European Commission

Management Plan 2016

DG Health and Food Safety

Contents

PART 1. Overview of main outputs for the year

General objective 1: A new boost for jobs, growth and investment

Specific objective 1.1: Effective preparedness, prevention, reaction and eradication of human, animal and plant diseases

Output table 1.1 is included in Annex 1.

Human diseases

In 2016, SANTE will adopt several implementing acts under Decision 1082/2013/EU on serious cross-border health threats. The Commission Implementing Decision on procedures of Early Warning and Response (EWRS) will define procedures for the functioning of the EWRS. A second implementing act on coordination of health threats coordination will establish the necessary procedures to ensure uniform implementation of information exchange, consultation and coordination between Member States and the Commission.

Developments in the area of communicable diseases require updating the list of communicable diseases which are addressed by routine surveillance at EU level. In order to put a new communicable diseases under EU surveillance (in 2016 SANTE will propose to include three vector borne diseases: Dengue, Chikungunya and Neuroborrelliosis), specific case definitions have to be developed to allow consistency in reporting to the ECDC. Preparatory work started in 2015 and the adoption of the updated list and definitions is planned for the end of 2016. This could include also Zika virus.

In addition, the following specific outcomes are expected for 2016:

- A Staff Working Document, on necessary changes to the European Centre for Disease Prevention and Control's (ECDC) structure and working practices as required by Art.31 of ECDC's Founding Regulation (851/2004/EC).
- Award of the market linked to the joint procurement procedure (started in 2015) for Personal Protective Equipment to protect healthcare workers against severe infectious.
- Continued preparatory work for a joint procurement procedure for pandemic vaccines with a view to publishing the call for tenders in 2017. The joint procurement agreement, signed so far by 22 Member States, defines mechanisms and procedures to allow Member States - on a voluntary basis - to jointly procure medical countermeasures to enhance their preparedness against health threats.
- An outline of concrete action to strengthen preparedness in the EU with a view to further supporting the implementation of core capacities under the International Health Regulations.

Animal diseases

The adoption of a new legal framework (EP and Council Regulation) for animal health is foreseen for May 2016. This will contribute to a more competitive and sustainable European livestock sector and the functioning of the EU's internal market in live animals and their products.

Following its adoption, SANTE will prepare several delegated and implementing acts to supplement the general measures in Animal Health Law to prevent epidemics, trade-related endemic diseases, and in general support long-term growth in the livestock sector.

Other significant activities foreseen for 2016 include:

- An external study examining the regulatory environment associated with intra-EU trade certification and exploring ways to alleviate some burdens.
- Emergency Decisions, adopted as necessary, according to the epidemiological situation.

- Adoption of the Commission implementing rules on safe imports, trade and related aspects.
- Formulation of a coordinated EU position for the General Session of the OIE at the end of May 2016 on the amendments of the OIE Terrestrial Animal Health Code, Aquatic Animal Health Code, Manual of Diagnostic Tests for Terrestrial Animals and Manual of Diagnostic Tests for Aquatic Animals. This an important action to ensure the EU's influence over international standards continues.

  A Tendering procedure for the purchase of new stock of the EU's existing foot and mouth disease (FMD) vaccine. Renewal of the stock will ensure that the EU is fully equipped to support the Member States with the right type and quantity of vaccines, in case of need, especially in light of the unfavourable FMD situation in North-Africa and in the Middle East.

The EU's financial contribution for animal disease eradication, control and monitoring programmes aims to progressively eliminate animal diseases and/or implement disease monitoring measures in Member States and the EU as a whole. It represents by far the largest amount of expenditure under the EU food safety budget.

Plant diseases

On the plant health side, the adoption of the new basic Regulation by EP and Council is foreseen. An action plan will be issued for the development of the delegated and implementing acts for the implementation of the new Regulation. Preparative work for the acts with strict deadline in advance of the adoption of the Regulation will be initiated. In parallel, the list of regulated harmful organisms and mitigating measures will be updated.

Emergency measures to control outbreaks of harmful organisms within the EU will be issued or updated as appropriate. Specific import requirements might be issued for trade lines with many import interceptions.

In addition, the focus will be put on crisis preparedness and crisis management in the plant health sector, including some concrete initiatives like:

- Commission Decision for Member States 2016 surveillance programs for EU co-financing
- Monthly publication of the list of import interceptions. Every 4 months, analysis of import interceptions by dedicated Commission Working Group, followed by presentation of actions to take at Standing Committee
- Monthly presentation of an overview of new outbreaks in the Union territory at Standing Committee, with possible discussion on follow-up, as appropriate
- Development of electronic database for outbreak notification
- Contingency plans by all Member States in case of a Xylella outbreak.

Following the withdrawal of the proposal on plant reproductive material a decision on the possible way forward to solve the problems of the existing legislation is needed. As regards new innovative solutions in seed production, the legislation will be amended on new fodder seed mixtures and on true potato seed. New innovative plant varieties will also supported by revising the proceeding before CPVO for variety (intellectual) protection. A proposal for simplifying the decision making process for equivalence decisions will be made.

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

Output table 1.2. is included in Annex 1.

In 2016, DG SANTE will continue its efforts to maintain a high level of food and feed safety.

In particular, it will:

- Adopt a report on National Action Plans under Directive 2009/128/EC on sustainable use of pesticides. This will provide information on how far Member States are progressing towards the sustainable use of pesticides and which actions have been taken so far.
- Launch a study to collect information on plant variety testing on value for cultivation and use in Member States to develop criteria and testing methods to improve sustainability of plant varieties (e.g. disease resistance, drought tolerance) and food production in EU. The report will be completed in the first quarter of 2017.

Regarding GMOs and with a view to inspiring confidence in new technologies as drivers of economic development, the Commission will a) implement the newly adopted GM cultivation legislation with authorisations with restricted scopes, b) contribute to the discussions on the proposal on GM food and feed giving possibilities to MS to take account of their national societal concerns (by in particular presenting elements as regards EU commodities and legal argumentations on the soundness of the proposal), c) adopt a legal interpretation of the Commission on the scope of the EU GMO legislation, which will bring clarity on the applicable legal framework to new breeding techniques and will help EU research institutions and business operators to take informed decisions on future investments in new technologies.

In 2016, DG SANTE will carry out some of the follow up actions set out in Regulation (EU) No 1169/2011 on the provision of food information to consumers. It is working on the report concerning the application to alcoholic beverages of the mandatory indication of the list of ingredients and of the nutrition declaration, from which they are currently exempted. In the area of origin labelling, following the adoption of a series of reports, an implementing act setting the modalities for the new rules on voluntary origin indications is being prepared.

DG SANTE is also working on an impact assessment on trans fats, following a report which suggested a legal limit for industrially produced trans fats as the most effective measure in terms of public health, consumer protection and compatibility with the internal market. The impact assessment is planned to be finalised in fourth quarter of 2016. Based on the impact assessment the Commission may propose an initiative aiming to restrict the use of industrially produced trans fatty acids in foods.

With a view to assist food business operators, and in particular SMEs, to easily identify the mandatory labelling requirements when they place foods on the EU market, DG SANTE is working on the creation of a user friendly IT tool encompassing all mandatory EU and national labelling requirements for specific categories of foods.

In the area of foods for specific groups, DG SANTE will carry out work to finalise the delegated Regulation on some slimming foods. It will also analyse whether specific rules are needed for "growing up milks" for young children (1-3 years) (also known as “young-child formulae”) and "sports foods" to ensure a high level of consumer protection and effective functioning of the internal market for these products. Two reports will be finalised, after consultations with EFSA, Member States and stakeholders, taking into account results of relevant market studies.

Concerning, food waste, DG SANTE will implement the action plan on the circular economy package as far as the prevention of food waste is concerned. Support to actions by all actors of the food chain and by Member States to prevent food waste whenever possible will contribute to the sustainability of the food chain and have both economic and environmental gains.

On food fraud, in 2016, DG SANTE will work on establishing synergies between the Food Fraud/Administrative Assistance and Cooperation, RASFF and TRACES networks in order to get the most of the means currently available to enhance our efficiency to detect and coordinate food fraud issues. Internal Commission coordination is also a priority together with enhancing the cooperation with police (EUROJUST ad INTERPOL) and justice (EUROJUST). New coordinated ‘baselines’ action will be launched, as the one already started on ecommerce of food, in order to establish the prevalence of issues in the domains studied.

In relation to animal welfare, DG SANTE will complete six outstanding actions of the EU animal welfare strategy adopted in 2012. This includes a recommendation on the welfare of pigs. In addition it will ensure a follow-up of the Eurobarometer survey as well as establish regular stakeholders'

dialogues to improve animal welfare. At the same time DG SANTE will continue exploring the potential market value of EU animal welfare standards at global level through its integration in international standards as well as in EU free trade agreements.

Market access for safe substances

DG SANTE will propose a number of authorisations in 2016 for substances used in the production and processing of food and feed, based on requests from food business operators and on the safety evaluations carried out by the EU agencies (EFSA, ECHA).

These include new substances and new uses of already authorised substances used as food additives (about 20 new authorisations and about 15 amended authorisations per year), food flavourings, novel foods (over 50 authorisations and notifications yearly), substances used in plastic food contact materials (20 substances added yearly to list of above 1000 permitted. In addition, over 100 authorisations for recycling processes of plastics used in food contact materials will have to be prepared with a view to be authorised in 2017 as well as GM food and feed.

New authorisations and renewal of previously authorised active substances in plant protection products and biocides will be proposed based on the outcome of the safety evaluations (about 60 regulations per year approving about 50 new substances).

Maximum residues levels (MRL) for pesticides will be set to allow circulation of food on the internal market at the same time as guaranteeing that food is safe, wherever it is bought in the EU. MRLs are also a requirement for the import of food from non-EU countries in order to maintain the same level of safety. There are around 50 MRLs decided for different substances yearly.

An important milestone will be the individual authorisation of 106 recycling processes for plastic materials coming into contact with food. The completion of this work will fully implement Regulation (EC) No 282/2008 establishing a level playing field for these business operators and will contribute to the circular economy.

DG SANTE will also propose withdrawal of certain substances (flavourings, pesticides) to ensure the quality and safety of products circulating on the internal market. In addition, DG SANTE has drafted a measure on bisphenol A (BPA) in food contact materials (migration limit for plastics as well as coatings) based on the EFSA opinion to harmonise the use of this substance in the EU in these materials, where diverging national measures currently exist.

Effective implementation of EU food legislation

Effective implementation of EU food legislation contributes to a level playing field for food business operators and ensures the effective functioning of the internal market.

In 2016, DG SANTE will continue implementing Regulation (EU) No 609/2013 on foods for specific groups (FSG) which requires the Commission to adopt a series of implementing measures. These include Commission Delegated Regulations on food for special medical purposes, on infant formula and follow-on formula and on total diet replacement for weight control.

These products are currently regulated under the old framework applicable to “dietetic foods” that Regulation (EU) No 609/2013 repeals from 20 July 2016 in order to simplify EU law. The delegated Regulations transfer existing rules applicable to these products and update them on the basis of latest scientific advice from EFSA, where available, and extensive consultations with Member States and interested parties.

In addition, a Commission Regulation to carry out technical adaptations to existing rules to make claims on "meal replacement products" for weight control will be finalised.

The Commission will also do its utmost to finalise the impact assessment linked to setting scientific criteria for the identification of endocrine disruptors, as required by the legislation on plant protection products and biocides. Soon afterwards the criteria will be proposed via corresponding draft legal acts.

Specific objective 1.3: Cost effective health promotion and disease prevention

Output table 1.3 is included in Annex 1.

Country knowledge

A report, "The Health at a Glance: Europe," is scheduled to be published in November 2016. It will provide a comprehensive picture of the EU's health situation and provide horizontal analysis on key issues.

In addition, preparation of health profiles will begin in collaboration with the OECD and Observatory on Health Systems and Health Policies.

All these initiatives respond to President Juncker's request in the mission letter to Commissioner Andriukaitis to develop expertise on performance assessments of health systems and to build up country-specific and cross-country knowledge. They also contribute to cost-effective health promotion and disease prevention by providing the necessary evidence base for such policies.

Tobacco

The new Tobacco Products Directive (2014/40/EU) must be transposed by Member States by 20 May 2016. For the Commission, the priority will be preparing the remaining implementing acts (mainly on ingredients, electronic cigarettes and measures against illicit trade), implementing the legislation in practice (including the development of IT tools and the setting up of a test panel) and international tobacco control (COP7 in India).

The Commission implementing decision on a priority list of additives will allow regulators to learn more about additives in tobacco products with a view to possible further regulation based on increased scientific knowledge. This is an important aspect of tobacco control policy as it increases knowledge about the toxicity, addictiveness and attractiveness of tobacco additives. From a broader perspective, this will discourage smoking, in particular among young people, promote public health and prevent disease.

The Commission implementing decision on technical standards for refillable cigarettes and the report on health risks aims to contribute to product safety and, from a broader perspective, improve health and prevent disease. These initiatives will allow regulators to learn more about the health risks related to electronic cigarettes with a view to possible further actions.

SANTE will also adopt Commission Implementing acts on determining characterising flavour and setting up an advisory Panel to assist Member States and the Commission in assessing tobacco products with a potentially characterising flavour. These provisions will effectively contribute to a better functioning of the internal market while ensuring a high level of public health.

The activities carried out by the panel will promote effective and uniform implementation of Directive 2014/40/EU. The assessment of tobacco products with potential characterising flavour will also increase the knowledge base for tobacco product regulation and policy and, from a broader perspective, contributes to improved public health and prevention of disease.

Chronic diseases

As part of a cross-cutting approach to support Member States in preventing and managing chronic diseases, action in 2016 contributes to an exchange of good practise, better networking of Member States and stakeholders, and creating incentives to develop and adapt innovation for the prevention, early detection and management of chronic diseases, including cancer, and rare diseases. Work will include joint actions as well as structured cooperation with Member States and stakeholders, including in the existing EU expert groups on cancer control, rare diseases and on mental health and dementia.

More specifically, in 2016:

A. A conference on "the prevention and management of chronic diseases" will be organised in April 2016. The Commission will present its plans on how to take forward the response to the burden of chronic diseases in support of Member State efforts in this regard.

B. Joint Actions with Member States on chronic diseases, rare cancers and dementia will be launched and developed to trigger networking and relevant health policy development/implementation across Europe (target date 31/12/2016)

C. The work of expert groups on cancer control, rare diseases and mental health and dementia will continue to develop and support the implementation of their work plans; an informal group of chronic diseases experts will accompany the process. The work of all these groups will be facilitated by the EU Health Policy IT Platform.

Member States have identified food reformulation and certain aspects of alcohol-related harm as particularly important for tackling chronic diseases and improving the sustainability of their health systems.

The work of the High Level Group on Nutrition and Physical Activity and of EU platform for action on diet, physical activity and health, and also of the relevant discussion fora on alcohol-related harm, will be instrumental for these purposes.

The 2014 Council Conclusions on Nutrition and Physical Activity called for reports on the implementation of the Action Plan on Childhood Obesity in 2017 and 2020. Accordingly, a tender will be launched in 2016 to commission the first report.

By working on food reformulation and certain aspects of alcohol-related harm where there is added value in coordinating European approaches, the Commission will be creating the conditions for more cost-effective health promotion and disease prevention. This will in turn improve the sustainability of health systems and contribute to boosting jobs, growth and investment.

Scientific committees

The 2016-2021 term of two new Committees, the Scientific Committee on Consumer Safety (SCCS) and the Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) will start in April 2016. They are expected to publish about 25 scientific opinions by the end of 2016 linked to risk assessments in the area of public health, consumer safety and the environment and help risk managers in all departments of the Commission to take evidence based decisions.

Specific objective 1.4: Effective, accessible and resilient healthcare systems in the EU

Output table 1.4 is included in Annex 1.

Antimicrobial resistance (AMR)

The evaluation of an EU Action Plan against rising threats from antimicrobial resistance will be launched in 2016 to assess its impact. It will focus on the achievements and failures of its 12 key strategic actions and assess their effectiveness and contribution to the management and control of AMR in the EU. The findings will enable the Commission to better identify what new or additional measures should be taken.

In addition, the following outputs are also expected:

- Completion of work on a preparatory action on the prudent use of antimicrobials in human medicine will produce policy recommendations to improve the appropriate use of antibiotics and reduce the risk to human health from infections due to resistant bacteria.
- A joint action by the EU and EU Member States under the Health Programme will aim to develop and exchange good practices in addressing AMR and healthcare-associated infections in the period 2016-2019.

Implementation of the Directive on patients' rights in cross-border healthcare

The proper transposition of the Directive on the application of patients' rights in cross-border healthcare is monitored, which will also ensure its implementation for the benefit of patients and clarify its *modus operandi*. Areas for improving cooperation among Member States include regional cross-border care, data exchange, better information to patients and healthcare providers via National Contact Points.

Innovative health technologies

The Communication on effective, accessible and resilient health systems identified eHealth as one of the tools and called for further efforts to develop effective and interoperable telemedicine services.

DG SANTE's eHealth policies and actions will be integrated into the Digital Single Market Strategy. In July 2016, SANTE will make a proposal for the health contribution to the implementation of the Digital Single Market 2017-2018, in particular on standardisation and interoperability for eHealth (telemedicine, mHealth). The Commission will make a proposal for recommendations on the efficient use of Big Data in health care and public health to the eHealth Network in November 2016.

The Commission began work in 2015 to set up a new eHealth Digital Service Infrastructure (DSI), co-financed under the Connecting Europe Facility (CEF), creating the basis for cross-border exchange of patient summary and ePrescription service and increasing access to health services cross-border. IT services for European Reference Networks (ERN) will be financed under the CEF. The indicative budget is EUR 15 million from the 2015 budget but further funding will be requested to cover all Member States and service elements.

DG SANTE will, with DIGIT and CNECT, build the eHealth DSI so that the technical core capability is ready for the exchange patient summaries and e-prescriptions towards the end 2016. In November 2016, agreements to set up the National Contact Points for eHealth will be signed with around 10 countries under the Connecting Europe Facility programme.

Blood, tissues and cells and organs

The supply of blood, tissues and cells is essential for the EU-28 healthcare systems. No surgery, emergency care or traumatology can be organised without blood. Tissues and cell therapies are needed to treat leukemia, to address increasing infertility, burnwounds and diseases like blindness. Organ transplants allow every year over 30,000 severely ill patients to take up an active and productive life again. These therapies are usually based on voluntary unpaid donations, and therefore come at the (limited) cost of preparing them.

The EU legislations, laying down safety and quality, date back from 2002 (blood) and 2004 (tissues and cells). Many technical and organisational evolvements have taken place since in this dynamic sector, and the implementation reports seem to indicate some need to align the legislation with this progress and innovation.

An evaluation of EU law on blood, tissues and cells planned for 2016 will allow identifying, specifying and quantifying possible issues, by bringing together recent sector knowledge and views of Member States and key actors in the field. This will help understand if, and how, our legislation at best allows EU citizens to access and benefit from these valuable therapies.

In the organs sector, DG SANTE will also evaluate the impact of the Organ Action Plan (2009-2015), which supports Member States in building more resilient and accessible transplant systems, including an increase of organ availability.

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

Output table 1.5 is included in Annex 1.

Medicinal products

In 2016, DG SANTE will present an assessment report (as required by Article 59(4) of Directive 2001/83/EC) on current shortcomings in the summary of product characteristics (SmPC) and the package leaflet (PIL) for medicinal products and how they could be improved in order to better meet the needs of patients and healthcare professionals. On the basis of the report, and consultation with appropriate stakeholders, SANTE will, if appropriate, present proposals in order to improve the readability, layout and content of these documents.

Orphan medicinal products

Regulation (EC) No 141/2000 was adopted in 1999 to encourage the development and authorisation of medicinal products for rare diseases. This legislation has been successful in supporting development of innovative treatments for the benefit of the patients. DG SANTE is looking into streamlining the regulatory framework on orphan medicinal products after 15 years of experience in this field. DG SANTE is reviewing the 2003 Communication on Regulation (EC) No 141/2000 on orphan medicinal products in order to adapt the text to technical progress and intends to present it as a Commission notice.

This notice will provide interpretative guidance to applicants of the Regulation (EC) No 141/2000 on orphan medicinal products with the aim of, e.g.:

- Facilitating the entry onto the European market of innovative products with a significant benefit over existing products;

- Encouraging the development of orphan medicinal products for communicable diseases (e.g. Ebola) with no or very low prevalence in the EU.

In addition to the interpretative guidance, certain definitions of Regulation 847/2000 require adaption to technical and scientific progress due to major developments in the field of biological medicines including advanced therapy medicinal products. For this reason, a revision of Commission Regulation 847/2000 on orphan medicinal products is also planned for 2016.

Advanced Therapy Medicinal Products (ATMPs)

ATMPs are innovative medicinal products based on cells or tissues as well as gene-therapy. Future ATMPs are expected to address some of the current areas of unmet medical need. Europe is strong on the research in the field and, from an economic standpoint, it is important to maintain and develop the competitiveness of the sector, in particular for SMEs and other small developers.

The manufacturing of ATMPs is faced with a number of difficulties due to factors such as the variability of the starting materials and the very small-scale production which is typical for these products. It is challenging for SMEs and university hospitals (which are at the origin of most of the developments in the field) to comply with the general GMP rules which have been designed for standardised products and large-scale production.

The adoption of Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products which is plan for 2016 aims to reduce burdens without compromising public health. This will improve the competitiveness of the sector in the EU and will contribute to the emergence of new innovative products for the benefit of patients.

Expert Panel on Investing in Health

The Expert Panel has worked only for two years but shown its value in providing consolidated, independent knowledge, completing so far six opinions on modernisation, quality and effectiveness of public expenditure in the health sector; further four will be completed by June 2016. The term of

the members will end in May and the new Panel will be nominated by September 2016. In autumn 2016, the new Panel will work on 3 opinions.

European Reference Networks (ERN)

The first ERN are expected to be operational in 2016. ERN will bring together highly specialised healthcare providers from different EU Member States in areas where expertise is rare. The ERN is one of the most important and innovative cross European cooperative initiatives in health care and the only at EU level with an institutional character and a legal base.

The call for interest for setting up a ERN will be launched in the first quarter of 2016. Independent Assessment Bodies contracted through a framework contract will carry out the assessment of the proposals. The proposals assessed positively will be considered for approval by the ERN Board of Member States. The target is to have 10 ERN established through 2016 call as well as set up the basic IT structure serving the Networks. The networks will be able to benefit from to grants under the work plan 2016 of the Health Programme for networking and management but not for clinical care of patients.

Specific objective 1.6: Effective, efficient and reliable official controls

Output table 1.6 is included in Annex 1.

DG SANTE's Directorate on Health and Food Audits and Analysis (formerly the Food and Veterinary Office – FVO)), carries out audits and related activities to ensure that EU legislation on food safety, animal health, animal welfare, plant health and some areas of human health is properly implemented and enforced. The effective enforcement of EU requirements in the above areas within the EU and in non-EU countries exporting animals, plants and products to the EU is key to maintaining high levels of food safety, animal health and welfare and plant health in the EU.

In 2016, the Directorate plans to adopt the Report on the operation of official controls in the Member States on food safety, animal health and animal welfare, and plant health. The report provides an overview of the delivery of official controls in the Member States in these areas as required by Article 44(4) and (6) of Regulation (EC) No 882/2004, based on the Member States' annual official control reports, as well as the controls carried out by the Commission. The report mainly covers 2014 and 2015 information on official controls.

In 2016, the Directorate aims to carry out 225 audits in Member States, candidate countries and non-EU countries exporting to the EU in the areas of food safety, animal health, animal welfare and plant health. However, the desired results and expected outcomes of audits and best practice identification and dissemination depend strongly on the willingness and vigour of Member States and non-EU country authorities to act.

In addition to its reports on individual audits, the Directorate also produces overview reports to ensure that the results of audit series are presented in a manner which facilitates understanding of the state of implementation of EU legislation and the problems and good practices identified across the MS.

In addition, up to 25 joint assessments together with designating authorities from Member States, EFTA and EEA countries on the performance and designation of Notified Bodies in the medical devices sector will be performed in 2016. The Directorate will also carry out a number of other related activities to improve the performance of control systems. Among those are:

- review of Member States' Annual Reports on the implementation of their Multi-Annual National Control Plans (MANCPs) under Regulation (EC) No 882/2004 ,
- organisation of regular meetings of networks of Member State officials responsible for the MANCPs and the performance of audits of official controls to facilitate exchanges of experiences and the preparation of guidance papers;

- organisation of meetings with Member State experts in a number of areas such as animal welfare, slaughter hygiene or live bivalve molluscs to discuss common problems and exchange best practices identified;
- evaluation of facilities of Border Inspection Posts;
- evaluation of Member States' and non-EU countries' residue monitoring plans;
- management of lists of approved non-EU country establishments for the production of food of animal origin;
- operation of the notification system for plant health interceptions, EUROPHYT.

As a complementary tool to DG SANTE's audits, the Better Training for Safer Food programme plays an important role in spreading knowledge and awareness of EU legislation, in promoting harmonisation and uniformity of control activities across the EU and in improving the ability of control staff to detect fraud and non-compliance on the EU market but also at its borders. In 2016, there will be around 15 contracts signed under the programme.

Specific objective 1.7: Increased EU influence in international fora

Public health

Increased EU influence in global health fora

The Commission will prepare an input to and participate in three Governing Bodies meetings in 2016. It will contribute to defining the EU position in these bodies. It will also cooperate with WHO according to the administrative arrangement on the objectives and modalities of the Commission/WHO EURO Office cooperation.

The European Union is a member of the WHO Framework Convention on Tobacco Control (FCTC) and is about to ratify the FCTC Protocol to Eliminate Illicit Trade in Tobacco Products.

DG SANTE actively participates in the on-going implementation work, among other as a Key Facilitator (KF) for the Working Group on Articles 9 and 10 of the Convention and by serving on the Panel of Experts on the FCTC Protocol.

In November 2016, the FCTC Parties will assemble for next Conference of the Parties (COP). The COP is the governing body of the WHO FCTC and is comprised of all Parties to the Convention. It keeps under regular review the implementation of the Convention and takes the decisions necessary to promote its effective implementation, and may also adopt protocols, annexes and amendments to the Convention.

It is instrumental that the Commission/DG SANTE is present during the COP and can report on the progress achieved with regard to tobacco control in the EU, in particular in terms of the on-going implementation of the Tobacco Products Directive. The EU is in a strong position to lead by example and provide for the necessary momentum for all the Parties to the Convention.

Increased international harmonisation through ICH & bilateral cooperation

International harmonisation through the International Council for Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) allows promoting both the competitiveness of the EU pharmaceutical industry and high EU standards. DG SANTE, with the support of the EMA, is heavily involved in the development of the new ICH Association and its activities. DG SANTE is notably a major contributor to the financing of the operations of the Association and the EMA is providing extensive technical expertise for the development of new ICH guidelines.

The European Commission has been driving the recent (2015) reform of ICH and has been actively drafting the Articles of Association and the Rules of Procedures for the reformed ICH which determines e.g. the rights and obligations of the new ICH members, including the obligations of new

regulatory members to implement ICH guidelines. DG SANTE will continue in 2016 working on the implementation of the reform.

Decisions on new guideline development will be taken when supported by the European Commission. Increased harmonisation through the adoption of ICH guidelines facilitates access to multiple markets, including those of US, Switzerland and Japan that are currently the three most important export markets for the EU. Moreover, DG SANTE is encouraging regulators from other important or emerging markets such as Russia, China, Australia or Brazil to join ICH as members and to implement its harmonised guidelines. In addition, DG SANTE is also promoting membership in ICH through the regular regulatory dialogues, in particular with China and India.

Animal health and food safety

WTO SPS Agreement

In 2016, DG SANTE will continue to represent the EU at the formal and informal meetings of the SPS Committee as well as at bilateral meetings in the margins of the Committee meetings. The work in the Committee will be prepared in cooperation with Member States through regular meetings of the expert group on SPS chaired by DG SANTE.

DG SANTE will make a robust defence of the EU policies which are frequently the subject of criticism in the Committee, notably endocrine disruptors, GMOs, novel foods or pesticides limits among others. In addition, DG SANTE will conduct an information session on novel foods to present the new Regulation to all interested WTO Members and to answer questions on its implementation.

DG SANTE will explore new initiatives or topics that could be incorporated into the agenda of the Committee with a view to publicising and promoting EU policies in the SPS field. With the same objective, DG SANTE will work cooperatively with like-minded WTO Members in areas of common interest and will continue its efforts to create coalitions around the EU views on the rights and obligations of the SPS Agreement. Together with DG TRADE, DG SANTE will also raise the offensive interests of the EU both in the plenary of the Committee and in bilateral meetings with relevant trading partners.

DG SANTE in its capacity as Notification Authority and Enquiry Point will also ensure the fulfilment of the EU transparency obligations under the SPS Agreement as regards notification of EU measures, comments on other Members' measures and provision of information.

Finally, DG SANTE will also contribute to Trade Policy Reviews of non-EU countries and will facilitate the work of other WTO Committees, notably the Technical Barriers to Trade (TBT) Committee, by providing all the necessary information regarding TBT measures in the areas of responsibility of DG SANTE.

International Standard-Setting Bodies

Similarly, DG SANTE will continue to represent the EU at the meetings of the International Plant Protection Convention (IPPC), the World Organisation for Animal Health (OIE) and Codex Alimentarius as well as at other relevant international organisations. DG SANTE will promote, and defend EU interests, ensuring that international standards are as closely aligned with EU views as possible. Equally SANTE will ensure we respect our international obligations and ensure that trade can continue under safe and fair conditions.

DG SANTE will represent the EU's interests by ensuring teams are composed of negotiators and technical experts. Where it is not possible to have international standards based on EU norms and values, these teams will make sure the effects of these standards on trade are minimal and will also seek to prevent trade disputes. In 2016, we will work on a number of important files including: dispute settlement cases in the WTO and IPPC, limiting the adoption of standards that authorise the use of substances which are banned in the EU, overcoming issues related to funding shortages, and, building strategic partnerships and alliances with other non-EU-countries.

DG SANTE will work with other Commission services, seeking to multiply the effects of its work and avoid duplication wherever possible. DG SANTE will also work with stakeholders, amongst them, the food and drink industry, and organisations dealing with animal and plant health.

Moreover, DG SANTE will share its expertise and experience through capacity-building in the areas of our multilateral work. By building capacity in partner countries, in 2016 we hope this will increase the opportunity for import of many raw materials into the EU (many of which are needed to produce the highly lucrative, finished products which are subsequently exported by the EU), and to develop and intensify relationships that will deliver support for EU positions, including votes where necessary, at the multilateral level.

General objective 2: A deeper and fairer internal market with a strengthened industrial base

Specific objective 2.1: Effective EU assessment of medical products and other treatment

Health Technology Assessment (HTA) presents information on a health technology, pharmaceutical product, medical device or health intervention, in a systematic and unbiased manner to inform decision makers on the safe and effective use of the technology. It is an important tool to achieve best outcome and value for money for patients, health professionals and health systems.

The Single Market Strategy and the 2016 Commission Work Plan called for a Commission proposal to reduce fragmentation and duplication in the internal market through further cooperation and mutual recognition in HTA procedures carried out by the Member States. SANTE will draft the inception impact assessment on the HTA initiative, with a view to launching a public consultation in June 2016.

In parallel, the scientific-technical work will be strengthened as the third Joint Action agreement on the EUnetHTA cooperation will be signed in May 2016 for a period of 4 years, paving the way for a permanent and sustainable system.

Specific objective 2.2: Stable legal environment and optimal use of current authorisation procedures for a competitive pharmaceutical sector and patients' access to safe medicines

Output table 2.2 is included in Annex 1.

Access to innovative medicines is a complex issue that depends on multiple stakeholders and factors including research and development, marketing authorisation procedures, Health Technology Assessment (HTA), and pricing/reimbursement decisions. Pharmaceutical companies want shorter approval times to facilitate innovation, reduce the time taken to access the market and to improve patient access to medicines.

Encouraging innovation in the pharmaceutical sector

Commission services will continue working with experts from Member states and the European Medicines Agency (EMA) (Expert Group on Safe and Timely Access to Medicines for Patients - STAMP) to optimise the use of existing legislative tools, raise awareness and improve clarity of regulatory scientific requirements. This will help adapt the regulatory environment to changes in the pharmaceutical landscape to improve market access for medicines and ensure patients continue to benefit from new, innovative, affordable and safe medicines in the future.

Specific initiatives include streamlining the procedures for products subject to accelerated assessment, optimising the time it takes to authorise innovative medicines of major interest to public health.

PRIME (PRIority MEdicines), a new scheme to support companies and academia - in particular SMEs - to develop promising new medicines to address unmet medical needs, will also be launched in 2016. PRIME will give developers of eligible products access to early dialogue with, and scientific advice from EMA to ensure that data generated during development meets the standards required for regulatory approval. The scheme is expected to support a faster evaluation and authorisation procedure for eligible products ensuring they reach patients sooner.

Secondary legislation to support the new EU clinical trials Regulation

A number of important elements of secondary legislation will be adopted in 2016 to support and supplement the EU's new clinical trials Regulation (Regulation (EU) No 536/2014). These will include a delegated act laying down the principles and associated guidelines for good manufacturing practice linked to investigational medicinal products for human use (medicinal products tested or used as reference in a clinical trial). They are important to ensure data generated during clinical trials is high quality, safe, reliable and robust and that they reflect technological progress and global regulatory developments in which the EU is involved.

They will also include an implementing act on the detailed arrangements for Good Clinical Practice inspection procedures, including the qualifications of the inspectors (already harmonised at EU level by Directive 2005/28/EC), and an implementing Directive laying down the principles and guidelines of good manufacturing practices for medicinal products for human use.

The new Implementing Directive will mainly carry over provisions laid down in Commission Directive 2003/94 (which will be repealed). It will maintain the high standards required to ensure the quality of medicinal products marketed in the EU.

Specific objective 2.3: Common Member States' tools and methodologies used for EU health systems performance assessments

Output table 2.3 is included in Annex 1.

In 2016, SANTE will start rolling out the first deliverables of the new, two-year *State of Health in the EU* cycle. The first cycle (2016-17) comprises a revamped *Health at a Glance: Europe* report (November 2016), twenty-eight country health profiles (November 2017) and a Commission Staff Working Document (November 2017).

By November 2016, the joint Commission-OECD report *Health at a Glance: Europe* 2016 will be published – a descriptive, horizontal starting point for the *State of Health in the EU* cycle, adjusted to the 2014 Commission Communication on effective, accessible and resilient health systems.

A pilot phase will also be completed for the country health profiles, in which one or two full country health profiles are prepared by the OECD and the European Observatory on Health Systems and Policies for internal Commission usage. These pilot country health profiles will be used to gauge feedback and to adjust, as necessary, the final deliverable of twenty-eight country health profiles by November 2017.

DG SANTE is also building expertise on the performance of health systems in EU Member States with a view to identify tools and methodologies that will contribute to better and more accessible healthcare and more efficient and more resilient healthcare systems.

To achieve this, DG SANTE has set up and co-chairs a Commission expert group on health systems performance assessment (HSPA) which establishes a policy priority for each calendar year. The objectives of ongoing work in the HSPA expert group is to progress towards a common methodology and related tools to develop performance assessment. In 2016, the expert group will continue to define indicators and tools to advance in the different criteria to assess performance, such as quality and access to care. This contributes to SANTE's specific objective 2.3 which aims to promote Member State use and application of the methods and tools developed at EU level through the expert group.

General objective 3: A reasonable and balanced Free Trade Agreement with the U.S.

Specific objective 3.1: A balanced SPS agreement with the US

Public health

A free trade agreement with the US and the mutual recognition of Good Manufacturing Practices inspections would allow the EU and the US to rely on each other's GMP inspections and exchange confidential information on inspection reports. This would entail significant cost savings for industry. It would also lead to a better use of respective inspection resources by avoiding the current overlap of inspections carried out by both parties of EU, US and non-EU countries facilities. Resources freed could be redeployed to other inspection priority areas in non-EU countries. This strengthened bilateral collaboration would thus provide greater capacity to control the safety of products irrespective of origin. This should lead to a reduction of risk and promote global adoption of high level standards of quality for the production of medicinal products. In 2016, the assessment of the EU and the US systems will be pursued and the framework for mutual recognition will be developed and included in the TTIP agreement.

Animal health and food safety

The achievement of a decrease in the number of trade irritants on the US side is one of the main aims of discussions under TTIP for the EU negotiators. Currently, the EU is excluded either wholly or partially from many important US agri-food markets due to Sanitary and Phytosanitary (SPS) barriers. The process of addressing trade irritants has been formalised between the EU and the US in the form of the TTIP "Action Plans", which are being negotiated in parallel to the TTIP SPS Chapter. A second Action Plan was agreed in 2015 which aims to address a number of SPS barriers in the short-medium term (18-24 months). Among the main such barriers to be addressed in this period will be those impeding EU Member States from exporting beef, sheep and goat meat, pasteurised dairy products, egg products and apples/pears. If the barriers are resolved, all interested EU Member States will have the opportunity to export these products to the US.

PART 2. Organisational management outputs for the year

1. Human Resource Management

With Jean-Claude Juncker taking office of the Commission at the end of 2014, important changes have been implemented on working methods, priorities and to rebalance competencies and files between the DGs including affecting directly DG SANTE. Although useful preparatory work has been carried out in the first 9 months of 2015 it is only since the appointment of the Director General of DG SANTE in September 2015 that concrete decisions and actions could be taken in order to incorporate above changes in DG SANTE's organisation and thus to shape the DG for the future.

This has led to a proposal for a new organisational structure for DG SANTE which will come into effect early 2016. Although the change is not revolutionary, it is certainly the first significant reorganisation since 2011. This has also provided an opportunity to make a significant mobility among DG SANTE managers, many of whom have particular specialist skills, taking account also of the geographical distribution of the DG over 3 Member States.

Above reorganisation is the first step of DG SANTE's overall strategic objective towards achieving organisational excellence as explained in its Strategic Plan 2016-2020. A fit for purpose organisational structure is the essential framework to ensure effective deployment and use of resources.

Subsequently the main focus will be shifted on specific action to develop, empower, and engage staff within a supportive and healthy working environment. Structures are important but will not provide results without transforming them into engaged teams.

Table 1 with the presentation of main outputs is included in Annex 1.

2. Better Regulation

The new organisational structure of DG SANTE enables the DG to focus better on the Commission's strategic priorities and to deliver on Better Regulation objectives. A Better Regulation unit is now in place to support the effective implementation of the Better Regulation agenda across the policy/regulatory cycle.

DG SANTE effort to fulfil the obligations stemming from that agenda and ensure policy objectives are achieved in the most efficient and transparent way will continue to be made in 2016, in particular through impact assessments, evaluations and fitness checks.

We are currently finalising the Fitness Check of the so-called "General Food Law" (Regulation (EC) No 178/2002), which has reviewed the key policy components of the founding act of the current EU food chain acquis, including its principles, the rules on crisis management and those governing the set-up and functioning of EFSA.

Two REFIT evaluations have started at the end of 2015 and will be pursued in year 2016:

1. the REFIT Evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005), which aims to provide an independent, evidence-based assessment of the implementation of that legislation;

2. the REFIT Evaluation of Regulation (EC) No 1924/2006 on nutrition and health claims made on food; the evaluation will in particular regard one of the features of the Regulation (the "nutrient

profiles"), and health claims made on plants and their preparations, along with the general regulatory framework for the use of plants and plant preparations in foods. The evaluation will assess whether those elements have proven to be “fit for purpose” and whether the Regulation, to date, with respect to these elements, has achieved, at minimum burden, its objectives of providing truthful information to consumers and of facilitating the free movement of foods bearing claims.

In year 2016 an important evaluation will start on Regulation (EC) No 652/2014 (which provides the common financial framework for EU expenditure in the food chain area).

In 2016, DG SANTE will also conduct the mid-term evaluation of 3rd EU Health Programme 2014-2020. As part of this evaluation a public consultation will be conducted prior to the conclusions if to modify Annex I (thematic priorities) of the Programme Regulation (EU) 282/2014. Moreover, in 2016, the Commission plans to adopt the Commission report on the ex-post evaluation of the 2nd Health Programme 2008-2013. In 2016, the Commission will also adopt the annual programme implementation report covering 2014 and the annual work for the year 2016 and for the year 2017. Prior to the adoption of annual work programme 2017, DG SANTE will run a multi-annual planning exercise to ensure balanced coverage of all thematic priorities, and alignment of the suggested actions with its Strategic Plan and Commission's major priorities.

Evaluation work will continue on a number of projects started in 2015, and several new evaluations will start in 2016 (the full list of both in given in Annex3). Each of them will ensure transparency and cover at least effectiveness, efficiency, relevance, EU-added value and coherence.

Work on the impact assessment for defining criteria to identify endocrine disrupting substances in the context of the implementation of the Plant Protection Product Regulation and Biocidal Products Regulation, will be finalised and will come to fruition in summer 2016.

3. External Communication activities

DG SANTE communication priorities for 2016 are in line with the President's political guidelines, his mission letter to Commissioner Vytenis Andriukaitis, the general and specific objectives of DG SANTE in our Strategic Plan and the Commission work programme for next year. Our communication will aim to raise awareness and build on the benefits and savings of effective protective systems in the Health and Food Sectors in the EU. Specific attention will be paid next year to emerging threats with serious economic implications such as antimicrobial resistance (and to highlight the EU as a global best practice region), the modernisation of national health care systems and the importance of a strengthened EU preparedness and crisis management in public health, food safety and plant health.

DG SANTE will prepare a separate communication strategy in line with the objectives and targets identified in the Strategic and Annual Management Plan for 2016. With this approach, communication is integrated upstream in the policy making process and communication priorities follow closely the political agenda. Communication plans on each priority are also developed, implemented, monitored and evaluated in close coordination with policy units. Significant communication actions are going to be carried out in the following areas:

In the context of the current evaluation and preparation of a new EU Action Plan on Antimicrobial Resistance, communication will build on the Eurobarometer results to be released in the second half of the year. AMR will be the theme of the 2016 EU Health Award for NGOs and also one of the topics of our participation in Green Week and Salon International de la Agriculture in 2016 (in cooperation with DG AGRI and DG MARE, in line with our 'One Health'/'From farm to fork' approach). A media seminar targeting journalists in the second half of the year will be also organised on this issue.

a) Communication in the health sector will support dissemination of and awareness on health innovation (focusing on access to safe and innovative medicines, Health Technology Assessment, e-health and European Reference Networks), effective, sustainable and resilient health systems

(collecting evidence on country health profiles, reduce the burden of major chronic diseases, use of structural funds for investment in health). The use of EU funds for health priorities – Health Programme calls for proposals & dissemination of results will also be given increased visibility. A wide range of tools will be used to this end: a media seminar, continuation of the campaign *Ex-Smokers Are Unstoppable*, web updates, e-news, social media (unpaid and paid) and visual communication such as factsheets and infographics.

b) DG SANTE will also be part of the Steering Committee in charge of the 2016 Corporate Communication Action "The Investment Plan and other Jobs and Growth initiatives". At least four health projects to be funded by the European Fund for Strategic Investments (EFSI) will benefit from reinforced corporate communication and will strengthen DG SANTE's links with the Investment Plan and other health-related initiatives contributing to the creation of growth and jobs.

c) Our communication will also stress the importance and economic relevance of a strong and efficient EU preparedness, prevention and response to crises in the health and food sector. Communication related to specific crises will continue to accompany management measures, including timely, proactive and reactive media relations, providing information about scientific evidence and measures taken. In this context, the increasing importance of plant health crises (as recently shown by *Xyllela*) will be, together with Food Safety controls the topic of a specific media visit in the second half of 2016. A series of four videos targeting competent authorities and stakeholders will also highlight the role of DG SANTE's Directorate on Health and Food Audits and Analysis. Their objective is to increase confidence in the EU control systems and recognition of the added value of action at EU level, which in turn should facilitate trade.

d) Special emphasis will be given to the EU role as a global health and food safety player by means of streamlined and mutually supported communication initiatives on priorities such as crisis preparedness, action on major threats like AMR or support for the health of refugees and migrants.

In addition to the communication actions referred to above, and regarding the communication infrastructure, the rationalised SANTE website will be migrated to a new platform Drupal in the framework of the Digital Transformation programme. SANTE web content will be further optimised according to the user test data and gradually integrated within a common Commission structure. Our social media will also boost the visibility of the political priorities (including the two DG SANTE dedicated Twitter accounts on food safety and health and social media buying). We will expand the use of visual communication via the @EU_Health Instagram account. Also in 2016, SANTE will start expanding its social media presence on Facebook - either by taking over the former Expo Milan dedicated page or by starting its own dedicated digital community.

Tables (3A – 3J) with the presentation of main outputs are included in Annex 1.

External communication overall spending

Annual communication spending (based on estimated commitments):	
Baseline (2015): €2.677.000	Target (2016): €2.543.000

Initiatives to improve economy and efficiency of financial and non-financial activities

SANTE is in the process of implementing the AGORA IT tool for "meetings". The aim is to manage the entire process from planning a meeting to reimbursing experts in one single electronic tool. Important parts of this tool should become operational in mid-2016. This is expected to reduce DG SANTE's administrative burden considerably.

ANNEX 1 Performance tables

General objective 1: A new boost for jobs, growth and investment

Specific objective 1.1: Effective preparedness, prevention, reaction and eradication of human, animal and plant diseases

Table 1.1

Relevant general objective(s): A new boost for jobs, growth and investment		
Specific objective 1.1: Effective preparedness, prevention , reaction and eradication of human, animal and plant diseases		Related to spending programme(s): Health Programme; Food and feed expenditure Regulation (EU) No. 652/2014
Main outputs in 2016:		
Policy–related outputs		
Description	**Indicator**	**Target date**
Human diseases		
Commission Implementing Decision on coordination of health threats coordination under Decision 1082/2013/EU on serious cross-border health threats (2015/SANTE/171)	Adoption in (comitology) committee for serious cross-border health threats by April 2016	April 2016
Commission Implementing Decision on procedures of Early Warning and Response under Decision 1082/2013/EU on serious cross-border health threats (2015/SANTE/172)	Adoption in (comitology) committee for serious cross-border health threats by April 2016	April 2016
Commission implementing Decision to adapt the list of communicable diseases under surveillance under Decision 1082/2013/EU (2015/SANTE/021)	Adoption in (comitology) committee for serious cross-border health threats by December 2016	December 2016
Commission implementing Decision to amend case definitions for diseases under Decision 1082/2013/EU (2015/SANTE/022)	Adoption in (comitology) committee for serious cross-border health threats by December 2016	December 2016
Animal diseases		
New legal framework for animal health in a form of the EP and Council Regulation	Adoption by the EP and the Council	May 2016
Commission Decisions on handling evolving epidemiological situations	Adopted emergency Decisions as necessary, according to the epidemiological situation. To be introduced in the AP in course of the year	In course of 2016
Commission rules on safe imports, trade and related aspects	Adopted Commission implementing rules. To be introduced in the AP in course of the year	In course of 2016
Plant diseases		
Commission Decisions on emergency measures against some specific pests	Adoption of Decisions as necessary according to (new) outbreak	31 December 2016

	situations	
Commission Decisions with specific import requirements for trade lines where there are too many import interceptions	Adoption of Decisions as necessary according to import interception notifications from Member States	31 December 2016
Adoption of Commission implementing legislation/guidance recognising innovative developments in seed production (1. fodder plants (2015/SANTE/698), 2.true potato seeds (2015/SANTE/568)	Adoption	1) 2nd quarter 2016 2) 4th quarter 2016
Adoption of Commission proposals to recognise EU equivalence with Ukraine and to move decision making to Commission level to meet increasing import requests due to globalisation of trade (2015/SANTE/669 and 2015/SANTE/668)	Adoption of two co-decision proposals	3rd quarter 2016
To support new innovative plant varieties by revising the proceeding before CPVO, (2015/SANTE/014)	Adoption	2nd quarter 2016
Main expenditure outputs		
Description	Indicator	Target
Human diseases		
Study on the added value of a strategic and life course approach to vaccination)	Final report with recommendations	July 2016
Study on shortcomings related to low vaccination coverage in health care workers (education and training of health care workers)	Final report with recommendations	July 2016
2 Case studies on environment and biological threats other than the ones caused by communicable diseases and making assessments of existing good practices in addressing health threats	Report and identification of good practices	July 2016
Study on the Public Health law network supporting the implementation of Decision 1082/2013/EU	Identification of gaps in national laws that could jeopardise the implementation of coherent preparedness planning in EU Member States	October 2016
Workshop targeting media, civil society and health professionals relating to the implementation of the Decision 1082/2013 on serious cross-border threats to health	Final report with concrete recommendations for future steps	July 2016
Study on the availability / supply capacities of critical medical countermeasures at Member States level and in the industry	Final report with concrete recommendations for future steps	July 2016
Intersectoral table top exercise on outbreak coordination and response involving public health and other sectors", mainly on climate change	Final report with concrete recommendations for future steps	July 2016
Animal diseases		
Reduction in the number of cases in wildlife in Member States where a programme is co-funded	Annual report	Less than 150 cases in 2017
Reduction in the number of classical BSE cases in Member States where a programme is co-funded	Annual report	Less than 5 cases in 2017
Reduction of herd prevalence of bovine tuberculosis in Member States where a programme is co-funded	Annual report	Reduction of 10% per year

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

Table 1.2

Relevant general objective(s): A new boost for jobs, growth and investment		
Specific objective 1.2: Safe and sustainable food and food production systems	Related to spending programme: Food and feed expenditure Regulation (EU) No. 652/2014	
Main outputs in 2016:		
Policy–related outputs		
Description	**Indicator**	**Target date**
Commission Report to Parliament and Council on National Action Plans under the Directive on Sustainable Use of pesticides (2015/SANTE/024)	Adoption	2nd quarter 2016
Report on food intended for sports people (2015/SANTE/057)	Adoption	2nd quarter 2016
Report on young-child formulae (2015/SANTE/059)	Adoption	1st quarter 2016
Report on the implementation of Directive 2009/41 on the contained use of genetically modified micro-organisms (2015/SANTE/429)	Adoption	3rd quarter 2016
Report on alcoholic beverages (2015/SANTE/681)	Adoption	3rd quarter 2016
To be merged in one initiative: Guidelines on allergen labelling according to Regulation (EU) No 1169/2011 (2015/SANTE/650) Q&A on Food Information to Consumers (2015/SANTE/647) General guidelines for implementing the principle of Quantitative Ingredients Declaration (QUID) (2016/SANTE/001)	Adoption	2nd quarter 2016
Report on the exercise on the delegated powers under Regulation (EU) No 1169/2011 (2015/SANTE/677)	Adoption	11 March 2016
Implementing act on the application of Article 26(3) of Regulation (EU) No 1169/2011 (2015/SANTE/670)	Adoption	4th quarter 2016
Report to the European Parliament and the Council on systems restraining bovine animals (2015/SANTE/548)	Adopted	8 February 2016
EU Guidelines on protection of pigs (2015/SANTE/387)	Adoption	8 March 2016
Report on the application of EU animal welfare rules at farm level (2015/SANTE/610)	Adoption	2nd quarter 2016
Report to the European Parliament and the Council on broilers' genetic selection (2015/SANTE/555)	Adoption	2nd quarter 2016
Market access for safe substances		
Authorisations for new substances and new uses of already authorised substances used as food additives, food flavourings, novel foods, substances used in plastic food contact materials	Adoption	Throughout the year
Authorisations recycling processes for plastics used in food contact materials	Adoption	Throughout the year
Authorisations and renewal of previously authorised active substances in plant protection products and biocides	Adoption	Throughout the year
Report on the sustainable use of biocides (2015/SANTE/180)	Adoption	1st quarter 2016
Guidance Document on the risk assessment of plant protection products on bees (2016/SANTE/036)	Adoption	3rd quarter 2016
Authorisations of GMO's food and feed uses, and for cultivation	Adoption	Throughout the year

Establishing maximum residues levels (MRL) for pesticides	Adoption	Throughout the year
Individual authorisation of 106 recycling processes for plastic materials coming into contact with food (2015/SANTE/203-332)	Adoption	4th quarter 2016
Withdrawal of certain substances (flavourings, pesticides)	Adoption	Throughout the year
Implementation of food legislation		
Commission Delegated Regulation on total diet replacement for weight control (2015/SANTE/146)	Adoption	3rd quarter 2016
Commission Delegated Regulation on food for special medical purposes (2015/SANTE/144)	Adoption	1st quarter 2016
Commission Delegated Regulation on infant formula and follow-on formula (2015/SANTE/145)	Adoption	1st quarter 2016
Commission Regulation for the meal replacements (2015/SANTE/666)	Adoption	3rd quarter 2016
Commission implementing Regulation on plant protection products to specify criteria to identify endocrine disruptors (2015/SANTE/001)	Adoption	3rd quarter 2016
Delegated Act on endocrine disruptors (biocides) (SANTE/10075/2016)	Adoption	3rd quarter 2016
Main expenditure outputs		
Description	Indicator	Target
Reduction in the number of confirmed cases of brucellosis in humans in Member States where a programme is co-funded	Annual report	Reduction of 2% per year
Reduction in the number of confirmed cases of *salmonella* in humans in Member States where a programme is co-funded	Annual report	Reduction of 2% per year

Specific objective 1.3: Cost effective health promotion and disease prevention

Table 1.3

Relevant general objective(s): A new boost for jobs, growth and investment		
Specific objective 1.3 : Cost effective health promotion and disease prevention	Related to spending programme: Health Programme	
Main outputs in 2016:		
Policy–related outputs		
Description	**Indicator**	**Target date**
Commission implementing decision on a priority list of additives (2015/SANTE/487)	Adoption	2nd quarter 2016
Commission implementing decision on technical standards for refillable cigarettes and Report on health risks of refillable electronic cigarettes (2015/SANTE/486)	Adoption	2nd quarter 2016
Commission Implementing acts on determining characterising flavour and setting up of an advisory Panel (originally scheduled for Q4 2015) (2015/SANTE/134 and 2015/SANTE/547)	Adoption	2nd quarter 2016
Main expenditure outputs		
Description	Indicator	Target
Health at a Glance: Europe 2016 report on the health situation in the EU Member States	Report published	4th quarter 2016
Joint Action on reducing alcohol related harm: guidance for policy makers on low risk drinking guidelines, survey methodology on consumption patterns and harmful use and a tool kit on best practises to reduce alcohol related harm.	Completion	4th quarter 2016
Policy brief and international conference by the project "Innovating care for people with multiple chronic conditions in Europe" (ICARE4EU)	Policy brief produced International conference held	February 2016
Platform on Knowledge Exchange of the Joint Action CHRODIS - an online help-desk for policy makers and a repository of best practices on chronic care	Platform operational	May 2016

Specific objective 1.4: Effective, accessible and resilient healthcare systems in the EU

Table 1.4

Relevant general objective(s): A new boost for jobs, growth and investment		
Specific objective 1.4: Effective, accessible and resilient healthcare systems in the EU		Related to spending programme(s) N/A
Main outputs in 2016:		
Policy–related outputs		
Description	**Indicator**	**Target date**
Evaluation of EU Action Plan against rising threats from antimicrobial resistance. (2015/SANTE/521)	Evaluation report published	First half 2016
Report on the implementation of the blood legislation (2015/SANTE/501)	Implementation report published	2nd quarter 2016
Report on the implementation of the organ legislation (2015/SANTE/504)	Implementation report published	3rd quarter 2016
Report on the implementation of the tissue legislation (2015/SANTE/505)	Implementation report published	2nd quarter 2016
Main expenditure outputs		
Description	Indicator	Target
Preparatory action: Antimicrobial resistance and causes of non-prudent use of antibiotics in human medicine (ARNA).	Publication of report of study with recommendations. Conference.	4th quarter 2016 2nd quarter 2016
Implementation of Council Recommendation on prudent use of antimicrobials in human medicine.	Report on implementation of recommendation by EU Member States published	2nd quarter 2016
Meeting of ministers of health and agriculture on antimicrobial resistance.	Ministerial conference and outcome statement	February 2016

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

Table 1.5

Relevant general objective(s): A new boost for jobs, growth and investment		
Specific objective 1.5: Increased access to medical expertise and information for specific conditions	Related to spending programme(s): N/A	
Main outputs in 2016:		
Policy–related outputs		
Description	**Indicator**	**Target date**
Assessment report on the package leaflet and the summary of product characteristics of medicinal products for human use (2015/SANTE/701)	Adoption	2nd quarter 2016
Revision of the Commission notice on orphan medicinal products (2015/SANTE/139)	Adoption	2nd quarter 2016
Revision of Commission Regulation 847/2000 on orphan medicinal products (2016/SANTE/043)	Adoption	4th quarter 2016
Guidelines on Good Manufacturing Practice specific to Advanced Therapy Medicinal Products ("ATMPs") (2015/SANTE/573)	Adoption	4th quarter 2016

Specific objective 1.6: Effective, efficient and reliable official controls

Table 1.6

Relevant general objective(s): A new boost for jobs, growth and investment		
Specific objective 1.6: Effective, efficient and reliable official controls	Related to spending programme: Food and feed expenditure Regulation (EU) No. 652/2014	
Main outputs in 2016:		
Policy–related outputs		
Description	**Indicator**	**Target date**
Report on the operation of official controls in the Member States on food safety, animal health and animal welfare, and plant health (2014/SANTE/011)	Adoption	2nd quarter 2016
Main expenditure outputs		
Description	Indicator	Target
BTSF: success rate of the tests performed by the participants after the training	Tests of participants	Success rate for more than 80% of the total number of participants
BTSF: overall satisfaction rate of participants attending the training	Satisfaction survey	Satisfaction rate of over 80%
EURLs: Percentage of success rate of proficiency tests organised by EURL for the NRL	Results of proficiency tests	Success rate of over 80%
EURLs: Satisfaction rate of participants at the annual workshop organised by the EUIRL, according to a standard survey	Satisfaction survey	Satisfaction rate of over 80%

Specific objective 1.7: Increased EU influence in international fora

None

General objective 2: A deeper and fairer internal market with a strengthened industrial base

Specific objective 2.1: Effective EU assessment of medical products and other treatment

None

Specific objective 2.2: Stable legal environment and optimal use of current authorisation procedures for a competitive pharmaceutical sector and patients' access to safe medicines

Table 2.2

Relevant general objective(s): A deeper and fairer internal market with a strengthened industrial base		
Specific objective 2.2: Stable legal environment and optimal use of current authorisation procedures for a competitive pharmaceutical sector and patients' access to safe medicines	Related to spending programme(s): No	
Main outputs in 2016:		
Policy–related outputs		
Description	**Indicator**	**Target date**
Commission Delegated Regulation laying down principles of good manufacturing practice for investigational medicinal products for human use and associated Commission guidelines (2015/SANTE/142)	Adoption	4th quarter 2016
Commission Implementing Regulation on the details arrangements for the Good Clinical Practice inspection procedures including the qualifications of the inspectors (2015/SANTE/140)	Adoption	4th quarter 2016
Commission Implementing Directive laying down the principles and guidelines of good manufacturing practices for medicinal products for human use (2015/SANTE/141)	Adoption	4th quarter 2016
Guideline on Guidelines on Good Manufacturing Practice for investigational medicinal products (2015/SANTE/532)	Adoption	4th quarter 2016
Report on EU pharmacovigilance activities (2012 - 2014) (2015/SANTE/589)	Adoption	2nd quarter 2016

Specific objective 2.3: Common Member States' tools and methodologies used for EU health systems performance assessments

None

General objective 3: A reasonable and balanced Free Trade Agreement with the U.S.

Specific objective 3.1: Decrease in trade irritants with US

None

Organisational management outputs for the year

1. Human Resource Management

Table 1

Objective: The DG deploys effectively its resources in support of the delivery of the Commission's priorities and core business, has a competent and engaged workforce, which is driven by an effective and gender-balanced management and which can deploy its full potential within supportive and healthy working conditions. **Main outputs in 2016:**		
Description	**Indicator**	**Target**
DG SANTE organisational structure is adapted in line with the operational needs of the SP.	New DG organigramme in place	01/02/2016
Organisational culture: Define the 'Health(y)' DG we want to be. Organisation of a DG SANTE Management seminar to set the tone and ensure alignment of all SANTE managers to the overall strategic 'organisational excellence' objective	SM identifies and communicates on vision and expectations (organisational identity) to Staff.	15/03/2016
Redeployment: Staff is allocated in line with the priorities and operational needs identified in the SP taking carefully account of the balance between the interest of the service and the interest of the individual staff member	Reinforcements of priorities have been organised.	01/04/2016
Recruitment of female managers: fill vacant management posts.	Recruit minimum two female HoUs and one female Senior Manager.	01/09/2016
Organisational change: Building effective teams and ensure staff engagement	At least all entities with new managers and/or significant change of staff members will participate into a team building exercise	31/12/2016
Organise staff development actions to improve engagement and empowerment: to assist staff in taking a more active role in making things better.	Organise learning events for all staff on key skills Implement DG SANTE's Internal coaching initiative	31/12/2016

2. Better Regulation

None

3. External Communication activities

Table 3.A

Objective: Informed policy decisions and better targeted communication campaigns on Antimicrobial Resistance at national, EU and international level, based on updated data and trends of knowledge by the general public on antimicrobial resistance. This objective contributes to specific objective 1.4. Effective, accessible and resilient healthcare systems in the EU and 1.8. Increased EU influence in international fora **Main outputs in 2016:** Antimicrobial Resistance Eurobarometer: summary, national factsheets, press material, web updates, social media promotion, to be presented at media seminar (tbc).		
Description	**Indicator**	**Target**
Eurobarometer on Antimicrobial Resistance in the 28 MS and non-EU countries, promotion of results	- number of respondents who have taken antibiotics - number who took antibiotics for a flu - respondents who are aware that antibiotics do not kill viruses	Maintain, at least, same trends as between 2009 and 2013 EB - 5% decrease in citizens who have taken antibiotics - 2% fewer people who take antibiotics for a flu - 4% decrease in citizens who are aware that antibiotics do not kill viruses
media seminar (tbc)	- Number of journalists attending media seminar - Percentage of journalists who write a follow-up article - Number of follow up articles	- Up to 30 journalists attending media seminar - 70% journalists write a follow up article in the next 3 months - 24 articles published
Web	- number of page views on DG SANTE Website section on AMR	- 5% increase of visits to DG SANTE Website section on AMR (baseline 2015: 31.200 visits)
Social media	- number of social media posts - social media reach (organic and paid)	- At least 10 dedicated social media posts (at least 2 paid) - 30.000 Twitter accounts reached

Table 3.B

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

Table 3.C

Objective: Increased awareness and stakeholder engagement on the European Reference Networks (ERNs) This objective contributes to specific objective 1.5. Increased access to medical expertise and information for specific conditions **Main outputs in 2016:** ERN call for proposals, technical platform, ERN 3rd conference, promotion (web, social media, media)		
Description	**Indicator**	**Target**
Communication activities on the ERNs process –promotion for February 2016 call for proposals -, 3rd ERN conference: media relations	– number of journalists attending the conference in autumn 2016 – number of articles covering the topic of ERNs following the conference in autumn 2016	– 5 journalists attending ERN conference in autumn 2016 – 70% journalists write an article on ERN topic following the conference
Web	– number of views on ERN web page on SANTE website	– 5% increase in ERN page views
Social media	- number of organic & sponsored @EU_Health tweets to promote the ERN call for proposals - reach of organic & sponsored @EU_Health tweets promoting ERN call for proposals	- 3 unpaid & 2 sponsored tweets - 22.000 accounts for organic reach tweets & 30.000 accounts for sponsored tweets

Table 3.D

Objective: Increased awareness and stakeholder engagement on the "State of the Health in the EU" cycle This objective contributes to specific objective 2.3 Common Member States' tools and methodologies used for EU health systems performance assessments **Main outputs in 2016:** joint Commission-OECD report Health at a Glance: Europe (descriptive, horizontal starting point for the State of Health in the EU cycle, adjusted to the 2014 Commission Communication on effective, accessible and resilient health systems) *NOTE: communication to be developed in cooperation with the OECD (channels, indicators and targets will be fine-tuned following the further negotiations on this action)*		
Description	**Indicator**	**Target**
Communication on the publication of the HaG report: media relations	– number of journalists attending the publication event (November 2016) – number of articles covering the report	– 15 journalists attending the presentation of the report – 70% journalists write an article on the report
Web	– number of views of the report/summary on SANTE website	– 5,000 web visits in the 6 months after the publication
Social media	- number of @EU_Health tweets to promote the report - reach of @EU_Health tweets promoting the report	- 10 tweets - 22.000 accounts for organic reach tweets

Table 3.E

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

iCoach	– number of tweets & Instagram posts – number of engagements on Twitter & Instagram – organic social media reach	downloads – 5 tweets & 5 Instagram posts / week – 200 Twitter engagements & 100 Instagram engagements

Table 3.F

Objective: Information on regulation of e-cigarettes, public health & single market benefits of Tobacco Products Directive are communicated to stakeholders and general public This objective contributes to specific objective 1.3. Cost effective health promotion and disease prevention **Main outputs in 2016**: Tobacco Products Directive (entry into force May 2016): awareness event –tbc-, press material, web, social media		
Description	**Indicator**	**Target**
Media, digital & visual communication on new binding tobacco legislation – possibly using World No Tobacco Day 2016 as a hook,	– number of views on dedicated policy page	– 10% increase in web page views (Baseline: 15.600 visits -page on tobacco products. Whole tobacco section – 422.900 visits)
Social media	– number of social media posts – social media reach (organic and paid)	– 5 unpaid & 2 sponsored tweets – 22.000 accounts for organic reach tweets & 30.000 accounts for sponsored tweets

Table 3.G

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

Table 3.H

Objective (definition): Increased confidence in the EU control systems and recognition of the added value of action at EU level, thus contributing to facilitate trade. This objective contributes to specific objective 1.6. Effective, efficient and reliable official controls **Main outputs in 2016:** series of four videos to be promoted on web, stakeholder events and social media		
Description	**Indicator**	**Target**
Series of four videos explaining the role of the DG SANTE's Directorate on Health and Food Audits and Analysis in the EU control systems and the identification and dissemination of best practices. The videos will primarily target stakeholders and competent authorities.	– Number of views in DG SANTE Website – Number of videos distributed in stakeholders meetings	– 400 video files distributed – 2.000 views (video to be released mid-2016)
Social media	– Number of dedicated social media posts – Reach of dedicated social media posts	– At least 4 dedicated social media posts – At least 20 000 accounts reached

Table 3.I

Objective: EU added value on Antimicrobial Resistance and 'One Health'/'From Farm to Fork' policies are raised in stakeholders' agenda and made known to visitors in key events This objective links to specific objectives 1.2 Safe and sustainable food and food production systems and 1.4 Effective, accessible and resilient healthcare systems in the EU **Main outputs in 2016:** Stand at International Green Week, Salon International de l'Agriculture, Salone del Gusto and JPO (in cooperation with DG AGRI and DG MARE), promotion and media relation activities, stakeholder events		
Description	**Indicator**	**Target**
Promotional stand and stakeholder/media events at 2016 International Green Week in Berlin, Salon International de l'Agriculture, Salone del Gusto and JPO	– number of visitors to the stand – number of participants who declare the event met their expectations (survey) – number of participants at stakeholders' events – satisfaction rate with the stand	International Green Week/SIA/Salone del Gusto: – 100.000 visitors/Fair – 75 % satisfaction – 15 participants in stakeholder events/Fair JPO: – 4.000 visitors at the stand – satisfaction rate 8.5/10
Media relations	– number of articles	– 2 articles
Social media	– number of dedicated social media posts – reach of dedicated social media posts	– At least 10 dedicated social media posts (per event) – At least 30 000 accounts reached (Twitter) – JPO: at least 5 dedicated social media posts with at least 15 000 accounts reached