action Plan on Childhood Obesity aimed at reinforcing and boosting individual Member States' responses to the continuous increase of overweight and obesity rates among children. The Group, Commission's core governing instrument of the Strategy for Europe on Nutrition, Overweight and Obesity related health issues, composed by representatives of the national authorities of all Member States, also continued its work to implement specific nutrients frameworks aiming at reducing levels of salt, fats, sugars and calorie contents of processed foods. Given the investment in the Action Plan and the technical and policy complexity of the nutrients frameworks, the results will mostly become visible in 2015.

Support for, and recognition of, innovation, which has an impact on health, helps to take up the challenge of sustainability in the health sector in the context of demographic change. The European Innovation Partnership (EIP) on Active and Healthy Ageing (AHA) has served as a frame for mobilising stakeholders and for creating ecosystems and collaboration networks that help disseminate and scale-up innovations in healthcare systems. Altogether, the Action Groups of the EIP on AHA are implementing programmes that promote the up-take of evidence-based and good practices for cost-effective disease prevention and health promotion reaching over 2 million patients and 30 million citizens in the EU.

Three years after its launch, EIP on AHA has made significant progress with the actual delivery of innovative programmes and services towards the targets set in its Strategic Implementation Plan²⁹. The Partnership is implementing in several regions innovative programmes for *e.g.* adherence to medication, prevention of frailty, chronic disease management, integrated care and independent living. The Reference Sites of the EIP on AHA have provided evidence that such innovative programmes bring benefits in terms

²⁸ http://ec.europa.eu/health/nutrition_physical_activity/high_level_group/index_en.htm

²⁹ http://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/steering-group/operational_plan.pdf

of health status, quality of life, and efficient use of resources in care systems, as well as growth opportunities³⁰. In addition, the Commission and the Partnership have developed a Strategy to scale-up successful practices³¹. Through the wide deployment of such innovative practices, the actions of the EIP on AHA are expected to improve the health status and quality of life of European citizens and contribute to an increase in HLY.

Furthermore, the “Outriders report” has confirmed that the EIP concept is the right approach to help enable future European economic growth and welfare. The report suggests that EIPs have been effective in their integrative function, bringing together different stakeholders and serving as an EU-wide observatory of good practices in innovation³².

A draft Communication "Progress from the European Innovation Partnership on Active and Healthy Ageing", prepared in 2014, sets out policy recommendations, with suggestions for an Active and Healthy Ageing Agenda for developing policy actions on selected topics. Given the change in College (and specifically, not to pre-empt any political decision by the new Commission), DG SANCO decided to postpone the date of adoption to 2015.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, the SANCO policy which aims at health promotion, diseases prevention, and support for healthy lifestyles is on course to meet its multiannual targets for this objective, as well as for its result indicators, with the exception of those indicators for which data is not available due to the change in indicator definition. The majority of outputs foreseen were finalized, while two are ongoing and one is being examined for congruence with new College priorities.

It is too early to fully assess the performance achieved through the Health Programme actions.

³⁰ http://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/how_to.pdf

³¹ http://ec.europa.eu/research/innovation-union/pdf/active-healthy-ageing/scaling_up_strategy.pdf

³² *Outriders for European Competitiveness –European Innovation Partnerships as a Tool for Systemic Change Report*, 2014. Independent expert group: chaired by Esko Aho, former Finnish Prime Minister.

1.1.10. HEALTH: specific objective 2.2 - Protect citizens from serious cross-border health threats

a) Performance table

Relevant general objective 2: 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 2.2: 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.				<input checked="" type="checkbox"/> Spending programme for health <input checked="" type="checkbox"/> Non-spending
Result indicator 2.2.1: 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)				
Baseline (2013)	Milestones		Current situation	Target
	2015	2017	2014	2020 (agreed in the programme statement attached to the Budget 2014)
0	4	14	0	28
Main outputs in 2014				
Description		Indicator		Target
Proposal on veterinary medicinal products		Legislative proposal		Adoption
Decision on serious cross-border threats to health		Implementing acts		Adoption
Pandemic preparedness		Joint procurement agreement		Conclusion
Joint procurement of pandemic vaccines		Framework contracts		Conclusion
Antimicrobial Resistance roadmap		Deliverables		Realisation
Stakeholder consultation on reference laboratories for human pathogens		Report		Preparation
Evaluation of the European Centre for Disease Prevention and Control (ECDC)		Communication from the Commission		Adoption
Implementation of the Council Recommendation on patient safety, including the prevention and control of healthcare associated infections.		Report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation on patient safety, including the prevention and control of healthcare associated infections.		Adoption
Procedures for verifying the equivalence of imported tissues and cells with EU quality and safety standards		Implementing Directive		Adoption

Implementing Directive (2006/86/EC) for the Tissues and Cells Directive (2004/23/EC) to make legally binding the European identifying code for donated tissues and cells	Amendment	The text was finalised and approved by Member States through a Regulatory Committee. Currently in scrutiny period (EP/Council), expected adoption April 2015	Adoption
Detailed rules for a unique identifier for medicinal products for human use, and its verification (falsified medicines)	Delegated act	Postponed to 2 nd half of 2015. Additional consultations with Member States are needed. in order to reach agreement on key elements of the proposal	Adoption
Preparedness and response planning	Trainings and exercises	1 command post exercise Quicksilver testing Member States preparedness and response capacity	Carried out

b) Narrative

Threat posed by existing and new communicable diseases may have devastating effects on the health of people and socioeconomics. To protect citizens from serious cross-border health threats, DG SANCO reinforced efforts to reduce antimicrobial resistance (AMR) and worked with Member States to ensure implementation of crisis management in real time and to strengthen concrete cooperation among Member States on communicable diseases.

AMR within a wide range of infectious agents is a serious cross-border health threat of broad and growing concern to citizens in Europe and beyond. Public health authorities increasingly pay attention to a serious problem that threatens the achievements of modern medicine. A roadmap on AMR and further action taken by the Commission to implement the AMR Action Plan contribute to combatting the rising threat from AMR in the human sector. All activities strive also to raise awareness of the need for further action in the field and contributed to put the topic on the global agenda such as the development of a global action plan on AMR. The legislative proposal on veterinary medicinal products adopted in 2014 addresses the public health risk of AMR, keeping antibiotics effective for people and animals alike (in line with the 2011 Commission Action Plan on AMR). Once adopted the legislation will stimulate competitiveness and innovation for European industry, improve the functioning of the internal market, reduce administrative burdens, address the public health risk of AMR and increase the availability of veterinary medicinal products.

Serious public-health threats do not stay within national borders and cannot be confined to a specific sector or dealt with by national governments acting alone. Improved cooperation and legally binding measures will make national governments better prepared to respond to cross-border health threats in the EU. Each country depends on the others' level of preparedness and response, and good coordination will better protect the public from such threats.

In 2014, the Commission's work has provided EU added value in protecting Union citizens from serious cross-border health threats. For example, preparations for possible Ebola cases included designating around 50 centres across the EU with more than 200

hospital beds, a network of specialised laboratories, ambulance and air transport, training of thousands of medical personnel and publication of information messages at air and sea ports and in the mass media. Medical specialists were helped to exchange information through an EU clinicians' network. The EU was able to keep open vital trade and transport links and provide many hundreds of healthcare workers to combat the epidemic on the ground in affected countries as well as treatment in the EU for several international health care workers who contracted Ebola.

The adoption of the Joint procurement agreement to procure medical countermeasures, its entry into force and signing by 18 Member States (as of 27 January 2015) has been a further milestone in securing a high level of preparedness across the EU and allows Member States to improve access to medical countermeasures and to get possibly better purchasing conditions. The elaboration of a Joint Action together with EU Member involving EU laboratories on emerging human pathogens and the completion of a study on a European system of reference laboratories for pathogens for humans marked an important step towards progress in identifying and developing coherent approaches and promoting their implementation for better preparedness and coordination in health emergencies. Among the various types of serious cross-border threats to health communicable diseases are most significant both in terms of frequency and public health impact. To protect citizens from communicable threats EU policy in this area has focused on surveillance and coordination of rapid response.

The updated Action Plan on HIV/AIDS for the period 2014-2016 has contributed to ensuring a high level of health protection in this area through ensuring continuity in the Commission's HIV/AIDS strategy, guiding the implementation of the most relevant actions, including consideration of options for future and providing the political leadership requested by civil society.

DG SANCO has also contributed to better coordination in health emergencies. The mid-term review of the Action Plan on Organ Donation and Transplantation revealed that the collaborative actions of the Action Plan helped individual Member States make good progress in organ transplantation and effectively increase transplant numbers.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, the SANCO policy which aims at protection of citizens from serious cross-border health threats is on course to meet its multiannual targets for this objective and result indicator. Both milestones for the indicator 2.2.1 – the first milestone for 2015 – 4 Member States to develop common approaches – and the second milestone for 2017 – 14 Member States to develop common approaches – are still achievable. Common approaches are assessed by the Health Security Committee on the basis of a synthetic progress report. The Commission compiles this report based of information on preparedness planning for cross-border health threats provided by Member States via a template which the Commission adopted on 25 July 2014 (Implementing Decision 2014/504/EU). Most outputs foreseen for 2014 were finalized or are in the process of being finalized, with the exception of two which were not under DG SANCO control (timely MS signature for vaccine procurement and contractor delivering as foreseen the ECDC evaluation).

1.1.11. HEALTH: specific objective 2.3 - Support public health capacity building and contribute to innovative, efficient and sustainable health systems

a) Performance table

Relevant general objective 2: 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 2.3: 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				<input checked="" type="checkbox"/> Spending programme for health <input checked="" type="checkbox"/> Non-spending	
Result indicator 2.3.1: Number of Health Technology Assessments produced per year (source: Programme Statement attached to the budget 2014)					
Baseline	Milestones		Current situation	Target	
2012	2015	2017	2014	2020 (agreed in the programme statement)	
2	6	10	9	50	
Result indicator 2.3.2: Number of Member States using the tools and mechanisms identified in order to contribute to effective results in their health systems – guidelines on patient summary set of data (source: Health Programme 2014-2020)					
Baseline		Milestones		Current situation	Target
2013		2015	2017	2014	2020
0		5	12	0 (14 countries joined the working group to prepare the implementation of the guidelines, no countries yet technically implementing)	28
Main outputs in 2014					
Description		Indicator		Current situation	Target
Health Technology Assessments		Number produced		9 adopted in the Joint Action EUnetHTA and the SEED project	6
Guidelines on ePrescription under the eHealth Network of the Cross-border Healthcare Directive		Guidance document		Adopted in November 2014	Adoption
Expert Panel opinions		Number produced		6 opinions	6
Health system cost-effectiveness assessments across Europe: a Life Table Analysis		Cost-effectiveness analysis study		Carried out in 2014, published in January 2015	Carry out
Strategies, good practices, scenarios of collaboration to empower patients with chronic diseases in disease management (EMPATHIE) Study		Catalogue		Published.	Production
Pharmaceuticals and medical devices		Early dialogue		Early dialogues carried out in the SEED (Shaping European Early Dialogues for health technologies) project .	Carry out
Strategies to recruit and retain health workers		Analysis		8 case studies with 40 interventions identified Report to be published May 2015	Carry out

Report on the continuous professional development of health workers (implementation of Action Plan for the EU health workforce)	Review and mapping	Published in January 2015	Carry out
Legal framework for electronic health records	Overview	Published in December 2014	Carry out
Costing/pricing of health services (External reference pricing of medicinal products: simulation-based considerations for cross-country coordination)	Studies	Published in 2014	Carry out
Directive on patients' rights in cross-border healthcare	Compliance check and communication actions	Completeness checks on going.	Carry out
Patient safety and Quality of Care	Eurobarometer survey	Carried out and published together with the second patient safety report in June 2014 (Special Eurobarometer 411).	Carry out
Blood transfusion (training programme, guide, web portal etc.)	Good practices	1 project	Launch
Audit of Notified Bodies responsible for class III medical devices by a team involving national and Commission staff	15	19	31/12/2014
Monthly vigilance coordination teleconferences with competent authorities for follow-up on high priority cases	10	12	31/12/2014

b) Narrative

DG SANCO's activities focused on encouraging the cooperation on health systems at EU level with a view to work with Member States towards more effective, accessible and resilient health systems. SANCO launched different initiatives to tackle emerging and pressing challenges to support Member States' health systems reform and ensure a high level of protection and safety. The Commission worked on methods and tools that should allow Member States to achieve greater effectiveness, accessibility and resilience of their health systems, in line with reform recommendations addressed to Member States in the context of the European Semester.

According to the European Commission's 2014 Annual Growth Survey (AGS)³³ "the top priority is to build growth and competitiveness" to build a lasting recovery. With this goal in mind, the AGS emphasises the need to improve the efficiency and financial sustainability of healthcare systems, while enhancing their effectiveness and ability to meet social needs and ensure essential social safety nets. It also acknowledges the importance of the healthcare sector in tackling the social consequences of the economic crisis, stressing that healthcare services are an area that will generate significant job opportunities in the years to come. It recommended that active social inclusion strategies should be developed, including broad access to affordable and high-quality health services.

³³ http://ec.europa.eu/europe2020/pdf/2014/ags2014_en.pdf

Capitalising on experience and work carried out over recent years, the Commission issued in 2014 a Communication on effective, accessible and resilient health systems (COM(2014) 215) with a view to develop an EU agenda covering actions to:

- (1) Strengthen the effectiveness of health systems
- (2) Increase the accessibility of healthcare
- (3) Improve the resilience of health systems

SANCO worked with other Commission services towards a consistent representation of health system reforms within the framework of the European Semester, building country-specific expertise and knowledge, contributing to the work on Country Specific Recommendations (CSRs) and developing the policy framework laid out in the Communication on health systems. In association with DG REGIO and DG EMPL, it elaborated a Guide to orient Member States and beneficiaries as to possible health investments under European Structural and Investment Funds (ESIF).

EU cooperation on eHealth, such as the adoption of guidelines on ePrescription and publishing an analysis of the legal regime for electronic health records, supported the Member States in identifying and building cost-effective innovative solutions, which in turn contributed to health system sustainability and created a basis for concrete cross-border collaboration.

The production of common Health Technology Assessments (HTA), adoption of a strategy for cooperation on HTA in 2015-2018, and launching of ‘Early dialogues’ (in the frame of the “Shaping European Early Dialogues for health technologies” – SEED project) allowed Member States use information from the joint work to improve access to new therapies, save the resources and improve the quality of deployment decisions.

The opinions of the Expert Panel on effective ways of investing in health as well as the work of the Expert Group on Health Systems Performance Assessment and a number of related studies aim to help the Member States to develop tools for the improvement of healthcare quality and efficiency and sustainability of health systems.

By providing innovative solutions for diagnosis, prevention and treatments, medical devices are increasingly important for patients and for health systems. Recent problems linked to the control of devices have threatened the confidence in innovative devices. These problems were tackled in a Joint Plan of immediate actions which positive results were outlined in a Commission Staff Working Document that also identified further actions needed until the strengthened requirements of the proposed new regulations are adopted by the legislators. One of the more efficient actions under the plan was the joint assessments by Member States and DG SANCO experts of the competence and resources of the notified bodies in charge of controlling the devices. Many of these were forced to improve their competence and control systems.

Stronger convergence of regulatory systems on the international level resulting in economies of scale ultimately improving healthcare system sustainability, were promoted through the SANCO contributions to the International Medical Devices Regulators Forum (IMDRF) and the on-going TTIP negotiations with the USA.

The Commission's non-food Scientific Committees have carried out risk assessment activities in the area of consumer safety, health and environment. The work of the Scientific Committees is vital for policy makers to ensure the highest level of health and environmental protection that European citizens expect from the EU institutions.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, the SANCO policy which aims to support public health capacity building and contribute to innovative, efficient and sustainable health systems is on course to meet its multiannual targets for this objective and result indicators. For result indicator 2.3.2 we consider that the target for 2015 is still achievable, considering that 14 Member States have joined the group to prepare the implementation of the guidelines.

Most outputs foreseen for 2014 were finalized, with only one being still ongoing – the compliance checks with the Directive on patients' rights in cross-border healthcare.

1.1.12. HEALTH: specific objective 2.4 - Facilitate access to better and safer healthcare for Union citizens

a) Performance table

Relevant general objective 2: 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 2.4: 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 for health <input type="checkbox"/> Non-spending
Result indicator 2.4.1: The number of Member States having adopted and implemented a national strategy for the prevention and control of health-care associated infections (HAI), and from 2014, monitor forthcoming ECDC indicators for hospitals for the prevention of HAI (source: Commission report (COM (2012) 658 final) on the implementation of the Council Recommendation 2009/C 151/01)				
Baseline	Milestones		Current situation	Target
2013	2015	2018	2014	2020
9	15	20	Not yet available	28
Result indicator 2.4.2: The number of functioning European Reference Networks ³⁴ (source: Health Programme 2014-2020)				
Baseline	Milestones		Current situation	Target
2013	2015	2017	2014	2020 (Health Programme 2014-2020)
0	2	10	0	22

³⁴ The Commission action (establishment and development of the cooperation framework, development of guidance and tools for the establishment and assessment of European Reference Networks (ERNs), support to the assessment process and approval of Networks by the ERN Board; organising the call for ERNs, communication and dissemination activities) influences the success of establishing and functioning of ERNs

Result indicator 2.4.3: Share of Population worried to suffer an adverse event while receiving healthcare (source: Programme Statement attached to Budget 2014)				
Baseline	Milestones		Current situation	Target
2009	2014	2017	2014	2020 (target agreed in the programme statement)
50%	45%	40%	The indicator has been dropped	30%
Result indicator 2.4.4: Number of Member States having implemented the provisions of the Council Recommendation of 9/6/2009 on patient safety, including the prevention and control of healthcare associated infections 2009/C 151/01 (source: Report from the Commission to the Council on the basis of Member States' reports on the implementation of the Council Recommendation on patient safety, including the prevention and control of healthcare associated infections (COM(2012) 658 final))				
Baseline	Milestones		Current situation	Target
2012	2014	2017	2014	2020
9	19	25	18	28 (all MS)
Result indicator 2.4.5: Number of Members of the European Reference Networks (source: Health Programme 2014-2020)				
Baseline	Milestones		Current situation	Target
2013	2015	2017	2014	2020
0	26	120	0	266
Main outputs in 2014				
Description		Indicator	Current situation	Target
Second Report on patient safety, including the prevention and control of healthcare associated infections		Adoption	Adopted in June 2014 accompanied by: - public consultation report ; - Eurobarometer report on citizens' experience and perception on safety and quality of care; - infograph on patient safety in the EU in 2014	Adoption
Delegated Decision and Implementing Decision on the criteria/conditions for and establishment/ evaluation of European Reference Networks (2014 Commission delegated decision 2014/286 /EU and implementing decision 2014/287/EU)		Adoption	Adopted on 10 March 2014	Adoption
Improve access and appropriateness of health services for migrants and ethnic minorities		Training packages for health professionals	Ongoing (work began in 2014 and will finish in early 2017)	Preparation and dissemination
Effective operation of the pharmacovigilance system in the EU		Joint Action facilitating collaboration among Member States (2013 – 2016)	Ongoing	Carry out

b) Narrative

Patient safety is a key element of well-functioning health systems and contributes to better and safer healthcare for Europeans.

The adoption of a Regulation on clinical trials on medicinal products for human use and the report on the application of the Regulation on advanced therapy medicinal products (ATMP) will play a very important role to ensure the highest level of patient safety. The new Regulation on clinical trials has set up clear and uniform rules for the authorisation and follow-up of clinical trials, thus ensuring increased legal certainty for sponsors. Furthermore the Regulation facilitates the conduct on multinational trials which are increasingly essential to develop new medicinal products for low prevalence conditions (like rare diseases). The Report on the application of the ATMP Regulation showed that, by subjecting advanced therapies to a prior marketing authorisation, the current regulatory framework has protected patients from unsound treatments. In addition, the report identified some possibilities to improve the regulatory environment for businesses and academia and thereby facilitate the emergence of new safe and efficacious products on the market.

The adoption of a Regulation on pharmacovigilance fees payable to the European Medicine Agency, the Delegated Regulation on good manufacturing practice for active substances as well as the ongoing cooperation in the Joint Action on pharmacovigilance fostered public health capacity and the safety of patients by ensuring, for example, that the active ingredients of EU medicines are manufactured according to adequate quality standards.

In 2014, the Commission conducted a public consultation on patient safety and quality of care and presented a second report on the implementation of the Council Recommendation on patient safety. On the basis of the findings of this report and the consultation, the Commission initiated discussions on possible action to further improve patient safety and to reduce unwarranted variation between and within Member States. There is a high interest in developing a broader EU agenda to address the issues that impact on quality in healthcare.

DG SANCO has been working on the preparatory phase for the establishment and running of European Reference Networks (ERNs). Those Networks will support access to better and safer healthcare for Europeans and aim to put together clinical expertise and share knowledge on specific areas of high-quality healthcare. By these means, patients will have easier access to medical expertise, even when geographical barriers exist. Furthermore, ERNs will create channels of communication between professionals and therefore convey information on specific topics.

DG SANCO was committed to carry out actions which aimed to reduce inequalities in health. Reducing health inequalities is one of the fundamental values of the EU Health Strategy and it is implemented through activities aiming to strengthen the health systems, diseases prevention and health promotion and combatting health threats. DG SANCO's work on reduction of health inequalities was carried via dedicated initiatives such as the conference in January 2014 which marked the end of the three-year Joint Action on health inequalities called 'Equity Action' and conference 'Health in Europe, making it fairer' in March 2014. These events aimed at supporting the policies of the Member States to improve the health of EU citizens by promoting fairness and equity in health in Europe, indicating the way for improvement of access to health and proposing the solutions for combatting discrimination in health. Moreover, they supported the Joint Actions on alcohol-related harm and nutrition and physical activity.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, mainly through the contribution of outputs to the achievement of the objective, the SANCO policy which aims to facilitate access to better and safer healthcare for Union citizens is on course.

Concerning the indicator 2.4.1 on the number of Member States having adopted and implemented a national strategy for the prevention and control of health-care associated infections information is not yet available since the work on ECDC indicators started in 2014 and it is ongoing.

Following discussions with the Court of Auditors on the relative merits of subjective and objective measurements of patient safety, the indicator 2.4.3 on the share of population worried to suffer an adverse event while receiving healthcare was dropped.

The 2014 milestone for the indicator 2.4.4: related to the number of Member States having implemented the provisions on patient safety has been almost reached (18 Member States instead of 19).

The milestones for indicators concerning the European Reference Networks (ERNs) – indicators 2.4.2 and 2.4.5 - will need to be reviewed. The implementing acts for the establishment the Networks were adopted later than forecasted in 2013 (when the goals were defined in the Health Programme) and therefore the milestones and goals cannot be reached. The establishment of ERNs is a complex procedure which involves several steps and tools. The first call for ERN is likely to be launched in December 2015. Only after this call and the assessment process and approval of Networks by the ERN Board of Member States, the Networks would be formally established, most likely not earlier than September 2016.

1.1.13. FOOD AND FEED SAFTY: specific objective 3.1 - Contribute to improve the effectiveness, efficiency and reliability of official controls and other activities

a) Performance tables

Relevant general objective 3: 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 3.1: 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 – common financial framework for the food chain <input checked="" type="checkbox"/> Non-spending	
Result indicator 3.1.1: Percentage of Food and Veterinary Office (FVO) recommendations following audits that Member States have satisfactorily addressed with corrective action Source Commission internal (FVO)			
Baseline (2013)	Current situation		Target (2014)
60% for recommendations from reporting cycles 2010 - 2012	74%		70% of all recommendations from these reporting years to be addressed
Main outputs in 2014			
Description	Indicator	Current situation	Target
FVO audits in the fields of food and feed safety, food quality, animal health and welfare and plant health	(1) Percentage of programmed audits completed (2) Overall use of capacity (percentage of the number of planned audits completed)	215 FVO audits completed in 2014 and indicator targets exceeded (1) 87% (2) 98%	(1) 80% (2) 90%
Official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health, plant reproductive material, plant protection products and amending [...] (Official controls Regulation)	Inter-institutional negotiations (meetings of Council Working parties and of the European Parliament) in view of adoption of a Regulation	Discussions on-going: 24 Council Working parties Numerous contacts with the EP leading to first reading	Preparing input
Report on the operation of official controls along the food chain		Report finalised and to be published at the beginning of 2015	2014
Update the list of food and feed (plant origin) subject to increased level of official controls at the EU borders.	Review of product list in Annex I to regulation (EC) No 669/2009	Four reviews during 2014	Adoption of quarterly updates (in the form of Commission implementing Regulations) to Annex I to Regulation (EC) No 669/2009.
Result indicator 3.1.2: Increased use of cross-border cooperation mechanisms between Member States in cases of intentional violations of food chain rules that could result in frauds. (5-point Action Plan on food fraud)			
Baseline (2013)	Current situation		Target (2017)
Number of EU relevant cases :16 ³⁵	40		+ 30 %

³⁵ The baseline of 4 specified in MP 2014 was an error, which is now corrected

Main outputs in 2014			
Description	Indicator	Current situation	Target
Operation of a network of national correspondents in relation to cross-border violations that could result in frauds.	Establishment of the network	(1) 2	(1) 3 meetings of network of national correspondents in 2014
Awareness raising of actors concerned by potential frauds along the food chain	Test version of an IT tool for the purposes of the network	(2) postponed to 2015 (3) October 2014	(2) Full scale test of the IT tool in 2014 (3) EU level conference on food fraud with actors from different enforcement agencies/actors
Result Indicator 3.4.2: BTSF training programmes (% rate of satisfaction and steady state of annual participants) (source: Commission internal)			
Baseline	Milestone	Current situation	Target
October 2013	2018	2014	2020 (internally agreed)
80% satisfaction rate/6100 participants trained	85% satisfaction rate /min. 6000 participants trained	85% satisfaction rate >6100 participants trained	87% satisfaction rate / min. 6000 participants trained
Main outputs in 2014			
Description	Indicator	Current situation	Target
Management of BTSF programmes	Monitoring of contracts, evaluation of reports, offers etc, meetings with contractors	100%	100%

b) Narrative

The effectiveness of controls depends on the capability of the EU system as a whole to detect violations of food chain requirements, and in particular of fraudulent practices, but also on the Member States' capability to ensure cross-border enforcement through mutual assistance.

The "Food Fraud Network"³⁶ has enabled Member States to exchange data and information on 40 cases of cross-border non-compliances, thus reducing the risk of sub-optimal enforcement due to the cross-border nature of the fraudulent activity. Both consumers and compliant businesses benefit of a more compliant environment along the food chain. Effective enforcement is an essential factor to ensure food safety along the chain in those cases where the requirements are disregarded are food safety requirements. The launching of the IT tool that will assist the members of the Network in their exchanges and cooperation has been postponed to 2015 to allow for proper testing and for the adoption of the rules necessary to ensure compliance with EU data protection rules.

On the other hand, the new interactive and high performance IT platform "iRASFF" was fully implemented in 2014. This new platform improves the process by which the control authorities notify the Commission about measures taken to deal with serious risks detected in relation to food or feed. The increase in follow-up of almost 15%

³⁶ This is a mechanism through which Member States' enforcers deliver on their obligations of mutual assistance and cooperation across borders for violations which might represent a fraudulent or deceptive practice

compared to 2013 indicates an intensified use of RASFF by Member States. RASFF notifications are mainly triggered by EU border controls or by controls on the internal market and this effective and reliable network in which information on risks is exchanged leads to more efficient and rapid risk management thus preventing potentially unsafe food from reaching the EU consumer. Moreover, the Food and Veterinary Office (FVO) increasingly uses trends on food risks notified to the RASFF as the basis for drawing up their annual audit programme. In addition, during 2014, several Better Training for Safer Food (BTSF) training programmes focused on training Member State competent authority control staff on iRASFF to ensure it is used in the most collaborative and efficient way.

BTSF continued to play a key role in improving the efficiency and reliability of official controls by delivering high-value training courses on EU legislation to Member State and non-EU country staff responsible for official controls in the sanitary and phytosanitary fields. Working in close collaboration with the FVO, other Commission services and Member States, BTSF provided a highly reactive and flexible programme which addressed emerging issues at short notice. This targeted training ensured that gaps in the knowledge of EU legislation in competent authority official control staff were addressed and this resulted in better trained staff and more efficient controls. Training for third country control staff on EU rules ensured greater compliance with the legislation and enhanced the trade of safe food.

A good level of enforcement is also a matter of awareness of the risks and issues linked to the occurrence of fraudulent and deceptive practices. The Food Fraud Conference in October 2014 provided last year a platform through which actors and stakeholders concerned by this issue discussed ways to strengthen official controls, as well as communication and collaboration among food law enforcement authorities, police, customs, judicial authorities, industry stakeholders and researchers.

Effective, efficient and reliable official controls are key elements to assure consumers, operators and trade partners that the measures put in place along the food chain for a safer, more competitive and sustainable market are implemented properly. The audits and related control activities of the FVO, in both Member States and third countries exporting to the EU, are targeted at verifying that national controls are carried out in accordance with EU legislation and that they are effective. The FVO makes recommendations in its audit reports to the country's competent authority to deal with any shortcomings revealed during the audits and subsequently monitors the actions by the competent authorities to address these. As shown by the result indicator (3.1.1.) above, 74% of recommendations made by the FVO in the respective 3-year reporting cycle were satisfactorily addressed by Member States with corrective action, exceeding the target set for 2014 and leading to an improvement of the control system.

Furthermore, the FVO published six overview reports in 2014 which summarised the results of audit series and formed the basis for discussions with Member State national authorities and dissemination of best practices identified. The audit reports and overview reports also provided feedback to risk managers in the Commission and assist them in taking specific, targeted actions, in developing policy, and keeping legislation fit for purpose.

In addition to the proposed outputs in the Management Plan 2014, the Commission

launched an external study to get data on the implementation of the zero tolerance policy of non-authorized GM food. The study findings will provide the basis to decide on a possible harmonisation of sampling methods and analysis with the objective to ensure consumer protection, effective and harmonised decisions of control authorities, as well as legal clarity for the food chain operators.

c) *Risk assessment (not applicable)*

d) *Conclusion*

As evidenced above, DG SANCO's policy part aimed at official controls enforcement is on course to meet its multiannual targets for this objective and result indicators, with some of the targets (for indicator 3.1.2 already fulfilling and going above the target established for 2017).

Most outputs foreseen for 2014 were also finalized, with only the test of the IT tool for the network of national correspondents being postponed to 2015 awaiting the adoption of the provisions ensuring compliance with EU data protection rules.

1.1.14. FOOD AND FEED SAFETY: specific objective 3.2 - Contribute to timely detection of pests and their eradication

a) *Performance tables*

Relevant general objective 3: 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 3.2: Contribute to timely detection of pests and their eradication, where they have entered the EU			<input checked="" type="checkbox"/> Spending programme - common financial framework for the food chain <input checked="" type="checkbox"/> Non-spending	
Result indicator 3.2.1: Percentage of the EU territory covered by surveys for pests, in particular for pests not known to occur in the Union territory. (source: Regulation (EU) No 652/2014)				
Baseline	Milestones		Current situation	Target
2012	2015	2017	2014	2020 (laid down in Regulation (EU) No 652/2014)
5%	50%	70%	No data available yet	100%
Result indicator 3.2.2: Percentage of the EU territory covered by surveys for pests considered to be most dangerous (as defined under Directive 2000/29/EC) (source: Regulation (EU) No 652/2014)				
Baseline	Milestones		Current situation	Target
2012	2015	2017	2014	2020 (laid down in Regulation (EU) No 652/2014)
100%	100%	100%	100%	100%
Result indicator 3.2.3: Time to eradicate such pests (For pests not known to occur in the Union, the number of days between finding and notification – 2012) (source: Regulation (EU) No 652/2014)				
Baseline	Milestones		Current situation	Target
2012	2015	2017	2014	2020 (laid down in Regulation (EU) No 652/2014)
10 days	8 days	4 days	8 days	3 days

Result indicator 3.2.4: Success rate in eradicating such pests (For pests not known to occur in the Union, the success rate of eradication of pests - 2012) (source: Regulation (EU) No 652/2014)			
Baseline	Milestones	Current situation	Target
2013	2017	2014	2020 (laid down in Regulation (EU) No 652/2014)
0	60%	0	95%
Main outputs in 2014			
Description	Indicator	Current situation	Target
Surveys for pests subject to EU emergency measures and EU Control Directives	% compliance with legal obligation	100%	100%
Managing of the current legislation and the preparation of secondary acts for the Plant Health proposal	Working group meetings	10 working group meetings and 2 informal COPHs meetings , 2 Task Force meetings Pinewood nematode	9
Managing of the current legislation and the preparation of secondary acts for the Plant Health proposal	Standing Committee meetings	12 Committees, 14 legal acts adopted	11
Plant Reproductive Material legislative proposal	Efficient and well prepared meetings at Council and EP in the context of the first/second reading of the proposal	Following rejection by the EP, the Commission decided to withdraw the proposal when adopting its Work Programme for 2015 on 16 December 2014.	1-2 Council working group meetings per month
Common Catalogues on plant varieties	Publication in the Official Journal	12 supplements and 2 complete editions prepared and published	12 supplements and 2 complete editions
Update current legislation	Adoption of implementing acts	8 Standing Committees to discuss and vote implementing measures 9 Commission Working Party/Expert Group meetings	7 Standing Committee meetings in view of the adoption of the implementing acts
Preparation of secondary acts of new Plant Reproductive Material	Preparation of delegated and implementing acts according to a fixed planning Launch of pre-normative studies (JRC)	The proposal was rejected by European Parliament, and therefore all activities were postponed.	10-20 working group meetings; organisation of a seminar on heterogeneous material; studies carried out
International co-operation on Plant Reproductive Material	Preparation of EU positions and active participation	6 meetings were attended and EU positions for 4 working parties were successfully coordinated	6 meetings (OECD Seed and FRM Schemes, UPOV, UN-ECE, ISTA), EU positions for 4 meetings (OECD, UPOV)
EU equivalence requests on Plant Reproductive Material	Evaluation of legal and practical equivalence, FVO mission	Legal evaluation carried out regarding Ukraine and started for Brazil with the help of FVO	2 countries
Managing the Community Plant Variety Office	Preparation of Administrative Council (AC) meetings and active participation, annual assessments	Attendance to 2 ACs, TLO attended, ad hoc legal WP met 3 times, report will be ready for AC in March 2015, annual appraisals of President and Vice President completed	2 AC meetings 1 TLO (technical liaison officers meeting) 2-3 legal working group meetings on CPVR

b) Narrative

To tackle effectively the emergence and spread of plant diseases, and drive Member States to proceed swiftly, several new pests were added to the existing list of regulated pests and specific measures were adopted with regard to the introduction into, and movement within, the Union territory of commodities that may host those pests. In particular, this was achieved by adopting measures banning the import of specific commodities from certain origins, or making them subject to conditions (for example strengthened conditions and pre-export checks for the import of citrus fruits from South Africa, prohibition of imports of certain plants from third countries where *Xylella fastidiosa* is known to occur, and import ban for mango fruits and four other species from India).

Moreover, to enable early detection and eradication of pests, several Commission Decisions were adopted and are expected to offer a strong incentive to Member States to take proactive and comprehensive action towards surveying, and possible detecting, the presence of the most important pests in their territories. This was promoted by introducing rules on the EU co-financing of national surveillance programmes to facilitate the earliest possible detection and eradication of several pests, by providing incentive to Member States to proceed with eradication measures and national financing of such measures (such as pinewood nematode, *Anoplophora chinensis*, citrus canker), and by introducing stringent rules for the notification of outbreaks of pests, including notification of suspected outbreaks.

To ensure the early detection and elimination of pests from the production chain of fruit plants as well as the good quality of the material, the existing rules on the production and marketing of propagating material of fruit plants were updated.

Finally, the discussion on the Commission proposal for a Regulation on plant health has continued at the Council working group. The proposal aims at introducing a more proactive approach with regards to protective measures against pests of plants and will introduce a new set of more effective rules. Following the rejection in March 2014 by the European Parliament of the Commission proposal for a Regulation on plant reproductive material, the Commission is carefully reflecting on ways to pursue the objective of simplifying the legislation while ensuring high quality and healthy plant reproductive material. This would contribute at the same time to enhanced competitiveness of the sector and creation of jobs as well as to prevention and eradication of pests.

Moreover, to support EU food business operators and in particular organic production, an opening for marketing populations of cereal seed was launched by a temporary experiment.

To support Union's farmers and food industry given that the EU is the world's biggest exporter of seed, DG SANCO provided for an active contribution to the work of international organisations: (1) enhancing the conservation of and access to plant and forest genetic resources (FAO, ITPGRFA) (2) ensuring the quality of plant reproductive material moving in international trade (OECD Seed and Forest schemes), and (3) supporting innovation in plant breeding through the intellectual protection of new plant varieties (UPOV).

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, DG SANCO policy part aiming at plant health is on course to meet its multiannual targets for this objective and for result indicators 3.2.2. and 3.2.3, the latter attaining already the target set for 2015.

Regarding result indicator 3.2.1, no data is available at this stage. The survey programmes are a new initiative emerging from Regulation 652/2014. They only started in 2014, with the very first programmes to be executed in 2015.

Regarding result Indicator 3.2.4., it is not possible yet to make a comprehensive assessment of the eradication rate, due to lack of comprehensive data. That assessment should be possible in a few years following the establishment of the IT platform recording the notifications of outbreaks of pests and the results of the respective measures, as well as the feedback of the survey programmes.

Moreover, the majority of outputs foreseen in 2014 were achieved, with the exception of those related to the Plant Reproductive Material Regulation, which was rejected by the European Parliament and all foreseen activities were out of purpose.

1.1.15. FOOD AND FEED SAFETY: specific objective 3.3 - Contribute to higher animal health status and support the improvement of the welfare of animals

a) Performance tables

Relevant general objective 3: 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 3.3: to contribute to a higher animal health status in the Union and to support the improvement of the welfare of animals			<input checked="" type="checkbox"/> Spending programme - common financial framework for the food chain <input type="checkbox"/> Non-spending
Result indicator 3.3.1: Number of Member States or regions thereof which are free from animal diseases for which a financial contribution is granted (source: Regulation (EU) No 652/2014)			
Baseline ³⁷	Milestone	Current situation	Target
2011	2017	2014	Increase in the number of free regions (2020, target from the programme)
Bovine brucellosis: 15 MS and 19 regions officially free	18 MS and 30 regions officially free	18 MS and 25 regions	Eradication except 1 MS
Bovine tuberculosis: 15 MS and 13 regions officially free	17 MS and 20 regions officially free	16 MS and 14 regions	Eradication except 1 MS
Brucella melitensis 20 MS and 18 regions officially free	24 MS and 28 regions officially free	19 MS and 26 regions	Eradication except 1 MS and 5 regions

³⁷ Source: annual reports from the Member States under Directive 64/432/EEC and 91/68

Result indicator 3.3.2: the increase of the number of Member States or regions thereof which are free from Aujeszky disease or with an approved eradication programme (source: Commission internal)			
Baseline ³⁸	Current situation	Target	
2011	2014	2015 (Commission internal target)	
17 MS and 98 regions	17 MS and 98 regions	Increase in the number of free regions	
Result indicator 3.3.3: Disease parameters such as incidence, prevalence and number of outbreaks (source: Regulation (EU) No 652/2014)			
Baseline ³⁹	Milestones	Current situation	Target
2011	2017	2014	2020 - overall decrease ⁴⁰
Classical swine fever - 0 outbreaks	0-5 outbreaks	1	0 outbreaks
BSE - 28 positive animals	15 positive animals	Provisional data indicates 2 classical BSE cases	5 positive animals
Scrapie (sheep/goats) - 17 % prevalence	17 % prevalence	final information not yet available	8 % prevalence
Rabies - 518 cases in wild animals	350 cases in wild animals	298	100 cases in wild animals
Main outputs in 2014			
Description	Indicator	Current situation	Target
Commission proposal for a Regulation on animal health	Follow up negotiations between co-legislators	The Council reached its first negotiating position end-2014. Latvian Presidency launched trilogues with the EP planned for February 2015. 12 Council working group meetings, 1 attaché, 2 Coreper (1 progress report, 1 negotiation mandate), 1 AGRIFISH Council meeting (progress report) 4 Committee meetings with the EP, 2 plenary sessions In addition many more informal exchanges with the Parliament and Council at a working level	Support negotiations
High level animal health conferences (bees and wild animals)	Number of conferences	1 conference on bee health. 1 conference on wildlife postponed to 4 May 2015	2
International Organisation for Animal Health (OIE)	Representation of the Commission	Coordinated EU position agreed and subsequently presented at the General Session	Coordinated EU position for the General Session of May 2014
Regulate zootechnics	Follow up Commission proposal	Technical examination of the proposal in the Council working group, while the Parliament started its work only towards the end of the year. 8 Council working group meetings + 1 Coreper, 1 AGRIFISH Council (progress report) 1 Committee meeting with the EP	Support negotiations between co-legislators

³⁸ Source: annual reports from the Member States under Directive 64/432/EEC

³⁹ Source: Animal Disease Notification System [ADNS]

⁴⁰ Target from the programme

		In addition many more informal meetings with the Parliament and Council took place at a working level	
Event for the mid-term progress of the EU animal welfare strategy	A conference	Conference performed in February 2014	1
Policy on restraining bovine animals by inversion or any unnatural position.	Report to the European Parliament and Council	Study almost completed. Final approval in progress.	Finalisation of the study
Information to consumers on the stunning of animals	A study	Completed.	Finalisation of the study
Education of veterinary practitioners on animal welfare	Number of foreseen workshops	Two regional workshops were completed (Poland and France) The third one will be held in Bulgaria in March 2015.	3
Brucellosis eradication programmes	Number of foreseen programmes	5	5
Bovine tuberculosis eradication programmes	Number of foreseen programmes	6	6
Ovine/caprine brucellosis eradication programmes	Number of foreseen programmes	6	6
Bluetongue eradication programmes	Number of foreseen programmes	18	18
Salmonella control programmes	Number of foreseen programmes	25	25
Swine diseases (classical swine fever, African swine fever, swine vesicular disease) eradication programmes	Number of foreseen programmes	10	10
Avian influenza survey programmes	Number of foreseen programmes	28	28
TSE monitoring and BSE/scrapie eradication programmes	Number of foreseen programmes	28	28
Rabies eradication programmes	Number of foreseen programmes	13	13

b) Narrative

The **animal health** policy area deals with transmissible, often epidemic animal diseases, some of which can also affect humans. Under the motto “prevention is better than cure”, the ongoing re-shaping of the legislative framework with the co-legislators contributes to a future higher animal health status in the Union. This will allow to move from the current, comprehensive but fragmented and rigid, set of EU legislation (dozens of basic acts) towards a single, coherent, robust but flexible one. For example, the foreseen new Regulation on animal health will tackle better emerging diseases focusing on EU priorities, will allow for more proportionate and tailor-made regional measures and will facilitate intra-EU trade of animals and products. These are key to ensuring a higher animal health and welfare status, contributing in the same time to the competitiveness and sustainability of the livestock sector and processing industry.

In parallel animal health epidemics were prevented and a number of epidemiological situations were successfully handled on the basis of existing legislation. The EU system comprises early detection mechanisms, network of labs, expert advice from several

sources (EFSA, regulatory Committee etc.) using properly implemented national contingency plans of the Member States and specific EU safeguard decisions. As a result African swine fever outbreaks were limited to four Member States and avian flu outbreaks remained sporadic in the affected four countries and did not spread between farms. Negative effects from these were kept to a minimum while epidemics could have had devastating effects on animal health and welfare, compromising in turn the sustainability of the sector. At the same time, efforts by the Commission vis-à-vis third countries, in line with international standards (e.g. OIE), helped to maintain external trade to the extent possible. This contributed indirectly to the Union food industry's competitiveness, as unjustified export restrictions by third countries can have severe effects on the livestock sector and processing industry by causing loss of market share.

The Union co-financing for veterinary programmes (which represent by far the largest amount of expenditure under the EU food safety budget) played a crucial role in the effective management of the targeted animal diseases, by ensuring disease surveillance and eradication, better targeting of the control of trans-boundary diseases of high EU relevance as well as prevention and rapid reaction to emerging and re-emerging animal diseases, which are a cornerstone of the EU Animal Health Strategy. This, in turn, has offered clear net economic benefits to the relevant sectors of the EU economy and to the smooth functioning of the single market, as well as the protection of consumers and public health (in the case of zoonosis), which represent key public goods for EU society.

On **animal welfare**, the Commission continued its work for the proper implementation of the current legal framework, leaving strategic questions on future initiatives to the new College. Actions taken included work with stakeholders, such as the declaration on alternatives to surgical castration of piglets, for which scientific studies were concluded and meetings were organised. This is contributing to the achievement of higher animal welfare by assisting industry to increase their levels of knowledge on alternative methods of castration.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, DG SANCO policy part aiming at animal health and welfare is on course to meet its multiannual targets for this objective and result indicators.

The majority of outputs foreseen for 2014 were finalized, with the exception of a conference and a workshop on animal welfare, which needed to be postponed to 2015 to allow focus on avian flu and African swine fever and to allow time for lessons to be drawn from these. Both diseases occurred in 2014 in wildlife. Additionally, due to the sensitive nature of the topics, the study on the opportunity to inform consumers on the stunning of animals, the guidelines on the welfare of pigs and the report on restraining bovines by inversion are awaiting for a decision by the College on the next steps.

1.1.16. FOOD AND FEED SAFETY: specific objective 3.4 - 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

a) Performance tables

Relevant general objective 3: 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 3.4: 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		<input checked="" type="checkbox"/> Spending programme - common financial framework for the food chain <input type="checkbox"/> Non-spending	
Result indicator 3.4.1: The number of cases of diseases in humans in the EU linked to food safety or zoonoses (source: Food Chain, Animal Health & Welfare, Plant Health & Reproductive Material Programme)			
Baseline	Milestone	Current situation	Target
2012	2018	2013	2020 ¹⁸
90 000 confirmed cases of human salmonellosis	67 000 cases	82,700 (approximation as latest results are from 2013, figures not yet available for 2014)	60 000 (sustained negative trend in incidence cases)
Main outputs in 2014			
Description	Indicator	Current situation	Target
Review of the Hygiene Regulations	Commission Proposal and follow-up	Under internal discussion based on new Commission priorities	Adoption and support discussions in Council and Parliament
Alignment of TSE Regulation (EC) 999/2001	Commission Proposal and follow-up	Under internal discussion based on new Commission priorities	Adoption and support discussions in Council and Parliament
Interim Report on the implementation of the 5-Year Action Plan on Antimicrobial Resistance (AMR)	Report	To be published February 2015	Publication
Meat inspection of cattle, horse, game and small ruminants	Legislative proposals	Under internal discussion based on new Commission priorities	Adoption by Comitology or delegated act
Medicated Feed Regulation	Council position, in EP vote in Committee	Adopted in September 2014 2 Council WP meetings EP 1 st reading and Council position expected in last trimester of 2015	Support discussions
Improve legal environment for feed use of safe by-products from food and biofuel industries	delegated/implementing acts to be presented and discussed	The action has been postponed due to the new proposal of medicated feed	Adoption of the acts
Authorisation of feed additives in the framework of Regulation (EC) No 183/2003	Number of decisions on authorisation	40	50-55
Result indicator 3.4.3: Review of Maximum Residue Levels of pesticides substances voted at the Standing Committee following EFSA's opinions as foreseen in Regulation (EC) No 396/2005			
Baseline	Current situation	Target (planning of scientific opinions)	
40 pesticide substances in 2013	63 (the target level has been exceeded)	50 pesticides substances in 2014	

Main outputs in 2014			
Description	Indicator	Current situation	Target
Cloning	Council position (expected 2 nd half of 2014)	Discussions in the EP and Council 1 Council working group meetings and informal exchanges with EP	Support discussion
Novel Food	Council position (expected 2 nd half of 2014)	2 trilogue meetings	Support discussion
Setting of new MRLs (Maximum Residue Levels) for pesticides substances including import tolerances and Codex MRLs (Reg. 396/2005)	Number of pesticides substances	60	60
Approval of pesticides in the framework of Regulation 1107/2009	Number of decisions on approval	32	40
Definition of EU multiannual monitoring programme for pesticides residues	Commission Regulation	Regulation (EU) No 400/2014	Adoption by end of the year
Evaluation of National Action Plans under Directive 209/128/EC	Commission Report to EP and Council	Draft report produced for intra-SANCO consultation	First draft by end of the year
Authorisation of food additives in the framework of Regulation 1333/2008	Number of decisions on authorisations	13 (some measures postponed due to additional information requested from applicant)	15-20
Follow up of the re-evaluation programme on food additives (Reg. 257/2010)	Assessment of EFSA opinions including measures to be taken, if needed	8 opinions adopted by EFSA were assessed	15-20
Assessment of the validity of enzyme application in view of the establishment of the EU Register (Reg. 1332/2008)	Number of applications assessed for validity	56 applications were introduced during 2014 by the enzyme producers	150-200
Follow up of the submission of data for further evaluation of flavouring substances as foreseen in Reg. 1334/2008	Measures taken following non-submission of data or following opinion of EFSA	14	10
Managing legislation in the area of pesticides, additives, enzymes, flavourings, food contact material and contaminants	Number of Standing Committees on pesticides (legislation and residues) and toxicology	15 meetings of the three relevant Committee sections	16

b) Narrative

To preserve the safety of food and sustainability of food production systems, the Commission ensures that only substances with no harmful effect are allowed at any step of the production chain, whether we are speaking of residues of plant protection products, or food and feed additives, flavourings, enzymes, etc.

Antimicrobial Resistance (AMR) continues to be one of the Commission's priorities. The holistic approach of the Commission's 5 year action plan against AMR, launched in 2011, was clearly evident in 2014 and the interim report, requested by the European Parliament, outlining progress to date is due to be published in February. Prudent use of antimicrobials is regarded as a cornerstone in addressing antimicrobial resistance due to

the possibility that AMR in animals is transmitted to humans through zoonotic bacteria, by direct contact or through the food chain. The adoption by the Commission in 2014 of proposals for veterinary medicinal products and medicated feed is thus the first step towards the development of tools to ensure that risks to human health arising from the use of antimicrobials in food producing animals are adequately managed. In addition, new legislation in force in 2014 will harmonise AMR monitoring and the patterns of multi-drug resistance in animals in the EU and data was published during the year on changes across time on the use of antimicrobials in veterinary medicine. These measures all contribute towards the objective of ensuring a higher level of safe food in order to reduce the transmission of AMR through the food chain.

The implementation of the EU legislation in the area of pesticides residues and plant protection products contributed to a high level of safety of food while improving the sustainability of food production.

- The approval system for pesticide substances ensured that only substances that have no harmful effects on human health may be used in the EU. In addition, the setting of maximum residue levels ensured that food products are safe for consumers. In particular, for the setting of pesticide residues, all targets were achieved in 2014. The target for the full review of maximum residue limits for pesticides of 50 substances was exceeded by 26% thanks to an improvement of the procedures in EFSA and SANCO. This allowed catching up with some existing backlog.
- To improve the safety of food products, criteria for assessing pesticide substances for their endocrine disrupting properties are needed. To this end, the Commission launched a public consultation and impact assessment for the establishment of criteria for endocrine disruptors in the context of the implementation of the Regulation on plant protection products.
- To promote the sustainability of food production, the framework for plant protection products used on minor crops needed to be improved. Following the report on the establishment of a European fund for minor uses in the field of plant protection products, the Commission launched the set-up of a coordination facility that will contribute to the food safety of crops. It will ensure that EU agriculture will have more approved tools available to control pests and diseases in speciality crops and contribute to the competitiveness of the sector. In addition it will foster the co-operation and work-sharing between Member States in this field and result in a more efficient use of limited resources.

The implementation of the EU legislation in the area of food contaminants, food additives, food flavouring and food enzymes contributed to a high level of food safety. The approval system for additives, flavourings and enzymes ensured that only substances that do not pose a safety concern for the consumers may be used in the production of food. For example, 14 flavouring substances were removed from the Union list, as required data was not provided and the safe use of these substances could not be assessed.

The legislation on food and feed contaminants ensured that limits are set in food and

feed products for contaminants to ensure a high level of food safety. Thus, the legislation has been completed with provisions on two new contaminants (citrinin and erucic acid) and has been updated taking into account new scientific evidence (provisions on cadmium) and experience gained in the implementation of existing provisions (provisions on polycyclic aromatic hydrocarbons). Furthermore discussions have been finalised with Member States on 5 other contaminants to keep the EU legislation on contaminants updated taking into account the latest developments in science. All these ensured that the legislation is up-to-date and provides a high level of consumer protection also with regards to newly identified health risks.

DG SANCO continued work with the European Parliament and Council on the medicated feed Regulation, novel food proposal and Directives on cloning for food production.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, DG SANCO policy part on food and feed is on course to meet its multiannual targets for this objective and result indicators, with result indicator 3.4.3 already surpassing the target by 26%.

The majority of outputs foreseen for 2014 were finalized, with a few exceptions, which were due to external factors or the change in Commission. Therefore, the following outputs were slightly below the target for reasons independent of DG SANCO:

- For the authorisations of feed additives, further data and evidence from the applicants was necessary to EFSA to correctly evaluate and ensure feed safety.
- For the pesticides active substances in plant protection products, achieving the target was dependent on EFSA conclusions which were not available, or applications were not submitted by operators.
- For enzymes, the dossiers need to be first submitted by the producers, who only presented 56 dossiers, below the expected number of 150-200 dossiers. Most of the submitted dossiers were assessed and followed up by the Commission as planned.
- All authorised food additives are subject to a re-evaluation by EFSA. The Commission closely follows these re-evaluations and if needed proposes measure to take into account the conclusions about the safety of these substances. Only eight opinions of EFSA were available for assessment in 2014.

A number of initiatives were postponed or put on hold during 2014:

- Adoption of Commission acts to improve legal environment for feed use of safe by-products from food and biofuel industries was postponed because the finalisation of the medicated feed proposal required more time than foreseen.
- The “omnibus” proposal for the alignment of EU legislation with the Lisbon Treaty, including the rules on Transmissible spongiform encephalopathies (TSEs), was withdrawn by the Commission and the task was recently given back

to the services. Current EU rules to control and eradicate BSE and other TSEs have been in force for over 14 years and DG SANCO will now carry out a review of current measures and include the alignment at that stage. Even though the EU is finally on the last pathway to eradicating BSE within its cattle population, the Commission remains vigilant and this stepwise approach ensures that all decisions are based on sound scientific advice and that a high level of food safety is maintained.

- The review of the hygiene regulations and the review of meat inspection were put on hold while the new Commission will reassess its priorities.

In addition to the outputs foreseen for 2014, the Commission contributed to achieving a high level of safety of food and feed by proposing to Member States GM food and feed authorisations addressed to biotechnology companies on the basis of positive EFSA opinions.

1.1.17. FOOD AND FEED SAFETY: specific objective 3.5 - Strengthen a basis for consumers to make informed choices to make safe use of food

a) Performance tables

Relevant general objective 3: 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 3.5: 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
Main outputs in 2014			
Description	Indicator	Current situation	Target
Application of Reg. 1169/2011 on food information to consumers ⁴¹ :	Deliver most of the prescribed implementing acts and reports within the deadlines foreseen ⁴²	0	2017 8 (i.e. 100% of provisions)
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)	Under preparation	adoption
Reporting on Trans fatty acids	Report foreseen in Regulation (EU) 1169/2011 on the provision of Food Information to consumers – Art. 30 (7)	Under preparation	adoption

⁴¹ This is a correction compared to the Management Plan 2014 where this indicator was listed as result indicator and it should be labelled as output indicator

⁴² As foreseen in Reg. 1169/2011

Implementation of the conditions of use of the "gluten free" and "very low gluten" statements	Implementing act as foreseen in Regulation (EU) 1169/2011 on the provision of Food Information to consumers – Art. 36 (3)	Adopted - Implementing Regulation (EU) No 828/2014 of 30 July 2014 on the requirements for the provision of information to consumers on the absence or reduced presence of gluten in food	adoption
Providing guidance on the compatibility of quality of natural mineral water with the unavoidable presence of trace amounts of certain substances.	Guidance for the application of the principle of 'original purity' of natural mineral waters as defined in Directive 2009/54/EC on the exploitation and marketing of natural mineral waters	Ad hoc working group of Member States experts set up. Discussions are ongoing with Member States' experts and industry representatives	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 by 2014	9 measures adopted ⁴³	4-6
Exemption of generic descriptors (denominations) from the scope of Regulation (EC) No 1924/2006.	Commission Decisions to be adopted by 2014	One application was received in 2014 and the Commission has been discussing it with Member States.	1-2
Infant formula and follow-on formula, cereal based foods and other baby foods, foods for special medical purposes, total diet replacement for weight control, transfer of rules on 'gluten-free' and 'very low gluten' statements under the Food Information Regulation	Consultations delegated/implementing acts foreseen by Regulation (EU) No 609/2013	EFSA was consulted and delivered three opinions (two adopted in 2014). 2 meetings of the Expert Group took place in 2014 to discuss the delegated acts. The implementing Regulation on "gluten-free" was discussed in one meeting of the PAFF Committee. More than 15 bilateral meetings were held with different stakeholders and NGOs on different matters. The draft measures have been prepared and are in the final stage of consultation with Member States and stakeholders	Preparation and completion eventual adoption
Milk-based drinks and similar products for young children and food for sportspeople	Reports required by Regulation (EU) No 609/2013	The reports are being prepared ⁴⁴ . EFSA, Member States and stakeholders were consulted on milk-based drinks for young-children (also called "young-child formulae")	Preparation

b) Narrative

Ensuring clear and unambiguous information to consumers enables them to make informed choices, leading to greater consumer satisfaction and enabling businesses to

⁴³ In 2014 EFSA issued 44 opinions following applications for health claims from the business operators and 47 Commission decisions were adopted through nine legal acts covering most of the 2014 opinions and a remaining backlog from a previous year.

⁴⁴ In preparation of the report on food intended for sportspeople a market study is currently carried out by an external contractor

unleash the great potential of the internal market.

The objective of adopting guidance on the compatibility of the unavoidable presence of certain substances with the quality of natural mineral waters is to ensure a common understanding by food business operators and controlling authorities of the definition of a natural mineral water. The aim is to prevent any obstacles to the free circulation of such products while at the same time ensuring that the product corresponds to consumer expectations, through the use of “soft law” that would not impose unnecessary administrative burdens on those concerned.

Authorisations of the new health claims and rejections of some applications for health claims provided for, on the one hand, a high level of protection of consumer enabling them to make informed choices while on the other hand, harmonising the internal market and ensuring fair competition. The establishment, in July 2014, of harmonised conditions for the use of the “gluten-free” and “very low gluten” statements under the rules on food information to consumers will not only continue ensuring that consumers throughout Europe have the same understanding of these statements and are not misled, but also extend such protection to non-pre-packed food (*e.g.* sold in restaurant). DG SANCO progressed on the elaboration of delegated acts laying down specific requirements for the different foods (under the scope of Regulation (EU) No 609/2013) which will ensure that products destined to specific vulnerable groups of consumers will be safe and suitable for the target population and will provide the necessary information to ensure correct use. Reports on the necessity of specific rules for milk-based drinks for young children (young-child formulae) and foods for sportspeople are also being finalised and will clarify whether rules are needed, among others, to ensure adequate information of consumers.

DG SANCO contributed to clarifying several aspects important to consumers and businesses alike. For example, the adoption in first reading of the amendment to the Honey Directive resolves the ambiguity as to the natural status of honey and provides accurate information to the consumers.

c) Risk assessment (not applicable)

d) Conclusion

As evidenced above, DG SANCO policy part on information to consumers is on course to meet its multiannual targets for this objective and result indicator.

The majority of outputs were finalized or are in the course of being finalized. Two reports foreseen for adoption in 2014 were slightly postponed:

- The adoption of the reports 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 was delayed due to the complexity and the wide scope of the underlying studies which required more time than foreseen.
- The report on trans fatty acids received considerable attention from various stakeholders. Although they were consulted through the Advisory Group on the Food Chain and Animal and Plant Health both orally and via a questionnaire, it was considered important to carry out an additional written consultation on the emerged options.

1.1.18. FOOD AND FEED SAFETY: specific objective 3.6 - Promote EU standards at the international and multilateral levels and to assist safe and smooth trade between the EU and third countries and to avoid that SPS measures could constitute unjustified barriers to trade

a) Performance tables

Relevant general objective 3: 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 3.6: to promote EU standards at the international and multilateral levels and to assist safe and smooth trade between the EU and third countries and to avoid that SPS measures could constitute unjustified barriers to trade			<input type="checkbox"/> Spending programme <input checked="" type="checkbox"/> Non-spending
Result indicator 3.6.1: participation at multilateral and bilateral meetings stemming from international obligations (source: relevant multilateral and bilateral international agreements)			
Baseline	Milestone	Current situation	Target
2011	2017	2014	2020 (from relevant international agreements)
100%	100%	100%	100%
Main outputs in 2014			
Description	Indicator	Current situation	Target
Representation in WTO SPS Committee	Committee meetings	All 3, including participation in 1 workshop	3
Representation in Codex	Committee meetings/task forces + Commission meeting	15 Committee meetings + 1 Commission meeting	16 approx.
Representation at other international meetings	Annual programme	Cartagena Protocol on Biosafety Meeting of the Parties (MOP) – 1 meeting	
Representation vis-à-vis third countries with bilateral agreements	Joint Management Committee (JMC) meetings	All 6 meetings took place.	Approx. 6
Negotiation of new agreements with third countries	Rounds of negotiations	Valuable input provided allowing to progress in the different negotiations.	Provide input to negotiations
SPS bilateral dialogue with third countries without formal agreement	Meetings with third countries	Numerous bilateral meetings took place: technical meetings, video-conferences, seminars, study visits, missions were also held in the margins of other multilateral meetings e.g. 25 bilateral meeting held in the margins of the WTO SPS Committee	Provide input to negotiations

b) Narrative

DG SANCO played a leading role in promoting the EU values and interests worldwide while, at the same time, contributing to generating new jobs and economic growth. DG SANCO objectives at the EU level in 2014 were met, and even surpassed. In the multilateral arena we succeeded in electing to the position of Codex Chair a European candidate, we succeeded in changing the interpretation on a particular rule on regional representation, we maintained our initiative on transparency in the SPS Committee obtaining three additional co-sponsors, we achieved all our desired outcomes in Cartagena negotiations, as well as a few extras.

As regards bilateral relations, DG SANCO has also succeeded in ensuring that imports from third countries meet the same stringent criteria as those applied to domestic production and in promoting our standards and exports worldwide and consequently in generating economic growth and jobs.

Multilateral processes, usually based on consensus, mean that often work progresses slowly. Nevertheless, once a standard is set by organisations such as Codex, the implications are important for trade as the EU, as well as international partners, has to follow these standards. In 2014, approximately 200 standards were adopted, with the EU reserving its position on a number of these, where the international standard is not in line with EU legislation. In the SPS context, work progressed on private standards and an EU initiative on transparency. A number of specific trade concerns with other third country measures were also raised by the EU (approximately 12 in total) while the EU responded to a number of trade concerns raised by others (approximately 12-15). In respect of the Cartagena Biosafety Protocol, the bi-annual Conference of the Parties Meeting of the Parties discussed a number of issues related to GMOs. In all cases, the EU was able to secure all items included in its negotiation mandate.

The EU worked closely with Member States to defend EU interests, which in turn facilitated the ability of industry to produce and trade more freely. The EU respected its international obligations for example in the WTO, on transparency, circulating approximately 70 notifications in 2014. The EU maintained its status as a reputable and reliable trading partner.

At the bilateral dimension, agreements are the most useful tool to effectively ensure that SPS trade conditions are fully respected and to address the regulatory differences between the EU and third countries. In these negotiations, DG SANCO successfully represented and defended the EU as a single entity.

During 2014, DG SANCO technically concluded negotiations of several agreements with key partners, such as Canada, Republic of Moldova, Ukraine, Georgia, Singapore and Ecuador (being part of the Colombia & Peru Multiparty Agreement). In addition, a number of on-going bilateral negotiations are on the table. These include the talks on with the US (Transatlantic Trade and Investment Partnership), Japan, Malaysia, Vietnam, Thailand, India and Morocco.

In 2014, SANCO properly ensured the implementation of the different existing agreements with an SPS component notably with the following countries: South Korea, Mexico, Chile, Switzerland, New Zealand, with the European Economic Area Agreement (EEA), with Central America (Costa Rica, El Salvador, Honduras, Nicaragua and Panama), with Colombia and Peru, Morocco, Israel, Tunisia and Algeria.

In relation to countries with which no formal Agreement exist, notably with Brazil, China and Russia, DG SANCO continued investing in the SPS dialogue aiming to establish a good cooperation and to solve SPS irritants affecting trade.

SANCO favourably contributed to the EU enlargement process and Neighbourhood Policy during the year of 2014. The important support and guidance work with candidate countries, potential candidates and neighbourhood countries has been progressing allowing to better align these countries with the EU norms and policies of

food safety, sanitary and phytosanitary policies.

On 8 April 2014, the EU initiated a WTO dispute against the Russian Federation as a response to the Russian Federation's ban on exports of pigs, pork and certain other products from all Member States due to the limited outbreaks of African swine fever (ASF) in Lithuania and Poland. The case which is the first of its kind as an SPS case opened by the EU against Russia, is progressing with some delay. The panel was established in July 2014 but only composed at the end of the year due to difficulties with determining the final list of panellists. In mid-January 2015, the EU made its first submission. The case is not expected to be concluded before the end of 2016. There remains the risk that Russia may try to delay the process so as to avoid a decision being taken in the near future.

c) Risk assessment

Management's vigilance as to the creation of international norms – *e.g.* ASF case opened against Russia – means that we ensure that SPS measures are prevented from being used as barriers to trade. The risk of this happening remains high particularly when some of our trading partners act with impunity. We do however seek to take immediate action where violations occur, even going so far as to open a dispute settlement case at the WTO in one instance. On the reverse side, there is also a risk that when we ourselves do not follow international standards that other third countries will do the same, but this risk is thought to be relatively low at present.

d) Conclusion

As evidenced above, DG SANCO policy part on the global dimension of DG SANCO policy is on course to meet its multiannual target for this objective and corresponding indicator. Also, all outputs foreseen for 2014 were finalized before the end of the year.

1.2 EU added value of spending programmes

Example – EU added value of eradication programmes

The EU animal disease situation has improved greatly over the years thanks to the successful implementation of the EU harmonized policy on animal health by Member States, in particular of the EU funded eradication programmes. The value resulting from the EU intervention is additional to the value that would have been otherwise created by Member States alone as will be outlined below.

The value of investing in preparedness, prevention and coordination of measures for certain notifiable diseases at EU level was clearly demonstrated by the rabies eradication programme – a zoonosis, i.e. an animal disease that can be transmitted to humans. Prior to 2000, actions were funded at Member States (mainly in the Western part of the EU (AT, BE, DE, FI, FR, IT and LU))

Due to the presence of a wild reservoir (notably in foxes) the disease could not be addressed at MS level as wild animals obviously ignoring national borders.

The cross border approach offered by the EU for eradication programmes focused on

the design of a harmonised strategic approach, on the sound technical approval of the programmes to make them compatible with the strategy and also on providing technical assistance and coordination of other actions, such as information sharing for the successful implementation of the programmes. In all, the EU was instrumental to the effectiveness of these and contributed to the full eradication of the disease in most of the previously affected Member States

This now even goes beyond EU borders as the ultimate goal is to establish a safety belt in the neighbouring countries of the EU like Russia, Ukraine and Belarus. Of course, this requires years to achieve. In 2015, the focus is now along the Eastern border of the EU where rabies infected areas still exist. Member States with an ongoing programme are FI (where there is no disease but a control programme is in place to protect from a possible introduction from neighbouring third countries), EE, LV, LV, PL, SK, HU, BG, RO, GR, IT, SI and HR. And the EU is also funding rabies eradication activities in Russian Federation, Belarus and Ukraine.

Another example of EU added value of the animal health spending is the African Swine Fever (ASF) outbreak. The short term objective in this case is to contain the spread, applying emergency measures as a first step. In 2014, this was shown by Europe's ability to limit the spread of African Swine Fever (ASF) outbreaks – another (extremely) contagious disease where the reservoir lies in wild boars – to a few Member States only (EE, LT, LV, PL), those bordering Belarus and Russia where the disease is endemic. Again, only the strategic approach designed by the EU and its consistent follow-up to ensure its implementation by the Member States made the effective fight against ASF possible. For example, previously different, fragmented wild boar hunting strategies in a mighty forest shared by these countries were harmonised; only one but important element for successful control from the many elements necessary. In 2015, in those MSs, annual ASF control and eradication programmes coordinated and approved by the Commission are running to eradicate the diseases and to try to avoid further introduction from neighbouring countries through wild boars. There as well, the EU programme contributed and keeps contributing to tackling the problem in the Member States and in those third countries, with the ultimate goal to eradicate the disease and to establish a protective belt in neighbouring countries for the future. Full success of this programme obviously depends also on cooperation by the third countries affected; the Commission is active in international fora which have the objective of ensuring such cooperation.

1.3 Economy and efficiency of spending and non-spending activities

According to the Financial Regulation (Art. 30), the principle of economy requires that the resources used by the institution in the pursuit of its activities shall be made available in due time, in appropriate quantity and quality and at the best price. The principle of efficiency concerns the best relationship between resources employed and results achieved.

The respect of these principles is pursued continuously through the implementation of internal procedures and predefined practices. These procedures ensure that activities are executed in an efficient manner and according to the principle of economy.

DG SANCO is continuously fine-tuning and adapting its internal arrangements to improve the efficiency and economy of its operations. In 2014, it continued to investigate ways to help the DG to face the constraints of reduced resources without disrupting delivery of its policies and activities.

The following two initiatives show how these principles are implemented in DG SANCO:

Example 1 – Improving animal disease eradication programmes

In 2014, DG SANCO paved the way for implementing the Common Financial Framework laying down provisions for the management of expenditure relative to the policy area Food and Feed⁴⁵. Throughout the year, DG SANCO prepared for the new instruments and procedures. Most importantly, DG SANCO introduced the “grant decisions” tool for the 2015 programmes such that only one decision is taken for each Member State, grouping together its programmes and including a flexibility clause that allows a Member State to shift up to 20% of the allocated funds between its programmes without the Commission’s intervention. This will reduce significantly the administrative burden of the annual reallocation exercise.

The new version of the online submission tool for Member States’ applications became fully operational and compulsory for all applications. This has reduced considerably the administrative burden in the planning phase for the 2015 programmes.

Example 2 - Adapting DG SANCO to reduced resources

Finding ways to simplify and gain efficiency has been a continuous development in DG SANCO since several years. In 2014, most importantly:

- The centralisation of the administrative management of public procurement procedures became fully effective in May 2014; new working methods have been developed and specific guidance and training given to all staff concerned; a new comprehensive guidance document for DG SANCO specific needs is under development. The centralisation has improved the quality of tender documents and freed resources in the policy Units. The preparatory work in 2014 paved the way for further efficiency gains as well as positive effects on planning and timeliness of procurement procedures.
- A new interactive tool for management reporting on budget implementation was introduced. Thanks to the tool, the time spent on drafting financial reports was reduced considerably; the reports are available on-line and are much more user-friendly and easier to read and before.

⁴⁵ Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014

2. MANAGEMENT OF RESOURCES

Assurance is an objective examination of evidence for the purpose of providing an assessment of the effectiveness of risk management, control and governance processes. This examination is carried out by management, who monitors the functioning of the internal control systems on a continuous basis, and by internal and external auditors. Its results are explicitly documented and reported to the Director-General.

The main reports produced are:

- Annual reports on budget implementation drafted by the Authorising Officers by Sub-delegation;
- Reports of the central financial cell on the results of the second-level ex-ante controls, and of the Public Procurement Committee ("Comité des Marchés Publics" - CMP) on ex-ante controls of public procurement procedures;
- Audit reports and the annual activity report of the on-the spot controls;
- Report of the Internal Control Coordinator on the annual assessment of the implementation of the internal control standards;
- Reports from Authorising Officers in other DGs responsible for managing budget appropriations in cross-delegation;
- Audit reports of the Internal Audit Capability (IAC) and the annual audit opinion;
- Observations and recommendations reported by the Internal Audit Service of the Commission (IAS) and the European Court of Auditors (ECA).
- Reports on control results from the Executive Agency CHAF-EA (former EAHC⁴⁶);

This section reports the control results and other relevant elements that support managements' assurance on the achievement of the internal control objectives⁴⁷. It is structured in three separate sections:

- (1) the DG's assessment of its own activities for the management of its resources;**
- (2) the assessment of the activities carried out by other entities to which the DG has entrusted budget implementation tasks; and**
- (3) the assessment of the results of internal and external audits, including the implementation of audit recommendations.**

⁴⁶ For simplicity, all references to the Executive Agency will be to the CHAF-EA, the name applicable from 2014

⁴⁷ Effectiveness, efficiency and economy of operations; reliability of reporting; safeguarding of assets and information; prevention, detection, correction and follow-up of fraud and irregularities; and adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the multiannual character of programmes as well as the nature of the payments (FR Art 32).

DG SANCO's financial management – overview

In 2014, DG SANCO managed financial operations under the following three policy areas: Consumer Affairs, Public Health and Food and Feed Safety. To give an indication of the relative financial weight of each area, the table below shows the distribution of commitment appropriations in 2014⁴⁸.

Table 2.1 DG SANCO commitment appropriations of 2014

a) Operational budget mainly for EU programme implementation

Policy area	Operational budget, implemented by (in EUR million) ⁴⁹				Total (in EUR million)	Policy share
	CHAF-EA ("entrusted" credits)	Other DGs (cross- delegations)	Operational credits	Administrative credits		
Food and Feed Safety	14,9	0,0	233,6	1,5	250,0	74%
Public Health	45,3	1,1	15,2	1,5	63,1	19%
Consumer Affairs	16,5	0,0	5,8	1,1	23,4	7%
<i>Subtotal</i>			254,6	4,1		
Sub-total policies	76,7	1,1	258,7		336,5	100%
Implementation share	23%	0%	77%		100%	

b) Operational budget for subsidies to agencies

DG SANCO's contribution to agencies	Total (in EUR million)
Executive agency (CHAF-EA) operating budget	7,3
EU agencies' operating budgets	174,4
Sub-total agencies	181,7
TOTAL DG SANCO	518,2

Table 2.1a) above shows that DG SANCO implemented 77% of its operational budget by direct centralised management (no intermediaries):

- In the policy area Food and Feed Safety, DG SANCO implemented its budget to a large extent through cost reimbursements to Member States mainly based on the co-financing of eligible costs. The main features of this management mode are explained in part 2.1.1 below (Annex 5.1.1 shows the corresponding internal control template).
- In the policy areas Public Health and Consumer Affairs, public procurement is the most important instrument of financial management (see part 2.1.2 below for more

⁴⁸ Commitments made on the basis of the final available credits taking into account EFTA credits, budget amendments and/or budget transfers

⁴⁹ The figures in table 2.1.a) correspond to the commitment appropriations implemented as shown in Table 2 of Annex 3, Title 17, without the credits entrusted to CHAF-EA and the administrative expenditure; furthermore, while Annex 3 includes the subsidies to EU agencies of EUR 174,4 million under "Public Health", table 2.1b) shows these commitments separately

detail and Annex 5.1.2 for the internal control template).

- The administrative credits included in the table above are support credits on the operational budget lines and used mainly for meetings, conferences, IT and communication services.
- DG SANCO implemented about 23% of its 2014 budget through entrusted entities, first and foremost by the Consumers, Health and Food Executive Agency (CHAF-EA). Around 0,3% of the commitment appropriations was implemented by authorising officers of other Directorates General (see part 2.2 below for more detail).

Table 2.1b) shows that DG SANCO paid subsidies to finance – partially or in full – the operating budgets of the executive agency, CHAF-EA, and EU agencies (for more detail see part 2.2 below; Annex 5.2 shows the corresponding internal control template).

2.1. Management of human and financial resources by DG Health and Consumers (DG SANCO)

This section reports and assesses the elements identified by management that support the assurance on the achievement of the internal control objectives. Annex 5 (internal control template) outlines the main risks together with the control processes aimed to mitigate them and the indicators used to measure the performance of the control systems.

2.1.1. Cost reimbursements to Member States in the policy area Food and Feed Safety

DG SANCO follows an integrated approach with the aim to ensure a high level of food safety, animal health, animal welfare and plant health within the European Union through coherent farm-to-fork measures and adequate monitoring.

In 2014, DG SANCO paved the way for the implementation of the Common Financial Framework (CFF) laying down provisions for the management of expenditure relative to the policy area Food and Feed⁵⁰. While the national programmes implemented in 2014 as well as other veterinary and phytosanitary expenditure of 2014 were still based on Council Decisions 2009/470/EC and 2000/29, Member States' programmes for 2015 mark the transition to the implementation of the CFF (see stages 1 and 2 below).

The table below shows that for 2014, the final available commitment credits implemented by DG SANCO amounted to EUR 235 million.

By far the most important instrument of budget implementation consists of direct financial contributions to Member States through cost reimbursements (76%).

⁵⁰ Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014

28 Member States submitted 141 annual animal disease eradication and monitoring programmes for implementation in 2014. In addition 11 files for cost reimbursements from nine Member States and one third country were introduced through the veterinary emergency fund; 26 files from 6 Member States for phytosanitary measures addressing the combat of organisms harmful to plants. Other non-typical grants concern mostly the funding of the 44 European Reference Laboratories.

The 2014 payment credits implemented directly by DG SANCO for the policy area Food and Feed amounted to EUR 204,7 million. These credits were implemented to 100%, but further to the shortage in payment credits, not all payments due in 2014 could be paid. During the Global Transfer, DG SANCO requested EUR 22 million additional credits which were not granted. Consequently, a payment to one Member State had to be made partially from the 2015 budget in early 2015.

Table 2.2 Food and Feed Safety

Commitment appropriations implemented by DG SANCO (without CHAF-EA and cross-delegations)	2014	2013
	€ million	€ million
Animal disease eradication programmes	166,8	197,4
Veterinary emergency fund (cost reimbursements to Member States)	6,9	8,0
Phytosanitary expenditure (cost reimbursements to Member States)	5,9	8,2
Other veterinary and food-and-feed-safety expenditure (non-typical grants)	31,8	24,5
Sub-total	211,4	238,1
Procurement	20,1	9,9
Other expenditure ⁵¹	2,1	
Administrative support credits	1,5	1,5
Total budget implemented	235,1	249,5

Control effectiveness as regards legality and regularity

DG SANCO has set up internal control processes aimed at ensuring the adequate management of the risks relating to the legality and regularity of the underlying transactions, taking into account the nature of payments. The control objective is to ensure that the residual error rate of DG SANCO's ex-post controls does not exceed the materiality threshold of 2%; materiality is assessed in accordance with Annex 4.

A common feature of the cost-reimbursements is that they do not follow the typical grant procedure of open calls for proposals given that the beneficiaries are Member States. Programmes are implemented annually, and payments of the financial contributions are based on Member States' annual cost declarations.

Against this background, the control process is divided into four distinct stages, each with specific control objectives. Key indicators have been defined for each stage as

⁵¹ In 2014, DG SANCO had to pay indemnities in response to damages claimed regarding a ban on imports of birds from third countries 2005-2007

described in **Annex 5**. The descriptions focus on the national programmes for animal disease eradication and monitoring as these account for more than 70% of the EU funds in the policy area Food and Feed. For other kinds of cost reimbursements the controls described below are implemented as far as applicable.

Stage 1: Programming and evaluating national programmes

In 2014, this concerned the invitation to Member States to submit their 2015 disease eradication and monitoring programmes by end of April 2014 according to the standard criteria and requirements set out in the “old” legislation of Council Decision 2009/470/EC. DG SANCO, assisted by external experts, evaluated the national programmes to ensure their good quality and their contribution to the achievement of the policy objectives at reasonable costs.

At the programming stage the key controls were mostly directive and preventive in nature: application guidelines for the Member States, IT tool for electronic submission of applications, assessment of the technical quality and financial analysis of the national programmes, and selection of independent external evaluators. The draft evaluation results were presented at the Standing Committee on Plants, Animals, Food and Feed (PAFF; previously the “Standing Committee on the Food Chain and Animal Health – SCoFAH”).

Stage 2: Approving national programmes and Grant Decision

Further to the presentation of the draft evaluation results of the national programmes for 2015 in the Standing Committee PAFF, DG SANCO facilitated the Member States’ finalisation of their programmes. In accordance with the CFF Regulation of May 2014, DG SANCO gave its technical approval of the submitted programmes by 30 November 2014 and prepared the award decision of the Acting Director-General as authorising officer by delegation. When drafting the grant decision by Member State, DG SANCO carried out a number of administrative and legal ex-ante checks with the aim to ensure compliance with the award decision and grant provisions recommended by DG BUDG. On 23 January 2015 the authorising officer by delegation formally approved the programmes and their associated funding in the corresponding grant decisions. As in previous years, in 2014 the deadlines fixed in the legislation were respected allowing a timely implementation of the 2014 programmes as well as a timely launch of the 2015 programmes of the Member States.

Stage 3: Monitoring national programmes and managing financial transactions

In 2014, DG SANCO monitored the implementation of the 2014 national programmes. Firstly, the progress made by the Member States was assessed on the basis of interim technical and financial reports. The objectives were (i) to ensure that the national programmes are implemented as planned and meet the objectives and conditions, and (ii) to increase the efficiency of the use of the credits. One of the results of the financial monitoring at the interim stage is the redistribution of EU funds between the different national programmes. In 2014, this led to a Commission Decision on the reallocation of EU funds for the national programmes implemented in 2014.

Secondly, DG SANCO examined the Member States’ final technical reports and checked

the correctness of the final cost claims. The depth of control depended on a risk analysis. The controls took place prior to the processing of financial transactions by the operational and financial actors involved in DG SANCO's financial circuit. The aim was to detect and correct errors before authorisation of a financial operation.

The first-level verification of each financial transaction was assured by the financial Unit responsible for the policy Directorate; a second-level ex-ante verification was carried out by the central financial Unit on a sample of commitments, payments and recovery orders. Checks were done at the desk prior to the authorisation of a transaction (ex-ante). For the second-level control, the selection of transactions to be verified was supported by the IT application "MUS-DICE" and based on a risk analysis with a set of risk criteria reviewed once a year. Since several years, the target is to cover 10% to 15% of the total number of transactions. In 2014, having verified 10% of all transactions, DG SANCO met the target; this resulted in a coverage of around 55% of the total of amounts committed, paid and recovered. None of the errors found had a financial impact.

Thirdly, on the basis of a risk analysis, a sample of ex-ante financial controls was carried out in the Member States to verify cost claims that were assessed as being exposed to a relatively high risk of error. In 2014, the ex-ante "on-the-spot" controls took place according to plan, and focused on the high risk areas as follows: (i) national programmes for animal disease eradication and monitoring: on special requests of the operational services or on exceptionally high amounts; (ii) veterinary emergency fund and plant health measures: commitments exceeding EUR 2 million or other exceptionally high amounts. In 2014, all mistakes found during ex-ante controls in Member States' cost claims were corrected prior to the authorisation of the payments.

Stage 4: Managing ex-post controls and error corrections

There is a risk that certain issues (errors or attempted fraud) cannot be detected and corrected during ex-ante controls at the desk; thus, DG SANCO complements its desk checks by ex-post controls in the Member States. The aim is to provide reasonable assurance on the legality and regularity of expenditure on an annual basis. The main indicator is the estimated residual risk of errors in payments with a materiality threshold of 2% (for more information on materiality see Annex 4).

For 2014, DG SANCO defined and implemented its on-the-spot control plan which was endorsed by DG SANCO's Audit Committee. It aimed at optimising the control impact through a risk based selection of payment transactions to be audited and sufficient audit coverage to lower the residual error rate. Since several years, the objective is to cover at least 20% of DG SANCO's total annual operational budget for payments in the policy area.

The 2014 audit plan was implemented as planned; the actual audit coverage amounted to about 50% of final payments made for the annual programmes. As foreseen, ex -post controls were carried out by DG SANCO's own competent staff and by an external audit service provider, independent of the operational Directorates and according to professional standards.

The errors detected during the ex-post controls finalised in 2014 result in an error rate

of about 0,2% (EUR 0,1 million) for the audited national programmes for animal disease eradication and monitoring of the years 2008 to 2012; the error rate detected in the Food and Feed policy area as a whole amounted to about 0,9% (EUR 0,3 million). The issues giving rise to corrections were common to a number of audited cost claims of Member States and EU Reference Laboratories, and were due mainly to an insufficient understanding of the eligibility rules. This resulted in claims for non-eligible expenditure, for example, staff costs, consumables or administration, identification of tested animals, not taking the salvage value into consideration, or over-estimation of the value of animals.

Of the errors detected in audits finalised in 2014, about 22% (EUR 0,07 million) was corrected in 2014 by issuing recovery orders. After correction, the residual error rate amounts to 0,8% for the overall ABB activity Food and Feed Safety. This is below the materiality threshold of 2% and confirms the downward trend, from 4,3% in 2011 to 3,4% in 2012 and 2,3% in 2013. Therefore in 2014, no reservation to the declaration is warranted.

The table below shows the main indicators that contribute to the Acting Director-General's reasonable assurance that the controls in place work effectively to ensure the legality and regularity of the financial transactions.

Table 2.3 Indicators of control effectiveness as regards legality and regularity in cost reimbursements

Indicators per stage of the procedure	Targets	2014	2013
Stage 1: Programming and evaluation			
Ratio of rejected national programmes to total programmes submitted: 152 programmes for 2015 submitted in 2014; (141 national programmes for 2014 submitted in 2013)	<i>n/a</i>	7,9%	1,4%
Ratio of modified programmes to total programmes retained after evaluation	<i>n/a</i>	79%	58%
Stage 2: Grant Decision on the national programmes and EU funding			
Ratio of grant decisions taken on-time as fixed in the legislation	100%	100%	100%
Stage 3: Monitoring of programme implementation and financial management			
Percentage of implemented final commitment appropriations	99%	99% ⁵²	99%
Percentage of implemented payment credits after global transfer	100%	100% ⁵³	100%
Correction rate of 2nd-level verifications : % of amounts with financial errors	< 2% <i>in value</i>	0,0%	0,2%
Correction rate of ex-ante on-the-spot controls :	<i>n/a</i>		
- Eradication programmes (<i>average of all corrections</i>)		0,4%	0%

⁵² Annex 3 shows a budget implementation rate of only 96,6%. However, the actual implementation rate amounts to 99,5% given that EUR 6,8 million of the 2014 of commitment appropriations under the Emergency fund measures were carried over to 2015 after a request for non-automatic carryover in January 2015

⁵³ Annex 3 shows a payment implementation rate of only 99%. However, the full budget was spent as the non-implemented credits correspond to assigned revenues which can and will be used in 2015. During the Global Transfer, EUR 22 million additional payment credits were asked, but not received

Indicators per stage of the procedure	Targets	2014	2013
- EU Reference Laboratories		4,8%	-
- Other veterinary expenditure		17,4%	-
- Veterinary emergency fund (<i>average of all corrections</i>)		-	14%
- Phytosanitary measures (<i>average of all corrections</i>)		-	33%
Number of registered " exception reports "	<i>n/a</i>	0	2
Instances of Article 66(2) of the Financial Regulation	<i>n/a</i>	None	None
Stage 4: Ex-post controls in the policy area Food and Feed			
Ex-post control detected error rate (ABB activity: Food and Feed)	<i>n/a</i>	0,9%	3,0%
Ex-post control residual error rate after correction (ABB activity: Food and Feed)	< 2%	0,8%	2,3%
Amount of net financial corrections identified in year N compared with amount of financial transactions audited	<i>n/a</i>	€ 0,3 million € 35,6 million	€ 1,6 million € 55,0 million
Financial corrections in year N linked to audits finalised in year N (until March N+1)	<i>n/a</i>	€ 0,07million 22% ⁵⁴	€ 1,4 million 87% ⁵⁵
Total correction of detected errors	<i>100%</i>	€ 0,07 million 22%	€ 1,6 million 100% ⁵⁶

Conclusion on legality and regularity in cost reimbursements

In conclusion, the analysis of the available control results, the assessment of the weaknesses identified and that of their relative impact on legality and regularity has not revealed any significant weakness which could have a material impact as regards the legality and regularity of the financial operations. It is possible to conclude that the control objectives as regards legality and regularity have been achieved.

DG SANCO's residual error rate in the animal disease eradication programmes amounts to 0,8%) for the ABB activity "Food and Feed Safety" as a whole. Thus, it does not exceed the materiality threshold of 2% and confirms the downward trend observed since 2011: residual error rate: 4,3% (2011); 3,4% (2012); 2,3% (2013). To reduce the error rate, in the past few years, DG SANCO has taken a series of mitigating actions; their cumulative effect has continuously reduced the error rate to an acceptable level. Therefore, DG SANCO can lift the reservation that was introduced in the Annual Activity Reports of 2011, 2012 and 2013.

Given the risk-based audit sample, the error rate is not representative. However, in the last four years, around 50% of the payments made relative to animal disease eradication programmes has been subject to on-the-spot controls, and most of the findings were systemic. Thus, the detected error rate in the non-representative sample is considered a sufficiently reliable source of information in the assurance building process.

⁵⁴ The low percentage of financial corrections in 2014 is due to one audit that was finalised only in December 2014. The recovery process is on-going in 2015

⁵⁵ Relative to audits finalised in 2013, 87% of the detected errors were corrected by March 2014. The remaining EUR 0,2 million were recovered in June 2014

⁵⁶ Taking the corrections made in 2013 and 2014 together, all detected errors prior to 2014 were corrected

Control efficiency and cost-effectiveness.

The principle of efficiency concerns the best relationship between resources employed and results achieved. The principle of economy requires that the resources used by the institution in the pursuit of its activities shall be made available in due time, in appropriate quantity and quality and at the best price.

This section outlines the indicators used to monitor the efficiency of the control systems, including an overall assessment of the costs and benefits of controls. The main indicators monitored in 2014 focussed on the timeliness of procedures and the resources employed.

Table 2.4 Indicators of control efficiency in cost reimbursements – timeliness

Indicators per stage of the procedure	Targets	2014	2013
Stages 1 and 2: Programming, evaluation and approval of national programmes and EU funding			
Ratio of decisions taken on-time to allow a timely start of the national programmes for 2014 (2013)	100%	100%	100%
Stage 3: Monitoring of programme implementation and financial management			
Payment times: payments made on time (in number) in amount	95%	(97%) 97%	(92%) 92%
Stage 4: Ex-post controls and error corrections			
Timely implementation of the annual ex-post control work programme (21 audit visits carried out in 2014; 25 in 2013)	100%	95%	96%
Percentage of financial audit recommendations accepted by the beneficiaries/Member States	100%	100%	100%
“Time to recover”: average days from finalising the audit report to issuing the debit note (10 debit notes in 2014; 20 in 2013)	n/a	72 days	120 days

In 2014, DG SANCO did not face any undue delays in its procedures. Good progress was made to increase the percentage of timely payments and to speed up the recovery process.

The costs of control cover the annual costs of both DG SANCO staff and external service providers carrying out the control tasks through the different stages of the control procedure. The figures in the table below are calculated on an all-cost basis without including an overhead rate.

Table 2.5 Indicators of control efficiency in cost reimbursements - resources⁵⁷

Indicators per stage of the procedure (average FTE times standard annual costs) ⁵⁸		2014 (€million)	2013 (€million)
Stages 1 and 2: Programming, evaluation and operational monitoring			
Cost of operational staff in the policy Units concerned	Number FTE: 7,2	0,9	1,0
Financial resources spent on external experts assisting in the evaluation of national programmes in the policy area Food and Feed Safety		0,1	0,1
Stage 3: Monitoring of financial transactions			
Cost of financial staff in the policy Units concerned	Number FTE: 8,5	1,0	1,0
Cost of staff involved in second-level ex-ante controls of the central financial Unit	Number FTE: 0,5	0,1	0,1
Stage 4: On-the-spot controls (ex-ante and ex-post)			
Cost of DG's internal staff dealing with on-the-spot controls	Number FTE: 5,3	0,7	0,8
Financial resources spent on external audit services In the policy area Food and Feed Safety		0,1	0,1
Total annual cost (without overhead rate)		2,9	3,1
Budget spent on "cost reimbursements" ("benefit" of the controls)		211,4	238,1
Total cost as % of total annual budget (commitment appropriations)		1%	1%

Conclusion on control efficiency in cost reimbursements

DG SANCO quantifies the costs of the resources and inputs required for carrying out the controls described in Annex 5. While most costs of controls are quantifiable in monetary terms, most of their undeniable benefits are not. 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 very significant to ensure value for money through improved quality, but the benefit is not quantifiable. The same can be said for DG SANCO's on-the-spot controls in the Member States: the benefits in non-financial terms include, first and foremost, compliance with regulatory provisions and deterrent effects but also improvements of the reporting systems in the Member States. Therefore, DG SANCO makes the assumption that without these controls, value for money in the cost reimbursements to Member States could not be ensured. Thus, the benefit is estimated at about 100% of the budget spent.

DG SANCO will analyse the evolution of the efficiency indicators over time to reach a conclusion as to the relative efficiency of the controls. This is not thus far possible, as this is only the second year in which DG SANCO has calculated and reported on these indicators. In addition, 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.

⁵⁷ For the costs of control, no targets are defined in monetary terms as in 2014 the information available is insufficient to analyse the evolution over time and/or to compare the figures with Commission benchmarks

⁵⁸ FTE = full time equivalent; standard annual costs: EUR 132.000 for officials and EUR 70.000 for contractual staff

2.1.2. Procurement in all policy areas

Control effectiveness as regards legality and regularity

DG SANCO has set up internal control processes aimed to ensure the adequate management of the risks relating to the legality and regularity of the underlying transactions, and the nature of the payments. The control objective is to ensure that the Director-General has reasonable assurance that the total amount of any financial operations authorised during the reporting year which would not be in conformity with the applicable contractual or regulatory provisions does not exceed 2% of the total expenditure.

Financial management and control is grouped around three core processes as described hereafter. A detailed overview is provided in Annex 5.

Stage 1: Assessing procurement needs and selecting the offer

DG SANCO starts the planning of a procurement procedure by assessing the procurement needs in the different policy areas.

- Based on the Multi-annual **Consumer Programme for the years 2014 to 2020**⁵⁹, a specific work programme for 2014 was adopted by the Commission on 19 February 2014. The total available budget amounted to around EUR 23,4 million of which DG SANCO implemented just under 30% (EUR 6,4 million) mainly⁶⁰ through public procurement using framework contracts, for example, for IT and communication services, as well as organising meetings and conferences. The larger part of the programme budget (EUR 16,5 million) was implemented by CHAF-EA (see the Annual Activity Report of CHAF-EA). In addition to the funds for the consumer programme, DG SANCO received EUR 0,5 million for one pilot project in the policy area Consumer Affairs.

Table 2.6 Procurement in all policy areas

Commitments (without CHAF-EA and cross-delegations)	2014 € million	2013 € million
Consumer Affairs	6,7	5,4
Consumer programme implemented by SANCO	5,1	4,3
Administrative budget of the programme implemented by SANCO	1,1	1,1
Pilot projects/preparatory actions implemented by SANCO	0,5	0,0
Public Health	16,7	13,9
Public Health Programme implemented by SANCO	8,4	8,1
Administrative budget of the programme implemented by SANCO	1,5	1,5
Pilot projects/preparatory actions implemented by SANCO	6,8	4,3
Food and Feed Safety	21,6	11,4
Budget for procurement implemented by SANCO	18,8	9,9
Administrative budget implemented by SANCO	1,5	1,5
Pilot projects/preparatory actions implemented by SANCO	1,3	-
Total budget implemented	45,0	30,7

⁵⁹ Regulation (EU) 254/2014 of 26/02/2014

⁶⁰ EUR 6,2 million was spent through public procurement and EUR 0,2 million through grants

- After the third **Programme of the Union's action in the field of health (2014-2020)** was adopted in March 2014⁶¹, the Commission decided on the specific work programme for 2014 on 26 May 2014 with a total programme budget of EUR 56,3 million. DG SANCO directly implemented 18% (EUR 9,9 million) almost exclusively through public procurement, mostly using framework contracts, for example for IT products and services and for communication actions; services were provided the Joint Research Centre (JRC) based on administrative agreements. In addition to the funds for the public health programme, DG SANCO received EUR 6,8 million for seven pilot projects of about EUR 1 million each.
- For **Food and Feed Safety**, most of the budget for procurement was spent on IT services and communication actions, almost exclusively using framework contracts. In addition EUR 5,6 million were spent on vaccine purchases based on Commission decision C(2014)8395 of 17 November 2014 and EUR 1,25 million for two Pilot Projects.

With regard to the choice of the right procurement procedure, the most important criterion is the size of the contract and the kind of the service needed. As in previous years, extensive use was made of DG SANCO framework contracts as well as those of other DGs (for example DG DIGIT).

In 2014, several types of procedures have been applied (see the table below and Annex 3). Following the open procedure, in the policy area Public Health, three service contracts of about EUR 1 million each and one service contract of around EUR 2 million was awarded for Pilot Projects. In the policy area Food and Feed Safety, one contract was awarded for a Pilot Project of EUR 0,3 million. In addition, the DG signed a contract of EUR 0,5 million for telecommunication services in Grange, Ireland.

The two restricted procedures were applied to small IT service contracts. The negotiated procedure was used firstly, to purchase and store vaccines for animal diseases for around EUR 2,0 million, and secondly, to secure the continuation of existing services in the policy area Public Health.

Table 2.7 Procurement contracts above € 60.000

Type of procedure	2014		2013	
	N° of contracts	Amount € million	N° of contracts	Amount € million
Open (Art. 127.2 RAP)	6	5,6	9	42,3
Restricted (Art.136.1(a))	2	0,1	1	0,4
Negotiated (Art. 134 RAP)	2	2,1	2	0,3
TOTAL	10	7,8	12	43,0

Centralisation of the administrative management of procurement procedures:

With a view to achieving a better quality in terms of tender documents, harmonisation and efficiency gains, DG SANCO centralised its administrative management of public procurement procedures which became fully operational in May 2014. The centralisation covered all new procurement procedures above EUR 15.000, including specific contracts on Framework Contracts with re-opening of competition. In 2014, a

⁶¹ Regulation (EU)282/2014 of 11/03/2014

few exceptions to the centralisation still existed for organisational/technical or geographical reasons; these concerned mainly the Communication Unit and the calls for tender managed by DG SANCO's site in Grange, Ireland.

To ensure good co-operation with the operational Units, the central Unit drew up new working methods and specific guidance; first training sessions were given to all staff concerned.

In 2014, all procurement procedures for contracts above EUR 130.000, including specific contracts on Framework Contracts with reopening of competition, which were not covered by the centralisation, were examined by DG SANCO's "Public Procurement Committee" or "Comité des marchés publics" (CMP). The CMP is designed as ex-ante control prior to taking an award decision. It gives an opinion on the compliance with Commission rules and procedures for public procurement, including the use of adequate contract provisions. The Committee consists of representatives of the central financial cell, the decentralised financial cells and of the legal affairs Unit. Furthermore, to improve the drafting of tender specifications by the policy Units concerned, the CMP may be asked to review the draft tender documents before the publication of the contract notice in the Official Journal. This control is at the discretion of the competent authorising officers, and in 2014 was used for one case.

Based on the first-year experience with the central management of procurement procedures, the role of the CMP is currently being reviewed to assess which procurement procedures should be subject to an independent ex-ante control and how this control should be designed and implemented to ensure an effective and efficient counterbalance.

Stage 2: Monitoring the implementation of procurement contracts and managing financial transactions

The second stage concerns the technical and financial monitoring of contract implementation. It falls under the responsibility of the operational Units and was not affected by the centralisation of the procurement procedures. The frequency and depth of the controls depends on the size, complexity and sensitivity of the contract.

The objective is, firstly, to ensure that the contractor meets the objectives, delivers good quality on time and complies with the contract provisions. Secondly, DG SANCO aims at detecting and correcting errors before a financial operation is authorised. DG SANCO's financial circuits foresee a first-level verification of each financial transaction by the financial Unit responsible; a second-level verification is carried out by the central financial Unit on a sample of commitments, payments and recovery orders. Checks are done at the desk prior to the authorisation of the transaction (ex-ante). The selection of operations to be verified is supported by the IT application "MUS-DICE"; this is based on a risk analysis with a set of risk criteria reviewed once a year.

In 2014, all detected errors with financial impact were corrected prior to the authorisation of the transactions.

Stage 3: Supervisory measures

With a view to measuring the effectiveness of ex-ante controls, DG SANCO has established diverse supervisory measures such as the reporting on exceptions and non-compliance events, defined as control over-rides or deviations from policies and procedures, and the results of other supervisory activities. In addition, DG SANCO's Internal Audit Capability conducts audits on procurement on a regular basis foreseen in the strategic audit plan. In 2014, an audit on costing practices in procurement was finalised (see part 2.3.1 below).

Ex-post controls on procurement contracts at the contractor's site are conducted only in exceptional cases when high risks were identified during ex-ante controls. In 2014, one audit was finalised on a three-year contract of an exceptional high value (EUR 31 million) and involving several sub-contractors. No quantifiable error was found.

Throughout the year, the functioning of the internal control system is closely monitored by the systematic registration of so-called "exceptions" and internal control weaknesses. For 2014, the underlying causes behind these exceptions and weaknesses were analysed and corrective actions planned and agreed by the Management Team.

Relative to procurement in 2014, nine non-compliance events were reported to Management. They all concern formal compliance issues, do not impact on the implementation of the budget, and have no bearing on the Acting Director-General's declaration of assurance. Some issues were recurrent, as they were due to the late adoption of the 2014 work programmes of the funding programmes in the policy areas Consumer Affairs and Public Health. Management assessed that, overall, the existing controls are sufficient and that no mitigating actions have to be taken.

Table 2.8 Indicators of control effectiveness as regards legality and regularity in procurement

Indicators per stage of the procurement procedure	Targets	2014	2013
Stage 1: Assessing procurement needs and selecting the offer			
Rate of open calls for tenders for which - No offer was received - The procedure had to be cancelled (<i>3 cancelled</i>)	0% 0%	0,0% 23%	*
Positive opinions of the procurement committee (CMP) compared to open calls examined by the CMP	<i>n/a</i>	60% (2 negative)	88% (2 negative)
CMP opinions followed by the authorising officers responsible	100%	100%	100%
Stage 2: Monitoring of contract implementation and financial management			
Ex-ante 2nd-level verifications coverage: % of transactions % of amounts	10% 50%	7% 55%	*
Ex-ante correction rate of 2 nd -level verifications: % of amounts with financial errors	< 2% <i>in value</i>	0,0%	0,0%
Number of registered " exception reports " relative to procurement procedures	<i>n/a</i>	9	14
Instances of Article 66(2) of the Financial Regulation	<i>n/a</i>	None	None

Indicators per stage of the procurement procedure	Targets	2014	2013
Late interest payments relative to total value of contracts (in 2014: 1 case; in 2013: 2 cases)	0%	0,0%	0,0%
Stage 3: Supervisory measures			
On-the-spot control: detected error rate in a procurement contract (one audit launched in 2013 and finalised in 2014)	< 2%	0,0%	n/a
Recovery orders booked in year N: (in number) in amount	n/a	(7) €0,07 million	(4) €0,43 million
For procurement: Ombudsman cases or legal proceedings open in year N	n/a	None	None

Ad *: The indicator was calculated for the first time in 2014 separately for procurements and grants.

Conclusion on legality and regularity in procurement

In conclusion, the analysis of the available control results, the assessment of the weaknesses identified and that of their relative impact on legality regularity has not unveiled any significant weakness which could have a material impact as regards the legality and regularity of the financial operations. DG SANCO considers it possible to conclude that the control objective as regards legality and regularity has been achieved.

Control efficiency and cost-effectiveness.

The principle of efficiency concerns the best ratio between resources employed and results achieved. The principle of economy requires that the resources used by the institution in the pursuit of its activities shall be made available in due time, in appropriate quantity and quality and at the best price. This section outlines the indicators used to monitor the efficiency of the control systems, including an overall assessment of the costs and benefits of controls.

The main indicators monitored in 2014 focussed on the timeliness of procedures and the resources employed. More indicators will become available in the course of 2015 (see Annex 5) thanks to DG SANCO's centralisation of procurement procedures that became effective starting from May 2014.

Table 2.9 Indicators of control efficiency in procurement - timeliness

Indicators on control efficiency in procurement	Targets	2014	2013
Stage 1: Rate of timely launched procurement procedures as specified in the annual work programmes	100%	100%	*
Stage 2: Payment times: payments made on time (in number) in amount	95%	(99%) 99%	(98%) 99%
Stage 3: "Time to recover": average days from information/confirmation date to issuing the debit note (in 2014: 7 debit notes; in 2013:4 debit notes)	n/a	41 days	88 days

Ad *: new indicator starting from 2014

In 2014, DG SANCO did not face any undue delays in its procedures. Good progress was made to speed up the recovery process.

The table below shows the costs of control. They cover the annual costs of DG SANCO staff carrying out the control tasks through the different stages of the control procedure and are calculated on an all-cost basis without including an overhead rate.

Table 2.10 Indicators of control efficiency in procurement - resources⁶²

Indicators for procurement⁶³ (average FTE times standard annual costs) ⁶⁴		2014 (€million)	2013 (€million)
Cost of operational staff in the policy Units concerned	Number FTE 9,0	1,0	1,3
Cost of staff involved in the CMP activities	Number FTE 0,4	0,1	0,1
Cost of financial staff concerned in financial circuits	Number FTE 7,0	0,9	1,0
Cost of staff involved in second-level ex-ante controls of the central financial Unit	Number FTE 0,5	0,1	0,1
Cost of DG's internal staff dealing with on-the-spot controls	Number FTE 0,0	0,0	0,1
Total annual cost (without overhead rate)		2,1	2,5
Budget spent on "procurement" ("benefit" of the controls)		45,0	30,7
Total cost as % of total annual budget spent through procurement (commitment appropriations)		5%	8%

Conclusion on control efficiency in procurement

DG SANCO quantifies the costs of the resources and inputs required for carrying out the controls described in Annex 5. While most costs of controls are quantifiable in monetary terms, most of their undeniable benefits are not. Therefore, DG SANCO makes the assumption that without a proper needs analysis, well drafted tender specifications and a high quality evaluation process, value for money in procurement could not be ensured. Thus, the benefit is estimated at about 100% of the budget spent through procurement.

In addition, DG SANCO will analyse the evolution of the efficiency indicators over time and/or compare them with relevant benchmarks to reach a conclusion as of the relative efficiency of the controls. This is not currently possible, as this is only the second year in which Directorates-General have calculated and reported on these indicators.

⁶² For the costs of control, no targets are defined in monetary terms as in 2014 not sufficient information is available to analyse the evolution over time and/or to compare the figures with Commission benchmarks

⁶³ For the costs of control, no targets are defined in monetary terms as in 2014 not sufficient information is available to analyse the evolution over time and/or to compare the figures with Commission benchmarks

⁶⁴ FTE = full time equivalent; standard annual costs: EUR 132.000 for officials and EUR 70.000 for contractual staff

2.1.3. Fraud prevention and detection

DG SANCO developed its anti-fraud strategy as foreseen in the Commission's overall anti-fraud strategy⁶⁵. Throughout 2014, the internal control officer monitored the implementation of the associated action plan and reported the results to DG SANCO management twice a year, at mid-term and at year-end. Already since 2013, actions are well on track, for example: (i) the active participation in the network "Fraud Prevention and Detection" (FPD) chaired by OLAF; (ii) the introduction of the standard anti-fraud clause for spending programmes under the new Multi-annual Financial Framework; (iii) an ethics awareness raising campaign addressed to all staff; and (iv) the establishment of standing operating procedures for the handling of allegations of fraud, other irregularities and OLAF cases.

Plans are to complete all actions by the end of 2015. Possible recommendations made by the Internal Audit Service of the Commission (IAS) in its on-going audit on the adequacy and effective implementation of the anti-fraud strategies of Directorates General (see part 2.3.2 below) will be taken into consideration. The controls to prevent and detect fraud are basically the same as those intended to ensure the legality and regularity of the transactions. In 2014, DG SANCO assessed the risk of fraud in the context of its risk management exercise. The fraud risks are addressed by specific controls designed and implemented to mitigate the risks. Activities and operations that are at a higher risk of fraud are subject to more in-depth monitoring and control such as an independent review of procurement procedures prior to the publication of the call for tender.

During the reporting year, DG SANCO did not have to transmit any suspicions of fraud to OLAF that implied effects on DG SANCO's budget. However, in 2014, OLAF has initiated three cases based on other sources of information which could have an impact on DG SANCO's activities and reputation; the investigations are on-going. In mid-2014, OLAF closed one case of the same nature from previous years without any findings; no follow-up action was addressed to DG SANCO. Throughout 2014, DG SANCO followed up on indicators related to fraud issues, introduced for the first time into the 2012 Management Plan (see table below). To conclude, no control weakness was observed that could have an impact on the assurance given for DG SANCO's activities in 2014.

Table 2.11 Indicators for fraud prevention and detection

Indicators for fraud prevention and detection	Targets	2014	2013
% of procurement and grant procedures subject to additional controls due to relatively high risks of fraud compared with other contracts	100%	80% (8 procedure out of 10)	25% (actual number of contract procedures: 4, but none finalised in 2013)
% of payments subject to close monitoring or additional controls due to relatively high risk of fraud	100%	91% (€1,3 million actually paid)	100% (€1,5 million actually paid)
Actions listed in the anti-fraud action plan (SEC(2011)787) and relevant to DG SANCO implemented on time	n/a	n/a (All actions implemented in 2013)	100% (2 actions finalised in 2013)
OLAF recommendations in investigation reports covered by appropriate follow-up and reporting	100%	n/a	100% 1 OLAF recommendation of 2013 closed in 2014

⁶⁵ COM(2011) 376 24.06.2011

2.2. Budget implementation tasks entrusted to other services and entities.

This section reports and assesses the elements that support the assurance on the achievement of the internal control objectives as regards the results of the DG's supervisory controls on the budget implementation tasks carried out by other Commission services and "entrusted entities" distinct from the Commission, such as EU agencies to which DG SANCO is parent.

As mentioned in "The DG In Brief", DG SANCO has entrusted parts of its budget for indirect management implementation by a number of cross-delegations and by the Executive Agency CHAF-EA. In addition, DG SANCO finances, partially or in full, the operating budgets of CHAF-EA and a number of EU agencies. In each case, DG SANCO's supervision arrangements are based on the principle of controlling 'with' the relevant entity. For details, see Annex 5.3 (internal control template).

Cross-delegations to other Authorising Officers by Delegation (AOD)

As in previous years, DG SANCO has cross-sub-delegated commitment and payment credits to six other DGs, mainly to support data collection in the area Public Health (ESTAT), for PMO reimbursements of experts and members of scientific committees for Consumer Affairs and Public Health policies as well as for IT tools in the policy areas Consumer Affairs and Food and Feed Safety (DG DIGIT).

Being Commission services themselves, the authorising officers in other DGs are required to implement the appropriations subject to the same rules, responsibilities and accountability arrangements as DG SANCO. The cross-delegation agreements signed with the DGs require the authorising officers to report on the use made of the delegated appropriations. In the reports sent to DG SANCO for 2014, the authorising officers did not communicate any events, control results or issues which could have a material impact on assurance.

Table 2.12 Cross-delegations to DGs

DG	2014 Appropriations	
	Commitments € million	Payments € million
ESTAT	1,1	0,2
PMO	-	0,5
DG DIGIT	-	0,2
DG JUST	-	0,1
DG MARKT	-	0,2
DG ENER	-	0,0
TOTAL	1,1	1,2

Consumers, Health and Food Executive Agency (CHAF-EA, former EAHC)

The Consumers, Health and Food Executive Agency (CHAF-EA, formerly the Executive Agency for Health and Consumers - EAHC) was created on 1 January 2005 with DG SANCO as the only parent DG. In 2014 the agency's mandate covered the implementation of the Public Health Programme, the Consumer Programme and the Better Training for Safer Food measures (BTSF)⁶⁶.

⁶⁶ Commission Implementing Decision No 2012/470/EU of 29.11.2012 amending Decision 2004/858/EC, as amended by Decision 2008/544/EC; OJ L 331/50, 1.12.2012

With effect from 1 January 2014, the agency's mandate was prolonged and its name changed to CHAF-EA⁶⁷.

The CHAF-EA receives a subsidy from the EU budget to cover its running costs (administrative or operating expenditure). The amount remained relatively stable over the past five years with slight adjustments for inflation. The use made of the subsidy is audited – inter alia – by the European Court of Auditors, which gave – since the beginning – a positive declaration of assurance to CHAF-EA.

Table 2.13 CHAF-EA – subsidies received

CHAF-EA (former EAHC)	2014 € million	2013 € million
Number of staff: 50		
Subsidy for administrative budget	7,3	7,2
Operational budget transferred from SANCO	76,7	74,8

DG SANCO follows up on the agency's consumption of both the administrative and the operational budget. To this end, DG SANCO carries out supporting and steering activities in relation to the agency, in particular through the quarterly meetings of the Steering Committee, which are chaired by DG SANCO's Deputy Director-General for Consumer Affairs and Public Health. The Steering Committee consists of five members, three of which are the DG SANCO Directors for Consumer Affairs and Public Health and Veterinary and International Affairs responsible for the programmes entrusted to the CHAF-EA, one external member and the chair person. The Steering Committee adopts the agency's annual work programme and draft administrative budget including the establishment plan. It is regularly informed through the agency's quarterly reports on the achievements of objectives, audit findings and relevant follow-up, as well as of any other important issue relating to internal control and financial management.

Furthermore, regular meetings at the level of the Units concerned in DG SANCO and CHAF-EA ensure the necessary co-ordination of activities. General guidelines for the day-to-day co-ordination between DG SANCO and the agency were adopted by the Steering Committee in February 2013; these are complemented by more specific guidelines for certain tasks transferred to the agency.

No serious control issue came to the attention of DG SANCO that would warrant a financial or reputational reservation in DG SANCO's 2014 Annual Activity Report. In the CHAF-EA's Annual Activity Report, the Director reported reasonable assurance on the delegated budget managed by him on behalf of DG SANCO (see the agency's 2014 Annual Activity Report).

EU Agencies

In 2014, DG SANCO was responsible for four EU agencies, of which three received an annual subsidy from the EU budget to finance their running costs (see the table in the next paragraph):

⁶⁷ Commission Implementing Decision No 2013/770/EU of 17 December 2013 establishing the Consumers, Health and Food Executive Agency and repealing Decision 2004/858/EC establishing the Executive Agency for Health and Consumer; Commission Decision C(2013)9505 of 20 December 2013 delegating powers to the Consumers, Health and Food Executive Agency with a view to performance of tasks linked to the implementation of Union programmes

- European Centre for Disease Prevention and Control (ECDC) located in Stockholm, Sweden⁶⁸.
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, notably risk assessments, operates the early warning and response system (*EWRS*) and provides scientific and technical assistance and training.
- European Food Safety Authority (EFSA) located in Parma, Italy⁶⁹.
EFSA provides independent scientific opinions and scientific and technical advice on food and feed safety.
- European Medicines Agency (EMA) located in London, UK⁷⁰.
EMA evaluates and supervise 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.
- Community Plant Variety Office (CPVO) located in Angers, France⁷¹.
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.

While the Director-General of DG SANCO is accountable for the legality and regularity of the payments of the subsidies to the agencies, accountability for the regularity and legality of this expenditure resides ultimately with the agencies themselves.

The use made of the EU funds by the agencies is checked – inter alia – by the European Court of Auditors, which gave all EU agencies to which DG SANCO is parent a positive declaration of assurance for the reliability of their 2013 accounts as well as for the legality and the regularity of the underlying transactions. The comments made by the Court on weaknesses in internal control systems did not affect DG SANCO's subsidy payments in 2014, and thus no reservation to DG SANCO's declaration is warranted.

Table 2.14 EU agencies – subsidies received

EU Agencies	N° of staff *		Total EU contribution	
	2014	2013	2014 € million	2013 € million
ECDC	299	303	60,5	58,3
EFSA	474	481	79,6	78,1
EMA ⁷²	754	751	34,3	40,3
CPVO ⁷³	47	48	n/a	n/a
Total	1.574	1.583	174,4	176,7

* Total number of human resources authorised under the 2013 budget

⁶⁸ 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

⁶⁹ 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

⁷⁰ 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)

⁷¹ 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

⁷² EMA's total 2014 budget amounted to EUR 282,5 million, mainly financed by fees. The EU contribution is a balancing grant.

⁷³ CPVO does not receive any EU subsidies; its 2014 budget amounted to EUR 14,7 million

DG SANCO, within the limits of its role on the EU agencies' Management Boards, follows up closely the improvements to be made by the agencies. The role of the Management Boards includes the approval of the agencies' draft annual budgets as well as the adoption of both the annual work programmes and the annual activity reports. They are regularly informed on the achievements of the agencies' objectives as well as on all other important issues relating to operational and financial management.

While three operational Units in DG SANCO are the primary interlocutors for the agencies, a horizontal Unit takes on a coordination role to promote a coherent approach towards all agencies and to exchange good practices. For example, each agency adopted its rules of “independence” and “conflict of interest”; DG SANCO actively monitored compliance with the Commission’s guidelines on independence in DG SANCO’s task force with the agencies and through bilateral contacts with the agencies. In addition to monitoring compliance, DG SANCO identifies and disseminates good practices in collaboration with the agencies.

No serious control issue came to the attention of DG SANCO that would have an impact on DG SANCO’s declaration of assurance (Table 2.15 below summarises the indicators of control effectiveness as regards legality and regularity). However, one issue is worth mentioning; it refers to European Medicines Agency (EMA):

In a ruling in November 2014, the EU Civil Service Tribunal annulled the appointment of EMA’s Executive Director following a legal action that had been filed by one of the non-selected applicants. The court found that the impartiality during the selection procedure was not fully guaranteed and therefore the preparation of the short-list was improper. The ruling revealed a problem inherent in the Commission’s rules of recruitment for Executive Directors of EU agencies; it did not point to an irregularity for which of DG SANCO would be responsible. Moreover, it was not based on any judgment of the qualities of the Executive Director. Continuity of operations in EMA was assured at all times by the Deputy Executive Director.

Table 2.15 Indicators of control effectiveness as regards legality and regularity

Indicators per type of “entrusted entity”	Targets	2014	2013
Cross delegations			
Reports of all AODs in other DGs received prior to finalisation of DG SANCO’s Annual Activity Report	100%	100%	100%
Issues raised by these AOSDs pertaining to the cross-delegated funds	0	0	0
Executive agency CHAF-EA			
Regular programme meetings between the agency and DG SANCO at operational level	yes	yes	yes
Steering Committee meetings with adequate quorum for voting (info: DG SANCO is the only parent DG)	4	4	4
Number of "exception reports" relative to the guidelines on the co-operation between DG SANCO and CHAF-EA	n/a	0	0
Budget execution rates of the operational budget transferred to the agency:			
commitments	99%	100%	100%
payments	100%	100%	100%
Director’s report on control results and error rates endorsed by Steering Committee prior to finalisation of DG SANCO’s Annual	yes	yes	yes

Indicators per type of “entrusted entity”	Targets	2014	2013
Activity Report			
Court of Auditors' assurance on the agency's accounts and implementation of the administrative budget of year N-1 without qualification	yes	yes	yes
Discharge granted for year N-1 and discharge recommendations implemented for year N-2	yes	yes	yes
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1 (€0,65 million/€7,27 million)	n/a	9,0%	7,7%
EU agencies			
Regular bilateral meetings between the agencies and DG SANCO at operational level	yes	yes	yes
Management Board meetings with DG SANCO's representation	4	4	4
Court of Auditors' assurance on EFSA's, EMA's and ECDC's accounts and implementation of their administrative budget of year N-1 without qualification	Yes 3 out of 3	yes 3 out of 3	yes 3 out of 3
Discharge granted for year N-1 and discharge recommendations implemented for year N-2	yes	yes	yes
Ratio of recovery of the positive budgetary outturn of year N to subsidy paid in year N-1 (€4,53 million/€172,17 million)	n/a	2,6%	2,5%

The table below shows DG SANCO's monitoring costs in respect to the subsidies paid to finance the running costs of the agencies. DG SANCO's annual costs encompass DG SANCO's staff carrying out the monitoring tasks through the different stages of the control processes as defined in Annex 5.2. The costs are calculated without including an overhead rate.

Table 2.16 Indicators of “control efficiency” – resources employed

DG SANCO's cost of monitoring the agencies in relation to the subsidies paid (average FTE times standard annual costs) ⁷⁴		2014 (€million)	2013 (€million)
Cost of staff in the central Unit ensuring co-ordination within DG SANCO and with the agencies	Number FTE 0,7	0,1	0,1
Cost of operational staff involved in monitoring the operations of the agencies	Number FTE 5,1	0,7	0,7
Cost of staff involved in budgetary, financial, audit matters and evaluation of the agencies	Number FTE 0,8	0,1	0,1
Total annual cost (without overhead rate)		0,9	0,9
Subsidies paid to the agencies		181,7	183,9
Total cost as % of total annual budget spent through procurement (commitment appropriations)		0,5%	0,5%

Overall, the costs of monitoring and supervision represent 0,5% of the total subsidy payments to the agencies' administrative budget. It is worth noting that none of the EU agencies to which DG SANCO is parent are carrying out budget implementation tasks on behalf of the Commission that would require an in-depth monitoring.

⁷⁴ FTE = full time equivalent; standard annual costs: EUR 132.000 for officials and EUR 70.000 for contractual staff

For the costs of control, no targets are defined in monetary terms, as in 2014 the available information is insufficient to analyse the evolution over time and/or to compare the figures with Commission benchmarks. As most of the controls are directive and preventive in nature, the overall control benefit is non-quantifiable. However, each agency undergoes an external evaluation on a regular basis.

Evaluation of the executive agency CHAF-EA

The latest cost-benefit analysis⁷⁵ on the CHAF-EA was carried out in 2013 and concluded that entrusting the executive agency with programme implementation tasks related to the Consumer Programme, the Public Health Programme and the food safety training measures would entail significant qualitative and quantitative benefits compared with the in-house scenario under which all aspects of the programmes would be managed internally within DG SANCO. The latest external evaluation of early 2011⁷⁶ showed that since its establishment the executive agency has had a positive impact in terms of service delivery and monetary costs compared with previous and alternative programme management options.

Evaluation of the EU agencies

No evaluation report has been finalised in 2013 or 2014.

Conclusion on “entrusted entities”

For the 2014 reporting year, the cross-delegated AODs and the executive agency CHAF-EA have themselves reported reasonable assurance on the delegated budget managed by them on DG SANCO’s behalf. They have signalled no serious control issues. In terms of economies of the transfer of budget management to the CHAF-EA, the latest cost-benefit-study of 2013 showed that entrusting the agency with budget implementation tasks entails significant qualitative and quantitative benefits compared with the in-house scenario under which all aspects of the programmes would be managed internally within DG SANCO. Since then, no organisational changes were made and no issues came to the attention of DG SANCO that would have an impact on this conclusion.

For all three EU agencies (EFSA, EMA and ECDC) for which DG SANCO was parent in 2014, the Court of Auditors gave a positive declaration of assurance for the year 2013. CPVO is not concerned as it does not receive any EU financial support. The comments made by the Court do not call into question DG SANCO’s reasonable assurance on the operating budget managed by the EU agencies.

From own monitoring and supervision work as a parent DG, nothing came to the attention of DG SANCO that would indicate that the reporting from the Agencies would not be reliable.

⁷⁵ Cost Benefit Analysis for the delegation of certain tasks regarding the implementation of Union Programmes 2014-2020 to the Executive Agencies (Final Report 19 August 2013); Article 3(1) of Regulation (EC) No 58/2003

⁷⁶ Every three years the performance of the agency is evaluated and the report to be sent to the European Parliament, to the Council and to the Court of Auditors (Regulation (EC) No 58/2003)

Consequently, in view of DG SANCO's residual responsibility for the management of the parts of the budget cross-delegated to authorising officers in other DGs and transferred to the executive agency, CHAF-EA, as well as for the funds paid to the operating budgets of the agencies, DG SANCO concludes that there are no control weaknesses affecting the assurance building in terms of the control objectives.

2.3. Assessment of audit results and follow-up of audit recommendations

This section reports and assesses the observations and conclusions reported by auditors which could have a material impact on the achievement of the internal control objectives, and therefore on assurance, together with any management measures taken in response to the audit recommendations.

2.3.1. DG SANCO's Internal Audit Capability (IAC)

Since several years, DG SANCO manages an internal Audit Committee chaired by the Director-General. It is attended by both Deputy Directors General, by the General Affairs (Resource) Director as well as by the Heads of Units "Audit and Evaluation" and "Budget, Finance and Controls". Directors attend for subjects falling under their responsibility.

The Committee met four times in 2014 to monitor on-going audit work especially of DG SANCO's Internal Audit Capability (IAC). In addition, it is regularly informed about DG SANCO's on-the-spot control programme, the audit activity of the Commission's Internal Audit Service (IAS) and of the Court of Auditors. It also approves IAC audit reports, the relevant action plans to implement audit recommendations and monitors the audit follow-up process.

Following a Commission decision on 5 November 2014 to centralise the Commission's internal audit function in the IAS, the IAC transferred all on-going audit work to the audit colleagues in the IAS with effect from 1 March 2015. DG SANTE's Management will work with DG IAS in a constant dialogue to ensure adequate audit coverage in the IAS three-year audit plan and in continuation of the good co-operation during IAS audits.

Audits of 2014

In 2014, DG SANCO's Internal Audit Capability (IAC) finalised six audit reports. They resulted in 14 very important recommendations while no critical recommendation was issued.

(1) Audit on Internal Control Standards 5, 6, 7 and 8 in DG SANCO

In 2014, the IAC finalised the 2013 audit on DG SANCO's implementation of four Internal Control Standards: ICS 5 "Objectives and Performance Indicators", ICS 6 "Risk Management Process", ICS 7 "Operational Structure" and ICS 8 "Processes and Procedures". The final audit report was issued in April 2014 together with the action plan. It was discussed with Commissioner Borg on 24 June 2014.

The auditor made two “very important” recommendations, firstly, to enhance certain aspects of DG SANCO’s risk management process and secondly, to update the assessment of sensitive posts and functions. In addition, the IAC issued five recommendations rated “important”. The action plan was adopted by the Audit Committee on 26 March 2014 and most of the actions were implemented in 2014: (i) DG SANCO improved its annual risk assessment by having introduced dedicated meetings on risks at Directorate level prior to the discussions in the Management Team; (ii) DG SANCO launched a screening exercise of staff jobs to identify – inter alia – possible sensitive posts; the results are a valuable input to the wider exercise of ‘Shaping SANCO for the future’; (iii) each policy Directorate launched an initiative to review the formulation of objectives and performance indicators per policy area in dedicated meetings and workshops; the exercise will be continued in 2015.

(2) Audit on the Business Continuity in DG SANCO (Internal Control Standard 10)

The preliminary analysis started already in 2012 with a review of a crisis management exercise. The audit fieldwork continued until September 2014. The final audit report was adopted by the Audit Committee on 12 December 2014. A discussion with Commissioner Andriukaitis took place on 24 February 2015.

The audit scope encompassed both the continuity in the daily business operations and the business continuity during crisis. One very important recommendation was made to update the Business Continuity Plan based on the outcome of a new Business Impact Analysis subsequent to the changes in role and responsibilities of the DG and the adoption of a new organisation chart by the College. Due to the recent finalisation of the audit, DG SANTE's management adopted the action plan in February 2015 with implementation targets by the end of 2015.

(3) Audit on Access to Documents in DG SANCO (Internal Control Standard 11)

The audit started in September 2014 and the final audit report was adopted by the Audit Committee on 12 December 2014. A discussion with Commissioner Andriukaitis took place on 24 February 2015.

The main audit objective was to assess whether DG SANCO has appropriate processes and procedures in place to ensure compliance with the legal provisions defined in Regulation 1049/2001 and the internal guidelines of the Commission. Moreover, the audit assessed the effectiveness of the process in DG SANCO. While the audit pointed to several important strengths, one outstanding issue led to a recommendation rated very important: it is linked to the poor physical state of the intermediate archives where continuous water leakages have already damaged documents and are threatening to do more harm. Due to the recent finalisation of the audit, DG SANTE's management adopted the action plan in February 2015 with implementation targets by the end of 2015.

(4) Audit on the Costing Practices in Procurement in Selected Funding Areas of DG SANCO

The audit fieldwork started in late 2013 and the final audit report was issued 5 August 2014. A discussion with Commissioner Andriukaitis took place on 24 February 2015.

The auditor made four “very important” recommendations to improve DG SANCO’s costing practices in procurement by drafting a guidance document to ensure a harmonised approach towards costing in the DG, by training staff involved in procurement, and by trying to increase price competition. In addition, the audit points to potential specific risks related to Pilot Projects and Preparatory Actions that should be mitigated.

The action plan was adopted by the Audit Committee on 5 December 2014 and its implementation is well advanced thanks to the centralisation of the administrative management of public procurement procedures which became operational in May 2014. Full implementation of all actions is foreseen by mid-2015.

(5) Audit on the Operations of Directorate F, the Food and Veterinary Office, in DG SANCO

The audit started in March 2014. The draft audit report was presented at the Audit Committee on 2 July and adopted by written procedure on 24 July 2014. A discussion with Commissioner Andriukaitis took place on 24 February 2015.

Two recommendations rated “very important” were made to improve certain aspects related to DG SANCO’s Food Veterinary Office (FVO): (i) in addition to the broadly set objectives at Directorate level specific objectives and performance indicators should be identified at Unit level; accordingly, risks not to achieve the objectives should be assessed at Unit level; (ii) work on the long-term strategy for the FVO with corresponding objectives and indicators should continue, specifically for the new areas of tasks to be undertaken by the FVO.

The action plan was adopted by the Audit Committee on 12 December 2014. The recommendation on specific objectives and risk assessment was implemented in late 2014/early 2015. The long-term strategy on the further development of the FVO will be finalised in the course of 2015.

(6) Audit on the External Stakeholder Consultations in DG SANCO

In September 2013, the IAC started an operational audit on external stakeholder consultations and issued its final report on 15 April 2014. It was discussed with Commissioner Borg in a meeting on 24 June 2014.

The auditors made four “very important” observations for which adequate actions were proposed by the auditee such as to (i) develop a termed improvement strategy for stakeholder consultations; (ii) improve its horizontal

coordination for online stakeholder consultations; (iii) foster its Personal Data Protection arrangements when carrying out online consultations; and (iv) harmonise the rules for holding meetings with stakeholders outside official channels. The implementation of the action plan is on-going and is expected to be finalised in the course of 2015.

On-going audit work to be finalised by end of February 2015

At the end of 2014, one audit was still on-going: Audit on the Operational and Financial Aspects of Funds Management in DG SANCO Veterinary Programmes. The draft audit report was issued on 16 February 2015 and adopted at the Management Team meeting on 2 March 2015.

DG SANCO's follow-up of IAC audit recommendations in 2014

The audit follow-up on open recommendations for Spring 2014 included five audits and a total of 24 open recommendations. All Units concerned provided information on the progress made to implement the open recommendations. Upon reviewing the input received at the desk and interviewing key persons as deemed necessary, the IAC concluded that 17 recommendations (71%) could be closed. Among the remaining seven open recommendations, two were rated very important. Neither of the two is due for more than half a year against the initial implementation date. The responsible Units continue to implement their planned actions with targeted deadlines.

The Internal Audit Capability in DG SANCO followed up on the remaining open recommendations until the end of its mandate. In total, 33 open recommendations were reviewed. The IAC concluded that 11 recommendations were implemented and could be closed (34%) while 12 (36%), although not yet fully implemented, could be transferred to management for a further risk assessment. Of the recommendations rated "very important", 10 remained open (30%) and will be suggested to the IAS for follow-up in accordance with the transfer of the internal audit function to the IAS from March 2015.

2.3.2. Internal Audit Services of the Commission (IAS)

Audits of 2014

(1) Audit on the management and supervision of outsourced IT Services

The IAS performed this audit in 2014 as a multi-DG, horizontal audit. The final audit report of 18 December 2014 includes an annex dedicated to DG SANCO with one recommendation rated "very important". It refers to the quality of tender documentation for DG SANCO's own framework contract for IT services. DG SANCO will implement the recommendation in the course of 2015 through its centralised administrative management of public procurement procedures which became effective in May 2014. It foresees – inter alia – the drafting of one single and comprehensive guidance document that will consolidate existing instructions and add new elements to improve the quality of tender documentation as suggested by the IAS and by DG SANTE's Internal Audit Capability in the audit on the Costing Practices in Procurement (see part 2.3.1

above).

- (2) Audit on the efficiency and effectiveness of the planning stage of the selection process

In the first half of 2014, the IAS finalised its multi-DG, horizontal audit on the selection process for new staff. The audit report was issued on 13 June 2014 and includes an annex dedicated to DG SANCO. No formal recommendation was addressed to DG SANCO.

- (3) Audit on the DG's anti-fraud strategies

The IAS started an audit on the adequacy and effective implementation of the anti-fraud strategies of Directorates General. It was a multi-DG, horizontal audit for which DG SANCO was selected as one of five operational DGs.

The audit is still on-going. On 2 February 2015, the IAS discussed its first audit results with DG SANTE. No issue has been raised that would have an impact on DG SANCO's declaration of assurance for 2014.

DG SANCO's follow-up on IAS audit recommendations

Follow-up work is organised through the Governance Risk and Control (GRC) IT tool managed by the IAS. At the end of 2014, DG SANCO implemented all open actions without undue delays; the IAS closed all open audits accordingly.

2.3.3. European Court of Auditors

Audits of 2014

- (1) 2013 DAS – compliance audit

In 2014, the Court finalised its annual report (2013 DAS) on the implementation of the budget. DG SANCO is part of the chapter 4 "Rural Development, Environment Fisheries and Health. The Court shows an average error rate of 6,7% for these policy areas. It is worth noting that the Court did not find any quantifiable error in DG SANCO's transactions of 2012 and 2013, be it for public procurement, eradication or emergency funds, or in any of DG SANCO's policy areas.

- (2) 2013 DAS – performance audit

In the framework of chapter 10 "Getting results from the EU budget" the Court audited 2013 Annual Activity Reports of several Directorates General. DG SANCO was included in the audit sample. The Court found that DG SANCO's objectives and indicators were very broad and not sufficiently specific. In May/June 2014, DG SANCO launched an initiative to improve the formulation of its specific objectives and performance indicators on the basis of the Multi Financial Frameworks (2014 to 2020) of the three policy areas. While the exercise is on-going in 2015, first results already fed into the drafting of the Management Plan for 2015.

(3) Special audits

In 2014, the Court did not publish a special report on a performance audit.

During an on-going performance audit on the animal disease eradication and monitoring programmes, no critical issue has been raised so far for DG SANCO.

In November 2014, the Court decided to close its 2013 performance audit on the EU approach to beekeeping without issuing an audit report. In a letter to the Commissioner the Court summarised the audit work finalised and highlighted a few points that are important to DG SANCO and will be born in mind when considering future activities in the field of beekeeping and bee health.

DG SANCO's follow-up on Court's audit recommendations

The follow-up of the Court's recommendations as well as recommendations made by the discharge authorities is organised through the RAD-database managed by DG BUDG.

For DG SANCO, four recommendations from previous years were open at the beginning of 2014 with deadlines in late 2014. All actions referred to the special report on the implementation of EU hygiene legislation in slaughterhouses in new Member States and were closed without delay as follows:

(1) Special Report on the implementation of EU hygiene legislation in slaughterhouses in new Member States (report published in October 2012, SR 14/2012)

The Court recommended that the Commission improves the supervision, guidance and training of hygiene implementation of newly acceding Member States. DG SANCO implemented all open actions within the set deadlines by the end of 2014 relating mainly to the following areas:

- In the context of auditing Member States' food and feed controls, the Food Veterinary Office of DG SANCO (FVO) reviews and updates its planning process on a regular basis to ensure that priorities for official control activities are set based on the latest information and taking into account factors such as risk, trade, policy and legislation;
- Better Training for Safer Food (BTSF) initiative: on the basis of the results from the most recent overall evaluation of the BTSF initiative of mid-2013, several actions were taken to achieve an even greater impact with the training programmes, for example, by (i) expanding the reach of the programme through a mixed model of learning and ensuring that training is also targeted at staff who occupy senior management or specific training positions; (ii) releasing the first five e-learning modules on five different technical themes; (iii) launching ad-hoc training activities addressing Member State specific weaknesses; (iv) improving dissemination at Member State level.

(2) Special Report on the management of conflict of interest in regulatory agencies (report published in October 2012, SR 15/2012)

In its audit, the Court evaluated the policies and procedures for the management

of conflict of interest situations in EU agencies. The Court identified a number of shortcomings of varying degrees in agency-specific policies and procedures as well as their implementation.

Since mid-2012 and throughout 2013 and 2014, DG SANCO followed up on the audit recommendations in full co-operating with the Secretariat General, other DGs and the agencies for which it is parent (namely ECDC, EFSA, EMA, and CPVO). All actions relate to the implementation of the Common Approach and its "roadmap" sent to the Council in December 2012.

Conclusion on audit results and follow-up

Based on the results of its audit and follow-up work as described in the objectives and scope of the engagements carried out in 2014, DG SANCO's Internal Audit Capability (IAC) issued a satisfactory audit opinion on 13 February 2015 stating that the internal control system in place in DG SANCO provides reasonable assurance⁷⁷ regarding the achievement of the business objectives set up for the processes audited, except for the very important audit recommendations as described above. All recommendations were accepted, and adequate actions are on-going.

All IAS audits carried out in 2014 concluded that the internal control system in place provides reasonable assurance regarding the achievement of the business objectives except for the very important recommendation on tender documentation mentioned above. None of the issues raised by the auditors met the materiality criteria set out in Annex 4: no critical recommendation was made; no significant repetitive error or material deficiency in the internal control systems of DG SANCO was highlighted. The weaknesses pointed out by auditors in the quality of tender documentation addressed mainly form issues rather than substance; no significant quantifiable errors were reported, neither were elements identified that could seriously damage the reputation of DG SANCO. Therefore, the identified weaknesses are not likely to have a bearing on the content of the annual declaration of the Director-General of DG SANCO.

DG SANCO's implementation of audit recommendations is assessed overall as positive: auditors find DG SANCO's actions appropriate and do not report any improper delays. This contributes to the assurance that a reservation to the declaration is not warranted.

⁷⁷ Even an effective internal control system, no matter how well designed and operated, has inherent limitations – including the possibility of the circumvention or overriding of controls – and therefore can provide only reasonable assurance to management regarding the achievement of the business objectives and not absolute assurance

3. ASSESSMENT OF THE EFFECTIVENESS OF THE INTERNAL CONTROL SYSTEMS

The Commission has adopted a set of internal control standards, based on international good practice, aimed to ensure the achievement of policy and operational objectives. In addition, as regards financial management, compliance with these standards is a compulsory requirement.

DG SANCO has put in place the organisational structure and the internal control systems suited to the achievement of the policy and control objectives, in accordance with the standards and having due regard to the risks associated with the environment in which it operates.

Changes in DG SANCO's control environment

✓ Handover from the previous Director-General

The previous Director-General left DG SANCO on 31 October 2014 after for four and a half years as authorising officer by delegation. She handed over all tasks and responsibilities to one of DG SANCO's Deputy Directors General who became acting Director-General on 1 November 2014. He also ensured continuity of operations as Deputy Director-General for the policy area Food and Feed Safety.

In the handover note, the outgoing Director-General provided reasonable assurance that the resources assigned to the activities of the DG have been used for their intended purpose, in accordance with the principles of sound financial management, and under the control procedures put in place to offer the necessary guarantees concerning the legality and regularity of the underlying transactions.

✓ Staff reduction

The 2014 establishment plan was reduced by 16 permanent posts, 8 posts for the annual 1%-staff cut and 8 posts for the 1%-internal redeployment tax. Although significant, the required number of posts was returned as planned (8 posts in 2012, 16 in 2013 and 16 in 2014) and most of the 14 posts to be returned in 2015 were already identified.

The reduction did not require any major changes to DG SANCO's organisation chart in 2014 due to the systematic work started in previous years of optimising DG SANCO working methods and processes. In particular two specific horizontal processes launched in 2013 were continued in 2014 to help the DG adapt to reduced resources without disrupting activity and policy delivery: the "Making DG SANCO a Leaner Organisation", and the "Simplification Group" on financial issues. Examples of what has been achieved in 2014 are given below under the standard "processes and procedures".

Annual assessment of internal control by management

In its internal control system, DG SANCO embedded monitoring measures to ensure that its management and internal control framework is effective. DG SANCO has also considered the risks and focuses its control resources on those areas where risks are the highest, while ensuring adequate control coverage over all activities.

The annual assessment on the implementation of the Internal Control Standards started in late 2014 and finished in the first quarter 2015 with the adoption of a summary note by the Management Team on 23 March 2015. The assessment was organised by the internal control officer who collected information through the following three main sources:

- (a) Desk review of documents produced by DG SANCO to implement the Commission's requirements, action plans stemming from management's risk assessment and the anti-fraud strategy; analysis of the use made of "exception reporting";
- (b) Analysis of the management reports received from the authorising officers by sub-delegation as well as the audit opinion of DG SANCO's Internal Audit Capability, and the audit observations of the IAS and the Court of Auditors;
- (c) Interviews with key staff supporting the set up and functioning of internal controls.

Throughout the year, the functioning of the internal control systems was closely monitored by the systematic registration of so-called "exceptions" and internal control weaknesses. The underlying causes behind these exceptions and weaknesses were analysed and discussed in the Management Committee "Policy, Legislation and Budget" on 25 February 2015; although some issues were recurrent, management assessed that overall, the existing controls are sufficient and that the procedures in place function well. In the meeting, the importance of exception reporting was underlined to ensure that all instances that constitute an exception are covered by an appropriate report.

All authorising officers by sub-delegation prepared their annual reports on budget implementation to the Director-General. No particular risks were identified, except for the following: in the policy area Food and Feed Safety, DG SANCO encountered one case of suspicions of irregularities in the Member States' programme implementation by a sub-contractor; immediate remedial action was taken with the effect that EU funds were not put at risk.

Prioritisation of Internal Control Standards

With a view to focusing its control resources on those areas where risks are assessed as highest, DG SANCO prioritises in each annual Management Plan one or more areas of internal control which are most relevant as regards their effective functioning while maintaining adequate control coverage over all DG SANCO's activities.

In 2014, DG SANCO deemed it necessary to enhance the effectiveness of the following three control areas: "Ethics" (ICS 2), "Objectives and Performance Indicators" (ICS 5) and "Processes and Procedures" (ICS 8). The standards were given priority mainly due to the new emphasis on anti-fraud measures, performance measurement of spending programmes, and continuous need for economy measures which warrant a special effort to simplify procedures, realise efficiency gains, reduce administrative burden and keep an eye on the cost of controls.

None of the issues call into question management's reasonable assurance regarding the adequate implementation of the standards.

✓ **Ethics and organisational values**

- Many new actions were launched in 2013 and continued in 2014 to raise awareness related to fraud prevention and a variety of other ethics issues, for example, DG SANCO's knowledge hour and specific guidelines on the subject "transparent and proud of it" covering a wide range of topics such as declarations of conflicts of interest, contacts with lobbyists, outside activities; new communication and clarifications on the procedure for "Whistleblowing" and protection of sensitive information. In addition, DG SANCO repeated its interactive training course on "dealing appropriately and effectively with lobbyists" on 28 March 2014, answering to the high demand of staff.

In October 2014, a dedicated interactive training session "DG SANCO - Ethics in practice" was organised. During this session, investigator colleagues from IDOC (Investigation and Disciplinary Office) presented case studies where participants could test their knowledge directly with the help of voting devices to clarify some of the more common ethical dilemmas we face in our work. The presentation is now available for all staff on DG SANCO's intranet.

As all these training and information activities have been very successful, they will be repeated in 2015. Given the good progress made in the last three years, the standard on ethics is no longer prioritised in 2015.

- Given the new Staff Regulations, DG SANCO implemented the new requirements on conflict of interest declarations (in case of reintegration after leave on personal grounds or upon first recruitment). The new electronic declaration form, available since March 2014 in Sysper, simplified the procedure related to the declaration of gainful employment of the spouse with a view to avoiding any possible conflict of interest arising. DG SANCO staff members are regularly reminded about this obligation and the deadline to introduce their declarations. By mid-July (official deadline) more than 200 colleagues fulfilled this requirement and submitted the electronic declaration.

In November 2014, another new ethics module covering the "ad hoc" declarations of conflict of interest was also introduced in Sysper. The "ad hoc" declaration concerns staff in active service who might find themselves

in a situation in which they have a personal interest that has the potential to directly or indirectly compromise their independence and, by extension, the Commission's interests. Staff in such a situation, or if in doubt as to whether the circumstances could lead to a conflict of interest, should notify the Appointing Authority by filling the "ad hoc" declaration in Sysper.

✓ **Objectives and performance indicators**

In May/June 2014, DG SANCO launched an initiative to review the formulation of objectives and performance indicators per policy area in dedicated meetings and workshops. While those policy objectives that will be achieved through the implementation of the budget are defined in the legal base, for example, of the multi-annual Programmes (2014-2020), the short-term aim was to reflect within Directorates on performance indicators, either to improve existing ones or to complement them. While the exercise is on-going in 2015, first results already fed into the drafting of the Management Plan for 2015. The standard remains a priority also in 2015.

✓ **Processes and procedures**

The standard was given priority in 2013 and 2014 mainly to increase the efficiency of processes and procedures. Thanks to several initiatives, good progress has been made and several actions will be continued beyond 2015. Therefore, it is no longer deemed necessary to prioritise the standard in 2015.

- In early 2014 DG SANCO started the **“transparency project”** to enhance the handling of the ever-increasing number, and complexity, of requests for **access to documents**. The main objectives are to better manage the associated risks and reduce the administrative burden for DG SANCO.

The step-by-step plan of the “transparency project” was endorsed by the Management Team in February 2014. Upon analysing the information received from all Units concerned, DG SANCO started to identify best practices and develop an action plan which should cover DG SANCO’s internal procedures and practices related to information management. The project will continue in 2015 and should bring major savings in the treatment of the many requests for information and access to documents.

- To **streamline the legislative process**, the Management Team adopted a new procedure setting out the practical arrangements to ensure an effective interaction between DG SANCO’s line services and the Legal Affairs Unit A2 on legal issues, including the formal consultations with the Commission’s Legal Service. As DG SANCO is a major legislative DG, ensuring that an efficient and effective legislative process is in place, contributes not only to better legislation but also to resource efficiency gains.
- To improve **financial management**, several actions were taken in 2014: (i) further to the introduction of electronic work flows for payments to IT contracts in 2013, important steps were taken to apply the electronic work flow also to other kinds of payments, for example, by harmonising the

electronic checklists; (ii) in mid-2014, a new interactive tool became operational to facilitate the reporting on budget implementation. With the tool, financial reports are assembled very quickly and available on a daily basis; they are much more user-friendly and easier to read than before. (iii) to facilitate the sharing of information on the implementation of spending programmes, DG SANCO created a platform in SharePoint in which standardised follow-up tables are regularly updated.

- DG SANCO centralised its administrative management of **public procurement** procedures. The new approach became fully operational in May 2014 when the new procedures were phased in and specific guidance and first training sessions given to all staff concerned. A comprehensive guidance document is under development and will be finalised by the end of 2015. The centralisation has improved the quality of tender documents and freed resources in the policy Units. The preparatory work in 2014 paved the way for further harmonisation and efficiency gains as well as positive effects on planning and timeliness of procurement procedures.

Risk management in 2014

Risk management in DG SANCO facilitates the establishment of specific internal control strategies focussing on the activities and domains representing the highest risks. To be effective, risk management is fully integrated into DG SANCO's planning and control cycle. Since 2010, this is achieved by including the identification of risks and mitigating actions into the harmonized template for Unit Management Plans (UMPs).

On the basis of a recommendation made by DG SANCO's Internal Audit Capability in early 2014 (see part 2.3.1 above), the risk assessment exercise for the 2015 Management Plan was strengthened: in November 2014, the internal control officer organised meetings with all Units per Directorate in which the concept of risk management was explained to colleagues in a customise way; this stimulated discussions on all kinds of risks the Units are facing in their policy area. Further to the input received from all Units, a risk assessment exercise at the level of the Management Team was prepared to identify DG SANCO's critical risks to be reported in the 2015 Management Plan. These are reported to the Commissioner together with action plans to reduce them to an acceptable level.

With a view to monitoring the implementation of the action plans, each year in August/September a progress report is prepared and communicated to the Commissioner in the context of the mid-term report. The 2014 report was discussed with the Commissioner in a meeting on 16 September 2014.

In 2014, no major events impacting the Acting Director-General's declaration of assurance occurred.

However, one issue is worth mentioning; it refers to the Ebola crisis:

In light of the current qualification by WHO of the Ebola outbreak as a PHE IC (Public health event of international concern in the sense of the International

Health Regulation) the need to accelerate the development of Ebola vaccines and treatments is recognised. In order to enable vaccines access as swiftly as possible, it is expected that special considerations that would go beyond the traditional approach to product development, clinical trial design, assessment and approval, will become necessary. This could entail serious safety and efficacy issues of a vaccine or a treatment for Ebola. Apart from a serious reputational risk, the situation could entail a critical risk for public health.

This risk could also occur in any other disease areas or outbreak situation where in light of various considerations and external pressure accelerated authorisation on the basis of very limited data could be expected from the Commission.

Shaping SANCO for the future

Recent reports of the IAS confirmed that DGs/Services should have sufficient and relevant information available about their management priorities and tasks, staff workload as well as required skills and competencies. This requires an effective HR planning (based on both a quantitative and qualitative analysis of the human resources) and a regular HR monitoring and reporting system. Despite full compliance with the standard on staff allocation, DG SANCO gave it priority in 2015 to highlight the need for continuous improvement by concrete actions.

- Establishing and maintaining the best possible match between the individual staff member and the tasks to be carried out is crucial in seeking efficiency and effectiveness. To this end, the Management Team decided in May 2014 to launch a staff-job analysis exercise limited to permanent officials in non-management jobs.

The first phase of the exercise launched in the summer of 2014, aimed to collect information from Heads of Unit on aspects of job sensitivity, seniority in the job of the jobholder, type of job profile (specialists versus generalists) and jobholder mobility needs. Due to the reorganisation of DGs at the end of 2014 this exercise was put temporarily on hold and will be continued in 2015 aiming at providing useful input into the design process of the new DG SANTE structure and finally into DG SANTE's multi-annual HR strategy.

As regards Management mobility the work to be carried out in the beginning of 2015 to ensure DG SANTE's organisational structure reflects the new Commission priorities and allows the DG to adapt to the new working methods of the Commission will also provide opportunities to ensure all management mandatory mobility requirements are respected.

- Effective Performance Management ensuring that the best is brought out of staff is more and more important in times of reduced resources. Therefore DG SANCO dedicated its December Human Resources Management Committee to engage in a discussion on this important issue. Two practical guides were presented to provide step by step assistance in dealing with the following challenges "*Stress-free Performance Appraisal*" and "*Effectively tackling unsatisfactory performance*".

Conclusion on the effectiveness of the internal control systems

In conclusion, management has reasonable assurance⁷⁸ that, generally, DG SANCO has suitable controls in place that are working as intended to manage key risks effectively. Identifying control weaknesses and putting in place improvements and reinforcements is an on-going effort in line with the principle of continuous improvement of management procedures.

No instances of ineffective controls came to management's attention that would have exposed the DG to serious risks. The weaknesses pointed out by auditors do not call the overall control effectiveness into question; they will be addressed by appropriate actions in the coming months.

4. MANAGEMENT ASSURANCE

This section reviews the assessment of the elements reported in Parts 2 and 3 and draw conclusions supporting of the declaration of assurance and namely, whether it should be qualified with reservations.

4.1. Review of the elements supporting assurance

The information reported in Parts 2 and 3 stems from the results of management and feedback received in audit reports of 2014. These reports result from a systematic analysis of the evidence available. This approach provides sufficient guarantees as to the completeness and reliability of the information reported and results in a complete coverage of the budget delegated to the Director-General of DG SANCO.

Concerning the overall state of the internal control system, management has reasonable assurance⁷⁹ that, generally, DG SANCO has suitable controls in place that are working as intended, risks are being mitigated and/or monitored and improvements and reinforcements are being made. No systematic weakness came to the attention of management that would have an impact on the declaration of assurance; neither were elements identified that could seriously damage the reputation of DG SANCO. This conclusion was corroborated by the audit opinion of DG SANCO's Internal Audit Capability and by the audit reports received from the Internal Audit Service of the Commission and the European Court of Auditors.

Given the results of its on-the-spot controls, with a residual error rate of 0,8% in the ABB activity Food and Feed, DG SANCO decided to lift last year's reservation taking into consideration that appropriate actions have been taken in the past few years. The cumulative effect of all these measures has continuously reduced the error rate to an acceptable level, i.e. below the materiality threshold of 2%.

⁷⁸ Even an effective internal control system, no matter how well designed and operated, has inherent limitations – including the possibility of the circumvention or overriding of controls – and therefore can provide only reasonable assurance to management regarding the achievement of the business objectives and not absolute assurance

⁷⁹ Even an effective internal control system, no matter how well designed and operated, has inherent limitations – including the possibility of the circumvention or overriding of controls – and therefore can provide only reasonable assurance to management regarding the achievement of the business objectives and not absolute assurance

4.2. Reservations and overall conclusion on assurance (if applicable)

The results of internal control reviews, risk management, ex-ante and ex-post on-the-spot controls, second level verification and follow-up on audit reports as described above indicate that DG SANCO's system of internal control has functioned effectively, as intended, in 2014 and has in general not identified material weaknesses.

In particular, DG SANCO's best estimate of the risks relating to the legality and regularity of the expenditure authorised during the reporting year is between 0,4 and 0,7%. This is the weighted average detected error rate which implies an amount at risk between EUR 1,6 and 2,8 million. The implementation of corrective measures following ex-post controls since 2009 have resulted in recovery orders and financial corrections of an annual average amount of EUR 2,3 million or 0,5% of the average annual payments made over the same period (EUR 455,2 million). This implies for 2014 an amount of EUR 2,2 million. This figure provides the best available indication of the corrective capacity of the ex-post control systems implemented by the DG.

Taking into account the conclusions of the review of the elements supporting assurance and the expected corrective capacity of the ex-post controls to be implemented in subsequent years, DG SANCO assesses that it has an effective, efficient, robust and reliable internal control system at its disposal. None of the issues raised by internal and external auditors met the qualitative materiality criteria: no critical recommendation was made; no significant repetitive error or material deficiency in the internal control systems of DG SANCO was highlighted; neither were elements identified that could seriously damage the reputation of DG SANCO. Therefore, the identified weaknesses are not likely to have a bearing on the content of the annual declaration of the Acting Director-General of DG SANCO and thus, it is possible to conclude that the internal control system provides sufficient assurance with regards to the achievement of the other internal control objectives and no reservation to the declaration is warranted.

DECLARATION OF ASSURANCE

I, the undersigned,

Acting Director-General for Health and Consumers

In my capacity as authorising officer by delegation

Declare that the information contained in this report gives a true and fair view⁸⁰.

State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the results of the self-assessment, ex-post controls, the work of the internal audit capability, the observations of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for years prior to the year of this declaration.

Confirm that I am not aware of anything not reported here which could harm the interests of the institution.

Brussels, 30 March 2015

(signed in Ares)

Ladislav Miko
Authorising Officer by Delegation

⁸⁰ True and fair in this context means a reliable, complete and correct view on the state of affairs in the service

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 Commission¹, I have reported my advice and recommendations to the Director-General/Head of Service on the overall state of internal control in the DG/service.

I hereby certify that the information provided in Parts 2 and 3 of the present AAR and in its annexes is, to the best of my knowledge, accurate and exhaustive.”

Signed in Ares

Matthew Hudson

Brussels, 27 March 2015

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

ANNEX 2: Human and Financial resources

DG SANCO Human Resources by ABB activity – 2014 *				
Code ABB Activity	ABB Activity	Establishment Plan posts	External Personnel	Total
17 02	Consumer policy	77	23	100
17 03	Public health	182	48	230
17 04	Food and feed safety, animal health, animal welfare and plant health	399	56	455
17 AWBL-01	Administrative support for 'Health and consumer protection' Directorate-General	91	22	113
17 AWBL-02	Policy strategy and coordination for 'Health and consumer protection' Directorate-General	32	9	41
19 AWBL-03	External service	5	3	8
Total		786	161	947

* in Addition SANCO recruits +- 20 contract agents to ensure the replacement of absent staff.

DG SANCO Global envelope 2014					
Code ABB Activity	Description	Credits in EUR	Commitments in EUR	Payments in EUR	Implementation
17.010211.00.01.10	Missions	3.885.500	3.885.500	2.937.108	100%
17.010211.00.01.30	Receptions	25.000	25.000	15.303	100%
17.010211.00.02.20	Meetings	1.397.946	1.397.946	1.061.076	100%
17.010211.00.02.40	Conferences	11.000	11.000	194	100%
17.010211.00.03	Committees	2.646.500	2.646.500	1.365.024	100%
17.010211.00.04	Studies and consultations	39.076	39.076	0	100%
17.010211.00.05	Information and management systems	66.710	66.710	0	100%
17.010211.00.06	Training	306.109	306.109	216.724	100%
Total		8.377.841	8.377.841	5.595.428	100%

Annex 3 Financial Reports - DG SANCO - Financial Year 2014

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 2014 (in Mio €)					
			Commitment appropriations authorised	Commitments made	%
			1	2	3=2/1
Title 02 Enterprise and Industry					
02	02 03	Internal market for goods and sectoral policies	0	0	
Total Title 02			0	0	
Title 17 Health and consumer protection					
17	17 01	Administrative expenditure of the `Health and consumer protection- policy area	24,44085662	24,39149955	99,80 %
	17 02	Consumer policy	5,85522729	5,79610771	98,99 %
	17 03	Public health	199,0561882	190,7182946	95,81 %
	17 04	Food and feed safety, animal health, animal welfare and Plant health	241,7223169	233,5635182	96,62 %
Total Title 17			471,074589	454,4694201	96,48%
Title 26 Commission's administration					
26	26 01	Administrative expenditure of the `Commission-s administration- policy area	0,6241628	0,50562448	81,01 %
Total Title 26			0,6241628	0,50562448	81,01%
Total DG SANCO			471,6987518	454,9750446	96,45 %

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

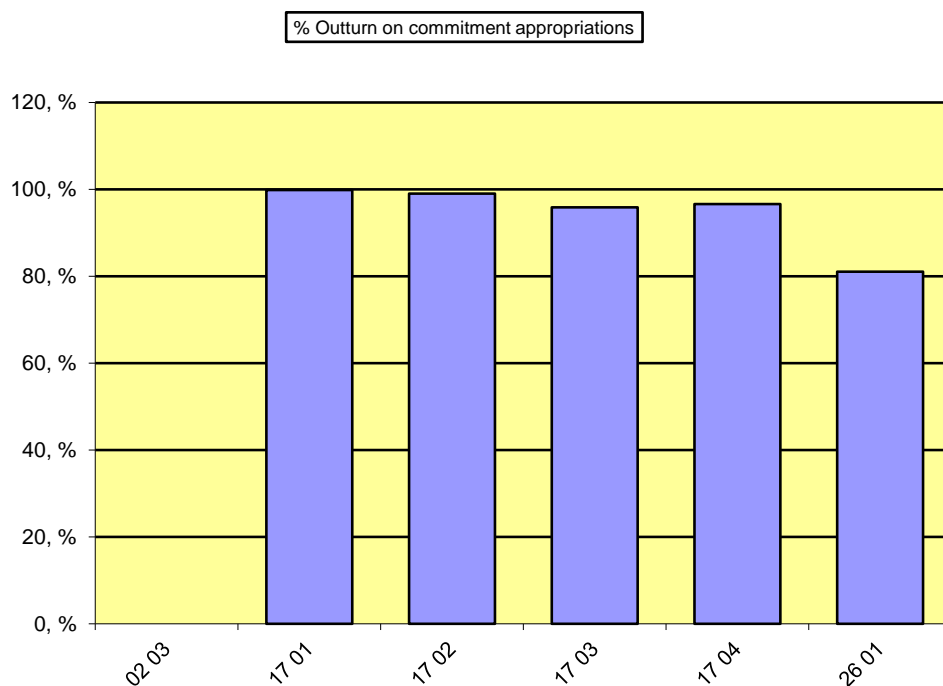


TABLE 2: OUTTURN ON PAYMENT APPROPRIATIONS IN 2014 (in Mio €)					
Chapter			Payment appropriations authorised *	Payments made	%
			1	2	3=2/1
Title 02 Enterprise and Industry					
02	02 03	Internal market for goods and sectoral policies	0,88857273	0,88819572	99,96 %
Total Title 02			0,88857273	0,88819572	99,96%
Title 17 Health and consumer protection					
17	17 01	Administrative expenditure of the `Health and consumer protection-policy area	32,59427145	24,220163	74,31 %
	17 02	Consumer policy	5,16081732	5,16081723	100,00 %
	17 03	Public health	187,5345538	184,793485	98,54 %
	17 04	Food and feed safety, animal health, animal welfare and Plant health	206,8469725	204,6734985	98,95 %
Total Title 17			432,136615	418,8479638	96,92%
Title 26 Commission's administration					
26	26 01	Administrative expenditure of the `Commission-s administration-policy area	0,80673789	0,46559198	57,71 %
Total Title 26			0,80673789	0,46559198	57,71%
Total DG SANCO			433,8319257	420,2017515	96,86 %

* 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"

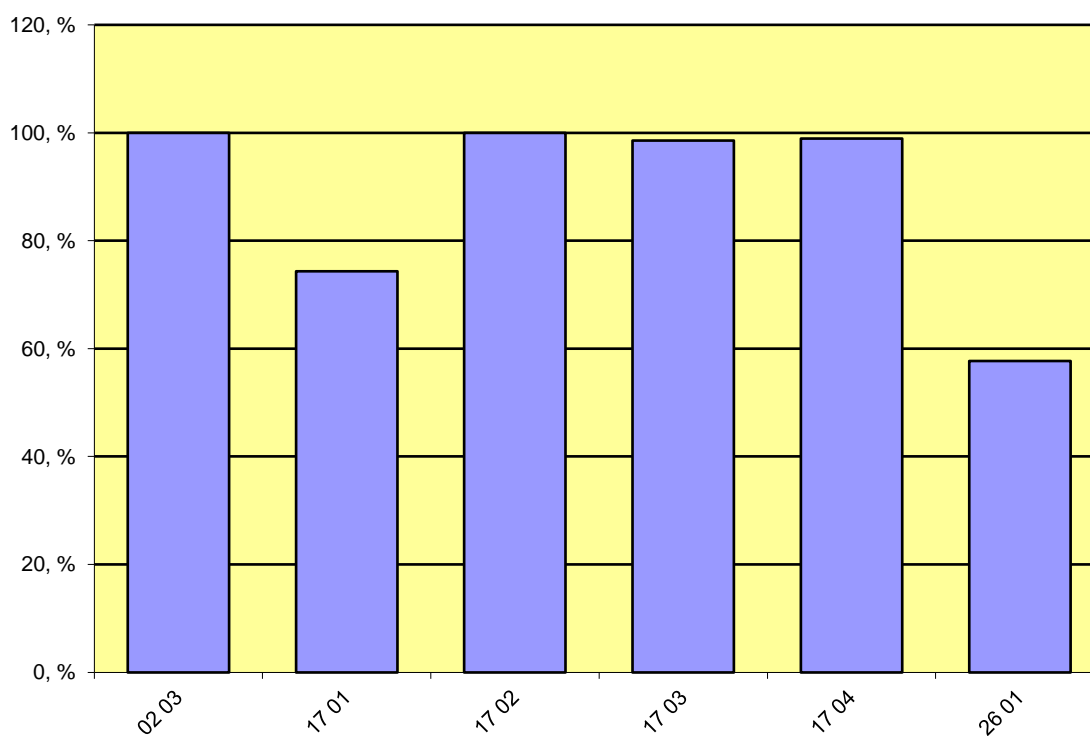


TABLE 3 : BREAKDOWN OF COMMITMENTS TO BE SETTLED AT 31/12/2014 (in Mio €)

Chapter			2014 Commitments to be settled				Commitments to be settled from financial years previous to 2014	Total of commitments to be settled at end of financial year 2014(incl corrections)	Total of commitments to be settled at end of financial year 2013(incl. corrections)
			Commitments 2014	Payments 2014	RAL 2014	% 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 sectoral policies	0	0,00	0	#DIV/0	0,27	0,27	1,39
Total Title 02			0	0,00	0	#DIV/0	0,27403	0,27403	1,38917458
Title 17 : Health and consumer protection									
17	17 01	Administrative expenditure of the `Health and consumer protection- policy area	24,39149955	17,47	6,92447526	28,39 %	0,00	6,92	8,15
	17 02	Consumer policy	5,79610771	1,30	4,49214439	77,50 %	0,93	5,42	5,56
	17 03	Public health	190,7182946	170,10	20,62045482	10,81 %	16,09	36,71	34,07
	17 04	Food and feed safety, animal health, animal welfare and Plant health	233,5635182	20,67	212,8959285	91,15 %	112,58	325,48	419,64
Total Title 17			454,4694201	209,54	244,9330029	53,89%	129,6050978	374,5381007	467,4189644
Title 26 : Commission's administration									
26	26 01	Administrative expenditure of the `Commission-s administration- policy area	0,50562448	0,30	0,20969859	41,47 %	0,00	0,21	0,18
Total Title 26			0,50562448	0,30	0,20969859	41,47%	0	0,20969859	0,18257509
Total DG SANCO			454,9750446	209,83	245,1427015	53,88 %	129,8791278	375,0218293	468,9907141

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

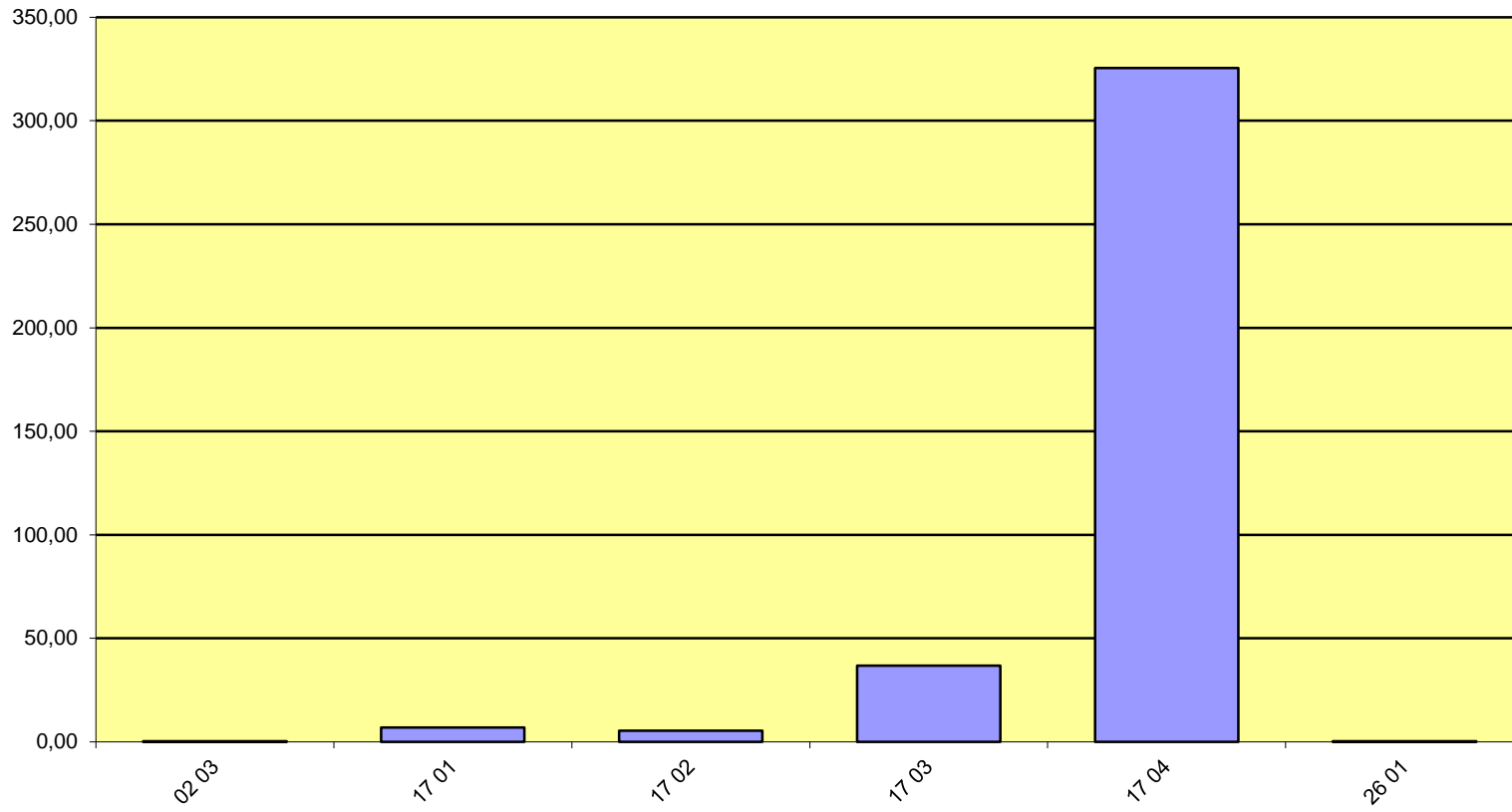


TABLE 4 : BALANCE SHEET

BALANCE SHEET	2014	2013
A.I. NON CURRENT ASSETS	19.225.335,64	19.612.514,86
A.I.1. Intangible Assets	806.129,00	240.852,06
A.I.2. Property, plant and equipment	17.649.385,84	19.062.572,53
A.I.6. Non-Current Pre-Financing	769.820,80	
A.I.7. OLD LT Pre-Financing	-	309.090,27
A.II. CURRENT ASSETS	20.466.686,36	18.209.540,14
A.II.1. Inventories	11.232.100,00	10.424.500,00
A.II.2. Current Pre-Financing	8.264.217,73	6.473.390,08
A.II.4. Exchange Receivables	453.818,73	145.261,52
A.II.5. Non-Exchange Receivables	507.418,36	1.156.315,66
A.II.7. Cash and Cash Equivalents	9.131,54	10.072,88
ASSETS	39.692.022,00	37.822.055,00
P.II. NON CURRENT LIABILITIES	(12.258.044,58)	(14.242.605,06)
P.II.2. Long-term provisions		-
P.II.3. Long-term financial liabilities	(12.258.044,58)	(14.242.605,06)
P.III. CURRENT LIABILITIES	(199.694.208,66)	(215.962.875,71)
P.III.2. Short-term provisions	(16.249.401,22)	(7.581.724,78)
P.III.3. Short-term financial liabilities	(1.984.396,84)	(1.964.832,35)
P.III.4. Accounts Payable	(21.205.537,26)	(27.883.668,37)
P.III.5. Accrued charges and deferred income	(160.254.873,34)	(178.532.650,21)
LIABILITIES	(211.952.253,24)	(230.205.480,77)
NET ASSETS (ASSETS less LIABILITIES)	(172.260.231,24)	(192.383.425,77)
P.I.2. Accumulated Surplus / Deficit	384217389,7	22810128,59
Non-allocated central (surplus)/deficit*	-211957158,4	169573297,2
TOTAL	0,00	0,00

It should be noted that the balance sheet and economic outturn account presented in Annex 3 to this Annual Activity Report, represent only the (contingent) assets, (contingent) 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 economic outturn account 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	2014	2013
II.1 REVENUES	2.383.026,45	90.719,45
II.1.1. NON-EXCHANGE REVENUES	(1.272.790,06)	(2.916.256,23)
II.1.1.5. RECOVERY OF EXPENSES	(529.534,90)	(2.227.630,27)
II.1.1.6. OTHER NON-EXCHANGE REVENUES	(743.255,16)	(688.625,96)
II.1.2. EXCHANGE REVENUES	3.655.816,51	3.006.975,68
II.1.2.1. FINANCIAL INCOME	(1,42)	(98.110,32)
II.1.2.2. OTHER EXCHANGE REVENUE	3.655.817,93	3.105.086,00
II.2. EXPENSES	377.365.443,38	361.316.541,64
II.2. EXPENSES	377.365.443,38	361.316.541,64
11.2.10. OTHER EXPENSES	38.124.579,37	29.106.589,83
II.2.2. EXP IMPL BY COMMISS&EX.AGENC. (DM)	169.788.932,05	162.213.159,74
II.2.3. EXP IMPL BY OTH EU AGENC&BODIES (IM)	166.187.333,06	167.949.033,71
II.2.4. EXP IMPL BY 3RD CNTR & INT ORG (IM)	3.215.696,38	1.755.739,74
II.2.6. STAFF AND PENSION COSTS	(94.839,78)	(61.217,49)
II.2.8. FINANCE COSTS	143.742,30	353.236,11
STATEMENT OF FINANCIAL PERFORMANCE	379.748.469,83	361.407.261,09

Explanatory Notes (facultative):

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It should be noted that the balance sheet and economic outturn account presented in Annex 3 to this Annual Activity Report, represent only the (contingent) assets, (contingent) 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 economic outturn account 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 2014 - DG SANCO

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	4	4	100,00 %	13,75			
30	1728	1694	98,03 %	16,45572609	34	1,97 %	34,91176471
45	217	205	94,47 %	19,33658537	12	5,53 %	68,25
60	63	62	98,41 %	20,17741935	1	1,59 %	73
90	122	121	99,18 %	40,00826446	1	0,82 %	190
183	1	1	100,00 %	170			

Total Number of Payments	2135	2087	97,75 %		48	2,25 %	
Average Payment Time	18,93489461			18,2831816			47,27083333

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	6	6	100,00 %	10,5			
30	825	769	93,21 %	18,3029909	56	6,79 %	40,16071429
75	3	2	66,67 %	50	1	33,33 %	85

Total Number of Payments	834	777	93,17 %		57	6,83 %	
Average Payment Time	19,8705036			18,32432432			40,94736842

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
6	64	321	15,04 %	2135	88.682.539,52	21,81 %	406.596.314,18

Late Interest paid in 2014			
DG	GL Account	Description	Amount (Eur)
SANTE	65010000	Interest expense on late payment of charges	0,00
SANTE	65010100	Interest on late payment of charges New FR	557,41
			557,41

TABLE 7 : SITUATION ON REVENUE AND INCOME IN 2014

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	97.780,73	-	97.780,73	97.780,73	-	97.780,73	-
57	OTHER CONTRIBUTIONS AND REFUNDS IN CONNECTION WITH THE ADMINISTRATIVE OPERATION OF THE INSTITUTION	661.528,08	244.140,81	905.668,89	661.528,08	244.140,81	905.668,89	-
59	OTHER REVENUE ARISING FROM ADMINISTRATIVE MANAGEMENT	652.412,56	-	652.412,56	652.412,56	-	652.412,56	-
66	OTHER CONTRIBUTIONS AND REFUNDS	6.477.872,93	210.616,38	6.688.489,31	6.477.872,93	9.984,25	6.487.857,18	200.632,13
Total DG SANCO		7.889.594,30	454.757,19	8.344.351,49	7.889.594,30	254.125,06	8.143.719,36	200.632,13

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

INCOME BUDGET RECOVERY ORDERS ISSUED IN 2014	Error		TOTAL Qualified		TOTAL RC(incl. non-qualified)		% Qualified/Total RC	
	Year of Origin (commitment)	Nbr	RO Amount	Nbr	RO Amount	Nbr	RO Amount	Nbr
2005	1	227.685,46	1	227.685,46	1	227.685,46	100,00%	100,00%
2006	1	6.402,08	1	6.402,08	1	6.402,08	100,00%	100,00%
2007	1	854,13	1	854,13	1	854,13	100,00%	100,00%
2008	2	137.786,82	2	137.786,82	2	137.786,82	100,00%	100,00%
2009	3	102.482,03	3	102.482,03	3	102.482,03	100,00%	100,00%
2010	2	33.137,00	2	33.137,00	2	33.137,00	100,00%	100,00%
2011	5	269.731,63	5	269.731,63	6	312.048,24	83,33%	86,44%
2012	3	1.633.971,27	3	1.633.971,27	4	1.711.104,27	75,00%	95,49%
2013	3	11.851,76	3	11.851,76	10	5.094.644,31	30,00%	0,23%
2014	1	395,14	1	395,14	2	11.656,46	50,00%	3,39%
Sub-Total	22	2.424.297,32	22	2.424.297,32	32	7.637.800,80	68,75%	31,74%

EXPENSES BUDGET	Error		Irregularity		OLAF Notified		TOTAL Qualified		TOTAL RC(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	154	20.397.252,02					154	20.397.252,02	164	20.720.758,27	93,90%	98,44%
CREDIT NOTES	22	686.231,86	1	763,31			23	686.995,17	54	1.048.576,10	42,59%	65,52%
Sub-Total	176	21.083.483,88	1	763,31			177	21.084.247,19	218	21.769.334,37	81,19%	96,85%
GRAND TOTAL	198	23.507.781,20	1	763,31			199	23.508.544,51	250	29.407.135,17	79,60%	71,70%

TABLE 9: AGEING BALANCE OF RECOVERY ORDERS AT 31/12/2014 FOR SANCO

	Number at 01/01/2014	Number at 31/12/2014	Evolution	Open Amount (Eur) at 01/01/2014	Open Amount (Eur) at 31/12/2014	Evolution
2010	1	1	0,00 %	55.377,62	55.377,62	0,00 %
2011	1	1	0,00 %	145.254,51	145.254,51	0,00 %
2013	3		-100,00 %	254.125,06		-100,00 %
	5	2	-60,00 %	454.757,19	200.632,13	-55,88 %

TABLE 10 : RECOVERY ORDER WAIVERS IN 2014 >= EUR 100.000

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

Total DG	
-----------------	--

Number of RO waivers	
-----------------------------	--

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TABLE 11 : CENSUS OF NEGOTIATED PROCEDURES - DG SANCO - 2014**Procurement > EUR 60,000**

Negotiated Procedure Legal base	Number of Procedures	Amount (€)
Art. 134.1(b)	2	2.127.000,00
Total	2,	2.127.000,00

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

Internal Procedures > € 60,000		
Procedure Type	Count	Amount (€)
Call for expressions of interest - Pre-selection of candidates (Art. 136.1(a) RAP)	2	127.276,00
Exceptional Negotiated Procedure without publication of a contract notice (Art. 134 RAP)	2	2.127.000,00
Open Procedure (Art. 127.2 RAP)	6	5.549.927,00
TOTAL	10	7.804.203,00

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 SANCO for making reservations are based on the standing instructions for the preparation of Annual Activity Reports¹. 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 SANCO with the resources allocated. It is a "mirror" image of DG SANCO'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 SANCO assesses both qualitative and quantitative aspects:

1. Qualitative criteria

DG SANCO 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 SANCO, 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;

¹ Latest available: SEC(2014)553 of 10 November 2014

- 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 DG SANCO's Internal Audit Capability (IAC), the Court of Auditors, the Commission's Internal Audit Service (IAS) or OLAF could lead to a reservation,

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

1.4 Significant reputational risks

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

2. Quantitative criterion

2.1 Erroneous transactions

In the framework of a transaction-based approach, DG SANCO considers that identified erroneous transactions which expose DG SANCO 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" approach².

2.3 Non-representative sampling:

When selecting the sample of transactions to be controlled on the spot, DG SANCO 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 SANCO'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 SANCO 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.

² http://intracomm.ec.testa.eu/budg/rep/aar/_doc/_doc/additional-guidance-error-rates.doc

ANNEX 5: Internal Control Template for budget implementation

The table below shows **DG SANCO's 2014 commitment implementation** without credits managed by cross-delegations (EUR 1,1 million), the Executive Agency for Consumers, Health and Food (CHAF-EA, former EAHC, EUR 76,7 million).

Type of budget implementation - direct management Commitments executed by DG SANCO		2014 € million	%	Number		Average € million	Control strategy
Cost reimbursements to Member States in the policy area Food and Feed (Co-financing based on Council Decisions 2009/470/EC and 2000/29)	Animal disease eradication programmes	166,8		28 Member States	141 Programmes	1,2	Annex 5.1.1
	Veterinary emergency fund	6,9		9 Member States	11 "Emergency files"	0,6	
	Phytosanitary measures ("Solidarity fund")	5,9		6 Member States	26 "Solidarity files"	0,2	
	Subtotal		179,6	41%			
Grants, direct management (Heterogeneous types of grants not following the typical grant procedure of an open call for proposal)	Subsidies to Reference Laboratories	30,5		44 Reference Laboratories		0,6	./.
	Other "grants" to Member States	0,2		28 Member States	28 Commitments	0,0	
	Direct grants to international organisations (OIE, UPOV)	1,1		2 Organisations		0,5	
	Subtotal		31,8	7%			
Direct grants to international organisations (WHO) and other	0,3	0,3		14 Beneficiaries		0,02	
Public procurement (According to Title V of the Financial Regulation)	Consumer Affairs	5,6					Annex 5.1.2
	Public Health	15,2					
	Feed and Food	20,1					
	Administrative support credits	4,1					
Subtotal		45,0	10%				
Subsidies to the operating budgets of the executive agency and the three EU agencies	CHAF-EA (former EAHC)	7,3		4 Agencies	4 Subsidies	45,4	Annex 5.2.1 5.2.2
	EFSA	79,6					
	ECDC	60,5					
	EMA	34,3	181,7				
TOTAL commitments		438,4	100%				

ANNEX 5.1: Internal Control Template for budget implementation under direct management

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

1. Type of expenditure: cost reimbursements to Member States

DG SANCO co-finances Member States' programmes for animal disease eradication and monitoring, veterinary emergency measures and phytosanitary measures through the reimbursement of eligible costs. In 2014, Council Decisions 2009/470/EC and 2000/29 were the basis for the corresponding expenditure in 2014.

In June 2014, the Common Financial Framework (CFF)¹ entered into force laying down provisions for the management of expenditure relative to the policy area Food and Feed. While the national programmes implemented in 2014 as well as other veterinary and phytosanitary expenditure of 2014 were still based on Council Decisions 2009/470/EC and 2000/29, Member States programmes for 2015 mark the transition to the implementation of the CFF.

The following descriptions focus on the national programmes for animal disease eradication and monitoring as these account for more than 70% of the EU funds in the policy area Food and Feed. For other kinds of cost reimbursements the controls described below are implemented as far as applicable.

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

- ! 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.

¹ Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014

Cost reimbursements to Member States				
Main 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) There is a risk that the eligibility, selection and award criteria are not adequate to evaluate the proposed national programmes and to ensure that the policy objectives are achieved.</p>	<ol style="list-style-type: none"> 1. For the last time applicable to 2015 programmes that were submitted by 30/04/2014: Commission Decision 2008/341/EC of 25 April 2008 lays down the criteria for the national programmes for the animal disease eradication, control and monitoring. 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. 3. DG SANCO provided standard electronic templates and application guidelines for the Member States' submissions; information meetings are held to explain the requirements. 4. Each year, DG SANCO 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 SANCO'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 ⇒ Target: qualitative analysis of reasons for rejections and adjustments in relation to priority diseases

Cost reimbursements to Member States				
Main 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"> 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 SANCO competent staff of the Unit concerned; External experts, selected through an open call for expression of interest (2012), advise in the technical evaluation; DG SANCO provides a guidance document with checklists and templates on the evaluation procedure; conflict of interest declarations; To ensure high quality and reasonable costs of the national programmes, <ul style="list-style-type: none"> DG SANCO competent staff requests to Member States additional information or modifications to improve their programmes if deemed necessary; A recapitulative table of the suggested financing with comments is provided to the AOSD before giving feedback to Member States; The draft final evaluation results are examined by the Standing Committee (PAFF) which gives an opinion on the draft list of programmes and their funding to be approved by the authorising officer by delegation in DG SANCO (see stage 2 on “contracting”). 	<ol style="list-style-type: none"> 100% vetting of external experts for technical expertise and independence; 100% of national programmes are evaluated following a standard procedure (technical and financial parts); <ol style="list-style-type: none"> 100% supervision of work of external evaluators in DG SANCO 	<p>Cost of control:</p> <ul style="list-style-type: none"> Included in general estimate of DG SANCO’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

Cost reimbursements to Member States				
Main 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>There is a risk that the national programmes for which a grant decision is taken by the authorising officer by delegation do not correspond to</p> <p>(a) the programmes and amounts agreed in PAFF and/or</p> <p>(b) the budgetary commitment.</p>	<ol style="list-style-type: none"> 1. Based on the results of the evaluation, DG SANCO facilitates the Member States’ finalisation of their national programmes; 2. DG SANCO gives its technical approval of the national programmes prior to preparing the grant decisions; 3. Following ex-ante checks on administrative and legal aspects of the grant decision, the authorising officer by delegation approves formally in a grant decision the programmes and their associated funding. 	<ol style="list-style-type: none"> 1. 100% of national programmes modified as requested by DG SANCO; 2. 100% of programmes to be technically approved prior to preparing the grant decision 3. 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 SANCO’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

Cost reimbursements to Member States				
Main 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>There is a risk 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"> Member States' reporting requirements for each programme until 2015 are set forth in Commission Decision 2008/940 (from 2016, Regulation (EU) No 652/2014 applies); Competent staff assess intermediate technical and financial reports for each programme and, if need be, funds are reallocated between programmes and Member States; Member States' present the results of their programmes to PAFF on their own initiative or when requested by DG SANCO; Annual technical and financial reports are assessed by competent staff prior to initiating payments; 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; Payments follow DG SANCO's financial circuits with 1st and 2nd level financial verifications, authorisations and encodings in ABAC reviewed by DG BUDG; 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

Cost reimbursements to Member States

Main 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) There is a risk that 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 complement the desk checks.</p>	<p>1a. DG SANCO'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 SANCO's Audit 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 SANCO 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%

Cost reimbursements to Member States				
Main risks	Mitigating controls	Control coverage	Costs and benefits of controls	Control indicators
b) There is a risk that the detected errors, irregularities or suspicions of fraud are not 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 SANCO'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 SANCO implemented; ⇒ Target: 100% <p>Efficiency Indicators:</p> <ul style="list-style-type: none"> - "Time to recover" from final 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 SANCO 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 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 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 SANCO 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 and Consumer 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 SANCO is very limited: In 2014,

- EUR 8,6 million were committed in 2014 for 10 Pilot Projects and Preparatory Actions;
- A total of 10 new contracts concluded in 2014 above EUR 60.000.
- By far most of the procurement procedures are based on framework contracts of DG SANCO or another DG, in particular DG DIGIT. DG SANCO 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 SANCO.

- ! 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. Not all indicators listed in the tables below were monitored in 2014. More information will become available in 2015 thanks to the centralisation of procurement procedures in DG SANCO.

Procurement				
Main 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>				
a) There is a risk that the needs are not well defined (operationally and economically) and that the decision to procure is inappropriate to meet the operational objectives. Poor planning or inadequate organisation of the procurement procedure could entail delays or interruptions of services leading to an underachievement of the policy objectives.	<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 the maximum value of a 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 Management meetings 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 	Cost of control: - Estimated staff costs for programming and planning and execution of the procurement procedures. Benefits of control: - Amount of rejection of unjustified purchases or services discontinued.	Effectiveness indicators: - Number of open calls covered by the annual work programme not launched in the same year as the work programme. ⇒ Target: 0% - Number of planned studies not retained in the register of Secretariat General. ⇒ Target: 0% - Depth of price calculation using the pricing methodology (according to template) ⇒ Target: 100% in-depth Efficiency indicators: - Timely launch of procurement procedures as specified in the annual work programmes ⇒ Target: 100%

Procurement				
Main risks	Mitigating controls	Control coverage	Costs and benefits of controls	Control indicators
<p>b) There is a risk that the best bids are not submitted due to a poor definition of tender specifications, exclusion, selection and award criteria or insufficient publication of the tender.</p>	<ol style="list-style-type: none"> To ensure a high level of expertise in drafting the tender specifications, DG SANCO competent staff of the policy Units write the specifications with the support of financial staff; DG SANCO uses templates for terms of reference, exclusion and selection criteria that follow the Commission guidelines; The central procurement committee (CMP) reviews the tender specifications prior to publication for certain sensitive procurements and on special request of the policy Unit. 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"> Tender specifications are drafted in the Units concerned with central support on request (depth of the support depending on needs). 100% where applicable Central ex-ante review of tender specifications for "Preparatory Actions" and "Pilot Projects". 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 calls falling within the scope of centralised procurement management having been organised by the central procurement management team Number of open calls for tenders for which, due to poor tender specifications, no offer is received. ⇒ Target: 0% Number of cancellations of open tender procedures due to poor definition of tender specifications ⇒ 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 DG SANCO internal rules (to be defined in 2015)

Procurement				
Main risks	Mitigating controls	Control coverage	Costs and benefits of controls	Control indicators
<p>c) There is a risk that the most economically advantageous offer is not selected due to a biased, erroneous or 'unfair' evaluation process. If procedures are not correctly followed, DG SANCO could be facing possible litigation and /or reputational damage.</p>	<ol style="list-style-type: none"> 1. Opening and evaluation procedures are formalised, implemented and documented; members of committees are appointed by the Authorising Officer responsible. 2. Persons involved in the formal procedures sign declarations of absence of conflict of interest. 3. Bidders are checked against exclusion and selection criteria published with the tender specifications. 4. The central procurement committee examines tender procedures > €130.000 and gives an independent opinion to the Authorising Officer responsible. 5. The Authorising Officer responsible validates the evaluation results and takes the award decision. 6. After the award decision, a standstill period of two weeks applies in certain procedures before the contract is signed to give unsuccessful tenderers the opportunity to raise concerns. 	<ol style="list-style-type: none"> 1. 100% of tender procedures are documented; for 100% of tender procedures > €60.000 committees are formally appointed. 2. 100% of evaluators. 3. 100% of bidders checked 4. Certain tender procedures (2014 transitional year to centralisation of procurement; new rules defined in 2015) 5. 100% validated 6. 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 case 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 value of successfully finalised tender <i>procedures (due to centralisation from 2014, first figures available in 2015)</i>

Procurement				
Main 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>There is a risk that the purchased products or services are not provided in accordance with the technical requirements and/or that the contractor fails to 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 SANCO 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 SANCO'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. 	<ol style="list-style-type: none"> 1 to 4. 100% covered by model contracts, monitoring of progress, financial circuits with assessment and validation of technical and financial reports (control depth depends on risk criteria); 5. 100% if conditions are fulfilled 	<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 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>There is a risk that ex-ante controls at the desk fail to prevent, detect and correct errors in procurement procedures or attempted fraud and that these issues become apparent only ex-post during supervisory checks.</p>	<ol style="list-style-type: none"> DG SANCO's ex-post control strategy includes procurement contacts of exceptionally high amounts or other high risks; the audit work programme foresees anti-fraud measures DG SANCO's internal audit capability includes in its mid-term audit plan audits or reviews of procurement procedures; the audit engagements foresee anti-fraud measures; Ex-post publication of the contractor; studies are published in a Commission register; The management of sensitive functions is centralised to ensure independent analysis and judgment. Exceptions and internal control weaknesses are reported and analysed. If deemed necessary, the file is referred to OLAF. 	<ol style="list-style-type: none"> Risk based audit sample (no minimum audit coverage foreseen as only on exceptional basis); Risk based audit plan 100% (depth varies with type of contract) High risk operations 100% of financial procedures 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. Number of weaknesses corrected. 	<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"> Time between audit visit and finalisation of audit report not exceeding the internal deadlines ⇒ Target: 100% on time 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 SANCO's control strategy related to the executive agency and one related to EU agencies for which DG SANCO 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 SANCO. According to the cross-delegation agreements that DG SANCO signed with the authorising officers responsible, they report annually on the use made of the delegated appropriations.

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

In 2014, DG SANCO managed financial operations under the following three policy areas: Consumer Affairs, Public Health and Food and Feed Safety. DG SANCO entrusted the Consumers, Health and Food Executive Agency (CHAF-EA, former EAHC) with the implementation of about EUR 76,7 million which amounts to 23% of the 2014 budget; cross-delegations were given to authorising officers of other DGs for about 0,3% of the total credits. DG SANCO itself implemented about 77% of the total budget (for the latter see DG SANCO's control strategies in Annex 5.1 above).

In addition, DG SANCO finances in full the running costs of CHAF-EA through the payment of a subsidy of EUR 7,3 million to the executive agency's operating budget. 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 SANCO's scrutiny rights and obligations, including documentary and on-the-spot checks and audits at the agency.

- ! DG SANCO'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. Delegated budget implementation tasks to the executive agency

Main 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>There is a risk that the establishment (or prolongation) of the mandate of the executive agency is affected by legal issues, which would 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. 2. The Member State Committee for executive agencies approves the Commission's proposals for establishing an agency and prolonging its mandate. 3. DG SANCO follows the Commission's models for the decisions on establishment and task delegation to the agency. 4. DG SANCO manages the interservice consultations and publications of the Commission Decisions. 	<p>100% in-depth controls at each stage on DG SANCO'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: Estimated SANCO 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: 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: before 1 January 2014

1. Delegated budget implementation tasks to the executive agency

Main 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>There is a risk that the financial and control framework deployed by the executive agency is not fully mature to guarantee that the control objectives are met.</p>	<ol style="list-style-type: none"> DG SANCO 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. According to the Act of Delegation, the agency submits to DG SANCO 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 2014 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 per year and not in 2014 (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. Delegated budget implementation tasks to the executive agency

Main risks	Mitigating controls	Control coverage	Costs/benefits of controls	Control indicators
Stage 3: Operations: DG SANCO's monitoring and supervision ("control with the executive agency") <i>Main control objectives: ensuring that DG SANCO 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>There is a risk that DG SANCO is not (timely) informed of relevant management issues encountered by the executive agency, and/or that DG SANCO does not react upon notified issues timely and adequately; 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 to the Commission.</p> <p>The Act of Delegation also specifies DG SANCO's scrutiny rights and obligations, including documentary and on-the-spot checks and audits at the agency.</p> <ol style="list-style-type: none"> 1. Regular meetings between the agency and DG SANCO are held at the level of the Units concerned to ensure the necessary co-ordination of activities; 2. Guidelines for the day-to-day co-ordination between DG SANCO and the agency are established; where necessary, they are complemented by specific guidelines for certain delegated tasks; 3. The Steering Committee, chaired by DG SANCO, 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 	<p>Coverage: 100% of the agency's activities monitored and supervised.</p> <p>Depth of control: risk based; DG SANCO 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 SANCO 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 SANCO at operational level ⇒ Target: to be defined per delegated programme - Number of "exception reports" to the guidelines on the co-operation between DG SANCO and the agency ⇒ Target: 0 - 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 SANCO'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 SANCO's Annual Activity Report ⇒ Target: qualitative analysis

1. Delegated budget implementation tasks to the executive agency

Main risks	Mitigating controls	Control coverage	Costs/benefits of controls	Control indicators
	<p>authority;</p> <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 SANCO's central financial Unit reports at least 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 as annex to DG SANCO'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 adoption 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 SANCO paid subsidies to the operating budgets of EU agencies

As in previous years, in 2013, DG SANCO was responsible for four EU agencies of which three received an annual subsidy from the EU budget. While the Director-General of DG SANCO is accountable for the legality and regularity of the commitments and payments of the subsidies to the agencies, accountability for the regularity and legality of this expenditure resides ultimately with the agencies themselves. The Director of the agency implements the agency's operating budget as authorising officer according to the financial regulation adopted by the 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.

- **European Centre for Disease Prevention and Control (ECDC)** located in Stockholm, Sweden² (*Budget 2014: total sum of human resources 299; EU funding 100%: EUR 60,5 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, Italy³ (*Budget 2014: total sum of human resources 474; 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, UK⁴ (*Budget 2014: total sum of human resources 751; EU funding 12%: EUR 34,3 million*)
EMA evaluates and supervises medicines for human and veterinary use; it provides the Member States and the institutions of the European Union with independent scientific advice on medicinal products for human or veterinary use. EMA's 2014 revenues amounted to EUR 282,5 million and stem to a large extent from fees.
- **Community Plant Variety Office (CPVO)** in Angers, France⁵ (*Budget 2014: total sum of human resources 47; 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 2014 revenues amounted to EUR 14,7 million and stem almost exclusively from fees.

² ECDC was established by Regulation (EC) No 851/2004 of the European Parliament and of the Council of 21 April 2004; OJ L 142/1, 30.4.2004.

³ EFSA was established by Regulation (EC) No 178/2002 of the European Parliament and of the Council; OJ L 31/1 of 1.2.2002.

⁴ EMA was established by Council Regulation (EEC) No 2309/93, which was replaced by Regulation (EC) No 726/2004 of the European Parliament and of the Council; OJ L 214/1 of 24.8.1993 and (OJ L 136/1 of 30.4.2004).

⁵ The CPVO was created by Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights; Official Journal L 227/1 of 01/09/1994.

2. Subsidy payments to EU agencies

Main 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>There is a risk that the establishment (or amendment) of the mandate of an EU agency is affected by legal issues, which would undermine the legal basis for the agency’s management of the EU funds paid by DG SANCO 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 SANCO manages the interservice meetings/consultations 2. DG SANCO 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 SANCO 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: 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 17% (see the introduction above).

2. Subsidy payments to EU agencies

Main 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>There is a risk that the financial and control framework deployed by the EU agency is not 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 SANCO, 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 SANCO, in co-operation with DG BUDG consults and monitors. 3. Each agency adopts its rules of "independence" and "conflict of interest". DG SANCO actively monitors compliance with the Commission's guidelines on independence in DG SANCO's task force with the agencies and through bilateral contacts with the agencies; In addition to monitoring compliance, DG SANCO identifies and disseminates good practices in collaboration with the agencies. 	<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</p>	<p>Cost of control: Included in general estimate of SANCO'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 6 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 risks	Mitigating controls	Control coverage	Costs/benefits of controls	Control indicators
Stage 3: Operations: DG SANCO's monitoring and supervision ("control with the EU agency") <i>Main control objectives: ensuring that DG SANCO 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>There is a risk that DG SANCO is not (timely) informed of relevant management issues encountered by the EU agency, and/or that DG SANCO does not react upon notified issues timely and adequately; this could reflect negatively on the Commission's reputation.</p>	<ol style="list-style-type: none"> 1. A coordinating Unit in DG SANCO 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 will be applicable; 2. Regular bilateral meetings take place aiming at ensuring 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 SANCO; 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 SANCO 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 SANCO 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 SANCO 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 SANCO 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 SANCO; 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 SANCO'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 6 above).</p>	<p>Effectiveness and efficiency indicators:</p> <ul style="list-style-type: none"> - Regular meetings between the agency and DG SANCO at management and technical level ⇒ Target: to be defined with each agency - Management Board meetings with DG SANCO 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 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 SANCO with information which may confirm or contradict the management reporting received from the agencies themselves.</i>				
<p>There is a risk that DG SANCO does not get sufficient information from independent sources on the EU agency's management achievements, which prevents drawing conclusions on the assurance for the subsidies paid to the agency; 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 SANCO monitors the agency's follow-up on the Court's recommendations; 3. Every year, the agency undergoes the discharge procedure; DG SANCO monitors the agency's follow-up on the recommendations made by the discharge authorities; 4. All 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 7 years (next in 2014 still on-going). 	<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 SANCO'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 6 above).</p>	<p>Effectiveness indicators:</p> <ul style="list-style-type: none"> - DG SANCO'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 risks	Mitigating controls	Control coverage	Costs/benefits of controls	Control indicators
<p>Stage 5: DG SANCO's payments of the subsidy</p> <p><i>Main control objectives: ensuring that DG SANCO 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>There is a risk that DG SANCO pays out the (next) instalment of the subsidy to the agency while not being aware of management issues that may lead to financial and/or reputational damage.</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 SANCO 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 SANCO's financial circuits with 1st and 2nd level financial verifications, authorisations and encodings in ABAC; 2. On the basis of the agency's final accounts audited by the Court of Auditors, DG SANCO recovers - if applicable – the unspent amounts of the instalments paid to the agency (and until 2013 interest earned); 	<p>Coverage: 100% of DG SANCO'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 SANCO'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 6: Implementation through national or international public-sector bodies and bodies governed by private law with a public sector mission (if applicable)

Not applicable

ANNEX 7: EAMR of the Union Delegations (DG DEVCO only)

Not applicable

ANNEX 8: Decentralised agencies (if applicable)

Included in Annex 5

ANNEX 9: Performance information included in evaluations

Title of the Evaluation: Evaluation on the implementation of the "Commission communication on combating HIV/AIDS in the EU and neighbouring countries, 2009-13" and the HIV action plan.	
ABB activity:	<i>Public Health</i>
Type of evaluation:	Choose from: Other (part of Impact Assessment)
Summary of performance related findings and recommendations:	<p>1. Contribution of the activity to Europe 2020 objectives or to other key policy objectives</p> <p>The 2009 Commission Communication on combating the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) sought to gear up the policy profile of the EU fight against HIV/AIDS until 2013, with a view to renew the policy to further strengthen EU policy in the area of HIV/AIDS prevention and control. Since HIV/AIDS disproportionately affects populations that are marginalised, this Communication is clearly in line with the EU 2020 priority of fighting social exclusion.</p> <p>2. Main result of the activity and EU added value</p> <p>The overarching aims of the evaluation were to assess the implementation of the Communication. Furthermore, the evaluation sought to inform options for medium- to long-term action at the EU level in this field in the EU and neighbouring countries.</p> <p>The current approaches to HIV surveillance in Europe rely primarily on proxy measures of the burden of HIV, such as new diagnoses of HIV (and AIDS) cases, and the numbers of those accessing HIV-related treatment and care services. However, these measures provide only limited insight into the nature of the epidemic; an observed change in the number of newly diagnosed cases can mean that there has been a change in HIV transmission (that is, new infection) or a change in testing of undiagnosed infections, or both. It is against this background that observed trends, and associated impacts of the Communication, have to be interpreted. Keeping this in mind, available data suggest that the rate of new diagnoses per year fell between 2009 and 2012 across the EU/EEA. The rate remained highest in the eastern part of the WHO European Region and lowest in the central part. The most common routes of transmission in the EU/EEA continued to be through MSM (men having sex with men), although heterosexual contact has become more important, while in the East region transmission tends to occur among PWID (people who inject drugs) and their sexual partners. However, data presented at the regional level conceal important differences between and within countries in the dynamics of the HIV epidemic.</p> <p>In order to determine the added value of European Union action in the domain of research, a specific survey was conducted. Given the fact that it is the responsibility of individual EU Member States to develop and implement national responses to HIV/AIDS, most of the respondents did not believe there to be a direct correlation between the observed changes in new diagnoses, and the 2009 Communication and its Action Plan. Among those who did believe that the Communication and its Action Plan have had an impact, the most commonly reported reason given was that the Communication focuses on at-risk groups and their ability to generate political support for HIV services.</p> <p>3. Issues of sound policy design, management and implementation; including</p>

	<p>efficiency and effectiveness.</p> <p>Based on the limitations of the data collected, it is difficult to draw firm recommendations on the contribution of EU-funded research. Where the evidence permits, we suggest that the European Commission:</p> <ul style="list-style-type: none"> • Continues to develop mechanisms that facilitate communication between scientists and practitioners and that better address the translation gap between basic and applied research. • Mechanisms may include continuing funding streams that (i) systematically require the collaboration of basic science and applied research to ensure that research is translatable into practice; (ii) incentivise the conduct of implementation research alongside studies that develop strategies for HIV/AIDS prevention, treatment, care and support, so providing insights into the ally focus on developing (and evaluating) research dissemination formats that effectively communicate HIV research findings to different audiences, including vulnerable population groups. <p>Considers establishing mechanisms within the new Health Programme that enable access to EU-funded interventions by organisations, such as NGOs, that are currently unable to meet the matched funding requirements and to so encourage their participation in pan-European projects.</p> <p>Lessons learnt:</p> <ul style="list-style-type: none"> • Weak impact of the EU HIV policy on Member States actions with no impact so far on HIV targets formulated in the Dublin declaration with a strong HIV progression ongoing and a still very late recruitment to treatment • Think Tank remains a valid instrument • EU funded HIV research is of high value but not really in support of the agreed EU HIV policies • Health Programme HIV projects are of high complementary value <p>Key policy recommendations of the evaluation are:</p> <ul style="list-style-type: none"> • Adopting a new European policy framework in order to ensure that HIV/AIDS remains implement policies and programmes to address prevention, treatment, care and support at the national and regional levels. • Supporting activities to strengthen the primary prevention of HIV/AIDS. There is a continued need to enhance awareness and understanding of HIV among key population groups, and the options for HIV testing at the community level, in order to reduce the number of undiagnosed cases. • Supporting activities targeting the most at-risk populations, in particular working with relevant stakeholders to address the needs of migrants and developing guidance on the financing and delivery of prevention, treatment, care and support services for this group. Considering the particularly vulnerable situation of migrants, in particular those with uncertain legal status, support action at the European level, bringing together the European Commission, the HIV/AIDS Think Tank and the Civil Society Forum, may be particularly suited to help improve specifically. •
Availability of the report on Europa:	Not published yet (Final Report to be edited and approved)