



European
Commission



Taking stock of EU PUBLIC HEALTH, FOOD SAFETY, ANIMAL and PLANT HEALTH POLICY achievements 2010-2014

INTRODUCTION



Health and safety of citizens is a core priority of the European Commission. EU health policy addresses a range of important issues relating to public health matters and safety of the food chain.

Good health is an integral part of thriving modern societies and a cornerstone of well performing economies. Good health for all means not just reacting to ill-health, but proactively promoting health and preventing diseases by focussing on key risk factors such as tobacco, nutrition, physical exercise and alcohol.

Emerging and pressing challenges continue to be the focus of our endeavours such as those relating to ageing and innovation and ever increasing patient expectation. The aim remains to contribute to the process of ensuring sustainable health systems well into the future. The rise in chronic diseases, as well as serious communicable diseases and health emergencies require our unwavering commitment.

The other cornerstone of this portfolio relates to the safety of food. The European Union's food safety policy aims to ensure that EU citizens enjoy safe and nutritious food produced from healthy plants and animals, whilst enabling the food industry to operate in the best possible conditions.

EU policy safeguards health along the whole "agri-food chain" – every part of the food production process from farming to consumption – by preventing food contamination and promoting food hygiene, food information, plant health and animal health and welfare. An increasingly important challenge has been the issue of protecting against food fraud.

In this publication you will find major examples which illustrate the achievements over the past years of this mandate of the European Commission. The successes achieved over this time demonstrate our strong commitment to ensuring the highest level of protection through effective and well-targeted policies and legislation on health and food safety.

Tonio Borg
European Commissioner for Health

OBJECTIVES OF OUR POLICIES

EU health policy complements the national health policies of EU Member States and is aimed at protecting and improving the health of all Europeans pursuing three main objectives:

- Preventing illnesses and diseases.
- Promoting healthier lifestyles.
- Protecting people from serious cross-border health threats such as pandemics.

The Treaty on the Functioning of the EU (art 168) and the Charter of Fundamental Rights of the European Union (art 35) provide the legal basis for the EU to be able to better shape its health policies and bring added value to national actions on health by bringing countries together to address common challenges through coordinated actions and good practice exchanges.

Hence, in accordance with the Treaty, the EU has taken a so-called “Health in All Policies” approach to support Member States’ efforts to tackle major health scourges and health threats with a cross-border dimension, to promote health and prevent diseases and to regulate the quality and safety of medicines, medical devices and substances of human origin used in healthcare.

The main objective of the **EU policy regarding food safety and animal/plant health** is to safeguard health along the whole ‘agro-food chain’ from farming to consumption. Its main aim is to prevent contamination of food and promote food hygiene through high standards. The three main objectives are:

- To ensure that food and animal feed are safe and nutritious.
- To ensure a high level of animal health, animal welfare and plant health.
- To ensure adequate and transparent information about the origin, content/labelling and use of food.

As regards animal welfare, the European Union considers animals as sentient beings and is legally obliged through **Article 13 of the Treaty on the Functioning of the EU** to pay full regard to the welfare of animals whilst at the same time respecting the customs of the Member States, in particular to religious rites, cultural traditions and regional heritage.

CURRENT & FUTURE KEY CHALLENGES OF EUROPEAN PUBLIC HEALTH AND FOOD SAFETY POLICIES:

- ▶ The **ageing population** is translating into a growing burden of age-related chronic diseases, such as cardiovascular diseases, diabetes or Alzheimer's disease and other dementias, with the problem of multi morbidity.
- ▶ This generates **growing demand** for efficient healthcare on one hand and **higher costs** and dwindling resources on the other, putting into question the **sustainability of health systems**.
- ▶ To remain sustainable in the long-term, health systems need structural reforms using **innovative technologies** and the most **cost-efficient, evidence-based** means possible.
- ▶ There is a growing overall burden of **chronic diseases**, both physical and mental, many of which are preventable and attributed to **tobacco and alcohol consumption, unhealthy nutrition, lack of physical exercise**, as well as social and environmental determinants.
- ▶ **Health inequalities** persist between and within EU countries. Health status and access to healthcare remain influenced by factors such as employment, income and education, demonstrating that it is the poor who tend to suffer from poorer health.
- ▶ An increasing **mobility of patients and health professionals** across the EU's borders calls for better co-operation in cross-border healthcare and more clarity of the rights of EU patients who seek healthcare outside their home country.
- ▶ **Serious cross-border health threats** caused by biological, chemical and environmental events call for a strengthening of multi-national surveillance and actions on improving health security across the EU, as with the current Ebola outbreak, and other on-going threats like Polio, Middle-East Respiratory-Syndrome Coronavirus and the ever present pandemic potential due to avian influenza.
- ▶ **HIV/AIDS, tuberculosis and Hepatitis C** remain crucial diseases that represent a challenge in Europe, despite the existence of effective means to treat them.

- ▶▶ The globalisation of markets for health products, devices and services, a sector where the EU is a world leader, brings significant market opportunities but also challenges for quality and safety standards; it calls for strengthening the EU voice in global health to promote EU standards, norms and values globally with third countries, in international organisations and in trade agreements.
- ▶▶ **Antimicrobial resistance** is a major challenge as the excessive and inappropriate use of antimicrobials in both the veterinary sector and in human healthcare has caused many microorganisms to become resistant to these agents. This means that we are now facing a growing problem of infections that cannot be treated.
- ▶▶ Ensuring the **safety and the integrity of the whole food chain** requires striking the right balance between safety objectives, consumer expectations, the competitiveness of economic stakeholders and the necessary space for innovation.
- ▶▶ Tackling food waste in order to strengthen resource efficiency and reduce environmental impact of the food and feed chain without compromising on human or animal health.
- ▶▶ The comprehensive framework to achieve those objectives needs to be constantly adapted to newly emerging challenges and the results have to be well communicated to stakeholders and trading partners.
- ▶▶ We strive to push the TC partners to apply conditions equally fair to products exported from the EU, and to **recognise the EU as a single entity** when it comes to export from the EU, in the same way as third countries partners do when exporting their products to the single EU market of 28 Member States and 500 million people. While we already have achieved a **high level of protection**, further progress is possible: the prevalence of risks to health can be further reduced and the possible effects of harmful substances need to be carefully addressed.
- ▶▶ There is a **need to efficiently manage scarce resources**: concrete expectations in terms of results to be achieved, in terms of measurable reduction of risk and/or improvements to current practice, with a focus on future enforcement, will need to be formulated before resources can be allocated
- ▶▶ The possibility of **fraudulent practices** has to be taken into account; on food fraud a wide range of capacity building and cooperation activities has been initiated and announced which will require substantial follow-up in the coming years.
- ▶▶ In the area of **animal welfare**, the emphasis on **better enforcement** has improved the harmonised implementation of EU rules, with legal action also being taken against those Member States which did not implement the rules in time or in an adequate manner.
- ▶▶ The wider **challenge to innovation** is to identify areas for which currently available instruments need to be further developed to meet changing circumstances. The tissues and cells sector, which is the backbone for advance therapies, is a good example for this challenge. Climate change, scarcity of resources, changing nutritional requirements and other factors may challenge the established approach to the food chain as a whole.

ACHIEVEMENTS

What has the EU done to address major health and food safety challenges in the period 2010 - 2014?

Over the past years, the Health Commissioner and Directorate General for Health and Consumers has strived towards fulfilling its mission of “making Europe’s citizens healthier, safer and more confident”. Be it legislation, international agreements or softer policy initiatives, all of the EU’s policy instruments in the area of health and food safety directly touch upon the daily lives of EU citizens. Let’s take a closer look...



1 CHANNELLING EU POLICIES AND FUNDS TO IMPROVE HEALTH AND HEALTH SYSTEMS

Regulation 282/2014/EC establishing the **3rd Multiannual Program of EU action in the field of Health for the period 2014 – 2020** was adopted in March 2014. The program is the main financial instrument supporting Member states' cooperation on key health issues where Europe can deliver added value to improve health across the EU.

With a total budget of around €450 million over 7 years, the program will support actions in 23 areas to help EU countries to find more innovative and cost-effective solutions to promote health and prevent diseases, **improve the capacity of their health systems to keep up with demographic and fiscal challenges**, to protect citizens from cross-border health threats and to pool resources on solving common concerns related to better and safer health and health care. The Commission continued to develop its activities on health following the principles and objectives set by the EU Health Strategy and has called, over the last few years, for "investing in health", thus promoting health as a value in itself and also a precondition to economic prosperity and social cohesion.

From 2010 to 2014, EU health policy put an increasingly strong focus on **supporting Member States' efforts to reform their health systems**. In addition to making such action a priority of the Health Program, in 2014 the Commission adopted a Communication on effective, accessible and resilient health systems highlighting a number of initiatives through which the EU can support policy

makers in the Member States. The focus is on methods and tools to allow Member States to achieve more effective, accessible and resilient health systems, in line with reform recommendations to Member States in the context of the European Semester. These tools and methods include, for instance, good information flows, which help identify strengths and weaknesses within systems and thereby facilitate evidence-based investment decisions, and planning of a health workforce of an adequate capacity and with the right skills.

To implement reforms identified in these recommendations, Member States are also encouraged to use European funding instruments, in particular the **European Structural and Investment Funds** to reduce health inequalities, improve healthcare infrastructure and healthcare access particularly for disadvantaged groups and more deprived regions across the EU.

The economic significance of health systems – and the need to reform them - is also reflected in the "European Semester" - the EU's annual cycle of economic policy coordination. Each year, the Commission analyses the EU's national economic and structural reforms and provides recommendations for the following 12-18 months.

Over the course of four consecutive European Semesters the importance of health system reform grew considerably, both in the number of recommendations as well as in analytic depth.

Under the very first Semester the Commission made country-specific recommendations linked to health systems reform to 4 EU countries. On 2 June 2014, the Commission presented recommendations to 16 EU countries. A guiding principle in this context is for health systems to become less reliant on hospital care over time.



2 HEALTH DETERMINANTS AND LIFESTYLE

Since the onset and development of many chronic diseases and premature mortality is influenced by common risk factors such as smoking, harmful alcohol consumption and unhealthy nutrition and lack of exercise, the EU has developed approaches in all these areas. Results of independent evaluations on the EU Strategy for Nutrition, Overweight and Obesity related health issues as well as the EU strategy to support Member States to reduce alcohol-related harm, demonstrate that even though such policy areas are national responsibilities, **joint work at EU level brings considerable added value.**

2.1 TOBACCO CONTROL

During the current mandate, there was a strong focus on regulating tobacco products



to ensure that they look and taste like tobacco and do not entice young people into starting to smoke, while ensuring the functioning of the internal market for such products.

The European Parliament and Council's adoption of the new **Tobacco Products**

Directive in April 2014 – on the basis of the Commission proposal of December 2012 – marked a major step forward in tobacco control and aligned EU policy with the WHO Framework Convention on Tobacco Control.

The Directive stipulates large **mandatory pictorial health warnings** on both sides of cigarette and roll-your own tobacco packages increasing the impact of health warnings throughout the EU. It also prohibits cigarettes and roll-your-own tobacco with **characterizing flavours** (fruit, candy, menthol). The Directive further introduces **safety and quality requirements for consumer electronic cigarettes** containing nicotine, enabling consumers to take informed decisions. In addition, **the Directive prohibits promotional and misleading elements** on tobacco products (e.g. 'natural', 'organic'), requires producers to submit reports to Member States on the ingredients used and introduces an **EU-wide tracking and tracing system** to combat illicit trade.

The Directive entered into force in May 2014 and gives Member States a transposition period of 2 years. Once the Directive is transposed, the EU will have in place solid rules on the manufacture, presentation and sale of tobacco products and this is expected to bring health and economic benefits for all stakeholders concerned, including governments and EU citizens.

A Protocol on the Elimination of the Illicit Trade in Tobacco Products was adopted by the Conference of the Parties to the WHO FCTC in November 2012. The Commission contributed to the successful outcome of the negotiations. The EU signed the Protocol in December 2013.

The EU has further encouraged Member States to **develop smoke free environments** to protect citizens from second hand smoke – in particular through the 2013 report on progress made towards the Council Recommendation on smoke free environments of 2009 - and launched the **‘Ex-smokers are Unstoppable’** campaign in 2011 to demonstrate the benefits of life without tobacco.



2.2 REDUCING THE HARM CAUSED BY ALCOHOL

To complement the **EU Alcohol Strategy**, the Member States, within the Committee on National Alcohol Policy and Action, endorsed an **Action Plan on Youth Drinking and on Heavy Episodic Drinking (Binge Drinking)** to guide future approaches and actions to tackle alcohol-related harm within key areas of the Strategy. The Commission has continued to support the **European Alcohol and Health Forum** which mobilises key stakeholders to commit themselves to the priorities of the EU Alcohol Strategy such as protecting young people and children from alcohol-related harm and preventing drink-driving.

2.3 FIGHTING OBESITY

The High Level Group on Nutrition and Physical Activity implemented **specific nutrients frameworks aiming at reducing levels of salt, fats and calorie contents of processed foods** and endorsed a 6 years' **action plan on childhood obesity** in February 2014. The **EU Platform for Diet, Physical Activity and Health** has brought together actors at European level to engage in concrete actions designed to tackle poor nutrition and physical inactivity. To date, the Platform has triggered 300 actions by

key EU stakeholders in industry and civil society such as a voluntary restriction of the marketing of soft drinks to children under 12 years old and the redesign of recipes to lower salt, sugar and fat levels.

2.4 REDUCING HEALTH INEQUALITIES AND FIGHTING DISCRIMINATION IN HEALTH

EU action on health inequalities is set out in the 2009 **Commission Communication on health inequalities “Solidarity in Health”**. It aims to support Member States and develop the contribution of EU policies towards addressing health inequalities. The Commission staff working document **“Report on health inequalities in the European Union”**, published in September 2013 describes the main actions that the Commission has taken to implement the Communication. It includes the work of the **EU Joint Action on Health Inequalities 2011–2014** being carried out by 15 EU Member States plus Norway. Under the EU Health Programme a number of projects were funded to address the health of specific vulnerable groups such as the Roma migrants. Reducing health inequalities was also included within the objectives for the European Structural and Investment Funds for the period 2014-2020.

The Commission is committed to combatting all forms of discrimination in access to health care with focus on specific areas where stigma and discrimination are a particular issue, including ethnic minorities, migrants,

people with mental disorders, HIV/AIDS and other chronic conditions. This issue has been discussed during a number of events including a high level conference “Health in Europe, - making it fairer” held in March 2014 in Brussels.

2.5 TRANSPLANTATION AND TRANSFUSION MEDICINE

In 2010 the European Parliament and Council adopted a directive setting minimum safety and quality standards for human organs intended for transplantation. Subsequently the Commission adopted legislation that aims at creating an effective vigilance system. A parallel Commission Action Plan (2009-2015) has fostered cooperation amongst Member States in order to increase organ availability and enhance efficiency of transplant systems. The mid-term review found important achievements relating to recruitment of transplant donor coordinators and setting-up living donation programmes.

The Commission has also set up rapid alert platforms to connect national authorities overseeing safety and quality of blood, tissues and cells and organs respectively. For tissues and cells, two Commission Directives are in the process of final adoption that will ensure a common traceability system and adequate safety and quality procedures for products imported into the EU from third countries.

3 COMMUNICABLE DISEASES AND PROTECTION AGAINST SERIOUS HEALTH THREATS

In 2013, the European Parliament and the Council adopted **Decision 1082/2013/EU to improve preparedness across the EU and strengthen the capacity to coordinate response to health emergencies** caused by communicable diseases, biological as well as chemical, environmental and unknown threats. Building on the lessons learned from assessment and management of communicable diseases like H1N1 pandemic influenza and SARS, the decision is an important step forward in improving health security in the European Union and protecting citizens from a wide range of health threats. The new legislation provides four major benefits: it strengthens preparedness planning, improves risk assessment and management of cross-border health threats, establishes the necessary arrangements for the development and implementation of a joint procurement of medical countermeasures and gives a formal base to the Health Security Committee to enhance the coordination of response to serious cross border threats to health.

On 25 July 2014, the Commission adopted an Implementing Decision on the template to be used by Member States for reporting information on preparedness planning. Member States are to report on their state of preparedness by November 2014. Based on this information the Commission will

produce a progress report for discussion in the Health Security Committee.

In 2014, the Commission worked closely with the European Centre for Disease Prevention and Control, the World Health Organization and the EU Health Security Committee to co-ordinate Member States' preparedness and capability to respond in an EU coordinated way to emerging threats, including the Ebola epidemic in West Africa and polio. The Health Security Committee endorsed a number of documents such as risk assessments, information for travellers, media messages translated in all EU languages, guidance document to be used at national level to respond to different events (e.g. Ebola, Polio, Middle East Respiratory Syndrome Coronavirus, West Nile virus).

As foreseen in the Decision, the Commission adopted in 2014 a **Joint Procurement Agreement of medical**

countermeasures, signed by 16 Member States by the end of September 2014, which allows Member States – on a voluntary basis – to buy vaccines and other medical countermeasures together so that, should there be an outbreak in Europe, all participating countries are able to provide their citizens with the necessary medicines.

At the end of 2011, the Commission decided to address antimicrobial resistance as a matter of priority, and published a 5-year Action Plan against Antimicrobial Resistance¹ (for more details see also page 20).

In 2012 and 2014, the Commission published comprehensive implementation reports on the prevention and control of health-care associated infections as foreseen by a Council recommendation of 2009. As a result, the European Centre for Disease Prevention and Control has been asked to prioritize work in this area to better support Member States.

The 'Communication on combating HIV/AIDS in the EU and neighbouring countries 2009-2013' focuses on measures for effective prevention, addressing key populations and priority regions, in particular in Eastern Europe. As an interim measure, the Commission has prolonged the Action Plan attached to the Communication for the period 2014-2016 in order to provide continuity of EU action beyond 2013.



1. http://ec.europa.eu/dgs/health_consumer/docs/communication_amr_2011_748_en.pdf

4 HEALTHY AND ACTIVE AGEING

The Commission endeavours to promote living longer and healthier. In this context, in 2011 the Commission launched the **European Innovation Partnership on Active and Healthy Ageing**, under the ‘Innovation Union flagship initiative’ of the Europe 2020 Strategy. This Partnership brings together an array of stakeholders from researchers to health authorities and aims to enhance Europe’s potential to tackle demographic challenges associated with ageing and to achieve **the goal of an increase in Health Life Years by 2 years by the year 2020** through improving health and quality of life, ensuring health and social care systems are sustainable and efficient and creating growth and market opportunities for businesses.



5 PATIENTS’ RIGHTS IN CROSS-BORDER HEALTHCARE

The year 2013 saw the entry into force of the **Directive on the application of patients’ rights in cross-border healthcare** which clarifies patients’ rights to access to high-quality and safe healthcare across the EU, and be reimbursed for it. For some treatments (e.g. those involving an overnight stay or highly specialised and cost-intensive equipment or infrastructure) the Directive allows for a system of prior authorisation. However, if patients face a medically unjustifiable waiting time for treatment at home, prior authorisation must be granted.

According to the Directive, each EU country must establish a **National Contact Point** which provides information on patients’ rights in cross-border healthcare (e.g. entitlements to healthcare, levels of reimbursement, procedures of prior authorisation), as well as information about the quality and safety standards used in their Member State along with other relevant information (e.g. procedures of appeal and redress, whether a provider is authorised to provide certain services).

The Directive further provides for European co-operation among Member States’ health systems on **Health Technology Assessment (HTA) and on eHealth in the form of high level networks**. The Commission adopted a **Decision setting up the eHealth Network (2011)** and a **Decision setting up the HTA Network (2013)**. The eHealth Network suggested in 2014 the setting up of four **cross-border eHealth services** (including exchange of patient summary data, e-prescriptions), financed from the Connecting Europe Facility starting in 2015.



6 CHRONIC AND RARE DISEASES

A strong focus was put on supporting Member States in addressing chronic diseases. In response to Council conclusions on innovative approaches to chronic diseases adopted in December 2010 and the UN High Level Meeting on non-communicable diseases in September 2011, a reflection process on chronic diseases with Member States and stakeholders identified a number of areas where EU action on prevention and management could be developed. The Commission has launched a Joint Action in 2014 to exchange good practices with regard to prevention of major chronic diseases in Europe. It also organised an EU Summit on chronic diseases in April 2014.

The Commission presented its roadmap for European action in the **e-Health Action Plan 2012-2020**. The Action Plan provides a long term vision for e-Health and innovative healthcare in Europe building on the EU 2020 strategy and its flagship initiatives 'Digital Agenda for Europe' and 'Innovation Union' including the European Innovation Partnership on Active and Healthy Ageing and the e-Health Governance Initiative. In spring 2014, the Commission adopted a **Green Paper on mobile health (mHealth)**, paving the way for future proposals.

Finally, the **Directive on the application of patients' rights in cross-border healthcare** foresees the establishment of **European Reference Networks** to boost cooperation and make better use of resources across the EU and give patients the highest quality of care particularly in the case of **rare diseases**. The Commission adopted secondary legislation on the rules and criteria for establishing such networks.

The Commission also adopted secondary legislation on the **recognition of prescriptions for cross border use** so that patients get the medicines they need across the EU.

In the area of cancer, as shown in the Commission report of September 2014, the Commission used all tools at its disposal to support Member States to shape national cancer plans, to coordinate initiatives on cancer via two dedicated Joint Actions with the Member States, guidelines on cancer screening and the development of a new quality accreditation scheme for breast cancer treatment units.

As demonstrated in the report on rare diseases of 2014, the Commission further supported Member States in shaping national plans on rare diseases, pull resources and expertise at European level, and has financed a number of pilot networks to improve access to diagnosis and care for specific rare conditions.

The EU played a key role in promoting a global approach on these issues, both in WHO, and through the UN General Assembly initiative on non-communicable diseases.

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7 PHARMACEUTICAL POLICY AND THE QUALITY AND SAFETY OF MEDICINES

The EU has one of the safest and most advanced systems for monitoring the quality, safety and efficacy of medicines and comprehensive and clear rules are in place for the authorisation and distribution of medicinal products.

7.1 PREVENTION OF RISKS FROM FALSIFIED MEDICINAL PRODUCTS

In order to further improve the EU's medicinal regulatory systems and protect patients from the risks associated with unauthorised 'fake' or 'falsified' medicines, in 2011 the EU adopted the **Directive on medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products**.

The Directive entered into force in 2013 and besides addressing the sale of falsified medicines over the Internet, its main measures concern:

- rules for imports of active substances from third countries, controls and inspections;
- rules for record-keeping by wholesale distributors;
- rules on inspections;
- and the obligation for manufacturers and distributors to report any suspicion of falsified medicines.

7.2 PHARMACOVIGILANCE

Rules on post-marketing monitoring, known as 'pharmacovigilance' ensure that once a medicinal product has been authorised in the Union and placed on the market, its safety is monitored during its entire lifespan to ensure that in case of adverse reactions the appropriate action is taken swiftly, including

additional warnings, restrictions of use or even withdrawal of the product.

In 2010, the Commission adopted a Regulation as regards **pharmacovigilance of medicinal products for human use**, laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use.

The new rules which became applicable in 2012 strengthened the monitoring of the safety of authorised medicinal products.

With this Regulation the EU introduced a new



symbol - a black inverted triangle - to identify medicines that are subject to additional monitoring by regulatory authorities after their release on the market. Hence, since January 2014 products that are subject to additional monitoring must include this symbol on the package leaflet and the summary of the products' characteristics along with information on how to report suspected side effects. This new system is intended to improve **transparency and patient safety** with regard to monitoring the safety and overall benefit risk of medicines. It is particularly important for patient involvement as patients now have the right **to report suspected adverse reactions to medicines directly** through their national authorities, doctor or pharmacist.

Finally, a Regulation on pharmacovigilance fees payable to the European Medicine

Agency was adopted in 2014 which enables the financing of the pharmacovigilance activities carried out at EU level under the 2012 pharmacovigilance legislation.

7.3 CLINICAL TRIALS

Clinical trials test new medicines and medical treatments on humans and are indispensable for developing and improving medicines while ensuring that EU patients have access to new and the most innovative and effective treatments, under high safety and ethical standards. Clinical trials are mainly conducted by the pharmaceutical industry in order to generate data on the safety and efficacy of medicinal products they are developing. In recent years, the number of clinical trials has been falling due to the high costs and lack of harmonization of the applicable rules for clinical trials in the European Union.

Hence, in 2012, with the aim of streamlining clinical trial rules and boosting clinical research and pharmaceutical innovation and investment in European healthcare while ensuring patient safety, patient rights and reliability of data, the Commission proposed a **Regulation on Clinical trials on medicinal products for human use**, repealing the 2001 Clinical Trials Directive.

The revised rules are modernizing existing legislation in this evolving sector by making it **easier to conduct clinical trials in more than one Member State in particular by:**

- streamlining the application procedure via a single entry point for all clinical trials conducted in Europe;
- having a **single authorisation procedure** for all clinical trials throughout the EU;
- strengthening the rules on the protection of patients and informed consent;
- **enhancing the transparency and openness** on the conduct and results of the clinical trial thanks to a compulsory prior registration on a EU portal;
- and **public access to results**.

These changes, which will provide academic institutions and the pharmaceutical industry with harmonized and clear rules governing research into new drugs, will contribute to enhancing competitiveness and bringing patient-oriented research back to Europe thus ensuring that EU citizens have access to new and safe innovative treatments.

The Regulation, which was adopted by Council and Parliament in April 2014, will come into effect towards the end of 2016 and will be directly applicable throughout the EU. Over the years, the European Commission has also authorised a number of innovative medicinal products in cooperation with the European Medicines Agency. For example, these medicines are particularly important for the treatments of patients with multi-drug resistant tuberculosis, leukaemia, HIV or advanced melanoma. Moreover, we have authorised more than 100 orphan medicinal products for the benefits of patients suffering from rare diseases.

7.4 PHARMACEUTICALS AT INTERNATIONAL LEVEL

The Commission has successfully initiated an ambitious reform of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). ICH was launched in 1990 to bring together the regulatory authorities of EU, Japan and the US along with experts from the industry in these regions to agree on common scientific and technical standards towards product authorisation (ICH guidelines). ICH has until now developed some 60 guidelines which are not legally binding but support and complement the EU legislation on pharmaceuticals. These guidelines are increasingly referred to as global standards. The reform process is reaching its final stage and is expected to improve ICH in terms of governance, global outreach, financing and transparency.

8 FOOD FOR SPECIFIC GROUPS OF THE POPULATION

More and more food products on the market **target specific groups of the population, for example:** infants and young children, athletes, pregnant women, older adults, and gluten intolerant consumers. EU rules in force for these products are complex and fragmented since different sets of rules and concepts have been developed at different times, which can overlap and create confusion for businesses and national authorities.

Through the new Regulation on Food for Specific Groups, the Commission has made it possible to streamline the rules that apply throughout the EU by **eliminating all those that are unnecessary and contradictory** and by replacing them with a new, simple and clearer framework.

The new Regulation will abolish the broad outdated concept of 'foodstuffs for particular nutritional uses', which has proven not to respond to today's market and legal context. It will cover only food for infants and young children, food for people with specific medical conditions and food for weight control that replace the totality of the daily diet.

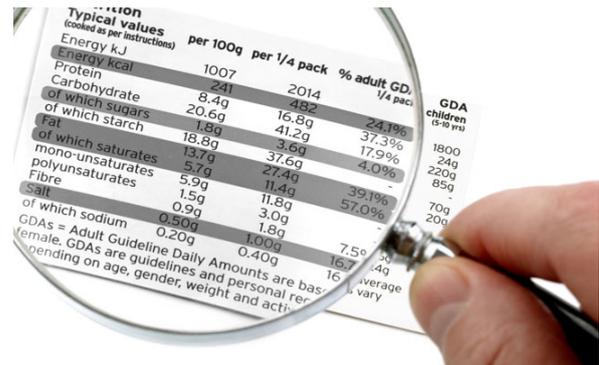
Under the new approach, food for other population groups will be covered by other more appropriate horizontal pieces of food legislation, to better protect consumers and provide a better environment for business. For example, rules on food for gluten intolerant consumers have been transferred under the Regulation on Food Information to Consumers.

The Regulation – adopted in June 2013 – will apply from July 2016 in order to give businesses sufficient time to adapt to the new rules.



9 FOOD INFORMATION AND FOOD LABELLING

The purpose of this Regulation, which was adopted in 2011, is to make food labelling easier to understand for consumers. This was achieved by simplifying and modernising



current legislation and introducing clearer rules regarding the presentation of food information. The new Regulation is now both forward-looking, tackling for example new information channels such as the Internet, and sufficiently flexible to respond to future developments.

The Regulation will require:

- a minimum font size for key information;
- the mandatory origin labelling also for fresh meat from sheep, goat, poultry and pigs, while the framing of voluntary origin indications will help prevent the risk of misleading consumers and will ensure a level playing field for food businesses;
- mandatory nutrition labelling to also be introduced to facilitate healthier food choices including: energy value, fat content, saturated fat, carbohydrate, sugars, protein and salt;
- and the mandatory labelling of nano-ingredients and extend the mandatory labelling of allergens to non-pre-packed foods including those sold in restaurants and cafes.

Most of the Regulation's framework will come into effect in December 2014, while the mandatory nutrition declaration will apply in December 2016.

10 HEALTH CLAIMS

Health claims have become a vital tool in the marketing of food products in order to attract consumer's attention. The legislation regulating health claims was adopted in 2006, entered into force in 2009 and gave the Commission the possibility to mandate the European Food Safety Authority (EFSA) **to verify every health claim on a food product through scientifically proven methods.** Following EFSA's scientific assessment and advice, the Commission was able to decide on whether the claims were unfounded and had no proven scientific health benefit.

As a result, a list of **254 permitted health claims has been adopted by the Commission** since May 2012, whilst some 1 995 submissions have not been authorised. Health claims that have not been authorised are prohibited on the EU market.

The authorisations are made available for anyone to view online in an interactive database called the *"EU Register of nutrition and health claims made on foods"*.

11 MAKING THE USE OF ADDITIVES SAFER AND MORE TRANSPARENT

At the end 2011, the Commission adopted implementing legislation to increase the **safety of food additives through a more transparent and regulated system.** The Regulation takes the form of a list, which applies from June 2013 and will allow national control authorities and businesses to easily access and identify which additives are authorised in the EU.

Apart from the list, the legislation also caters for:

- well determined conditions under which additives may be added to food;
- food categorisation where additives are listed according to the categories of food to which they may be added;
- a programme for the full re-evaluation of the safety of all authorised additives;
- and clear guidelines for applicants requesting new uses of food additives.

Similarly, for flavouring substances the Commission adopted an EU list of flavouring substances which has applied since April 2013. This list with about 2 500 substances improves the transparency to citizens and industry alike; consumers, food business operators and national food control authorities can now consult online a database in order to identify which flavouring substances are authorised in food. All substances in this list have undergone a thorough risk assessment or are in the final phase of being assessed by EFSA following a positive assessment by other scientific bodies. Substances not included in the list are now forbidden.

12 BAN ON BISPHENOL A (BPA) IN BABY BOTTLES

BPA is an organic molecule that is used to manufacture food and drink containers including polycarbonate baby bottles. Small amounts of **BPA can be released from such containers into food** stored therein if they are heated at high temperatures.

The Commission asked EFSA to evaluate the risk of such migration. In September 2010, EFSA concluded that use of BPA in food and drink containers is safe if a daily intake of 0.05 milligrams BPA per kilo of bodyweight is not exceeded and that the exposure of all groups of the population is normally far below this limit.

However EFSA highlighted that infants fed using polycarbonate infant feeding bottles have the highest exposure to BPA. Given a possible particular vulnerability of infants to potential effects of BPA and the availability of alternative materials, and taking into account the precautionary principle, the Commission adopted a **ban prohibiting the use of BPA in the manufacture of polycarbonate infant feeding bottles**. This ban entered into force in March 2011.

The ban demonstrates the Commission's determination to ensure the highest possible level of health protection and to further reduce exposure to the most vulnerable part of our population – babies and infants.



13 ACTION PLAN FOLLOWING THE HORSE MEAT FRAUD

In the beginning of 2013, the so-called “horse meat scandal” shook the **confidence of consumers** in buying beef products due to the fact that there were meat products being marketed and labelled as beef, but

actually consisted of traces/parts of horse meat. The result was that consumer's lost confidence in the labelling of meat products and trust in the food industry.

The Commission launched a **5 point action plan** to be carried out over the short, medium and longer term as a reaction to the scandal and to avoid the re-occurrence of a similar scandal:

1. The Commission has dealt with the issue of **food fraud** by strengthening existing tools and mechanisms, and in particular the network of national enforcers dealing with cross-border cases of



food fraud. The “Food Fraud Network” has enabled Member States to start exchanging information and alerts in case of possible violations and will be soon equipped with a dedicated IT tool that will ensure smooth and effective cooperation among national control authorities.

2. The Commission has also put together, and funded, **two EU-wide testing programmes** (in 2013 and 2014) to assess the presence of undeclared horse meat in beef products and react appropriately through the newly set up channels if any fraudulent activity is detected. Furthermore, such coordinated testing programmes will be organised in other parts of the food chain.
3. The Commission also proposed a mandatory recording of **horse passports** in a central national database, based on animal health and zoo-technical legislation.
4. The proposed new rules on **official controls** took into account recent lessons from the horse meat scandal, and include provisions to require appropriate and dissuasive financial penalties for food fraud as well as unannounced official controls specifically targeted at the detection of food fraud.
5. The last point is on **origin labelling** and proposed mandatory origin labelling of unprocessed meat of sheep, goat, pig and poultry and a review to prevent the misleading use of voluntary origin labelling indications on food.

14 PROTECTING EUROPE'S BEES

Pesticides have been identified as one of the many possible threats for the European honey bee population.

In spring 2012, new scientific evidence on the sub-lethal effects of neonicotinoids



(NNI) was published in an independent scientific review. This led to an EU wide debate in the scientific community and among stakeholders requesting a ban on seed treatment with neonicotinoids. The Commission immediately requested EFSA to issue an opinion on the use of three neonicotinoids (Tiametoxam, Clothianidin and Imidacloprid) concerning risks they pose to bee-colony populations. EFSA concluded that the substances pose a **high acute risk for bees** as regards exposure to dust, to residue in pollen, nectar and to guttation.

Taking the scientific **risk assessment carried out by the European Food Safety Authority into account and applying the precautionary principle**, the Commission considered imposing restrictions on the use of these three substances. In May 2013, the Commission adopted a decision **stating conditions for the use** of the three

substances and banning the use and sale of seeds treated with plant protection products containing these active substances. The decision bans any use of the three active substances for the treatment of seeds of plants that are attractive to bees with the exception of green houses.

The decision is yet another step in the Commission's overall efforts to tackle various threats to the European honey bee population, as highlighted in with the *Commission's honey bee health communication* published in 2010.

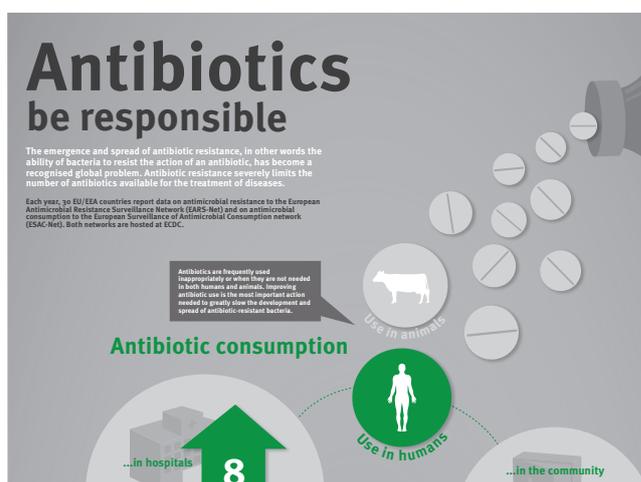
Another notable achievement included EU co-financed bee health surveillance studies in 17 EU Member States. In these studies, which were the first and biggest of their kind worldwide, 31 832 colonies in 3 284 apiaries were visited 3 times in 2012-13 by 1 354 inspectors. The results of these studies have deepened our knowledge-base on the health status of Europe's honey bees in the EU. This, along with many other EU efforts and good practices were appreciated by key scientists, policy makers and stakeholders in the first ever, ground-breaking Commission Conference for Better Bee Health in April 2014. The conference confirmed that while the Commission can help in many aspects, beneficial changes for sustainable beekeeping need the cooperation of a wide range of local actors in the fields and apiaries.

15 COMBATING AMR THROUGH VETERINARY MEDICINES AND MEDICATED FEED

In 2011 the Commission adopted an EU Action Plan against the rising threats from Antimicrobial Resistance, setting out **recommendations for Member States to reduce AMR** through coordinated efforts such as improving research/innovation, exchange of good practices and introducing a new set of rigorous measures for better surveillance of antimicrobial use and prevention of bacterial infections in healthcare facilities. This **5 year Action Plan sets out 12 concrete actions** involving various sectors such as agriculture, trade, veterinary medicine, medicine and animal husbandry. It was recognised that a holistic approach is needed requiring joined efforts from the EU, the Member States, healthcare professionals, industry, farmers and many others.

Through this action plan, the Commission is aims to reduce the impact and decrease the spread of AMR. Based on a holistic approach, the actions target:

- mitigating the risk of developing AMR in humans from the use of antimicrobials both in humans and animals by ensuring their appropriate use, and promoting microbiological diagnosis as the means to determine, to the extent possible, the need for antimicrobials;
 - putting in place effective ways to prevent microbial infections and their spread;
 - developing effective antimicrobials or alternatives for treatment of human and animal infections;
 - improving monitoring and surveillance in human and animal medicine;
 - joining forces with international partners to contain the risks of spreading AMR from international trade and travel and through the environment;



- and reinforcing research to develop the scientific and innovative means to combat AMR.

16 GMOS

In addition to the Action Plan, the EU's Public Health Programme has supported AMR-related research projects and over recent years, there have been several research projects carried out to better understand and monitor this phenomenon, thanks to EU funding through the Seventh Framework Programme.

In 2013, the Commission issued a **Roadmap on the implementation of the Action Plan** giving a comprehensive record of its progress. It outlined that achievements have been made on improving monitoring and surveillance, making better use of antibiotics in animals and humans and preventing the spreading of microbial infections.

In September 2014, the Commission adopted two legislative proposals aimed at reviewing and modernising the rules applicable to **veterinary medicinal products and medicated feed** across the EU. The objectives of the new rules are: improving the health and wellbeing of animals, tackling AMR in the EU and fostering innovation.

The proposal on veterinary medicinal products aims in particular to make more medicines available in the EU to treat and prevent diseases in animals. To combat AMR and to help keep antibiotics effective in humans and animals, it introduces the possibility of restricting the authorisation and use in animals of certain antimicrobials that are reserved to treat human infections.

The proposal on medicated feed aims in particular at ensuring the appropriate standards of product quality and safety in the EU, whilst simultaneously paving the way for better treatments for diseased animals. AMR will be tackled through measures such as a ban on medicated feed being used preventively or as growth promoters. Additionally, EU wide residue limits for veterinary medicines in ordinary feed are established at a level to avoid the development of AMR.

In line with the political guidelines of President Barroso of September 2009 asking for the possibility *"to combine a Community authorisation system, based on science, with freedom for Member States to decide whether or not they wish to cultivate GM crops on their territory"*, the Commission issued in July 2010 a proposal to amend the GMO legislation.

The objective was to offer Member States a wider margin of manoeuvre to decide on GMO cultivation on their territory while not affecting the present authorisation system, which is based on scientific advice from EFSA concerning risk to health and the environment.

The proposal will give Member States the legal basis to restrict or prohibit cultivation of GMOs in all or part of their territory that have first been authorised at EU level.

The European Parliament broadly supported the proposal in July 2011. The Council adopted a first reading Common position in July 2014 which also supports the objective of the proposal.

In the last quarter of 2014, it is expected that an agreement between the European Parliament and the Council will be reached to finally conclude and adopt this major piece of legislation early 2015.

The other important achievement in the field of GMOs is the adoption by the Commission in 2013 of Regulation (EC) No 503/2013 which aims at reinforcing and improving the authorisation process of GM food and feed, and clarifies the requirements for submitting an application.

17 ANIMAL WELFARE STRATEGY 2012-2015

Since the Lisbon Treaty, animals have been recognised as 'sentient beings' which means they are capable of feeling pleasure and pain. Recent years have also shown a steady rise in level of consumer interest in the way animals are produced, and there is a growing demand for better information on the treatment and wellbeing of animals in general.

With the aim of improving animal welfare standards, the Commission **adopted a new strategy dealing with the protection and welfare of animals** kept in farms, living in zoos or used for scientific experiments.

This animal welfare strategy which runs from 2012 to 2015 adopts a multi-level approach and includes:

- supporting EU countries in their compliance with EU rules;
- improving the training of animal keepers and veterinarians who inspect farms;
- building international cooperation toward improving animal welfare worldwide;
- improving consumer information and their empowerment;
- and improving cooperation between farmers, officials and consumers.

There have been major achievements in the welfare of laying hens and pigs. On 1 January 2012, the **Directive on the protection of Laying Hens** introduced a ban on barren cages in all farms, and a high level of compliance in Member States has been achieved. Similarly, on 1 January 2013, the Directive on the **Protection of Pigs** introduced provisions on the grouping of sows in all farms across the EU. In the same year, its application has modified the farming conditions, providing better welfare for pigs.

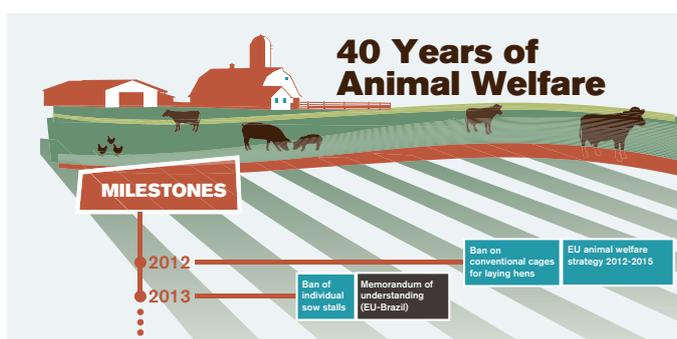
The Commission made significant

efforts to secure Member State compliance as the deadlines from these pieces of legislation approached. Enforcement proceedings were initiated immediately in cases where compliance was not achieved within the deadline and ran alongside ongoing efforts to support the achievement of full compliance as necessary.

The Regulation on the **Protection of Animals at Time of Slaughter** which came into force on 1 January 2013 is already delivering results in terms of improving animal welfare at slaughter. In the framework of the proposal on **official controls** (see point 20), the Commission introduced the possibility to establish **EU reference centres for animal welfare** at slaughter which could contribute to a better understanding and implementation of the EU's legislation on animal welfare.

As part of the Commission's initiative to find more efficient and better ways to overcome shortcomings in official controls EU's legislation on animal welfare during transport, a network of experts to exchange good practices was set up. This has yielded increased co-operation between national competent authorities and improvements to national official controls have been observed in this area as a result.

The testing on animals of finished cosmetic products has been banned in the EU since 2004 and the testing of cosmetic active ingredients since 2009. A marketing ban on animal tested cosmetics has also been in place since 2009 with an exception in the case of testing for the most complex human health effects until March 2013. After due consideration, the Commission decided not to take up the option to extend this exception to the marketing ban which became complete on 11 March 2013.



18 COMBATTING ANIMAL DISEASES

The EU co-financing for the implementation of eradication, control and surveillance programmes represents by far the largest amount of expenditure under the EU food safety budget. It aims to support – both financially and technically – the Member States to put in place specific measures for tackling animal diseases in the EU.



Since 2010, the EU invested more than 1 billion euros in co-financing programmes and targeted 13 priority diseases. Over these last five years, commitments in this area experienced a favourable downward trend, dropping by more than 100 million euros since 2010.

This reduction of the EU financial support corresponded to the last years in the EU, where the implementation of veterinary programmes has resulted in:

- the improvement of both human and animal health, by reducing disease prevalence and safeguarding public health, in the case of zoonosis (diseases

that can be transmitted from animals to humans);

- net benefits in economic terms for the EU as a whole, notably through: protecting the value of the sector; contributing to market stability; ensuring safe trade; increasing trade with other regions of the world and reducing human health costs.

In most cases, targeted diseases have been effectively contained and brought under control. Many have been progressively eradicated from large areas of the EU. The result has been a significant expansion of “disease free zones” in the EU.

Among the best achievements, was the implementation of the mandatory BSE monitoring and eradication programmes in cattle, which has led to a dramatic decline in BSE cases; trade in live cattle, beef and bovine products from Member States most affected have been restored, and consumer confidence has been boosted.

Positive results have also been achieved in the case of rabies, with the steady eradication of the disease from several Member States, on a scale which has never been experienced anywhere else before.

The Bluetongue programmes have also played an important role in the control and eradication of this disease, proving very successful as the disease has effectively been brought under control and BTV-1 and BTV-8 serotypes virtually eliminated throughout the EU.

Since 2007, these programmes fall under the new EU Animal Health Strategy, which sets out EU policy objectives in the field of animal and public health.

The legislative financial framework was recently revised and modernised through the adoption of Regulation (EU) 652/2014, in force since 30 June 2014, which lays down provisions on the management of expenditures in relation to the food and feed area, including veterinary programmes.

19 ANIMAL CLONING AND NOVEL FOOD

In December 2013, the Commission adopted two proposals for directives on animal cloning in conjunction with a new proposal for a novel foods regulation.

The first proposal would ban **animal cloning for farming purposes** and import of live clones (animals or embryos) for farming purposes produced in non-EU countries. The second would **ban the marketing of all food from clones**.

The proposals embrace diverse interests and address animal welfare and ethical concerns, in a balanced and proportional manner.

The **proposal on novel food** creates a centralised authorisation system, which will allow a much greater degree of certainty for applicants seeking the authorisation of a novel food. Novel food generally refers to food which was not consumed in the EU to a significant degree before May 1997, i.e. before the current Regulation entered into force and in particular to food produced using new techniques and technologies.

It clarifies the definition of a novel food, including new technologies which have an impact on food and it also creates a simpler and faster process to traditional foods from non-EU countries to be placed on the EU market. The proposal also foresees that an authorisation of an innovative novel food which is based on newly developed scientific data can be protected for 5 years.

20 SMARTER RULES FOR SAFER FOOD

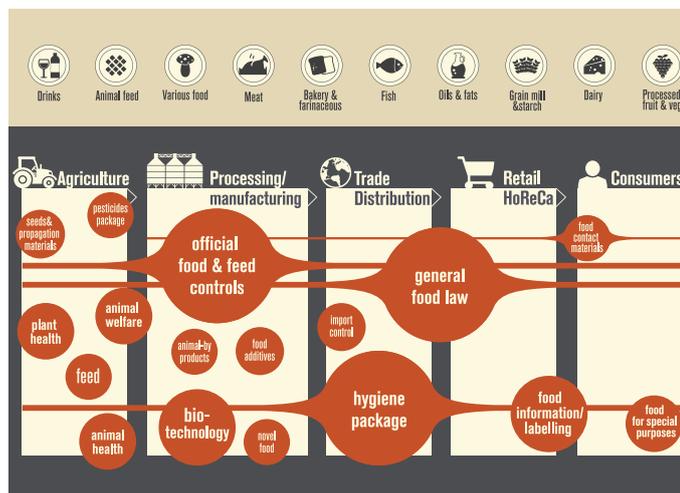
Adopted by the Commission in May 2013, this package is designed to strengthen the enforcement of health and safety standards for the whole agro-food chain.

The package includes measures that provide a modernised, simplified and risk-based approach and introduces more efficient control tools to ensure the rules are applied effectively. The proposals also reduce red-tape and burdensome processes and procedures for farmers, breeders and food businesses operators. It also consists of proposals on official controls, animal health, plant health and plant reproductive material (including seeds).

The Commission recognised the need to strengthen **official controls** in the wake of recent scandals. The new rules follow a more risk-based approach by allowing national competent authorities to focus their resources on the most relevant issues. Member States will also be asked to fully integrate anti-fraud checks into their national control plans and to ensure that financial penalties in these cases are set at truly dissuasive amounts. Concerning the financing of the system, the proposal foresees that the current system of fees for the effective implementation of controls will be extended to all sectors of the food chain. Special consideration is given to SMEs and micro-enterprises which are exempted from the costly

elements of the legislation (in-line with the Europe 2020 objectives, providing support for both micro-enterprises and SMEs in order to boost innovation and competition).

The legislation regarding **animal health** aims to improve standards



and to provide a common system to better detect and control disease. The system will be enhanced in such a way that those working to protect our food chain, such as farmers and veterinarians, will be granted the capability to react quickly and limit the spread of diseases, therefore minimising the impact on livestock and consumers. Sound animal health rules are important both in relation to potential impact of animal diseases on human health (zoonoses such as avian flu, rabies, etc.) and for the EU livestock sector. Its competitiveness, sustainability and jobs benefit from the smoothly regulated functioning of the single market. This opens also the possibility for the EU to capitalise on its high animal status by exporting animal products.

Since the value of crops in the EU is valued at 205 billion euros annually, the need to protect this sector is considered a priority. Through a modernised approach regarding **plant health**, the Commission has enhanced the protection of European agriculture and forestry by upgrading the existing health regime. More focus on high risk trade and increased traceability of planting material will be applied. Better surveillance and early eradication of outbreaks of foreign pests along with measures of financial compensation for growers who fall victim to pests will be introduced.

The proposal on **plant reproductive material** aims to provide more harmonised, simplified and flexible rules for the marketing of seeds and other plant reproductive material. This regulation proposed introduces a broader choice of new, improved and tested varieties, traditional varieties and material needed for low input, organic agriculture.

The objective is to assure the identity, health and quality of the plant reproductive material while supporting sustainable production, adaptation to climate change and biodiversity protection.

While the texts on animal health, plant health and official controls had their first reading in the European Parliament in April 2014 and now are awaiting the first reading in the Council, the plant reproductive material proposal is again under consideration by the Commission following the different positions of Council and Parliament.

21 REDUCING FOOD WASTE

The Commission established in 2012 a stakeholder working group under the Advisory Group on the Food Chain, Animal and Plant Health in order to identify best possible actions at EU level and facilitate sharing of best practices. In order to contribute to information and awareness-raising, the Commission has developed a dedicated “food waste” website and produced video and other materials to support information campaigns.



The Commission has also launched discussions with Member States on date marking in relation to food waste prevention and is strengthening co-operation with Member States to identify opportunities for food waste prevention all along the food production and consumption chain.

The legislative proposal reviewing waste targets, published on 2 July 2014, calls on Member States to develop national food waste prevention strategies with an aim of reducing food waste by 30% by 2025. The proposal makes reference to the need to prioritise redistribution of surplus food to people and use as a resource for animal feed over industrial uses. Excess food should as a priority go to people in need and the Commission, together with Member States and stakeholders in order to facilitate food donation in the EU.

22 INTERNATIONAL DIMENSION

Sanitary and Phytosanitary (SPS) import requirements aim to ensure that animals, plants and food products from non-EU countries marketed in the EU achieve an equivalent level of health protection than those domestically produced within the EU. These requirements are not only in full compliance with commitments under the World Trade Organization (WTO-SPS), but they include trade facilitation measures to allow a fair and easy trade without jeopardising the level of protection.

In addition, the EU is a single market of more than 500 million of consumers, allowing the free circulation of goods in 28 Member States. Third countries partners have clear advantages and they benefit from the EU being a single entity when exporting to the EU.

However, when it comes to EU exports the situation is different. EU exporters meet frequent difficulties due to import requirements in non-EU countries not respecting the WTO-SPS rules or due to SPS requirements being used as barriers to trade. But the most serious issue is that often third countries do not recognise the EU as a single entity for exports. Often authorisations by non-EU countries only concern individual EU Member States and contain clauses implying that the products to be exported are exclusively originated from plants/animals “born and raised” in the exporting Member State.

These requirements are against the EU principle of free circulation of goods established in the Treaty and breach solidarity among EU Member States.

Agreements are the most useful tool to re-balance this situation and to ensure that SPS trade conditions are respected and address the regulatory differences between the parties. In addition, under these Agreements, partners do not negotiate with the individual EU Member States, but with the Commission on behalf of the EU as a single entity. The Commission does not accept clauses that could breach EU legislation and ensures the solidarity among EU Member States.

During this mandate the Commission has concluded Agreements with South Korea, Central America, Colombia-Ecuador-Peru, Singapore, Canada, Moldova, Ukraine and Georgia. The EU has launched or continued is continuing negotiations with USA (T-TIP), Japan, Malaysia, Vietnam, Thailand, India, MERCOSUR, Morocco and the Gulf Cooperation Council. Furthermore, in applying existing Agreements with Canada, New Zealand, US, Chile and Mexico, the Commission has established a certain number of harmonised health certificates for exports from the EU to these countries. These certificates include the same conditions for all EU Member States, have abolished certain trade barriers opening the export market for some EU products, and have given a significant contribution to the recognition of the EU as a single entity for exports in these countries.

