



Brussels, 6.5.2013  
COM(2013) 264 final

**COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE  
EUROPEAN PARLIAMENT**

**Healthier Animals and Plants and a Safer Agri-Food Chain**

**A modernised legal framework for a more competitive EU**

## CONTENTS

1.	The current context .....	4
1.1.	Animal Health .....	4
1.2.	Plant health.....	4
1.3.	Plant reproductive material .....	5
1.4.	Official controls .....	5
1.5.	Management of expenditure.....	6
2.	The need to modernise the EU legal framework for animals, plants and the food chain .....	6
2.1.	Animal health.....	6
2.2.	Plant health.....	7
2.3.	Plant reproductive material .....	7
2.4.	Official controls .....	8
2.5.	Management of expenditure.....	8
3.	The ‘Review Package’ .....	8
4.	The content of the ‘Review Package’ .....	9
4.1.	The Animal Health Law .....	9
4.1.1.	Main changes .....	9
4.2.	The Plant Health Law.....	10
4.2.1.	Main changes .....	11
4.3.	The Plant Reproductive Material Law .....	12
4.3.1.	Main changes .....	12
4.4.	The Regulation on Official Controls.....	14
4.4.1.	Main changes .....	14
4.5.	Management of expenditure.....	16
5.	Conclusion.....	16

# COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT

## Healthier Animals and Plants and a Safer Agri-Food Chain

### A modernised legal framework for a more competitive EU

#### Introduction

Ensuring a high level of health for humans, animals, and plants is a Treaty objective of the EU. Over time, the EU has built up a comprehensive body of law designed to prevent and manage risks to animal and plant health and the safety of the food chain at EU and national level. The law in these policy areas is enforced by means of a common set of rules on official controls to be carried out by the competent authorities in the EU Member States.

The legal framework which the EU has developed so far has proven, overall, to be effective in preventing and countering risks. However, the modern global market increasingly exposes the EU to new risks and constantly calls for innovation and competitiveness. This and the experience gained with EU law in this area, points to the need to simplify and update available instruments and to further integrate the approach across the different areas.

The Commission therefore conducted a revision of the current legal framework for animal health, plant health, plant reproductive material and official controls aimed mainly at increasing effectiveness, consistency and legal clarity in those areas. In doing so, it was seeking to foster the productivity, smooth functioning and accessibility of the internal market and to reinforce the EU's competitiveness on a global scale. Thus, the review is ultimately contributing to delivering smart, sustainable and inclusive growth in line with the EU 2020 goals.

This Communication presents the resulting four legislative proposals in the four areas of animal health, plant health, plant reproductive material and official controls (the 'review package') and explains, for each of them, the current context, the rationale behind the package and the main improvements introduced.

The review package also includes a fifth proposal establishing a multiannual programme for EU financing of actions aimed at ensuring a high level of health for humans, animals and plants along the agri-food chain and in related areas while allowing businesses to operate in an environment that favours competitiveness and job creation.

Food production and consumption is central to any society, and has economic, social and, in many cases, environmental consequences. The agri-food industry is the second largest segment of EU industry. The total output of the food chain is worth some €750 billion a year. The sector employs over 48 million people, from primary production through to retail and catering. There are around 14 million primary agricultural producers and 25 million food businesses operating along the EU agri-food chain.

## 1. THE CURRENT CONTEXT

In order to afford citizens a high level of human, animal and plant health while encouraging the efficient functioning of the internal market, EU legislation provides a set of harmonised rules to prevent, eliminate or reduce health risks to humans which may arise along the agri-food chain and in the two areas most closely related to it, i.e. plant and animal health. Overall, EU rules aim at addressing health risks proper — i.e. risks to the integrity of humans, animals and plants from microbial and chemical contamination, diseases and pests — but they may also include measures ensuring productivity and diversity in plant production (for food security purposes) and regulating specific production methods (e.g. animal welfare and geographical indications).

### 1.1. Animal health

Animal health is a concern for all. Currently, EU intervention is focused on preventing and controlling transmissible diseases that may have significant health and economic impacts. The impact of an animal disease outbreak can vary widely, but it usually poses a direct risk to animal and often public health, partly through food of animal origin. However, there can also be indirect negative effects (possibly economic or social), including the cost to livestock farmers and related industries of dealing with disease and of business disruption, the cost to the public sector of eradicating and monitoring the disease, and changes in consumption patterns. Often, disease outbreaks also have significant effects on international trade in animals and animal products.

Across the EU, the farming sector is the largest user of animals, with at least 2 billion birds (chickens, laying hens, turkeys, etc.) and 334 million mammals (pigs, sheep, goats, cattle, fur animals, etc.). There are 13.7 million animal holdings in the EU. The value of livestock farming output in the EU is €156 billion a year.

### 1.2. Plant health

Plant health is a key factor in sustainable and competitive agriculture, horticulture and forestry. A large proportion of the food we consume, and of the feed fed to food-producing animals, comes from plants. The first objective of plant health rules is to protect the living products (i.e. trees, shrubs and plants) of EU agriculture, horticulture and forestry, public and private green (for example street trees, plants within public / private gardens) and the environment by preventing the entry and spread of non-native pests. Plant health rules secure safe trade by imposing EU import requirements and conditions for the movement of plants and plant products within the EU. Outbreaks of listed pests have to be eradicated or, if that is impossible, contained to protect the rest of EU territory. A second objective is to ensure that healthy plant material is used at the beginning of the chain of plant production, by preventing the spread of pests in seeds and planting material.

The value of crops grown in the EU is €205 billion annually. Without the protection afforded by plant health rules, EU agriculture, horticulture and forestry would suffer severe economic damage. A range of internationally regulated pests threatens the cultivation of crops such as wheat (value of EU exports: €9 billion), potatoes (EU production value: €9 billion) and tomatoes (production value: €9-12 billion).

### 1.3. Plant reproductive material

Plant reproductive material is the cornerstone of agricultural, horticultural and forest production. It is the first link in the agri-food chain, affecting the diversity, health and quality of plants and food. Plant reproductive material is controlled to ensure the identity, health and quality of the material for the benefit of its users, e.g. farmers, gardeners or foresters. The objectives of EU legislation on plant reproductive material are to improve agricultural, horticultural and forest productivity, ensure the smooth operation of the EU market for those products and the competitiveness of the sector on a global scale.

Today, the EU commercial seed market is worth approximately €6.8 billion, which represents more than 20% of total worldwide sales of commercial seed. The EU is a net exporter of seeds.

The EU sector is also highly competitive in world trade: it is the world's largest exporter of seeds, with an estimated export value of €4.4 billion, representing roughly 60% of the total worldwide seed export value of €7.7 billion.

### 1.4. Official controls

A high level of health along the agri-food chain depends on consistent, effective and timely enforcement of EU standards by the Member States. The correct application of agri-food chain rules and of the rules on animal health and animal welfare, on plant health, on plant reproductive material and on plant protection products must be ensured across the EU for humans, plants and animals to be healthier and for the internal market to thrive and work smoothly. For this to be possible, the relevant authorities in the Member States must be given a clear, reliable and consistent legal environment in which to make effective and efficient use of enforcement tools, and of official controls in particular. They also need appropriate resources to ensure continuity and consistency in their work, on the basis of needs linked to enforcement objectives.

More than 100 000 full-time staff are assigned to performing official controls in the EU, which involve inspections and other control-related activities. To give but a few examples: some 70 000 samples a year on average are analysed by over 270 accredited laboratories checking for pesticide residues. In 2010 alone, 736 806 samples were taken to check veterinary residues. Some 320 000 samples from domestic poultry and wild birds were analysed in 2011 purely in relation to avian influenza.

The efficient operation of an EU-wide system of official controls is of paramount importance both for exports and imports. The EU's capacity to export to non-EU countries relies on the added value that its products can be shown to have compared to those of competitors from outside the EU. This can be only be achieved by having an efficient official controls system which ensures that high standards of safety and quality are consistently enforced and the corresponding expectations of trade partners are met. In the other direction, the EU is the world's largest importer of live animals, food and feed. Checks carried out by the Member States' competent authorities on products arriving from non-EU countries ensure that the latter comply with EU standards or with standards which offer an equivalent level of protection.

In 2010 EU food and beverage imports were worth €78 billion, and exports €73 billion. The EU imported 79.3 million tonnes of food and live animals and 3.4 million tonnes of beverages in 2010, with a trade deficit of 14 million tonnes for food and live animals, and a surplus of 6 million tonnes for beverages.

## **1.5. Management of expenditure**

The current legal basis for EU funding is: Council Decision 2009/470/EC for veterinary eradication programmes and veterinary emergency measures; Council Directive 2000/29/EC for plant health measures; and Regulation (EC) No 882/2004 of the European Parliament and of the Council for funding measures regarding EU reference laboratories, Better Training for Safer Food (BTSF) and other measures deployed to implement official control rules.

In 2011 €314.6m was mainly allocated to animal disease eradication programmes. Expenditure on laboratories, BTSF and other measures represented 9% of the total. 7% was allocated to plant health operational measures, while 3% was allocated to the emergency fund for veterinary and other diseases.

## **2. THE NEED TO MODERNISE THE EU LEGAL FRAMEWORK FOR ANIMALS, PLANTS AND THE AGRI-FOOD CHAIN**

### **2.1. Animal health**

The current EU animal health legislative framework consists of around 50 basic directives and regulations, some of which were adopted in the early 1960s. Since then a body of over 400 veterinary acts — most of them drawn up between 1988 and 1995 for a Community of only 12 Member States — has been built up. Meanwhile, new challenges have emerged: diseases have sprung up which were unknown a decade ago, while others (e.g. foot and mouth disease, bluetongue and avian flu) have recently reappeared, reminding us of the serious risks they pose. Trading conditions have also changed radically, with the volume of trade in animal products increasing significantly both within the EU and worldwide.

In 2004 the Commission launched an independent evaluation to assess the performance of the Community Animal Health Policy (CAHP) over the previous decade. Although both this evaluation and the later consultations concluded that, overall, the current system was functioning properly, it also revealed the need for a revision of the current rules to address the following issues:

- the complexity of the policy framework;
- the lack of an overall animal health strategy;
- insufficient focus on disease prevention;
- the possibility of improving intra-EU trade in live animals.

## **2.2. Plant health**

Since their introduction in 1977, plant health rules have protected the EU against the introduction and spread of many pests. Currently, Council Directive 2000/29/EC is the main instrument in this area. However, with trade globalisation and climate change the EU is facing a higher risk of entry of new pests, increased opportunities for their establishment and spread as well as increased vulnerability of agricultural and natural ecosystems.

An evaluation of plant health rules carried out in 2010 showed that the current regime must adapt in order to address new risks effectively. Indeed, in the last ten years major outbreaks of dangerous import-related pests affecting forestry (e.g. pine wood nematode, citrus longhorn beetle, and red palm weevil) have raised awareness among policy makers and the public of the cost and impact of inadequate protection. The main problems identified by the 2010 evaluation related to:

- insufficient focus on prevention in relation to imports presenting high risks;
- the need to focus on pests which spread across Member States and so are a priority for the EU;
- the need for more effective instruments for controlling the presence and natural spread of pests;
- the need to modernise existing instruments for intra-EU movement (i.e. plant passports and protected zones).

## **2.3. Plant reproductive material**

The EU legal framework for plant reproductive material has developed since the 1960s. It consists of 12 basic Council directives and nearly 90 secondary acts covering variety listing for the purpose of authorisation for marketing and specific marketing requirements for different species.

While EU legislation has achieved the initial objectives of guaranteeing free marketing and ensuring the safety and quality of plant reproductive material, the following issues require further attention:

- the complexity and the fragmentation of the current legislation;
- the considerable administrative burden for authorities, as most of the tasks on registration and certification need to be carried out by official authorities;
- the lack of consistency with other EU policies (e.g. sustainable agriculture and forestry, biodiversity protection, climate change, the bio-economy);
- the lack of a consistent approach to recovering the costs of registering varieties and certifying plant reproductive material.

## **2.4. Official controls**

Official controls are governed by Regulation (EC) No 882/2004. Evidence of its implementation has been collected primarily through on-the-spot auditing by experts of the European Commission, but also through feedback from Member States and stakeholders regarding the actual day-to-day implementation. This evidence confirms that the main changes introduced by the 2004 Regulation to the way competent authorities organise and carry out official controls along the agri-food chain has laid the basis for a more integrated and horizontal, and thus more efficient, approach to enforcement. At the same time, it points to a set of shortcomings which call for further improvements, in particular:

- simplification of the overall legal framework, which currently suffers from the remaining fragmentation, overlaps and gaps, and therefore differences in interpretation and implementation at national level;
- more consistent use of the ‘risk-based controls’ principle;
- more systematic and consistent use of administrative cooperation tools and of computerised information systems;
- the repeal of unnecessary administrative requirements.

As regards the financing of official controls and the need to ensure steady and consistent funding of the work of the competent authorities, the evidence also points to current uncertainties about the long-term sustainability of official controls. An external study carried out in 2011 found that the Regulation’s provisions on financing official controls from fees are not fully delivering on the objective of ensuring an adequate level of resources to conduct official controls.

There is also evidence that the current rules are failing to ensure a fair and consistent approach across sectors: only some sectors are charged, and fees are not calculated in a uniform and transparent manner across Member States, or in a manner that rewards operators’ compliance.

## **2.5. Management of expenditure**

The current legal framework has to be adjusted in line with the proposed changes in the different policy areas to ensure their objectives are met. Furthermore, management of expenditure is currently complex and needs aligning with the Multiannual Financial Framework (MFF). A new legal basis is therefore needed.

## **3. THE ‘REVIEW PACKAGE’**

To pursue the objective of strengthening, modernising and streamlining the current legal environment in order to ensure a high level of protection of human, animal and plant health, the Commission is putting forward a package of five proposals to revise EU rules:

- laying down animal health requirements (the Animal Health Law);



- laying down protective measures against pests of plants (the Plant Health Law);
- governing the production and placing on the market of plant reproductive material (the Plant Reproductive Material Law);
- governing official controls and other official activities performed to ensure compliance with the entire set of agri-food chain rules (including the above) (the Regulation on Official Controls); and
- governing the management of EU expenditure in the main areas of the agri-food chain.

All five legislative proposals covered by the package are to be submitted to the European Parliament and Council for adoption under the ordinary legislative procedure (under Articles 289(1) and 294 of the Treaty on the Functioning of the European Union). The European Economic and Social Committee and the Committee of the Regions will be asked for an opinion.

## 4. THE CONTENT OF THE ‘REVIEW PACKAGE’

### 4.1. The Animal Health Law

The EU Animal Health Strategy 2007-2013 was adopted in 2007<sup>1</sup>. At its heart is the notion that ‘prevention is better than cure’ and its goals are to ensure a high level of public health and food safety; to support farming and the rural economy; to improve economic growth, cohesion and competitiveness; and to promote farming practices and animal welfare which minimise environmental impacts. Later on, the Action Plan for the implementation of the strategy<sup>2</sup> referred to the development of an EU Regulation on animal health, referred to here as the Animal Health Law (AHL), as one of the main deliverables of the strategy for a modern and innovative legal framework supporting the achievements of the above goals. The Commission’s proposal for the AHL is the result of extensive consultations of interested parties.

#### 4.1.1. *Main changes*

**Simplification, modernisation and increased consistency** across EU animal health legislation have been major driving principles of the revision process in this area.

In line with this approach, the AHL lays down the foundations for a **wide and comprehensive legislative framework** for EU animal health policy. It clearly sets out the overarching principles and objectives necessary to reduce animal disease further while maintaining the EU’s economic competitiveness. Detailed provisions — such as specific disease control measures, identification and registration rules for certain species, and specific measures on intra-EU movement for particular species — are to be dealt with by means of delegated or implementing acts. Using these acts

---

<sup>1</sup> [http://ec.europa.eu/food/animal/diseases/strategy/index\\_en.htm](http://ec.europa.eu/food/animal/diseases/strategy/index_en.htm).

<sup>2</sup> COM(2008) 545 final, [http://ec.europa.eu/food/animal/diseases/strategy/documents\\_en.htm](http://ec.europa.eu/food/animal/diseases/strategy/documents_en.htm).

to introduce more specific rules or requirements allows the flexibility and speed needed to react to rapidly changing scenarios and veterinary emergencies.

**Enhancement of disease surveillance, disease notification and reporting networks** will better support early detection and control of diseases, including emerging diseases such as those linked to climate change, and ensure greater convergence with international standards.

#### *Simplification and clarification*

A **simpler legislative framework** will help authorities and operators to understand and use it, ensure their actions are more consistent and objective-focused, and set out general principles to be followed to promote disease prevention and control. This has the potential to **reduce the administrative burden** on them by cutting down the time taken to familiarise themselves with the legislation and by introducing scope for simplifying certain administrative requirements and making them more coherent including a more coherent and consistent legal framework for vaccination.

The new AHL will **clarify the animal health responsibilities** of operators, veterinarians and others, partly by requiring a basic level of knowledge for the first time.

#### *Introducing new technologies*

The AHL will allow more scope for using **new technologies** for animal health activities such as monitoring pathogens, electronic identification and registration of animals and electronic certificates. Use of new technologies and systems will tend to reduce the administrative burden on both veterinary authorities and operators in their day-to-day work.

#### *Increased flexibility through the use of a risk-based approach*

Criteria for **listing animal diseases, categorised** systematically and on a scientific and evidential basis will be introduced. This will allow the EU to better prioritise the use of its resources, giving less priority to diseases which pose less risk.

Wider use of '**compartmentalisation**' will be permitted (i.e. where some farms are considered safe even during disease outbreaks), allowing a more risk-based approach to animal disease control and potentially fewer trade restrictions.

## **4.2. The Plant Health Law**

The Commission's proposal for a Regulation on protective measures against pests of plants, referred to here as the Plant Health Law, meets the request of the Council of 21 November 2008 for an evaluation of the EU plant health rules, considering the need to amend the existing legal framework and the impact of such amendments. Stakeholders and Member States authorities were extensively consulted throughout the revision process.

Against this background, the proposed Regulation aims to overcome the flaws identified following the evaluation of the plant health rules in 2010 and to put in place a robust, transparent and sustainable regulatory framework that is 'fit for

purpose'. Overall, synergies with the plant reproductive material regime are reinforced, while avoidable duplications and unnecessary burdens are removed. Official controls by Member States' competent authorities on operators' compliance with EU plant health requirements are covered in the proposal for a Regulation on Official Controls.

#### 4.2.1. *Main changes*

##### *Scope*

The geographical scope of the proposed Regulation is **limited to the territories of the Member States in Europe**, excluding overseas countries and territories and outermost regions, where the pests against which the EU needs to be protected are indigenous.

The proposed Regulation covers all organisms directly harmful to plants, i.e. insects, mites, nematodes, pathogenic micro-organisms and parasitic plants (now called pests). It covers both **quarantine pests** and **quality pests**, as currently regulated under the 'Marketing Directives' for seed and plant propagating material. Criteria for deciding on the appropriate assignment of pests (quarantine or quality) are provided in the Annexes to the Regulation. The Annexes also set out principles and measures for the management of phytosanitary risks.

**Exports** of plants, plant products and other objects to third countries are also covered by the proposed Regulation. Exports are governed either in accordance with the relevant EU requirements, or, if the non-EU country's rules so allow or that country so agrees, in accordance with the requirements of that country. The proposal also provides for the introduction of a **pre-export certificate**, for cases where plant material is exported from a Member State which is not the Member State of origin. The pre-export certificate is meant to replace the informal guidance document currently in use.

##### *Enhanced prevention on import and reinforced early action against outbreaks*

Prevention is enhanced by empowering the Commission to adopt precautionary measures concerning new, **high-risk planting material imported from non-EU countries**, based on a preliminary risk assessment, for a time limit of four years. This time span is considered necessary to perform a full risk assessment and rule on the appropriateness of permanent measures. The proposed Regulation provides that **when passengers bring regulated plants into the EU territory in their luggage** they must now comply fully with the relevant requirements and prohibitions.

Furthermore, the proposed Regulation obliges Member States to carry out **surveillance in their territory for the presence of pests** in areas where they were not previously known to occur. If pests are detected, Member States will be expected to carry out eradication measures, including the demarcation of a restricted area consisting of an infested zone surrounded by a buffer zone. In addition, enhanced levels of preparedness and surveillance are required for quarantine pests identified as **priority pests**. Surveillance and eradication obligations will not apply to quality pests.

The proposed Regulation empowers the Commission to adopt implementing acts to contain (control) quarantine pests that cannot be eradicated from the EU territory.

#### *Reinforcement and modernisation of the internal market provisions*

Where plant material is to be moved within the EU, the proposed Regulation provides for the mandatory use of a plant passport, attesting compliance with the legislation on quarantine and quality pests. The **passport**, simplified and standardised under the Commission's proposal, is to be **issued by operators, under the supervision of the competent authorities**. Operators will have to store the information necessary to trace infested consignments, but the passport can contain data carriers (barcodes, etc.) instead of the current lot number. Where planting material requires both, a plant passport and a certification label under EU law on plant reproductive material, the two labels can now be combined in a single document, thus reducing the administrative burden on operators. Plant passports will be required **for all nursery stock, but not for sales to final non-professional users**.

### **4.3. The Plant Reproductive Material Law**

In 2007, Member States in the Council asked that the existing legislation on marketing plant reproductive material be made simpler. Following an external evaluation<sup>3</sup> in 2007-2008, an Action Plan<sup>4</sup> was adopted in 2009. The Commission's proposal for a Regulation on the marketing of plant reproductive material (referred to here as the Plant Reproductive Material Law, builds on extensive consultations of Member States, stakeholders and the Community Plant Variety Office (CPVO).

#### *4.3.1. Main changes*

The major principles behind the revision were **simplification**, modernisation, cost reduction, greater efficiency and **increased flexibility** for operators, ensuring an appropriate level of harmonisation across the EU and horizontal coordination with other, mostly environmental EU policy objectives.

#### *Simplification and modernisation*

These objectives have been achieved by replacing the **12 directives** currently dealing with specific types of plant reproductive material, such as agricultural crops, fruit plants, ornamental plants, vegetables and forest reproductive material, with **one regulation**. It introduces **harmonised basic rules** to all types of plant reproductive material (such as freedom from harmful organisms and defects) while maintaining stricter rules for important plants marketed throughout the EU, e.g. listed plant species, the varieties of which have to undergo tests for distinctness, uniformity and stability and certification and inspections for marketing. In addition, the scope of the law is extended to exports and to supply for industrial processes.

---

<sup>3</sup> FCEC (2008), *Evaluation of the Community acquis on the marketing of seed and plant propagating material (S&PM). Final Report.*

<sup>4</sup> SEC(2009) 1272 final.

### *Flexibility, cost reduction and efficiency gains*

The aim of significantly reducing the overall administrative burden and cost has been achieved by giving operators and competent authorities considerable **freedom in completing registration and certification tasks** and by introducing the **principle of cost recovery** for variety registration (and for certification via the Regulation on Official Controls). However, micro-enterprises will be exempted and fees could be reduced for varieties with an officially recognised description and for registration of heterogenous material, in the interest of conserving genetic resources and biodiversity.

The new legislation fosters flexibility in variety registration by allowing most registration tasks for new varieties to be performed by operators under official supervision if the operator requests this.

The current obligation to notify the Commission of a variety and include it in the Common Catalogues before marketing throughout the EU will be abolished to **speed up innovation**, i.e. **market access for new plant varieties**. Registering a plant variety in one Member State will be sufficient.

The **CPVO** will have a greater role in **variety registration**. The CPVO will manage the EU Plant Variety Database instead of the Commission and the option of registering a variety directly with the CPVO will be introduced. To ensure the quality of the registration process, national variety examination centres will be audited by the CPVO. The CPVO will also continue to harmonise testing protocols for new varieties. In addition, a **‘one-key, several doors’ approach** will enable a new variety to be registered for marketing purposes and granted plant variety rights under a single procedure.

The process of **certifying plant reproductive material** lots before marketing will also be made more **flexible**. The option of certification by the operator under the official supervision of a Member State competent authority will be extended to all listed species and to all marketing categories of plant reproductive material.

### *Horizontal coordination with other EU policy objectives*

In order to improve biodiversity and conservation of plant genetic resources on farm, the requirements for **traditional and conservation varieties** and other material, e.g. heterogenous and niche market material, have been considerably reduced. No variety testing and certification are required. This will considerably improve market access for such material. Traditional and conservation varieties can be registered at low cost on the basis of historical data by using a variety description recognised by the competent authority. In addition, the rules have been amended to cater for the possibility to authorise for marketing of heterogenous material (e.g. populations) and niche market material in small quantities by micro-enterprises.

Testing protocols for the **agricultural sustainability criteria** (e.g. for disease and drought resistance) for variety registration will be harmonised for the first time to steer **plant breeding** in a more **sustainable direction**. However, the Member States may continue to manage testing of new varieties for value for cultivation and use, based on their agro-ecological conditions.

#### 4.4. The Regulation on Official Controls

The proposal to amend the general framework for official controls laid down in Regulation (EC) No 882/2004 incorporates the outcome of a number of evaluations which have dealt with the different aspects of that framework.

Options for revision were extensively discussed with Member States within the Working Group on the General Application of Regulation 882/2004 and at the preparatory stages of two studies (in 2009 and 2011) carried out on the state of application of the rules governing the financing of official controls. Stakeholders were consulted in the Advisory Group on Food Chain and Animal Health and Plant Health.

##### 4.4.1. Main changes

###### *Consolidation of the integrated approach, with sector-specific flexibility*

One major novelty is the broadening of the scope of the rules on official controls, and in particular, their extension to relevant controls on plant health, plant reproductive materials and animal by-products, which until now have been governed by sectorial provisions not fully consistent with the approach laid down in Regulation (EC) No 882/2004. The current detailed set of rules applicable to official controls on residues of veterinary medicines will be repealed to allow this area to be regulated in a more risk-based, but still health-protective way, under the same legislative framework.

This revision will have a significant impact on the legal framework governing official controls on products from non-EU countries. It provides a set of common rules for all control activities to be performed at EU borders on animals and goods from non-EU countries which require increased attention for health reasons. In this context, it introduces Border Control Posts (BCPs) designed to replace the current Border Inspection Posts (BIPs — for animals and derived products), Designated Points of Entry (DPEs — for feed and food products of plant origin) and Points of Entry (plants and plant products). A uniform set of rules will apply to controls carried out at the BCPs and a Common Health Entry Document (CHED) will be used for prior notification of the arrival of consignments and to record official controls and decisions (replacing the standard documents currently in use in each sector)<sup>5</sup>. While documentary controls will remain systematic for all regulated goods and for animals, common criteria will ensure that identity and physical controls do not exceed what is required having regard to the risk posed by different categories of products.

Provision is made for adopting further rules for specific sectors by means of delegated and implementing acts.

---

<sup>5</sup> I.e. the Common Veterinary Entry Document (CVED) in the area of veterinary controls, the Common Entry Document (CED) for non-veterinary controls, and the phytosanitary certificate currently in use in the plant health sector.

### *More effective enforcement mechanisms*

A number of changes will ensure that the toolkit offered by Regulation (EC) No 882/2004 to national enforcers is made simpler to use and more effective:

- for each of the sectors covered by the package, each Member State will be asked to designate a single authority responsible for coordinating preparation and ensuring the coherence of a multi-annual control plan and to act as a contact point for the Commission and other Member States in relation to official controls;
- electronic handling and processing of the CHED for all animals and goods subject to controls at the border will be introduced;
- while the requirement for all official laboratories to be accredited against ISO standard 17025 is reaffirmed, transitional measures and temporary or permanent derogations are provided for as appropriate.

The proposal also aims at improving the usability of the rules on ‘administrative assistance’, i.e. the mechanisms which allow cooperation between national control authorities on cross-border enforcement issues, where violations of EU rules need to be pursued not only in the Member State in which the violation was detected but also in the Member State where it originates. A new EU wide mechanism for the rapid exchange of information related to serious and widespread violations will enable Member States to address fraudulent practices more effectively.

### *Financing of official controls*

Allocating appropriate resources to official controls is essential to prevent major disruptions to the EU’s system of official controls in the agri-food chain and to guarantee its capacity to anticipate and respond to health emergencies as effectively as possible.

The proposal builds on the current system of mandatory fees (at present only charged to certain operators and/or for certain controls). It strengthens the principle according to which competent authorities should be able to charge businesses in order to recover the costs they incur in carrying out their official control duties along the agri-food chain and in certain related areas (e.g. veterinary and phytosanitary controls, controls on plant reproductive material).

A number of improvements to the current set of rules are proposed with a view to ensuring a consistent and steady stream of resources to the competent authorities and to eliminating the known shortcomings of the existing system:

- mandatory fees will be charged to all registered food and feed businesses and to operators in the plant and plant reproductive material sectors so as to spread the cost of controls across the entire chain;
- fees will enable the competent authorities to fully recover the costs incurred, so as to make their revenues less dependent on national budgetary policies and reduce the risk of under-resourcing as a result of funds being reallocated to competing priorities;

- more equity and fairness will be achieved by ensuring that the methods used to calculate the fees and the list of costs covered are fully transparent, and by requiring Member States to reward consistent compliance by operators (e.g. with reduced fee rates);
- as a rule, micro-enterprises will be exempted from the payment of the fees.

#### **4.5. Management of expenditure**

The main objective of the Commission’s proposal on management of expenditure is to accompany proposed changes in the relevant policy areas and to seek alignment with the EU’s Multiannual Financial Framework, while allowing the use of reserves in the agricultural sector under certain circumstances, for example in response to crises.

Regarding plant health, in order to protect the EU against the introduction and spread of pests, survey programmes for the presence of pests will be funded as well as phytosanitary support measures for the outermost regions of Member States. The new framework will also allow funding of initiatives designed to update legislation in order to keep up with technological and scientific development and to ensure efficient and effective enforcement. In case of emergency measures, Union co-financing will be possible as of the entry into force of the Plant Health Law for compensation to growers for the lost value of plant material subject to destruction.

### **5. CONCLUSION**

The proposed legislative package is the result of a major revision of the most relevant components of EU legislation governing the production and placing on the market of food, the safety of the food and feed chain, and the health of plants and animals.

The revision in question has involved experts from the Member States, and all concerned stakeholders, since 2004 in the case of the animal health legislation and for more than three years in the other areas. It was carried out to assess the fitness for purpose of the vast range of rules which the EU has produced over time to deliver the Treaty objectives of ensuring a high level of health for humans, animals and plants during the various processes along the path from farm to fork (from primary production to the consumption and disposal of food). Production methods and techniques have changed, globalisation and increased exchanges are having an impact on the spread of hazards and risks, new hazards and risks have arisen, and consumers’ expectations and education have evolved with all that.

This comprehensive revision has resulted in the proposed changes to the animal health legislation, to the legislation governing plant health and plant reproductive material and to the rules on official controls and other official activities along the agri-food chain. These changes aim to deliver a more effective and modern legal framework for those issues, to increase the flexibility and proportionality of rules established in some cases more than 40 years ago and, overall, to better meet the needs of citizens and businesses.