



EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Annual Activity Report

2010

DG SANCO

Table of contents

1.	PART 1. POLICY RESULTS	3
2.	PART 2. MANAGEMENT AND INTERNAL CONTROL SYSTEMS.....	16
2.1.	Introduction to DG SANCO	16
2.2.	The functioning of the entire internal control system	23
3.	PART 3. BUILDING BLOCKS TOWARDS THE DECLARATION OF ASSURANCE (AND POSSIBLE RESERVATIONS TO IT).....	25
3.1.	Building blocks towards reasonable assurance	25
3.1.1.	Materiality defined	25
3.1.2.	Building block 1: Assessment by management.....	25
3.1.3.	Building block 2: Results from audits during the reporting year	32
3.1.4.	Building block 3:Follow-up of reservations and action plans for audits from previous years.....	35
3.1.5.	Building block 4: Assurance received from other Authorising Officers in cases of crossed sub-delegation	37
3.1.6.	Completeness and reliability of the information reported in the previous paragraphs.....	37
3.2.	Reservations	37
4.	PART 4. DECLARATION OF ASSURANCE.....	38

1. PART 1. POLICY RESULTS

1.1. Level of policy area

Pursuing our mission of "*Making Europe's citizens healthier, safer and more confident*" we provided essential contributions in 2010 to the main Commission Work Programme priorities of tackling the crisis and strengthening the citizen's agenda. The impact of our actions contributed to boost EU competitiveness and support the EU 2020 strategy objectives.

Important *policy areas were added* to SANCO's responsibilities, such as Pharmaceuticals, Medical devices and Cosmetics. Additional responsibilities in relation to Biotechnology and Pesticides were also transferred from other Commission services. A fourth Agency was added to SANCO's responsibilities: the *European Medicines Agency (EMA)*. The legislation on Consumer contracts and marketing law was transferred to other services.

Following the arrival of the new Commission in the beginning of the year the main priority actions of the Commission were announced. As a result, much emphasis was put on the preparation of initiatives listed in the first *Work programme of the new Commission* and foreseen for adoption in the next few years. These include proposals for new legislation on Animal Health and on Plant Health and initiatives on Alternative Dispute Resolution (ADR) and Collective redress as well as the strengthening of Health security in the EU.

The year saw the adoption of important *initiatives setting the policy direction* on several issues at the centre of the political debate, such as GMO cultivation, animal cloning, pandemic influenza preparedness and BSE follow up measures. The Consumer Market Scoreboards provided essential data for the re-launch of the internal market.

Ongoing work to *improve the existing regulatory framework* through better regulation to maximise benefits and minimise burdens for society included preparation of revision of the legislation on General Product Safety, Tobacco Products, Medical Devices, Seed and Propagating Materials, Veterinary Medicinal products, Medicated Feed, Clinical trials and Official controls along the food chain. Important agreements were reached between the co-legislators on legislation for cross-border health care, for falsified medicines, for pharmacovigilance and for the quality and safety of organs for transplantation.

Proper *implementation, enforcement and management* of existing legislation remained key to both ensuring a high level of safety and to avoid problems in trade. The biggest share of the DG's resources is attributed to this objective. On *enforcement* we pursued two goals: more efficient governance networks across Europe and rules that are easier to implement and keep up-to-date. The *Food and Veterinary Office's (FVO's) audits* remained crucial in contributing to the effective and coherent implementation of legislation on feed and food safety, animal and plant health and animal welfare.

On *good governance* shared action with external stakeholders was a priority. Our capacity to assess the *impacts of proposals* and to analyse alternatives for action remained a priority area. Sound scientific evidence was ensured through the *opinions* of both the Regulatory Agencies and the three "non-food" Scientific Committees and the association of *national centres of expertise*.

Early warning and crisis preparedness remained essential to deal effectively with human, animal or plant health emergencies. Our *business continuity* preparedness was further strengthened.

The DG continued to develop actions to reinforce the global presence, for instance through stronger *international relationships*, through multilateral rule-making in various fora, as well as through bi-lateral relations, including negotiations of agreements on more efficient cooperation. *Communication* continued to be developed as an integral part of the policy-making. Effective communication was further mainstreamed in the design of all our policies.

DG SANCO contributed to the Commission participation in the *World Expo 2010 in Shanghai* through events both on Food Safety and Health issues (June) and on Consumer and Product Safety issues (October). The SANCO events were attended by high level Chinese representatives. The general objective of the SANCO presence was to inform about the EU systems in these policy areas and to underline the wish to cooperate with Chinese authorities and develop our dialogues and cooperation mechanisms with our main stakeholders.

DG SANCO supported further the development of its agencies, the *Community Plant Variety Office (CPVO)*, the *European Centre for Disease Control (ECDC)*, the *European Food Safety Authority (EFSA)* and the *European Medicines Agency (EMA)*.

The *Executive Agency for Health and Consumers (EAHC)* implemented part of the EU Health Programme, the Consumer Programme and the Better Training for Safer Food initiative. The SANCO activities related to the Agency are reported separately in this report. The Agency contributed efficiently to the achievements of policy results in the policy areas described in this chapter.

As indicated in the table below most of the indicators of the *General Objectives* developed positively:

GENERAL OBJECTIVES OF THE POLICY AREA HEALTH AND CONSUMERS

GENERAL OBJECTIVES		Impact Indicators			
	Objective	Indicator	Target (long-term)	Milestones (if any)	Current situation
1.	Increase consumer welfare through greater empowerment and effective protection	Portion of consumers having internet access that make EU cross-border internet purchases vis-à-vis those who make only domestic purchases.	Narrowing the gap between domestic distance purchasing and cross-border distance purchasing		<p>2010</p> <p>33% made a domestic such purchase</p> <p>7% cross-border</p> <p>26% difference</p> <p>2009</p> <p>33,4% made a domestic such purchase,</p> <p>7,8% cross-border.</p> <p>25, 6% difference in 2009.</p>

GENERAL OBJECTIVES		Impact Indicators			
					2008 30% made a domestic such purchase 8% cross-border 22% difference 2006 41% made a domestic such purchase 6% cross-border 35% difference
		Proportion of consumers that think that a significant number of goods are unsafe	Sustained decrease to 25% (2013)		20% (2010) 25% (2009) 18% (2008)
		Share of consumers feeling adequately protected by consumer protection measures	80% (2013)		57% (2010) 55% (2009) 50% (2008)
2.	Protect and improve human health	Number of Healthy life years (HLY) at birth	Positive mid and long-term evolution		Male 61.6 (2007) Female 62.3 (2007)
3.	Ensure food is safe and wholesome	Incidence of Main food-Borne disease (BSE and salmonella) in the EU	Sustained negative trend	Each year a 30% decrease in BSE cases and 5% decrease in salmonella cases in humans compared to previous year	40 % annual decrease in BSE cases (2010) and 25 % decrease in human salmonella cases comparing 2009 with 2008.
4.	A high level of animal health and welfare and plant health protection	Share of animal disease eradication programmes satisfactory implemented by Member States	95% (2012)		95% (2010)
		Number of outbreaks of bluetongue disease	Below 10 000 (2012)		180 (2010)

1.2. Level of ABB activities

1.2.1. ABB activity Consumer Policy

Important new information on consumer conditions in the Internal Market and national markets was made available through the third and fourth editions of the **Consumer Markets Scoreboard**. The third Scoreboard monitored progress towards the integration of the retail side of the single market and measured consumer conditions, an important framework condition for growth, in each of the Member States through a new index. The fourth Scoreboard, for the first time, ranked 50 of the most important consumer markets according to their functioning, revealing major problems in key services markets. As a result, market studies into the markets for meat, internet service providers and on e-commerce were launched. The Commission adopted a recommendation on the classification of consumer complaints and an accompanying staff working document. A major study on consumer decision-making in retail investment services was published. Two major conferences, on consumer complaints and on behavioural policy-making were organised, with improved datasets and extended screening, including the announcement of a market study into retail electricity markets.

2010 was an important year for the preparation of the initiatives on **Alternative Dispute Resolution (ADR)** and **Collective redress** foreseen for 2011. A public consultation on

ADR was prepared, to be launched in January 2011. A joint public consultation on Collective redress was prepared, to be launched in February 2011. During 2010, several initiatives which have an impact on consumers were taken by DG MARKT (in particular in the area of retail financial services) and we worked successfully in order to have consumers' interests taken into account. In addition, we launched a joint initiative on bank fees. *The Financial Services Users Group (FSUG)* was established jointly with DG MARKT. 20 experts were selected, out of whom 11 representing consumers and individual investors

A *market monitoring study* performed through field tests ("Mystery shopping study") was conducted to monitor the level of compliance of markets with the Financial Instruments Directive (MiFID) in relation to the provision of investment advice. A study was launched to audit transparency and comparability tools in Member States in relation to bank fees. Another "Mystery shopping study" was launched to investigate the banking industry's compliance with the Common Principles of Bank Account Switching, a self-regulatory initiative implemented in all Member States.

Following the Report on the implementation of the *General Product Safety Directive (GPSD)*, the process was launched for reviewing this instrument, assessing the impacts of the options and working towards a future legislative proposal. A public consultation was carried out during the summer of 2010, which culminated in an international stakeholder conference. Issues such as market surveillance cooperation and coordination were identified for further study before the impact assessment report is finalised.

2010 saw a strong consolidation of product safety market surveillance cooperation in the European Union with joint surveillance actions covering five product groups (i.e. ladders, food-imitating child appealing products, children's fancy dresses, laser pointers and high-visibility clothing). These actions, together with the exchange of officials programme, further strengthened the exchange of information and best practices between the Member States, resulting in *better coordination and a higher quality of the market surveillance* efforts in the EU.

The number of notifications on dangerous consumer products distributed through the *RAPEX system* increased again in 2010 (2.244 notifications compared to 1.993 notifications in 2009, an increase of 13%). 2010 was the first year of the *application of the new RAPEX guidelines*.

Funding of about €1.31 million was granted to *ANEC, the European consumers' voice in standardisation*. The work of ANEC contributed to stronger and even more relevant safety standards for consumers' products such as toys, electrical appliances, furniture, and child care articles. The same amount was granted to *BEUC, the European Consumer organisation*, which contributed to the promotion of consumer rights (mainly financial services, energy, health, safety, food, consumer redress, etc).

The Commission continued support to the *European Consumer Centres' network (ECC-Net)* with an overall budget €4.5 million. A study on the evaluation of the ECC-Net was launched. After five years of operations, the study looked into the performance of the network and if the terms of reference should be kept the same, if some of them should be discontinued and if other tasks could be added. The results of the study will be ready by the beginning of 2011 and will be discussed with the Member States.

On the international level, the negotiations for an *agreement on cooperation and information exchange in consumer product safety with the United States* started, with a view to finalising the agreement conditions in 2011. The Commission continued

negotiations with the US on *cooperation on enforcement of consumer protection laws*. However, negotiations reached a standstill due to data protection issues. The Commission regularly reported to Council on the status of the negotiations and the main issues discussed with the US counterpart. Co-operation with *third countries* and *effective integration of consumer interests in other EU policies* was further enhanced.

As regards the effective *mainstreaming of consumer policy and the integration of consumer interests in other EU policies*, the main 2010 deliveries in areas of strategic importance for consumers were:

- **Energy:** SANCO produced both evidence and policy in the area of energy and consumers. A staff working document and related market study on the retail electricity market was adopted, presented in the 3rd Citizens' Energy Forum in London and reflected in the December Energy Council conclusions. SANCO worked with the Belgian EU Presidency for the priority area on "energy and consumers" towards the adoption of Council conclusions on this issue. SANCO also provided very substantial input into the Energy 2020 proposition.
- **Transport:** SANCO provided input on the consumer perspective into several transport files highly relevant for consumers: the White Paper on Transport, the CARS 21 Clean and Fuel Efficient Cars initiative, the Experts Group on the Future Fuels initiative and the Urban Mobility Action Plan.
- **Sustainable consumption:** SANCO was actively involved in the Retail Forum for Sustainability and the European Food Sustainable Consumption & Round Table that elaborate and discuss sustainable consumption voluntary measures with the large retailers and the food chain representatives. SANCO also supported the role of consumers to foster and develop sustainable consumption, for example with actions concerning the education and training of consumers.
- **Digital Agenda:** SANCO was actively involved in the making of the Digital Agenda. SANCO participated in the IA steering group for a legislative instrument for collective rights management, the Impact Assessment on customs enforcement of Intellectual Property Rights (IPR) and the Communication on the IPR enforcement directive. SANCO has influenced the processes so that the impact of consumer is taken properly into account.

The *annual Consumer Summit* covered six workshops linked to integration and enforcement such as energy, financial services and sustainability, delivering tangible political outputs. *An information campaign* was carried out in Bulgaria. In the *education sector*, a new DOLCETA module on financial literacy for teachers was published and the preparation of a module for food safety started. The 2010-11 edition of the *Europa Diary* was produced and distributed. The three Masters Courses in consumer policy completed the first course year of the first student cohort, and two started a second cohort. Ten Training for Consumer Empowerment (TRACE) courses were organised, in particular for the benefit of the consumer organisations of the new Member States.

The *mid-term evaluation* of the current (2007-2013) Consumer Policy Strategy and its related financial Programme was carried-out. Its results, available at the beginning of 2011, will feed into the preparation of the post-2013 Consumer Policy Strategy and Programme.

The development of the *Cosmetic Products notification Portal* (CPNP) has substantially progressed in close collaboration with relevant stakeholders. A first prototype showing

some of the functionalities of the system was presented to and welcomed by stakeholders. The development of the application will continue in 2011 with the objective of having the application operational in January 2012.

1.2.2. *ABB activity Public Health*

The intensive work continued in 2010 on implementation of the goals of ***EU health strategy 2007-2013*** that sets out an overarching framework for EU actions in the area of Health. The Second Programme of Community Action in the Field of Health (2008-2013) is a key financing instrument supporting the objectives with a total budget of € 321.5 million. The initial budget for 2010 amounted to €45.7 million.

In March 2010, the Commission adopted a Communication on ***Global Health*** calling for the establishment of a more coordinated global health governance, for the promotion of amore universal access to health services and for better coherence between EU internal and external health policy.

The cooperation with the ***World Health Organisation (WHO)*** was strengthened: in September 2010, Commissioner John Dalli and Regional Director WHO for Europe Zsuzsanna Jakab made a joint declaration in Moscow setting out their vision on how we can both work together in the future to promote the health of European citizens.

In 2010, the Council and the European Parliament adopted ***new legislation, a Regulation and a Directive, on pharmaco-vigilance***. This new legislation will strengthen and rationalize the current system for monitoring the safety of medicines on the European market. It will help improve patient safety and public health through better prevention, detection and assessment of adverse reactions to medicines.

In July 2010, ***a directive on the quality and safety of human organs*** intended for transplantation was adopted by the Council and Parliament in first reading. The Directive aims to reduce the risks to patients across Europe, maximise the benefits of transplantation for the EU citizens, increase trust in transplantation systems, facilitate exchanges of organs and finally ensure high quality transplantation for all Europeans. The network of the Competent Authorities was established and the first Competent Authority Meeting took place in September 2010. Moreover, a Workshop with journalists from Member States was organised in November 2010 on the issue of organ donation and transplantation and several articles have been written by the participants.

A Decision on ***the European Databank on Medical Devices (Eudamed)*** was adopted. Eudamed will strengthen the market surveillance by providing competent authorities with relevant information. The database will contain in particular data on registration of manufacturers and devices and data relating to certificates. The use of Eudamed will be mandatory as from 1 May 2011.

The Commission adopted a report looking at the public health, ethical, liability, economic and environmental aspects of the ***reprocessing of medical devices*** in the EU. The Commission is assessing possible further actions on reprocessing that could be taken in the context of the revision of the medical devices Directives in order to ensure a high level of protection for patients.

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An agreement between the co-legislators on the *Directive on falsified medicines* was reached in 2010. It aims to better protect patients by introducing harmonised, pan-European safety and control measures that will ensure easier identification of falsified medicines, and improved verifications and controls at borders and within the EU.

An agreement between the co-legislators reached in second reading in 2010 concluded the procedure for the *Directive on patients' rights in cross-border health care*. This Directive will benefit patients across Europe by clarifying their rights to access safe and good quality treatment across EU borders, and be reimbursed for it. It will bring about closer and improved health cooperation, including the recognition of prescriptions, between Member States. Health experts across Europe will be able to exchange best practices and mutually benefit from innovations in health technology assessment and e-Health. The Commission is already preparing for actions deriving from its implementation.

In 2010, work continued on the *proposals to modify the Directive and the Regulation on information to patients about medicinal products submitted to prescription*. The European Parliament adopted a first reading position on these proposals whereas the Council did not want to discuss them. The Commission will work on modified proposals to be submitted in 2011.

Preparatory work for the *revision of the tobacco products Directive* concerning the manufacture, presentation and sale of tobacco products, continued in 2010. The current tobacco products Directive dates back from 2001 and international and scientific developments as well as the good functioning of the internal market require reflections whether the Directive fully responds to the challenges and ensures a high level of health protection. A public consultation was launched in 2010, which resulted in 82 000 online answers. The Commission proposal is planned to be submitted in 2012.

A Joint Action on *Health Technology Assessment (HTA)* was launched at the beginning of 2010 and will last for three years. It aims to test a shared methodology to make joint EU HTA reports on selected health technologies; and develop tools for interaction between European HTA agencies.

Following the 2009 H1N1 flu pandemic, the Commission adopted in November 2010 a staff working paper on *lessons learned from the H1N1 pandemic and on health security in the EU*. Further recommendations will be integrated in the proposal for a revision of the Decision on communicable diseases combined with an initiative on prevention and control of other serious cross-border health threats at EU level (the so-called "*health security initiative*" in CWP 2011).

Furthermore, the EPSCO Council of 7 December welcomed progress towards *the setting up of a mechanism for joint procurement of pandemic influenza vaccines and antivirals* allowing Member States, on a voluntary basis, common acquisition of these products or common approaches to contract negotiations with the industry. The Commission committed to come up with a proposal in 6 to 9 months on joint procurement of pandemic influenza vaccines.

The EU Platform for Action on Diet, Physical Activity and Health has so far delivered close to 300 commitments and celebrated five years of active work in 2010. The first external evaluation report of this platform, published in July 2010, concluded that self-regulation commitments in the areas of advertising and marketing to children and

food/drink reformulation are having an impact, which could be further strengthened. In December 2010, the ***first implementation progress report for the Strategy for Europe on Nutrition, Overweight and Obesity related health issues*** was published. One of the first priorities of cooperation for the High Level Group on Nutrition and Physical Activity was an EU framework on salt reduction – in June 2010, EU Health Ministers adopted Council Conclusions calling on Member States to pursue efforts in implementing salt reduction.

Commissioner Dalli attended the World AIDS conference in July 2010 which demonstrated the EU engagement in the fight against HIV/AIDS.

Following the successful launch of the ***European Partnership for Action Against Cancer***, the focus in 2010 was the preparation of the comprehensive set of actions for the initial period of the European Partnership until the end of 2013. One of the important aims of the Partnership is to stimulate Member States to develop cancer plans by the end of the Partnership. This work of the Partnership will be mainly taken forward through a Joint Action launched in 2010.

Another major cancer achievement of 2010 was finalising the preparatory work leading up to the publication in February 2011 of the ***European Guidelines for quality assurance in colorectal cancer screening and diagnosis***. The guiding principles and recommendations should be followed in the Member States and allow EU citizens wherever they live to benefit from the same level of quality.

Two Joint Actions were initiated as part of the implementation of the 2009 Council Recommendation on ***rare diseases*** to respectively support the database Orphanet and EUROCAT (EU-wide network of surveillance of congenital anomalies). In addition, a Commission Decision was adopted to appoint the members of the newly created EU Committee of Experts on Rare Diseases (EUCERD) which started its activities in December 2010.

As a follow up to the 2009 Commission Communication on ***Alzheimer's Disease*** and other dementias, the Joint Action ALCOVE (ALzheimer COoperative Valuation in Europe) was launched in 2010. The Council Conclusions on Non-Communicable Diseases adopted in December 2010 reflected progress made in this area. .

The Commission reached important achievements in producing ***sound evidence for decision making*** in the health sector. The Commission devoted a strong effort in improving the availability and the international comparability of health data: in 2010 a new joint data collection together with WHO and the OECD was launched to gather data on non-monetary health statistics¹.

In October 2010, SANCO launched a test version of ***Heidi*** (Health in Europe: Information and Data Interface), a wiki-tool for sharing and developing information coming from experts and different data sources across Europe, which aims to be the one-stop-shop for health information in Europe.

The Europe 2020 strategy recognised the need for prompt action to address the ***challenge of demographic change***, viewing ***ageing*** not as a problem, but as a ***significant untapped growth opportunity***. The pressing societal challenge of health and ageing was therefore

¹ A first joint collection between EC, WHO and OECD to collect data on health expenditure and financing was launched in 2005, based on the system of health accounts (SHA).

reflected in the Innovation Union Communication that introduced the *European Innovation Partnerships*, tested through the launch of the pilot partnership *on active and healthy ageing*. The objective of the partnership is to *increase* by 2020 *the healthy lifespan of EU citizens*, measured by HLYs, *by 2 years*, and in doing so pursue a **triple win** for Europe: 1) improved health and quality of life of older people; 2) more efficient and sustainable health systems; and 3) fostered competitiveness and growth of EU businesses for active and independent living of older people.

A comprehensive report was issued jointly with the OECD: "**Health at a Glance: Europe 2010**". This report covers all EU Member States, including those that are not members of the OECD, and presents key trends on health, health systems and health expenditure across Europe.

Other *core business activities* in 2010 were *inter alia*:

- Adoption by the Commission of 1279 decisions of marketing authorisations of medicinal products, on the basis of opinions of the European Medicines Agency (EMA).
- Implementation, enforcement and monitoring of EU Public Health Law on substances of human origin, on tobacco products and on pharmaceutical products.
- Adoption of 52 opinions on health and environmental risks by the three Scientific Committees advising the Commission in the fields of health, consumer safety and the environment, supporting the development and implementation of relevant EU policies and regulatory instruments.
- Continuation of collaborative risk assessment projects with partners in the Transatlantic Risk Assessment Dialogue and organisation of a 2nd International Conference on Risk Assessment (January 2011).

The second edition of the EU Health Prize for Journalists was organised in 2010: 438 journalists from the 27 Member States submitted 745 articles in all official EU languages (60% increase compared with 2009). The Prize got a wide media coverage in the EU.

The *Public Health Website* (http://ec.europa.eu/health/index_en.htm) reached the top 20 of EUROPA's websites with over 300.0000 pages seen annually², a constant increase since the launch in 2006. Since its revamping, finalised in 2010, all the linguistic versions are now on line.

1.2.3. *ABB activity: Food Safety, Animal Health & Welfare and Plant Health*

Regulation (EC) No 669/2009, which entered into application on 25 January 2010, introduced, for the first time, a harmonized system at Member States' level on border *controls on imports of feed and food of non-animal origin*. Two Regulations amending Annex I were adopted in 2010 and the procedure for adoption of its third review was started.

Work started on the review of Regulation 882/2004 on *official controls along the food chain*, in particular in the areas of inspection fees, controls on residues of veterinary

² Latest available data from April 2010

medicines (Directive 96/23/EC), and border veterinary controls (Directives 97/78/EC and 91/496/EEC) for the purpose of simplifying and consolidating the general framework related to official controls.

A Commission Staff Working Document on the *Better Training for Safer Food (BTSF)* programme identified the principal challenges which BTSF is currently facing and a series of possible actions to overcome them. Globally, training in 2010 involved almost 6.000 participants attending around 140 training activities with a budget of approximately €14 million.

Under the Simplification Rolling programme, the implementing measures for the *Rapid Alert System for Food and Feed (RASFF)* were finalised and tabled for adoption in January 2011 and there was an increase of 11.6% in the follow-up of notifications and alerts by Member States and third countries. The *TSE Roadmap 2* was adopted providing a strategy on Transmissible Spongiform Encephalopathies for the next 5 years with the clear message that any amendment to the legislation should maintain the EU's high level of protection of human and animal health and of food safety and should be backed by solid science. Work also progressed on the revision of the total feed ban provisions.

Other measures adopted include regulatory amendments to the food hygiene regulations regarding chilling of poultry meat, bivalve molluscs, fishery products and production of collagen. In addition, a Communication on the future necessity and use of *mechanically separated meat (MSM)* in the EU was adopted, including the information policy towards consumers. A 5 year strategy on *antimicrobial resistance (AMR)* covering aspects of public health, food safety and animal health and welfare as well as the use of antimicrobials in human and animal medicine is under preparation and is due for publication end 2011.

The comprehensive proposal regarding a new flexible approach on *GMO cultivation* was adopted in July. The legal framework for the authorisation of *GM food and feed* was carefully applied respecting the high safety standards. The first EU authorisation for the cultivation of a GMO in more than 10 years was given in March.

There was progress on the politically important *Food Information* proposal with the European Parliament adopting its position and Council reaching a political agreement for its Common Position. Work will continue in 2011 to reach an agreement on the final text.

To protect citizens against misleading health claims on food, the Commission works to *establish lists of permitted health claims*, based on the scientific assessment of the European Food Safety Authority (EFSA) and following authorisation procedures at EU level. In 2010, 3 health claims were authorised and 15 were rejected. At the end of the process, only substantiated health claims will be permitted on the EU market. Concerning *nutrition claims*, an amendment adding 5 new nutrition claims was adopted in early 2010.

The need to optimise the existing legal framework on *dietetic foods* to take into account the more recent developments in food legislation (food supplements, fortified foods, claims) and to clarify their interactions with the dietetic food legislation is considered under the revision of the framework Directive on dietetic foods. An impact assessment supporting the revision of the legislation on dietetic foods received a favourable opinion of the Impact Assessment Board on 20 December 2010. The adoption of a new proposal by the Commission is foreseen for mid-2011.

The legislation in the area of *plastic food contact materials* was simplified and amended in order to ban the use of *Bisphenol A* in plastic infant feeding bottles so as to accommodate new data on possible health effects. 21 new substances to be used in plastic food contact materials and 6 new substances for *novel food* for marketing in the EU were authorised. For *Contaminants* and *Residues*, a revision of the current Directive 96/23/EC will establish a simpler framework for Member States. The proposal could be adopted in 2011.

Concerning the implementation of the new legislation on *plant protection products* (PPP) some important first steps have been taken in order to facilitate the transition from the old to the new system as from 14 June 2011. A series of workshops and expert meetings covering different aspects of the new legislation (e.g. mutual recognition, data requirements and risk envelope concepts) have been organised.

31 decisions were taken on active substances which were part of the review programme of *existing active substances* and which fell under the provisions of Regulation (EC) 33/2008. For another 23 active substances falling under the same Regulation, draft decisions have been presented to the Standing Committee of the Food Chain and Animal Health with a view to put them forward for a formal vote in early 2011.

The expert group on the framework Directive on *sustainable use of pesticides* has been re-established and reorganised and will meet for the first time in January 2011. Discussions on the implementation of *integrated pest management (IPM)*, which will become obligatory as from 2014, have been started with experts from Member States and stakeholders with a view to support a more harmonised approach between Member States. SANCO is also represented in the discussions on implementation and control of IPM under the reform of the Common Agricultural Policy (CAP).

On *cloning*, the Commission adopted a report to the Council and the European Parliament on all aspects of animal cloning for food production. On *nanotechnologies*, the definition agreed in a Council position was supported by the European Parliament. If a revised text is adopted in the conciliation phase there will also be a provision to adopt the definition to scientific progress and internally agreed definitions.

In the animal health area an amendment to the *"Pet" Regulation* (Regulation (EC) 998/2003) was adopted by Council and European Parliament. This was the first act with provisions adapted to Article 290 of the TFEU laying down a legal base for the Commission to adopt delegated acts for certain preventive health measures on diseases other than rabies. The amendment fully harmonises the requirements, and prolongs, for a limited time, the transitional regime in place for certain pathogens.

The Commission also adopted a *Communication on bee health*. In recent years higher mortality of bees was reported worldwide, including in the EU, but so far scientific studies have determined neither the causes nor the extent of the problem. In the meantime the Commission has launched a number of initiatives to address the concerns of the beekeeping sector. In the Communication the Commission sets out its ideas on these specific actions.

The *review of the existing animal health legislation* continued with the drafting of an overarching EU Animal Health Law. It will provide the principal rules for fundamental issues, such as responsibilities of animal keepers, business operators, competent veterinary authorities, as well as those concerning disease prevention and protection from biological threats (biosecurity). Implementation and enforcement in the animal health

area will also be assisted by careful alignment of the applicable general rules on official controls as laid down by Regulation (EC) 882/2004.

As regards *animal welfare*, in 2010 the First International Conference on Animal Welfare Education was organised jointly by the Belgian Presidency of the European Union and the European Commission. The motto of the Conference was "Everyone is responsible" and it was chosen to reflect the principle of collective responsibility right across the board, from farmers to professionals, civil society, government officials and all citizens. The Commission also launched a preparatory action for the renovation of high quality control posts. The purpose of the action is to improve the conditions under which animals are rested in control posts for very long journeys through better facilities.

The main challenge faced in 2010 for the *feed sector* consisted in the optimal management of the launch of the re-evaluation process of authorised feed additives, as provided for by Article 10(2) of Regulation (EC) 1831/2003. All essential feed additives were submitted by operators within the deadline which ensures continuity of the relevant authorisations and therefore supports good animal health and welfare in the EU. In addition, the Commission adopted more than 30 Regulations on the authorisation of new feed additives and extension of these feed additives to other species.

Concerning feed marketing the main achievement consisted in the establishment of management tools for the implementation of Regulation (EC) 767/2009 on the placing on the market and use of feed. In particular, the Catalogue of feed materials was created and subsequently collaboration started with feed business operators in order to adapt it to scientific, technological and market developments.

The key initiatives undertaken in 2010 in the field of *plant health, seeds and plant propagating material and plant variety rights* were the ongoing global revisions of the legislation in all three policy areas. For seeds and plant propagating material, the evaluation of the current legislation and impact assessment for new policy options was largely finalised in 2010. For plant health, the evaluation of the current regime was finalised and the impact assessment for future policy initiated. For plant variety rights, the evaluation study was initiated. The planned revisions will result in a modernised legal framework to allow a better protection and a more competitive environment for trade and movements of plant material into and within the EU.

The Commission's strategy in the *plant health* field focussed on a correct implementation of existing legislation, while developing a new plant health law. Upon request of certain Member States and in order to ensure a better and harmonised protection against the spread of new pests and diseases in the Union, the EU co-financed national eradication campaigns against harmful organisms for a total amount of €7, 3 million.

In parallel, the initiative to develop a *new common plant health strategy* has been further elaborated. During 2010, an overall evaluation of the current plant health regime has been finalised to prepare an impact assessment for new policy. In the sector of plant reproductive material, an increasing part of the work concentrated on the review of the legislation.

The common catalogues on varieties of agricultural and vegetable plant species were updated 12 times and both had a consolidated edition published. Altogether over 1800 new varieties of agricultural plant species and 1000 vegetable varieties were included in the catalogues. In 2010 the number of applications for *plant variety rights* increased compared with 2009. Currently, more than 17 500 varieties of plants are protected under

the EU system. As the Community plant variety rights regime dates back more than 15 years. SANCO launched an external evaluation. In the field of *plant genetic resources*, some preparatory meetings for the upcoming meeting of the contracting parties of the International Treaty in 2011 were organised.

Co-operation at *international* level remained an effective tool to deal with safety hazards of products at source, developing common strategies and exporting our regulatory standards and model as much as possible. Focus was placed on multilateral rule-making fora to reinforce our global presence, such as WTO, FAO, WHO food standards programme, CODEX Alimentarius, OECD, UPOV and the World Organisation for Animal Health (OIE), as well as on bilateral relations and agreements. The Commission transmitted to the European Parliament and the Council a report on the effectiveness and consistency of sanitary and phytosanitary controls on imports of food, feed, animals and plants which demonstrate that the EU has an effective system in place to ensure that consistent controls on imports are carried out across the 27 Member States.

The activities included the coordination with two agencies; the *European Food Safety Authority (EFSA)* in Parma and the *Community Plant Variety Office (CPVO)* in Angers.

To monitor the effective implementation and enforcement of EU feed and food safety, animal health, animal welfare and plant health standards by Member States and third countries exporting to the EU remained an important core business activity. In 2010, SANCO's audit service, the *Food and Veterinary Office (FVO)* located in Grange, Ireland, carried out 248 audits. 143 of these were in Member States, 22 audits took place in candidate countries and 83 in other third countries.

In 2010, the FVO concluded a first cycle of general audits to all 27 Member States in the framework of the Official Food and Feed Control Regulation (Regulation (EC) 882/2004), and the reports on these are in preparation. In candidate countries, the Office continued to monitor the state of preparedness for accession while the majority of the audits carried out in third countries were a review of existing approvals for exports to the EU, new requests for such approvals, or audits in countries where potential food/feed safety risks were identified..

The audits are instrumental in ensuring the credibility of the EU framework of legislation relating to food safety, animal and plant health and its enforcement by Member States. This is in turn essential to the continued consumer and business confidence in safety of, as well as the proper functioning of the internal market and trade with third countries in, food and food products.

SANCO is actively monitoring *progress on follow-up to audit recommendations* issued to competent authorities. As part of the SANCO follow-up strategy, the FVO carried out “general follow-up” audits in eleven Member States in order to verify the completion and effectiveness of corrective actions taken by the Member States in response to its audits. The end year 2010 target for achieving satisfactory commitments from Member States in response to recommendations made in the three year cycle 2007-2009 was set at 90%. This was broadly achieved with an outturn of 89%. The end year result for verification of action taken in response to these Member State commitments was 65%, exceeding the target set at 60%.

The FVO audit results also provide important input to the continuing review of EU legislation in terms of its suitability, and effective operation on-the-ground. Technical assistance to third countries in order to meet EU standards is also an increasing priority.

2. PART 2. MANAGEMENT AND INTERNAL CONTROL SYSTEMS

2.1. Introduction to DG SANCO

DG SANCO's mission is to protect and improve the health of citizens, to increase consumer welfare through greater empowerment and protection and to assure a high level of food safety, animal health, animal welfare and plant health. SANCO pursues its mission whilst focussing on a prudent management and control of the related finances.

The mission statement and the main priorities and objectives for 2010 were reviewed in the framework of the Management Plan (MP).

To monitor the execution of MP activities, a specific process has been set up consisting of bilateral meetings between the Director-General, individual Directorates and Unit Managers, as well as weekly management meetings of the Director General with all Directors.

2.1.1. DG SANCO in 2010: legal bases, financial envelopes and financial circuits for the three policy areas.

Consumer Affairs

On 13 March 2007 the Commission adopted the Consumer Policy Strategy for 2007-2013. The strategy sets out the challenges, role, priorities and actions of EU consumer policy. The overall objectives of the strategy are to empower consumers, to enhance their welfare and to protect them effectively. In order to achieve the strategy's objectives, European Parliament and Council Decision 1926/2006 establishing a programme of Community action in the field of consumer policy (2007 – 2013) provides a total budget of €155,7 million for the period 1 January 2007 to 31 December 2013.

In line with SANCO's financial control environment, the specific work programme for 2010 was adopted by the Commission on 21 December 2009. The total budget available for 2010 amounted to €20,2 million in comparison to €20,8 million in 2009. The 2010 budget included €0,9 million administrative budget and €19,3 million operational budget out of which almost 70% (€13,8 million) were implemented by the Executive Agency for Health and Consumers.

For the share of credits managed by DG SANCO in 2010 (€8 million), grants account for 15% and contracts for 85% of the total amount (see Table 1).

Public Health

On 23 October 2007, a White Paper on the European Health Strategy was adopted which, as of 2008, became the main basis for EU Public Health Policy. The overall objective is to contribute to increasing the number of healthy years of EU citizens by helping to promote health and prevent diseases, by protecting the population against health threats and by fostering co-operation between health systems. In order to support the strategy's objectives, European Parliament and Council Decision 1350/2007 establishing the Second Programme of Community action in the field of health (2008-2013), with a total budget of € 321,5 million for the period 1 January 2008 to 31 December 2013 was adopted.

The specific work programme for 2010 was adopted by the Commission on 18 December 2009. The total budget available for 2010 amounted to €46,1 million - a slight decrease

in comparison to last year's budget of €47,1 million. Out of the total available, almost 90% (€ 40,8 million) were implemented by the Executive Agency for Health and Consumers. DG SANCO implemented the remaining €6,6 million plus €16,9 million from the Tobacco Fund for the Tobacco Campaign, a Europe-wide media campaign to improve public awareness, especially among young people, of the harmful effects of tobacco consumption in any form.

The share of credits managed by DG SANCO was implemented through contracts, including the contracts for the Tobacco Help Campaign (see Table 1).

Food and Feed Safety

The integrated approach to food safety aims 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. Its financial instruments are under the centralised direct management mode (co-financing, no intermediaries) based on the reimbursement of actual eligible costs. The credits devoted to this area of activity fall under Heading 2, agriculture, and have been agreed for the period 2007 – 2013 with DG AGRI. For 2010, the available credits amounted to approximately €352,9 million which represents an increase of almost 20% in comparison to 2009.

A major portion of the budget, €293,5 million, is dedicated to animal disease eradication and monitoring programmes, including conditions of animals that could pose a public health risk, by providing funds to supplement national financial resources for approved programmes. Steps were also taken in 2010 to facilitate improved management in this area including the introduction of electronic submission of programmes and setting out an improved definition of eligible costs. An amount of €30 million was budgeted for the emergency fund for veterinary disease epidemics. A share of the Better Training for Safer Food measures, €13,3 million, was implemented by the Executive Agency.

For the credits managed by SG SANCO, procurements represent 5,8%, grants 4,2% and cost reimbursements 90 % of the total amount. Cost reimbursements are, to a large extent, similar to grants and, in financial terms, they are by far the major financial instrument used by DG SANCO: in 2010, € 296,5 million committed compared to the DG's total amount of commitments of €329,7 million – see Table 1.

Executive Agency for Health and Consumers

The Executive Agency for Health and Consumers (formerly the Public Health Executive Agency) was created on 1 January 2005. In 2008, the Agency's mandate was prolonged and expanded to include the Consumer Programme and the Better Training for Safer Food measures.

DG SANCO carries out supporting/steering activities in relation to the EAHC, in particular through the meetings of the Steering Committee, which is chaired by SANCO's Director-General and consists of four other members, three of which are the SANCO Directors responsible for the programmes entrusted to the EAHC. The Steering Committee meets four times a year and adopts the agency's work programme, annual management plan and draft budget. The Steering Committee is also regularly informed on the establishment of internal control standards in EAHC, audit findings and relevant follow-up, as well as of any other important issue relating to financial management.

Internal market for goods and sectoral policies

In 2010, DG ENTR transferred credits to DG SANCO for the implementation of certain actions in the policy area internal market (see part 2.1.2 below). The 2010 budget implemented by DG SANCO amounted to almost €51 million and concerned mainly the European Medicines Agency (EMA).

Financial Circuits and programme management

In DG SANCO, all financial transactions are carried out under direct centralised management.

As in previous years, all financial transactions (commitments, payments, recovery orders, etc.) and contracts/grant agreements related to operational expenditure in the three policy areas (Public Health, Consumers and Food and Feed Safety policy) are checked, authorised and signed by the sub-delegated authorising officers in charge of the activity. Each sub-delegated authorising officer is assisted by a decentralised financial cell which verifies and completes the files of the financial transactions and contracts/grant agreements before they are signed. Operational initiation and verification is carried out by members of staff of the different policy areas.

In addition, SANCO's central financial cell performs a second level ex-ante desk verification, based on a sample of transactions. The annual target is to cover about 75% of the monetary value of all transactions of the reporting year (commitments, payments, recovery orders). Furthermore, the DG's centralised on-the-spot control programme plays a prominent role in the financial control environment, verifying the eligibility of the costs claimed at beneficiary's level and going to Member States. Its annual objectives are to cover at least 20% of DG SANCO's annual operational budget and 5% of the annual payment transactions.

Public procurement is highly regulated via a Public Procurement Committee ("Comité des Marchés Publics" - CMP). This control framework within the DG provides assurance that public procurement procedures have been complied with in DG SANCO (see point 3.1.2 for details).

In Table 1 below you will find SANCO's key financial figures for 2010.

Table 1: Commitments 2010 – Operational credits implemented by DG SANCO

Policy Area	Number of Commitments	Total Amount €million	Average amount €million
Internal market:			
Subsidy (EMA)		48,18	n.a.
Contracts	11	2,79	0,29
Total		50,97	
Consumer Policy:			
Grants	6	1,18	0,20
Contracts	55	6,89	0,13
Total	61	8,07	
Public Health:			
Subsidies (EFSA and ECDC)		132,54	n.a.

Policy Area	Number of Commitments	Total Amount €million	Average amount €million
Contracts	119	23,50	0,20
Total		156,04	
Food & Feed:			
<i>Animal Health & Welfare and Plant Health</i>			
Cost reimbursements	175	296,51	1,69
Grants	3	0,64	0,21
Contracts	62	14,95	0,24
Sub-total	240	312,10	
<i>Feed and Food safety</i>			
Grants	73	13,60	0,19
Contracts	24	4,03	0,17
Sub-total	97	17,63	
Total			
Cost reimbursements	175	296,51	1,69
Grants	76	14,24	0,19
Contracts	86	18,98	0,22
Grand total	337	329,74	

The final situation on commitments on the 2010 budget shows an overall implementation rate of 96% (2009: 97 %).

Table 2 below gives an overview of the execution of the 2010 payment credits (related to operational credits).

Table 2: Execution of 2010 payment credits managed by DG SANCO

Policy Area	Payment credits 2010 €million	Payments 2010 €million	Level of execution %
<i>Consumer Policy</i>	13,16	10,70	81%
<i>Public Health</i>	178,17	151,35	85%
<i>Food and Feed Safety</i>	291,19	264,41	91%
Total	482,52	426,46	88%

The overall level of payment execution in 2010 of 88% was slightly higher than in 2009, when it was 85%.

As regards Consumer Policy and Public Health, there was an over estimation of the needs in payment credits due to over optimistic forecasts for the payments.

For Food and Feed Safety, as in previous years, despite the fact that the overall level of execution increased in 2010 to 91% (83% in 2009), most of the under execution in value, €26,8 million (€58 million in 2009), is due to unforeseen circumstances: the Eradication

Measures account for an under execution of €9 million (€20 million in 2009); other veterinary expenditures - €6 million; Phytosanitary expenditure - €5 million; Feed and Food safety – €4 million; and the Pilot Projects – €2 million.

A complete description of the management and control systems related to cost reimbursements, grants and contracts is available in Annex 5.

2.1.2. Human Resources

Integrating new functions and policy areas in DG Health and Consumers.

President Barroso announced on 27 November 2009 that certain functions and Units will move from DGs Enterprise and Environment to SANCO, and one Unit will move from SANCO to DG JLS. Based on a College decision on 17 February 2010, 20 staff (including contract agents and other temporary staff) left SANCO with the Unit Consumer Contract and Marketing Law to JLS. At the same time, the Pharmaceuticals and Medical Devices/Cosmetics Units arrived to SANCO from DG Enterprise, totalling 59 staff members. From DG Environment 15 colleagues joined SANCO.

Integrating the new colleagues to the organisation and welcoming them was a major effort but went smoothly. After the initial integration on 1 March 2010, a major organigramme change was adopted in April that created a new Deputy Director General post. A further small adjustment of the organigramme took place in July. Special induction training was organised for the new colleagues and the Human Resources Unit met the new Units on several occasions to ensure a smooth continuation of work. However, the physical office space became a major problem which is still unsolved, with the two Units arriving from DG ENTERPRISE remaining in the BREY due to lack of space in B232/F101.

Recruitment and mobility

All in all 2010 marked the first year of zero growth in staff. A lengthy process of integrating staff from the 10 new Members States (EU10) was completed. The recruitment from Bulgaria and Romania (EU2) is progressing as planned. Several Temporary Agents have meanwhile passed a competition and were recruited as permanent officials, effectively reducing the dependence on temporary staff. Time-limited posts were also decreased in response to the extension of the executive agency EAHC.

The situation led to a historically low vacancy rate at the beginning of 2010, around 3%, which continued throughout the year. The SANCO policy on external staff continued to be implemented with a particular focus on maintaining the sustainability of SANCO's policy of systematically replacing absent staff. This is in line with SANCO's commitment to help balance professional and private life and to ensure equal opportunities for all staff.

The Human Resources Management Committee adopted in June an updated policy on mobility. The policy in particular seeks to ensure possibilities for mobility under a zero growth of staff.

2010 saw four senior management changes, and several senior and middle-Management recruitment processes were underway.

Based on SANCO's proposal, DG HR and EPSO decided that SANCO can organise a selection process for Temporary Agents for the Food and Veterinary Office (Directorate F) in Grange in 2011.

Developing Good Working Conditions

The SANCO 2010 Away Day took place in September and was attended by staff from Brussels, Luxembourg and Grange. The main theme and the morning session was "SANCO in the World", highlighting the many aspects of our international work. The event was very successful according to the participants. The professional training elements concentrated on change management and communication.

SANCO continued to implement its effective teleworking and flexitime schemes that contribute to the work-private life balance. As part of the efforts to promote equal opportunities, SANCO's EO Network carried out a maturity assessment of SANCO's equal opportunities policies.

The Human Resources Unit organised exchange of officials between DGs as a joint initiative of six DGs and facilitated communities of practice. The initiative 'Greening SANCO' was transformed in the Commission-wide EMAS programme, aiming at reducing the DG's environmental footprint, with information and awareness-raising sessions, events and tours open to all staff.

Some organisation of office space took place in line with the revised Housing Conditions Manual and the changes in the organisation but the major re-grouping of Units was postponed to 2011.

While DG SANCO is located over three different sites, this does not affect its global efficiency. Following the transfer of activities from DG ENTR to DG SANCO, DG SANCO is also located over two different places in Brussels, which does not help the integration of new colleagues or operational efficiency.

Careers and training

In 2010, the ambitious team coaching programme of 2008-2009 was followed up and closed. The results were presented during the Commission's annual Learning Day in November. In June, SANCO published Guidelines for Organisational Development Group Learning Events.

Altogether, SANCO organised 44 general and technical courses in Brussels and Luxembourg tailored to SANCO's specific needs. Each course in SANCO was evaluated in terms of the meeting the participants' objectives, content, trainers and the overall rating (satisfaction). The average mark of the overall rating was 2.5 (scale 0-3) which confirms the overall satisfaction of staff with the courses offered.

SANCO organised a 2-day management seminar in April. The systematic investment in individual coaching programmes for managers at different levels shows the importance SANCO attaches to the development of modern management.

The average target of 10 learning days per person was fully met (10.5). In comparison with 2009 there was a slight increase of 0.23 days. The analysis of the training carried out was improved. Based on the analysis of Training Maps a number of recommendations were agreed upon in June. The training needs assessment in November

confirmed the high appreciation of SANCO training by staff and helped to plan the 2011 training offer.

The effective communication on training continued with the regular Training Bulletin which was later re-named into a Training News. The Training Correspondents' network continued its work.

The second round of the new appraisal and promotion system was carried out. SANCO made a significant effort to improve communication and transparency to enable staff to understand how the fair and efficient result was arrived at. According to DG HR tests, SANCO implemented the system fully in line with rules, meeting all deadlines and other obligations.

The key elements, such as a real dialogue between the jobholder and the reporting officer, setting up objectives and training maps, and better career planning continued to be positive aspects of the system. The appeal rate in SANCO decreased substantially, from 14% to 8%. The latter figure was about half of the Commission average. More than 140 DG SANCO officials were promoted.

Services at the Luxembourg site

The Human Resources needs of the colleagues on the Luxembourg site were catered for by a dedicated team working on recruitment, training and well-being. Similarly, the administrative unit in Grange provided HR services to staff.

2.1.3. Major events of 2010 having an impact on DG SANCO's reputation

No major events impacting the Director General's declaration of assurance occurred in 2010. However, it is worth mentioning that DG SANCO omitted to mention Christian religious holidays from the 2010/2011 edition of the Europa Diary. Immediate remedial action was taken to rectify this omission through a corrigendum.

2.1.4. Handover from the previous Director General and Deputy Director General

The previous Director General left DG SANCO on 31 March 2010 and was immediately succeeded on 1 April 2010 by a new Director General, who had been formerly the Deputy Director General (DDG) in our DG. Since 1 April 2010, the continuity of operations for the DDG post has been ensured until the end of the year by an Acting Deputy Director General. The new DDG took up his position on 16 January 2011; an additional DDG took up his position on 1 March 2011.

In the handover note, the outgoing Director General and Deputy 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.

2.2. The functioning of the entire internal control system

2.2.1. Compliance with the requirements of the control standards

A thorough self-assessment and review on the compliance and effective implementation of the Internal Control Standards was carried out in the 4th quarter 2010. The review was based on initial self-assessments carried out by a selected number of SANCO staff in management and other positions. The results of these assessments were then discussed and assessed by the members of the various SANCO Management Committees (Audit Committee, Budget Committee, IT Committee, and Human Resources Committee). Finally, the results of these second assessments were presented to, and validated by, the Management Team. The results proved to be very satisfactory and indicated a high level of effective implementation of the internal control standards.

2.2.2. Effectiveness of implementation of the prioritised control standards

As required by the revised internal control framework a certain number of internal control standards were identified in the Management Plan 2010 and the necessary actions were taken with regard to their effectiveness in 2010. Two internal control standards were prioritised. The results on each priority standard are as follows:

- ICS 13 related to accounting and financial reporting, with a special focus on ensuring that financial and management information produced by DG SANCO, including financial information provided in the Annual Activity Report, has to be in conformity with applicable accounting rules and the Accountant's instructions. DG SANCO re-assessed its financial reporting procedures with a view to further improve the quality of the financial data reported:
 - publication of reports on budget execution, RAL and open invoices on IntraSANCO (available to the entire DG) and in Infoview;
 - weekly verification of open invoices and monitoring of payment delays;
 - reports discussed in the Budget Committee (reporting standard);
 - use of Vision as a tool for budgetary planning and follow-up of budgetary execution;
 - update of Vision reports and publication in Infoview;
 - in order to ensure that errors and inconsistencies are detected and corrected as quickly as possible and to guarantee the quality of the financial reporting, DG SANCO put in place two types of controls over the financial and accounting data:
 - daily checks on selected transactions - second level ex-ante verification in the central financial cell, covering 75% of the monetary amount of the transactions;
 - monthly, quarterly and annual checks on the overall accounting data to ensure reliable financial reporting, based on accounting risk assessment and an annual revision programme approved by DG BUDGET.

These controls cover all transactions registered by DG SANCO, whether they are financed by administrative or operational budget lines and whether they are implemented by the central or the decentralised financial cells. The identified

errors are communicated immediately to the responsible financial cells for correction.

- ICS 15 related to the assessment of internal control systems, with a special focus on Management's assessment of the effectiveness of the DG's key internal control systems, including the processes carried out by implementing bodies at least annually. Based on the results of the thorough self-assessment conducted in late 2010 (see part 2.2.1 above), DG SANCO plans to introduce a more comprehensive approach in 2011, in order to perform an in depth analysis of individual standards so as to be able to detect as early as possible weakness in the internal control framework. Therefore, DG SANCO prioritised this standard again in 2011.

2.2.3. Conclusion

DG SANCO has put in place monitoring measures which ensure that its management and internal control framework is effective. DG SANCO has also considered the critical risks (see point 3.1.2 for details) and focuses the control resources on those areas where risks are the greatest, while ensuring adequate control coverage over all its activities. Based on all information and the above analysis, it can be stated that DG SANCO has an effective, efficient, robust and reliable internal control system at its disposal. This conclusion has been corroborated by the reports received from the authorising officers by sub-delegation.

2.3. Information to the Commissioner

The main elements of this report and declaration of assurance have been brought to the attention of Commissioner Dalli.

In general, the following specific working arrangements were agreed between DG SANCO and the Cabinet of Commissioner Dalli:

- DG SANCO keeps the Commissioner informed in a timely manner of any circumstances that may hamper the implementation of SANCO's work programme;
- Weekly coordination meetings with Cabinet take place;
- DG SANCO is reporting (twice a year) on management, internal control and audit issues (in March through the AAR and in September through the mid-term report).
- Other appropriate information is communicated to the Commissioner whenever deemed necessary by the Director-General.

3. PART 3. BUILDING BLOCKS TOWARDS THE DECLARATION OF ASSURANCE (AND POSSIBLE RESERVATIONS TO IT)

3.1. Building blocks towards reasonable assurance

3.1.1. *Materiality defined*

The criteria used in DG SANCO for making reservations are based on the Standing Instructions for the preparation of Annual Activity Reports for 2010.

Consequently, the main indicator used to judge whether a reservation should be made is the standard quantitative materiality threshold of 2%, i.e. when the value of the transactions affected by the deficiency represents more than 2% of the budget of the ABB activity.

In addition, 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 effect of the weakness;
- the existence of effective corrective actions to correct the weakness.

For a detailed explanation see Annex 4.

3.1.2. *Building block 1: Assessment by management*

DG SANCO has reasonable assurance that its management and internal control systems were effective and efficient during 2010.

The reasonable assurance of the Director-General of DG SANCO 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 is based on the following elements:

Internal control standards. As described in Part 2 of this report, the internal control standards have been effectively implemented during 2010.

Risk management is part of an effective internal control system. It facilitates the establishment of specific internal control strategies focussing on the activities and domains representing the highest risks. To be effective, risk management must be fully integrated into the planning and control cycle.

Risks were identified for 2010 and reported to the Commissioner. Action plans were developed to address these risks and to reduce them to an acceptable level. During 2010, a progress report was prepared in order to monitor the implementation of the action plans. This was done in the context of the mid-term review of the Management Plan.

After having invested considerably in 2009 in improving the risk management activities with six (in-house) risk management courses, tailored to the individual Directorates' specific working environment, DG SANCO made further efforts in 2010 to harmonise and consolidate the quality of its risk management. This resulted in increased preciseness

and completeness of risk definitions, concrete action plans and clear progress reporting, as well as more harmonisation and consistency in risk definitions between Units and Directorates, in particular due to the introduction of a harmonized template for Unit Management Plans (UMPs). Each Unit received tailored feedback on how to improve risk definitions and actions plans in the context of the preparation of 2011 UMPs. In addition, a workshop with the participation of a specialized consultant was organised (as part of the preparation of the 2011 Management Plan) in late 2010 for the Management Team in order to determine DG SANCO's critical risks for 2011 and to decide on mitigating actions.

Subsidies to regulatory agencies: in 2010, DG SANCO was responsible for three regulatory agencies receiving subsidies from the EU budget: EFSA, ECDC and EMA. In 2010, DG SANCO contributed €75 million, €58 million and €48 million respectively. While the Director-General of DG SANCO is accountable for the legality and regularity of the commitments and payments of these subsidies to the agencies, accountability for the regularity and legality of this expenditure resides ultimately with the agencies themselves. The use made of the subsidies by the regulatory agencies is checked – inter alia – by the European Court of Auditors, which gave EFSA and ECDC a positive declaration of assurance for the year 2009. For EMA, the Court gave a positive opinion on the reliability of accounts but a qualified opinion on the legality and the regularity of the underlying transactions, in particular related to EMA's procurement procedures. Given that the issues raised by the Court do not have a quantifiable effect on DG SANCO's subsidy payments to EMA, no reservation to DG SANCO's declaration is warranted. However, DG SANCO, within the limits of its role on EMA's Management Board, will closely follow up the improvements to be made by EMA.

Ex-ante desk controls of financial transactions: the mandatory first level ex-ante financial control of all financial transactions submitted by beneficiaries gives a visa on 100% of the transactions and ensures that costs have been claimed correctly and budgets have not been exceeded.

Second level ex-ante desk verification of financial transactions: is carried out to provide the delegated and sub-delegated authorising officers with feedback on the legality and regularity of the financial files that are presented for their authorisation. This function operates on a sampling basis based on the level of risk involved. Second level verification reports distinguish between financial errors (all errors affecting the amounts paid to beneficiaries) and formal errors (which cover all other types of breaches related to the legality and regularity of SANCO's underlying transactions). The function ensures that errors are detected, identified and that corrective action is taken.

The statistics provided by the second level verification are set out in the following table.

(1) Table 1: Results of 2nd level ex-ante verifications

		31/12/2009		31/12/2010	
		Number of transactions	Total Amount in €million	Number of transactions	Total amount in €million
A	Total number of transactions introduced by DG SANCO	3.826	1.097,99	3.755	1.171,08
B	Number of 2 nd level verifications	541	850,35	462	877,51
B/A	% of transactions verified	14%	77%	12%	75%
	<i>Typology of refusals affecting the legality and regularity (amounts of the transactions, not errors)</i>				
C	Formal errors	11	1,88	5	0,48
D	Financial errors	5	0,82	4	3,92
E	Total	16	2,69	9	4,40
E/B	refusal %	3,0%	0,3%	2%	0,5%
D/B	% of transactions with financial errors	0,9%	0,1%	1,0%	0,5%

Comments:

The selection of financial (commitments and payments) transactions to be subject of 2nd level ex-ante verification is based on an ex-ante risk analysis.

- (1) High rate of coverage: the number of financial transactions verified (12%) covers 75% of the total amount.
- (2) The amount of the transactions (A) and the verified amounts (B) include both commitments and payments.
- (3) The % of transactions with a potential financial impact is limited (1,0% in 2010 as compared to 0,9% in 2009) and the estimated amount of the errors themselves (0,5 %) is negligible. All detected errors were corrected prior to authorisation of the transaction, and hence have no impact on the declaration of assurance regarding the legality and regularity of SANCO's financial transactions
- (4) Most of the formal errors identified in 2010 relate to coding errors, such as different bank account numbers as compared to the data on the Legal Entity Sheet, or the substantiating documents do not correspond to the declared amounts.

Public Procurement Committee ("Comité des Marchés Publics": CMP) verifies that the procedures for Public Procurement have been correctly followed. This Committee consists of representatives of the central financial cell, the decentralised financial cells and of the legal affairs unit. It verifies the correct application of procedures for contracts

equal to or above €150.000. When the CMP delivers a negative opinion the Authorising Officer by Sub-Delegation needs to inform or request the approval of the Authorising Officer by Delegation in order to be able to make the corresponding commitment and sign the contract. In addition (s)he has to point out what remedial action has, or will be, taken in order to avoid future negative opinions.

In 2010, five contracts totalling around € 20,5 million were presented to the CMP, of which 4 received a positive opinion. A negative opinion was given for a contract concerning the "Youth Health Initiative". The number of files submitted to the CMP (5 in 2010 compared to 21 in 2009) decreased considerably due to the transfer of the three programmes (consumers, public health and better training for safer food) to the Executive Agency for Health and Consumers.

On-the-spot controls can either be ex-ante or ex-post. For these controls, DG SANCO has a dedicated sector within the General Affairs Directorate, independent of the operational Directorates. The 2010 on-the spot control work programme was presented to the Audit Committee in its meeting of January 2010.

The assurance provided by the on-the-spot control activities is an important building block upon which the assurance for the legality and regularity of SANCO's financial transactions is based.

On-the-spot controls are carried out on the basis of a risk-based control programme following DG-wide consultation. It is designed to detect and correct the highest financial errors and to minimise the residual risk of error in the remainder of SANCO's areas of spending.

Ex-ante "on-the-spot" controls are carried out prior to authorising final payments, the aim being to correct all detected errors and avoid undue payments. In 2010, these controls were carried out according to plan and focused on the high risk areas as follows:

1. For all claims on the veterinary emergency fund that exceeded €2 million and at the request of the operational services (7 control missions).
2. For 5 of the most important claims (in amount) relating to veterinary programmes.

Ex-post "on-the-spot" controls are carried out after the final payment has been made (7 control missions).

The results of completed on-the-spot ex-post controls by ABB activity in 2010 (and compared to 2009) are:

Consumers

Amounts in ('000€)	2009			2010		
	Number	Amount Controlled	Amount Correction	Number	Amount Controlled	Amount Correction
Completed controls consumers	3	262	0	4	4.866	20
			<i>0,0%</i>			<i>0,4%</i>

Comments:

1. The projects which were controlled were selected on risk-based criteria and not randomly.
2. The results of the ex-post controls in the area of consumer policy show that they have no impact on the reasonable assurance given by the Director-General.
3. No weaknesses in the internal control systems were detected and there is no need for a reservation for final payments in this policy area.

Public Health

Amounts in ('000€)	2009			2010		
	Number	Amount Controlled	Amount Correction	Number	Amount Controlled	Amount Correction
Completed controls public health	4	2.451	148	14	6.920	430
			6,0%			6,2%

Comments:

1. The projects were selected on risk-based criteria and not randomly following the ex-post control work programme for 2010. The selected projects are not representative of all the projects financed in the public health sector.
2. The detected error rate of 6,2% relates to grants.
3. The detected errors resulted in corresponding recovery orders and have thus been corrected.
4. The majority (72%) of the 2010 payments in the area of public health policy relate to procurement contracts. The award of these contracts have been subject (all contracts equal or above € 150.000) to ex-ante verifications and validations by DG SANCO's Public Procurement Committee (CMP). Payments are made according to the price fixed in the contract on the basis of validated deliveries. Paying a fixed price agreed in a procurement contract involves a much lower risk of error than reimbursing actual costs based on third party declarations. Therefore, the 100% ex-ante desk controls are considered sufficient to ensure an error rate of 0% in the related payments. Neither the audit observations on tender procedures of DG SANCO's Internal Audit Capability (see part 3.1.3.1, point 1, below) nor the Court's finding on DG SANCO's verifications of deliveries (see part 3.1.3.3 (i) below) have a bearing on this assessment.

Assuming that payments for procurement contracts are free of error together with the fact that the detected errors related to grants were corrected, it can be concluded that the residual rate of error is below the materiality threshold of 2%.

5. A reservation on payments related to the ABB activity Public Health as a whole is therefore not warranted.

Veterinary expenditure

Amounts in ('000€)		2009			2010		
		Number	Amount controlled	Amount correction	Number	Amount controlled	Amount correction
Completed controls	veterinary	30	14.157	970	25	51.185	1.942
				6,9%			3,8%

Comments:

1. Ex-post on-the-spot controls completed in the area food safety (veterinary) policy in 2010 point to a correction rate of approximately 3,8%. These relate to payments made mainly between 2005 and 2008.
2. The projects were selected on risk-based criteria and not randomly. The selected projects are therefore not representative of all the projects financed in the food safety sector.
3. The coverage of ex-post controls in 2010 equals 30% of payments made in 2007 and 30% of payments made in 2008 in accordance with the 2010 ex-post control work programme.
4. The issues that gave rise to correction and which were common to a number of audits were:
 - (1) The failure of Member States to take note of the fact that lesser cost reimbursements are applied by the Commission in cases where there had been excessive delays by Member States in reimbursing their farmers. Commission Decision 2008/940/EC has since been adopted and now requires detailed ex-ante information on this point from the Member States. This decision applies to programmes for the eradication, control and monitoring of animal diseases to be implemented from 1 January 2009, thereby eliminating payment delay issues as a source of future ongoing corrections.
 - (2) Disagreements between the auditors and the Member State authorities on the real market valuation of animals required to be slaughtered.
 - (3) A not always good understanding by the Member State of the eligible expenditures. A new definition (more precise and restrictive) of those eligible expenditures was introduced in the Commission decision for the veterinary programmes starting on 1 January 2011.
5. In addition, since 2010, the most important claims (in amount) relating to veterinary programmes are audited ex-ante "on-the-spot". More than 40% (in amount) of payments in 2010 in the veterinary area were audited ex-ante "on-the-spot".
6. Consequently, taking account of the fact that corrective measures were introduced by Commission Decision 2008/940/EC, the new definition of the eligible expenditures, and the very large coverage of the controlled and corrected amounts, the residual error rate lies well below the materiality threshold of 2%. DG SANCO does not feel it is appropriate to make a reservation in the 2010 AAR.

Key indicators supporting reasonable assurance for direct centralised management

<i>Input: resources devoted to ensure legality and regularity of underlying transactions</i>	2009	2010
Number of DG's internal staff dealing with ex-ante verification (full time equivalent)	12.5	12.5
Number of DG's internal staff dealing with ex-post controls	4	6
Number of DG's internal staff in Internal Audit Capability	3,5	3,5
Financial resources used to fund external audit activities	€80.000 for Public Health, €250.000 for Food and Feed	€50.000 for Public Health, €210.000 for Food and Feed
Number of financial transactions	3.826	3.755
Amount of financial transactions	€1.098 million	€1.171 million
<i>Output: controls during project implementation</i>	2009	2010
Number of financial transactions subject to a non favourable opinion during ex-ante financial verification	<u>ALL SANCO</u> 2nd level: rejected - 16, observations - 105 <u>ALL SANCO</u> 1 st level: rejected - 89, observations - 0	<u>ALL SANCO</u> 2nd level: rejected - 9, observations - 124 <u>ALL SANCO</u> 1 st level: 158 rejected, observations - N/A
Number of financial transactions subject to a 2nd level ex-ante verifications at the desk (target 75% of total amount)	<u>ALL SANCO</u> Number: 541 (14%) Amount: € 850 million (77%)	<u>ALL SANCO</u> Number: 462 (12%) Amount: € 877 million (75%)
Number of registered exception procedures	<u>ALL SANCO</u> Type 1 (reported to DG): 9 Type 2 (approval from DG): 3	<u>ALL SANCO</u> Type 1 (reported to DG): 12 Type 2 (approval from DG): 0
Number of instances of overriding controls	<u>ALL SANCO</u> None in addition to exception reports	<u>ALL SANCO</u> None in addition to exception reports
<i>Output: controls carried out during the ex-post phase of projects</i>		
Amount of financial transactions affected by ex-post control (population of year n)	€178,0 million	€163,0 million
Amount of financial transactions actually verified/audited ex-post (sample of which some audits not yet finalised in year n)	€36,1 million	€99,0 million

<i>Input: resources devoted to ensure legality and regularity of underlying transactions</i>	<i>2009</i>	<i>2010</i>
<i>Result of controls</i>		
Amount of net financial corrections identified by finalised ex-post controls in year n/compared with amount of financial transactions actually verified/audited ex-post in year n (= average detected error rate)	€1,1 million €16,9 million (6,6 %)	€2,4 million €63,0 million (3,8 %)
Amount of recovery orders linked to ex-post controls issued in year n	1.118.000	2.568.831
Amount actually recovered compared with recovery orders issued for the same cases	172.361	744.022 ³

3.1.3. Building block 2: Results from audits during the reporting year

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

In 2010, the SANCO's Internal Audit Capability finalised four audits of which one financial audit. The other three audit assignments focused on operational rather than financial aspects.

The areas for improvement identified by the IAC are the following:

1. For contract management in the field of public health and grant management with international organisations

The Internal Audit Capability issued a satisfactory audit opinion. The five very important recommendations relate to (i) improvement of tender procedures regarding the determination of the maximum value of the contract and the comparison of the bid's prices; (ii) negotiation of estimated budgets for grants to International Organisations; and (iii) availability of a long-term planning document for expensive or complex databases.

2. For the supervision of regulatory agencies under SANCO responsibility

The audit concluded with a satisfactory opinion as regards DG SANCO's supervision activities and the controls put in place. One very important recommendation was made to improve the capacity of DG SANCO to supervise the regulatory agencies. Given the limited weight of the Commission representatives at the Management Board, the existing tools for evaluating the performance of the agencies should be strengthened. To facilitate an efficient monitoring by DG SANCO, the agencies need to improve their work plans by defining a consistent set of multi-annual and annual objectives as well as result oriented indicators.

3. For the management of veterinary programmes in DG SANCO

³ Not all recovery orders have already been issued due to recent closing of some files.

The Internal Audit Capability gave a satisfactory opinion except for the following two areas for which three very important recommendations were made:

- (i) The management of both the use of appropriations and the allocation of funds to the relevant programmes must be strengthened. The initial estimation of the amount to be allocated to each programme need to be better substantiated and documented.
- (ii) DG SANCO's control of data provided by the Member States in their funding requests should be reinforced with the support of suitable IT tools.
- (iii) To ensure the achievement of the programmes' long-term goals, DG SANCO should improve the monitoring of the progress made by each programme through a consistent set of targets for eradication complemented by milestones.

4. For crisis preparedness and crisis management in DG SANCO (during the 2009 H1N1 outbreak)

The Internal Audit Capability issued a satisfactory audit opinion regarding compliance with the internal procedures of DG SANCO during the crisis. Improvements should be sought as pointed out by the auditors in three very important recommendations: (i) the scientific capability of DG SANCO needs to be increased; (ii) the development and production systems for pandemic vaccines should be streamlined in order to promote more rapid and secure availability; and (iii) the working methods of DG SANCO in crisis management should be revised and the role of the Health Security Committee need to be further clarified.

3.1.3.2. Internal Audit Service (IAS) of the Commission

In 2010, the only audit carried out by the IAS in DG SANCO was the follow-up audit on the 2008 audit on grant management in the Food and Feed area (see part 3.1.4.3 below). No new audit recommendation was addressed to DG SANCO.

3.1.3.3. European Court of Auditors

1. European Court of Auditor's 2009 Annual Report

The Court published its final audit report in the Official Journal on 9th November 2010. Chapter 3 includes three specific observations concerning DG SANCO:

- (i) In the public health area, the Court criticised that DG SANCO had not adequately verified the delivery of services it had paid for. DG SANCO considered it appropriate to carry out the checks on a sample basis, but agrees to carry out additional controls in the future.
- (ii) In the food and feed area, the Court considered that DG SANCO should have made a reservation in the 2009 AAR due to the error rate of 6,9% found during ex-post controls. DG SANCO disagrees with the Court due to the fact that the high error rate was related to one case with a unique risk exposure under isolated circumstances that have not since recurred in DG SANCO. Net of this non-representative error, the 2009 error rate in the food and feed area amounted to 1% which is below the materiality threshold of 2%. Hence, no reservation was warranted.

- (iii) On animal disease eradication programmes, the Court criticised several aspects of the internal control system demanding a more systematic segregation of functions, a clearer definition and distinction of the roles and duties of initiating and verifying officers, a periodically reviewed formal risk analysis, a standardised report of the veterinary officers on the implementation of the programmes, standardised checklists for the controls performed, and an increase in the number of ex-post audits to provide assurance that payments are free from material error.

DG SANCO believes that the duties and roles of all officers involved in the relevant transaction are clearly set out in the job descriptions. Nevertheless, improvements will be sought to further clarify the segregation of duties and to standardise internal control, reporting and checking keeping in mind that the nature of the programmes is not fully comparable (eradication vis-à-vis monitoring). During past ex-post controls, DG SANCO had checked, on a two-year basis, more than 35 % of the amounts paid. Moreover, assurance that payments are free from material error does not rely only on ex-post controls. In 2009, taking all the building blocks of the internal control system together, DG SANCO had reasonable assurance based on management's assessment of the entire internal control system, audit results, follow-up of previous year's reservation and action plan for audits from previous years and the assurance received from other authorising officers in cases of crossed sub-delegation.

2. European Court of Auditor's special audit on veterinary checks for meat import

In January 2009, the ECA started its special audit on the Commission's management of the system of sanitary checks for meat imports following the 2004 Hygiene legislation reforms. The Court focussed on how the Commission ensures that, firstly, the information systems relating to sanitary checks on meat imports (TRACES, RASSF) are performing effectively and that, secondly, the national systems for managing sanitary checks are working properly. After the finalisation of the contradictory procedure between the Commission and the Court, the final audit report is expected to be published in mid March 2011.

3.1.3.4. Assurance gained from building block 2

Based on the results of its audit and follow-up work as described in the objectives and scope of the engagements carried out in 2010, DG SANCO's Internal Audit Capability (IAC) issued a satisfactory audit opinion stating that the internal control system in place in DG SANCO provides reasonable assurance⁴ regarding the achievement of the business objectives set up for the processes audited, except for the twelve very important audit recommendations described above. Some of the very important recommendations were made to improve the management of the animal disease eradication, control and monitoring programmes. The Court of Auditors had also pointed out weaknesses in this area.

⁴ 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*.

However, 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; 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.

3.1.4. Building block 3: Follow-up of reservations and action plans for audits from previous years

3.1.4.1. Previous year's reservations

In previous years, the Director General did not make any reservation to the Declaration.

3.1.4.2. Follow-up on recommendations of DG SANCO's IAC

In 2010, the IAC continued its bi-annual follow-up checks encompassing eight audits with a total of 106 recommendations. At the end of 2010, 23 recommendations were still open of which 9 very important, 11 important and 3 desirable. Based on its 2010 follow-up exercise, the Internal Audit Capability gave an overall positive assessment with 78% of all IAC recommendations implemented and actions taken carefully across DG SANCO.

3.1.4.3. Follow-up on recommendations of the Internal Audit Service (IAS)

1. 2006 IAS audit on DG SANCO's large IT-systems

After the IAS's first follow-up audit, three issues remained open in late 2009. DG SANCO effectively implemented the relevant actions to the effect that, by mid 2010, the IAS had closed all recommendations.

2. 2008 IAS audit on grant management in the Food and Feed area

In its audit, the IAS had raised several issues relative to the financial management of the veterinary sector and issued ten recommendations. During the follow-up exercise in June 2010, the IAS closed six recommendations that DG SANCO had implemented in a timely manner. For the other four recommendations, DG SANCO has either already taken appropriate action or is well advanced in implementing its action plan. One very important recommendation pertaining to the animal disease eradication fund will become due in mid 2011. The issues raised by DG SANCO's IAC and the European Court of Auditors for the same field of activity will be taken into consideration.

3. 2009 IAS audit on grant management in the Executive Agency for Health and Consumers (EAHC)

As a result of this audit, some recommendations were addressed to the agency and some to SANCO. The implementation of the action plan is ongoing, with most of the target dates due in 2011. The IAS has not yet carried out a follow-up audit.

Two very important recommendations were addressed to DG SANCO: (i) to improve priority setting in the work programmes for public health and to ensure coherence with the resources available in the agency; (ii) to better integrate the requirements of the delegation act into the guidelines and arrangements for the coordination between DG SANCO and the executive agency. For both recommendations, DG SANCO had launched appropriate actions to be finalised in the course of 2011.

3.1.4.4. Follow-up on European Court of Auditors' previous recommendations

1. European Court of Auditor's 2007 Annual Report

The Court's Annual report 2007 stated that payments were made for veterinary measures in the absence of all the necessary supporting documentation. DG SANCO has taken corrective action by introducing, for new contracts, a clause stating that the producer of the vaccines has to prove that the vaccines were sent to the location as determined by the Commission.

2. European Court of Auditor's 2008 Annual Report

From the European Court of Auditor's 2008 Annual Report, none of the issues addressed by the Court and accepted by DG SANCO remained open in 2010.

3. European Court of Auditor's Special Report No. 2/2009 on the Public Health Programme

In June 2009, the Court presented its Special Report on the Public Health Programme (PHP). In this report, the Court called into question the utility of certain parts of the PHP for the programming period 2003 - 2007. No critical or very important recommendation was made. DG SANCO concluded that any successive Public Health Programme should set out an explicit intervention logic, substantiating the utility and increasing the European added value of the programme. Specific indicators will be developed and monitored during the lifetime of the programmes. The 2010 evaluation of the Public Health Programme is an important input to the review process. It will be complemented by an ex-ante impact assessment to analyse the different policy options and their respective impacts for a possible successive programme after 2013.

3.1.4.5. Assurance gained from building block 3

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.

3.1.5. Building block 4: Assurance received from other Authorising Officers in cases of crossed sub-delegation

In 2010, DG SANCO cross-delegated activities to five other DGs (ENTR, ESTAT, INFSO, JUST and PMO). The Director-General of DG SANCO is ultimately responsible for these activities, but the legality and regularity of the resulting financial transactions is ensured by the internal control systems put in place by the authorising officers to whom these cross-delegations have been given. These authorising officers have reported to SANCO on the use made of the cross-delegations. These reports did not indicate any irregularities.

DG SANCO also received cross sub-delegations from eight other DGs (AGRI, AIDCO, DIGIT, ELARG, ENTR, ENV, RTD and MARKT) and reported to these DGs on the use made of these delegations.

3.1.6. Completeness and reliability of the information reported in the previous paragraphs

The information provided in the previous paragraphs give a complete and reliable view on the quality of DG SANCO's internal control environment covering the total budget delegated to the Director-General.

3.2. Reservations

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 2010 and has not identified material weaknesses. DG SANCO therefore makes no reservation.

4. PART 4. DECLARATION OF ASSURANCE

I, the undersigned,

*Director-General of the
Health and Consumers
Directorate General,*

In my capacity as authorising officer by delegation

Declare that the information contained in this report gives a true and fair view⁵.

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, 31 March 2011

(Signed)

Paola Testori-Coggi

⁵ *True and fair in this context means a reliable, complete and correct view on the state of affairs in the service.*