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IMPACT ASSESSMENT

Accompanying the document

Proposal for a REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

laying down general provisions for the management of expenditure in the field of food chain, animal health and welfare, and on plant health and plant reproductive material ("feed and food expenditure")

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Glossary

AHL	Animal Health Law
AHS	EU Animal Health Strategy 2007-2013
AI	Avian Influenza
BSE	Bovine Spongiform Encephalopathy
BTB	Bovine Tuberculosis
BTSF	Better Training for Safer Food
BTV	Bluetongue Virus
CA	Competent Authority
CAHP	Community Animal Health Policy
CAP	Common Agricultural Policy
CRSS	Cost and Responsibility Sharing Scheme
CSF	Classical Swine Fever
CVO	Chief Veterinary Officer
DG	Directorate General (of the European Commission)
EFSA	European Food Safety Authority
EURLs	EU Reference Laboratories
FAOSTAT	Food and Agricultural Organisation, United Nations, Statistics Division
FCEC	Food Chain Evaluation Consortium
FMD	Foot and Mouth Disease
GNI	Gross National Income
HPAI	High Pathogenic Avian Influenza
IA	Impact Assessment
IASG	Impact Assessment Steering Group
IPPC	International Plant Protection Convention
LPAI	Low Pathogenic Avian Influenza
MFF	Multiannual Financial Framework (2014-2020)
MS	EU Member State
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Co-operation and Development
OIE	World Organisation for Animal Health
PHL	Plant Health Law
PHR	Plant Health Regime
PPP	Public-Private Partnership
PRM	Plant Reproductive Material
SBV	Schmallenberg Virus
SMEs	Small and Medium Sized Enterprises
SPS	Sanitary and Phytosanitary Measures agreement
TFEU	Treaty on the Functioning of the European Union
TSE	Transmissible Spongiform Encephalopathy
vCJD	variant Creutzfeldt-Jakob Disease
WHO	World Health Organisation
WTO	World Trade Organisation

Section 1: Procedural issues and consultation of interested parties

1.1 Background

For some years, the Commission, specifically DG Health and Consumers, has been working on the revision of EU policy for animal health, animal welfare, plant health, plant reproductive material, feed and food safety, and the official controls that underpin the effective implementation of these policies (hereinafter together referred to as "food safety policy"). This overall revision is intended to drive EU policy more strategically, making it more effective, and allowing more flexibility when new changes arise. This assessment evaluates the impacts of options to modernise the financial framework for the food safety policy areas.

The overall budget of €1.891bn from 2014 to 2020 (in current prices) for the food safety financial framework has already been proposed by the Commission within the context of the Multiannual Financial Framework (MFF), published in June 2011 (budget line named 'food safety' under Heading 3 'Security and Citizenship')¹. Therefore, this impact assessment for the financial measures is intended to consider the likely impacts of the options available for the legislative proposal establishing the financial framework related to food safety, including plant health, animal health and official controls, within this existing context. It brings together relevant work carried out for the impact assessments of the individual policies, along with other recent relevant evidence, such as audit reports and consultation results.

This is intended to be a "proportionate" level of analysis in line with the Commission guidelines on Impact Assessment.

As the budget has already been developed and proposed in the context of the Multiannual Financial Framework, and the policies are at an advanced stage of development with significant analysis of impacts already behind them, and also considering the limited timescale to meet the Secretary General's request, this assessment concentrates on the best ways in which the budget can be spent to support the policies in question. Moreover, no specific tools to demonstrate the cost-effectiveness of the food and feed spending have been implemented within the current monitoring and evaluation system so far. Therefore this assessment will take a light-touch proportionate approach to demonstrate the importance of EU funding in this area and considers some alternative options.

Within the food safety policies under consideration, rules governing expenditure are already in place. In particular, this proposal precedes the 'Healthier Animals and Plants for a Safer Food Chain Package' which includes proposals for:

- the animal health policy, which aims to protect and raise the health status and condition of animals in the EU, in particular food-producing animals, whilst permitting intra-EU trade and imports of animals and animal products in accordance with the appropriate health standards and international obligations;
- the plant health regime (PHR), whose objective is to protect EU agriculture and forestry by preventing the entry and spread of non-native harmful organisms (pests and pathogenic micro-organisms affecting plants);
- the marketing of seed and propagating material of agricultural, vegetable, forest, fruit and ornamental species and vines ("plant reproductive material"), which ensures that EU criteria for health and quality are met;
- a legislative framework for the organisation of official controls concerning food and feed safety, animal health and welfare, plant health and plant reproductive material, established to ensure that the sectorial rules are enforced by Member States (MS) across the EU in a harmonised manner.

1.2 Supporting Impact Assessments and Consultations

Because all four policies have been under revision for some time, they are individually supported by their own impact assessments, and details of these policies have been extensively discussed with stakeholders in various consultation fora. There are four relevant impact assessments and regulations under consideration, in the areas of: animal health; plant health; plant reproductive material; and

¹ http://ec.europa.eu/health/programme/docs/maff-2020_en.pdf (see page 25)

official controls. This package, aimed at modernising and integrating the EU policies in these sectors, has been developed as a result of a long series of studies, analyses and evaluations. The most relevant ones, as well as their main conclusions and recommendations, are listed below.

Animal Health

In 2004, the Commission launched an independent evaluation to assess the performance of the Community Animal Health Policy (CAHP) over the previous decade and its coherence with other EU policy interventions. The evaluation recommended - among other things - the adoption of a single regulatory framework defining and integrating common principles and requirements of existing legislation for animal health.

The resulting EU Animal Health Strategy 2007-2013 (AHS) "Prevention is better than cure" and its subsequent Action Plan identified the main objective of the Strategy in the development of an EU Animal Health Law (AHL).

The Impact Assessment for the Animal Health Law therefore looked at ways in which the strategy could be best implemented, including making improvements to existing measures, as well as the main objective of consolidating and simplifying the legislation.

The new AHL will replace the current animal health legislative framework, which involves almost 60 basic directives and regulations, some of them adopted as early as 1964, and is expected to affect the veterinary *acquis communautaire*, which covers now more than 400 acts.

Plant Health

Based on the conclusions of the Council of November 2008, the Commission initiated a comprehensive evaluation of the EU plant health regime (PHR) from the introduction of the internal market (1993) and contracted the necessary study out to an external consultant.

The consultation concerned changes to the EU plant health regime itself as well as elements of the regime to be transferred to or from the PRM regime and the future EU regime on official controls on food and feed, animal health and welfare, plant health and plant reproductive material.

The internal process to develop the IA was further supported by a second contract with the consultant for a study on the quantification of costs and benefits of amendments to the regime, supplementary to the data that had been collected during the evaluation. The IA recommended that an increase in certain aspects of plant health spending would have significant benefits that outweighed the costs.

The impact assessment, approved by the Impact Assessment Board in 2011, explores substantially increasing the Union's financial support for plant health, in particular to expand the scope of Union financial support to surveillance programmes for speedy detection of harmful organisms, and to compensation to operators for the value of plant material destroyed during eradication. It furthermore outlines the extension of the scope of the EU reference laboratories system, financially supported by the EU to plant health and the provision of transitional EU financial support for the accreditation of the corresponding national reference laboratories. The Commission's proposal for the 2014-2020 MFF itself also underlines the need for an increased budget for plant health.

The new Plant Health Law (PHL) will replace the main instrument of the PHR, which is Council Directive 2000/29/EC on protective measures against the introduction into the Community of organisms harmful to plants or plant products and against their spread within the Community. It will also replace six Council Directives for the control of specific harmful organisms, and will affect the phytosanitary *acquis communautaire*, covering at present more than 60 acts.

Plant Reproductive Material (PRM)

Based on the results of the evaluation of the European Union legislation on the marketing of seed and plant propagating material (PRM) conducted in 2007/2008 by the Food Chain Evaluation Consortium (FCEC), the Commission services developed a PRM Action Plan which was presented in 2009. They were followed by a study on variety registration conducted by the same consortium in 2010 and by a PRM certification study conducted by the Commission's services.

The Impact Assessment on PRM was built on the results of these preparatory works, and focused on the simplification of the basic legal acts, on improving the effectiveness and efficiency of the system, and on horizontal coordination with recent, already adopted EU policies.

In particular, the current legal framework, which consists of a horizontal Council Directive on the Common Catalogue of varieties of agricultural plant species and 11 vertical Council Directives on the marketing of commodities of seed and propagating material, is to be replaced by one single piece of legislation.

Official Controls for Feed and Food

Regulation (EC) No. 882/2004 on Official Controls provides a harmonised framework of general rules for the official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

In September 2011, a report examining the impacts of potential revisions to this Regulation was published. This external study presents results of the research conducted and impact analysis on options proposed by the Directorate-General for Health and Consumers to change the current system in order to improve shortcomings identified in an evaluation of the Regulation conducted in 2008.

In July 2009 the Commission issued a report for the European Parliament and the Council to review the experience gained throughout the first years of application of Regulation (EC) No 882/2004. It indicated that improvements could be made to meet the Commission's Smart Regulation Agenda objective of simplifying regulation. This would also address the issues of administrative burden reduction and fostering competitiveness.

In addition, DG Health and Consumers has conducted further analysis on the alignment of other EU sectorial legislation on official controls (animal health, plant health, plant reproductive material) with the overarching principles established in the Regulation.

These works led to the development of an Impact Assessment, addressing shortcomings stemming from the incomplete implementation/achievement of certain principles/objectives, and from the fact that the integrated approach to official controls is only partly consolidated.

From the very start of the processes accompanying the package, key stakeholders, Member States' competent authorities, international organisations and trading partners have been closely involved and have played a crucial role in the discussions. In addition, in accordance with the Commission's standards for consultation, economic and social stakeholders such as European associations with an interest in food and feed and the interested public have been consulted on a number of occasions.

1.2.1 Multiannual Financial Framework

On 29 June 2011, the European Commission presented its proposal for the multi-annual budget for 2014-2020 which will start in 2014. "A Budget for Europe 2020" is aimed to respond to today's concerns and tomorrow's needs, and focuses on priority funding at the EU level that provides true added value. This upcoming EU budget remains focused: the overall amount proposed for the next seven years is €1,025 billion in commitments (1.05% of the EU GNI) and €972.2 billion (1% of EU GNI) in payments. The overall food safety budget €1.891bn from 2014 to 2020 (in current prices) has been proposed by the Commission as part of the overall MFF.

As was made clear in a letter of 26 November 2010 to the President of the European Parliament and the President in office of the Council, the Commission indicated that it considers that:

"European added value is a key test to justify spending at EU level even if the added value of a political project cannot be reduced to a balance sheet".

Therefore the general objectives of the initiative also include those laid out in the Commission working paper discussing the necessity for added value in the new Multiannual Financial Framework. These concentrate on the necessity of added value in EU financial contributions²:

- The EU budget should focus on EU added value, meaning the delivery of objectives that can be achieved better through spending at EU level rather than at the level of the individual Member States. The design of both the Multiannual Financial Framework and the sectorial instruments and programmes should be such that the contribution of the expenditure at EU level is made obvious.
- EU added value should be prominent in areas of spending linked to the EU core competences (for example, agriculture, where more than 70% of total spending is at the EU level), or closing missing links (for example, key cross border infrastructures in energy, transport and ICT) or because the issues at stake are of such a magnitude that individual actions by the Member States would not meet the objectives (for example, large-scale research infrastructures or the combatting the consequences of climate change).
- Pooling resources at EU level should also generate economies of scale and better results than the same amounts separately spent at national levels (for example, in the areas of research or education mobility).

²http://ec.europa.eu/budget/library/biblio/documents/fin_fw1420/working_paper_added_value_EU_budget_SEC-867_en.pdf

1.2.2 Consultations

Due to the limited timescale within which the present impact assessment has been developed, no specific consultation was carried out to involve the stakeholders in the process.

Nevertheless, no radical changes can be envisaged at this stage, in keeping with the formal consultations already conducted in the frame of the proposals of the "Healthier Animals and Plants for a Safer Food Chain Package". These are considered to provide sufficient evidence of the support expected by the interested parties.

Moreover, broad discussions carried out within different fora (such as CVOs' meetings, Advisory Groups and Working Groups involving both representatives of national authorities and experts from the private sector) also demonstrate the overall satisfaction with the current funding policy of both public authorities and the private sector, therefore any major change to the current approach is not considered necessary.

1.3 Steering Groups

This impact assessment was guided by an internal DG Health and Consumers steering group. An Impact Assessment Steering Group (IASG) was also convened, which DG Health and Consumers (SANCO) chaired, and to which the Secretariat-General (SG), Legal Service (SJ), and Directorate-Generals for Budget (BUDG) and Agriculture and Rural Development (AGRI) were invited. The group met twice in September 2012.

The first meeting of the IASG was held on the 6th September 2012 in Brussels. The following DGs participated in the meeting: SG, SJ, BUDG, AGRI, and SANCO. A preliminary discussion on procedural issues, IA objectives and policy options proposed took place; particular emphasis was given to data collection needs. Attendees agreed on the need to focus the further assessment on policy options 3(a) and 3(b), which are illustrated in Section 4.

The second meeting was held on the 20th September in Brussels. DG SANCO chaired the meeting and SG and DG AGRI participated. A draft of the IA was discussed. The approach was broadly endorsed, with some changes requested, particularly the better alignment of objectives with the individual policy objectives.

No third meeting was arranged, in agreement with the participants, as it was not considered necessary in the light of both the limited timescale available and the proportionate approach required to develop the present impact assessment.

1.4 Impact Assessment Board

The meeting with the Impact Assessment Board took place on 7th November 2012. Following this discussion, an opinion on the draft IA was issued. The Board stressed the need to strengthen the report by focusing on five main recommendations for improvement. The main comments and main changes made following the meeting are outlined in the table below:

(1) Identify the existing evaluation gaps.

<i>Describe in detailed how the existing budget is allocated and managed.</i>	<ul style="list-style-type: none">• Overview of budget allocations per MSs and their evolution over time• Examples of less successful interventions and lessons learnt• Current eligibility conditions and funding rate mechanism	Sections: – 2.1 – 5.3.1 Annex 1
<i>Clarify which of the available (feasibility) studies, evaluations or audits providing adequate information about the cost-effectiveness of past EU food</i>	<ul style="list-style-type: none">• Works indicating the added value of EU (co-)funding• No cost-effectiveness analysis conducted so far• Way forward towards a	Sections: – 1.2 – 1.2.1 – 1.2.2 – 1.3

<i>and feed expenditure.</i>	systematic approach to monitoring and evaluation	<ul style="list-style-type: none"> - 2.1 - 2.2.2 - 7
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(2) Better explain the problems.

<i>More clearly spell out the need to reprioritise and re-allocate resources between the animal and plant health areas/activities in order to better address the major risks.</i>	<ul style="list-style-type: none"> • Need for a flexible approach in planning the food safety expenditure • Analysis conducted within other works of the "Healthier Animals and Plants for a Safer Food Chain Package" (e.g. more investments in preventions, increased attention to plant health) • No major risks due to the current framework 	Sections: <ul style="list-style-type: none"> - 2
<i>Demonstrate the need for a separate food and feed emergency fund on top of the envisaged Global Agricultural Risk Management Fund and to finance training activities for third countries.</i>	<ul style="list-style-type: none"> • Need to access a "crisis reserve" to be recurred when ordinary emergency measures (e.g. "Veterinary emergency fund" for animal diseases) are not sufficient to deal with the emergency • Need to prevent the entrance into or the spread within the EU borders of diseases and pests from neighbours countries. 	Sections: <ul style="list-style-type: none"> - 2.1 - 2.2.1 - 2.5
<i>Provide a detailed analysis of problems and issues related to the EU expenditure management, including high error rates.</i>	<ul style="list-style-type: none"> • No major problems affecting the current framework • No high error rates identified within this assessment or previous works 	Sections: <ul style="list-style-type: none"> - 2
<i>Better describe all the direct and indirect beneficiaries of the EU support and explain how and to what extent they are affected by the identified problems.</i>	<ul style="list-style-type: none"> • Outline of indirect beneficiaries of the EU measures • Further details already spelt out in the individual IAs of the package 	Sections: <ul style="list-style-type: none"> - 2.3

(3) Better explain policy options and consider additional ones.

<i>Clearly indicate how priorities will be set and how the budget will be allocated.</i>	<ul style="list-style-type: none"> • Flexibility of the food safety expenditure: prioritising annually adjusted • Nature of budgetary allocations per macro area • Overview of budgetary allocations since 2005 • Focus on Veterinary programmes 	Sections: <ul style="list-style-type: none"> - 2.1 Annex 1 Annex 2
<i>Better explain the content of the envisaged Cost and Responsibility Sharing Schemes</i>	<ul style="list-style-type: none"> • Overview of the assessment conducted only in the field of veterinary emergency 	Sections: <ul style="list-style-type: none"> - 4.3 - 5.3.1

<i>and justify why the current standard co-financing rate should be increased.</i>	<ul style="list-style-type: none"> measures • More consistency among funding rates across the funding areas • Contribution to economic recovery 	Annex 4
<i>Present other, more realistic and diversified, policy options that would duly reflect the identified problems and their drivers and would imply re-prioritisation and spending less on certain activities.</i>	<ul style="list-style-type: none"> • Reformulation of the options proposed in the previous draft IA and their link to the problems/drivers identified • No need to develop additional policy options in the light of the minor problems identified • Limited timescale available since the request for the present IA 	Sections: <ul style="list-style-type: none"> – 1 – 4
<i>Consider alternative delivery mechanisms related, for example, to the institutional set-up, eligibility criteria such as the minimum size of the co-funded programmes, payment methods, fraud prevention, controls, etc.</i>	<ul style="list-style-type: none"> • No need to further develop the analysis given the absence of any major problem affecting the present framework 	

(4) Improve the assessment and comparison of options.

<i>Assess and present the benefits of EU intervention with more caution, particularly in view of the lack of evidence on the cost-effectiveness and added value of past food and feed expenditure.</i>	<ul style="list-style-type: none"> • Clarification of the available information (notably internal and external works, consultations) providing evidence of the added value of the current food safety expenditure, given the absence of a cost-effectiveness analysis 	Sections: <ul style="list-style-type: none"> – 2.1 – 2.2
<i>Indicate the budgetary impact on individual Member States and assess the economic impacts for different sectors and on SMEs in greater detail.</i>	<ul style="list-style-type: none"> • Quantitative analysis conducted in terms of macro areas of expenditure 	Sections: <ul style="list-style-type: none"> – 5.3.1
<i>Clarify when methodological tools to assess the impacts of EU intervention will become available and to what extent they might have an impact on the foreseen budgetary allocation, or result in different spending per Member State.</i>	<ul style="list-style-type: none"> • New methodological tool available in the upcoming months: continuous and analytical evaluation of the cost-effectiveness of all actions implemented under the food and feed expenditure 	Sections: <ul style="list-style-type: none"> – 7
<i>Compare a wider set of alternative policy options in terms of effectiveness, efficiency as well as coherence.</i>	<ul style="list-style-type: none"> • No need to develop and compare a wider set of policy alternatives in the light of the minor problems identified • Limited timescale available since the request for the present IA 	Sections: <ul style="list-style-type: none"> – 1 – 2.2

(5) Strengthen monitoring and evaluation.

Set out concrete arrangements for monitoring, reporting and evaluation, taking due account of the respective responsibilities of all levels of government and actors involved.	<ul style="list-style-type: none"> Outline of the ongoing work within DG Health and Consumers to develop and implement, with the cooperation of national public authorities, a systematic approach to monitor and evaluate the performance of all actions implemented in the frame of the food and feed expenditure. 	Sections: <ul style="list-style-type: none"> – 3 – 4 – 5 – 7
Re-define policy objectives in sufficiently concrete terms and define reliable monitoring indicators, including the benchmark against which their performance will be measured. Explain how data will be collected, by whom and at what point of time.		

Section 2: Problem definition

EU financial support for food safety, animal health, plant health and official controls has been examined in a number of audits, studies and analyses. In light of the extensive consultation conducted within these tasks, the current system is generally considered to add monetary value over and above the amounts contributed and to work fairly well in its existing format. Nevertheless, it is acknowledged that the current financial framework in the food and feed area is not always supported by a systematic approach to carry out *ad hoc* evaluations, so a cost-effectiveness analysis allowing the overall performance of the related expenditure to be assessed has not so far been implemented. Therefore, the revision of the overall Multiannual Financial Framework and of the individual policies presents an opportunity to assess the current situation and look at how it could be improved further, as well as tying it more effectively to the objectives of the Commission and the EU, including the Europe 2020 goals.

It is also important to recognise that there are a number of problems, reflected in the various sectorial impact assessments, some of which the financial support for the sectors can help to solve. These are outlined further below and must be borne in mind when developing objectives and solutions.

2.1 Current policy and financial framework

The 2011 food safety budget was just under €314.6m. The overwhelming majority of the EU co-funded activities have their legal basis in one of the three following pieces of legislation:

- Council Decision 2009/470/EC (e.g. Veterinary Eradication Programmes, Veterinary Emergency measures)
- Directive 2000/29/EC (e.g. Plant Health measures)
- Regulation 882/2004 (e.g. EU Reference laboratories, Better Training for Safer Food)

The budget is split between several different budget lines. A short overview of spending in 2011 is presented below in Table 1, and a breakdown of the budget over the period 2007-2011 is presented in Annex 1.

As a snapshot of the EU food and feed expenditure, the amount executed in 2011 are given in Table 1. The distribution presented above reflects the latest prioritisation of the funding, which is decided and adjusted on an annual basis to ensure that it is fully appropriate to the prevailing situation. The Commission, with the Member States, regularly assesses the changing external environment to evaluate the need to adapt the budget to respond better to coming challenges; and priorities are sometimes shifted accordingly.

Table 1: Food safety expenditure 2011

Measures	Amount executed (€)	Legal basis
Veterinary Eradication, Monitoring and Control Programmes	238.0 m	Dec. 2009/470/EC
Veterinary Emergency Fund to MSs	10.0 m	Dec. 2009/470/EC
Plant Health Measures	19.2 m	Dir. 2000/29/EC Reg. 882/2004
EU Reference Laboratories	14.3 m	Reg. 882/2004
Better Training for Safer Food	14.4 m	Reg. 882/2004
Other operational measures	16.0 m	Dec. 2009/470/EC Reg. 882/2004
Administrative measures and miscellaneous	1.7 m	Various sectorial legal bases
Total	314.6 m	

Nevertheless, the distribution of financial allocations to the macro-areas presented in Table 1 have broadly been consistent from year to year, as confirmed by the evolution of the annual budgets executed since 2007 which is shown in Annex 1. A more detailed planning of these items far in advance is not practical. Indeed, the expenditure within these areas is by its nature variable, as it has to be adjusted in keeping with a number of factors (not necessarily consisting in large emergencies); notably the epidemiological evolution, which is not easily predictable. Therefore, some inherent room for flexibility is considered essential when drafting a minute provisional multiannual budget.

A focus on the total budget for Food and Feed executed in the year 2011 reveals that some 75% of the total budget for Food and Feed executed in the year 2011 was allocated to programmes for the eradication, control and surveillance of animal diseases and zoonoses, henceforth referred to as **Veterinary Programmes**. These programmes aim to progressively eliminate a number of listed animal diseases which are endemic in certain areas of the Union, by means of a wide range of measures including vaccination, testing of animals, and compensation for slaughtering or culling. EU funding to support these measures is allocated according to priority, whereby the greatest weight is given to diseases of public health importance and those that have major economic impacts due to trade implications and income losses for farmers, for the wider livestock industry, as well as adjacent sectors (rural economy etc.). The rationale for intervention is therefore directly linked to the protection of animal health, human health in the case of zoonoses and, also, to the importance of the livestock sector in the EU.

EU co-funding for monitoring, eradication and control activities for some animal diseases has been available and distributed to Member States for some time. This is the case for the monitoring programmes for classical swine fever (CSF), and the eradication measures for bovine brucellosis and bovine tuberculosis, and ovine and caprine brucellosis.

During the 1990s, the co-funding of eradication and monitoring measures of these diseases made up more than 80% of the overall EU funding on the programmes and the financial contribution was distributed among roughly ten Member States, mainly those in the Mediterranean area (Spain, Italy, Portugal, France) where most of these diseases were traditionally endemic.

In recent years, diseases such as avian influenza and bluetongue have emerged, or re-emerged, in EU territory. The EU has, therefore, extended its financial contributions to combat and monitor such diseases and an increased number of Member States have benefited from this co-funding. At the same time, EU policy to combat certain diseases has evolved significantly with increasingly focused and targeted measures following new scientific insights into the epidemiology of each disease and the risks of introduction, spread and transmission to humans (e.g. in the case of enzootic salmonellosis and Transmissible Spongiform Encephalopathy (TSE) programmes). Current ongoing eradication, monitoring and control programmes involve 10 of the 25 diseases covered by EU co-financing³,

³ Council Decision 2009/470/EC - Annex I

notably: Brucellosis (bovine, ovine and caprine), bovine Tuberculosis, Bluetongue, Salmonellosis, African Swine Fever, Classical Swine Fever, Swine Vesicular Disease, Avian Influenza, Transmissible Spongiform Encephalopathies and Rabies. Examples of positive case studies regarding some of these diseases are presented in Annex 2, while the main reasons behind less successful stories are outlined in the next section (Added Value from EU co-financing).

Almost 3.2% of the Food and Feed expenditure was allocated through EU co-financing to Member States under animal health emergency measures in the event of outbreaks of certain listed epidemic livestock diseases. The current EU rules provide for co-financing (or complete funding) of the actual direct costs incurred for eligible expenditure. The eligible expenditure comprises: compensation to owners for the market value of compulsorily slaughtered animals or destroyed eggs; the compulsory slaughter of animals; the destruction of carcasses and/or eggs; the cleaning and disinfection of holdings; the destruction of contaminated feed stuffs and/or milk; the destruction of contaminated equipment; the purchase of vaccines; and vaccination.

The expenditure for **Plant Health** measures represented the second largest item funded in 2011, amounting to 6.1% of the overall allocation for Food and Feed. It mostly relates to eradication measures, and to the containment of outbreaks of plant pests and diseases. The EU plant health regime (PHR) is mainly aimed at protecting European agriculture and forestry by preventing the entry and spread of non-native harmful organisms (pests and pathogenic micro-organisms), by securing safe trade by the establishment of EU import requirements and intra-EU movement conditions for plants and plant products. Outbreaks of the listed organisms have to be eradicated or, if that is impossible, contained to protect the rest of the EU territory. A second objective of the regime is to ensure the availability and use of healthy plant material at the beginning of the chain of plant production by preventing the spread of harmful organisms with seeds and planting material. This objective is shared with the EU regime for plant reproductive (planting) material, whose health is critical to tackle organisms (e.g. viruses) against which no pesticides are available.

More than 4.5% of the budget considered was spent to finance the Commission training initiative **Better Training for Safer Food**. It is focused on ensuring harmonised and efficient controls by training national authorities in Member States, and in some cases, candidate countries, keeping them updated on EU law, with a view to ensuring and maintaining a high level of consumer protection and of animal health, animal welfare and plant health. It comprises programmes on different subjects related to the verification of compliance with food and feed law, animal health and welfare rules and plant health rules. In 2011, 151 training activities took place, involving some 6,100 participants. Moreover, 29 thematic programmes were carried out, 8 of which took place in targeted third Countries. The number of training sessions, participants and thematic programmes has progressively increased in the last few years. Between 2006 and 2011, almost 25,000 people took part in the training.

In the frame of official controls, another 4.5% was allocated to the network of **EU Reference Laboratories (EURLs)**. The 47 EURLs have their tasks designated in EU legislation, and contribute to all aspects of food safety by providing information on analysis methods and organising comparative tests with the national reference laboratories, coordinating the application of the methods and research into new analysis methods, organising training and advanced courses for national reference laboratory staff and providing scientific and technical assistance to the Commission.

A breakdown of the last 5 years of the food safety budget, including details about allocation per Member State and their evolution over time, is available in Annex 1. An overview of how much is spent on prevention, surveillance, eradication and containment is also given.

Added Value from EU co-financing: example case studies

Most of the EU food safety budget is spent on veterinary programmes, which represent about 78% of recent spend. Case studies of seven of the ten diseases which are currently funded are presented in Annex 2. These have been partially or wholly successfully tackled with the help of EU veterinary programmes and co-financing. In the first case study, rabies is examined. This disease has been largely eliminated in Europe through a successful wildlife vaccination programme, virtually wiping out a significant public health risk. Salmonella is the subject of the second case study, demonstrating that the compulsory co-financed control programmes implemented since 2004 have almost halved the number of human cases in the EU. BSE was a new and poorly understood disease in the 1980s, but since then, concerted EU action has almost eradicated it in Europe. Trade in live cattle, beef and

bovine products from countries most affected has been restored, and consumer confidence has returned. The fourth case study looks at bovine tuberculosis, a challenging disease to control because of its slow development and, in certain areas, wildlife reservoirs. Nevertheless, success has come in some areas: we concentrate on Spain, where the possibility of obtaining officially free status is close. Classical swine fever used to be endemic in the EU but has been virtually wiped out with the help of EU co-financed programmes. Bovine brucellosis has also been totally eradicated in most EU countries: how Ireland gained officially free status with the help of an EU co-financed programme is examined. Lastly, avian influenza, which has made increasing incursions into the EU in recent years through wild bird spread, has been successfully contained through monitoring and surveillance; reducing the risk of both economic losses to farmers, and also the emergence of a zoonotic strain dangerous to humans.

These are examples of virtuous cases providing evidence of the positive value for money offered by the implementation of EU veterinary programmes.

On the other hand, as already anticipated, one deficiency affecting the current framework is the lack of a systematic approach to the monitoring and evaluation of the performance of the measures implemented in the frame of the food safety expenditure, including the veterinary programmes. Therefore, as will be further explained in Section 2.2, the ability to demonstrate the effectiveness of the financial management is sometimes limited.

Taking into account this lack of cost-effectiveness tools, a continuous evaluation of the programmes co-financed at EU level is nevertheless possible, and has been conducted in the last few years. This evaluation has been based on tangible results of EU action to support the MSs in eradicating, controlling and monitoring certain animal diseases. These studies have shown the overall success of the veterinary programmes but also highlighted some less virtuous stories where particular implementation issues adversely affected the performance of the programme.

Many veterinary programmes, especially eradication activities, are by their nature long-term, therefore results are often achieved a long time after the implementation of specific measures. For example, the eradication of tuberculosis, which cannot be tackled by means of a large-scale vaccination campaign, is likely to require a period exceeding ten years to be completed. Therefore, a proper evaluation can only be carried out in the medium to long term.

Unfortunately, there are also stories of lower performance of programmes co-financed by the EU; these cases are almost always due to problems with implementation at national level.

The Member States affected often face structural difficulties such as budgetary problems or staffing issues (insufficient staff or inappropriate allocation of staff) which, despite all efforts, hamper the proper implementation of the defined actions. From the EU point of view, it is opportune to recognise that these difficulties at national level can be accentuated by the ungainliness of the co-funding system, which sometimes takes some time to reimburse programmes already implemented.

It can also be that these failures are attributable to socio-cultural issues, such as inadequate coordination between national and regional/local players, or lack of dialogue (communication) between public and private sector. An improved commitment by the Member States is essential to resolve these issues.

It is also important to note that, where programmes have failed to perform due to poor or incorrect implementation at Member State level (central, regional or local level), the Commission has taken effective corrective action or imposed penalties in terms of not approving the programme or reducing the funding in subsequent years.

An example of this is the eradication of brucellosis in sheep and goats in Greece: the Commission approved programmes during the period 2005-2007 and in 2009 (in 2008 and 2010 Greece did not submit a brucellosis eradication programme for sheep and goats). Due to the poor implementation of the programme a 100% penalty was applied subsequently and no payments were made.

In the light of this unsuccessful experience, the recent decision of the Commission to reapprove a programme for 2011, 2012 and 2013, was only possible on the condition of a clear commitment from Greece to cooperate in implementing the action agreed, but also thanks to the EU engagement to meet Greece halfway by providing it with additional staff (only for 2013) to make up for the lack of human resources at national level.

2.2 Problem identification

As already mentioned, the present revision mostly addresses the need to adjust the legal current framework to the financial requirements of the new MFF 2014-2020 (Driver 1). In addition, it

represents an opportunity to introduce some improvements to cope with a few minor drawbacks affecting the current financial management tools (Driver 2).

The problems of the current financial framework are partly due to the changed sectorial needs identified in the respective policy reviews, which are about to be set out in new Commission proposals. Those needs should be reflected in the future financial legislation and in its implementing tools. The justification for those changes has been extensively provided in the sectorial impact assessments and is simply summarised here (Driver 3).

2.2.1. Driver 1 – Legislative framework: The current legal framework is over-complex and sometimes out of date

Problems:

- Lack of alignment with the newly proposed MFF 2014-2020
 - Potential administrative burdens for MSs in keeping up to date and fully complying with administrative and funding requirements.
- a) The current revision of the financial framework through the introduction of the new Multiannual Financial Framework will remove the 'food safety' budget lines (which cover all the animal health, plant health and official controls spending in question) from Heading 2 of the overall EU budget 'Preservation and Management of Natural Resources', which includes the Common Agricultural Policy budgets. They will be moved into Heading 3, to be called 'Security and Citizenship'. This means that the current legal base for financial controls and management of funding (Regulation 1205/2005) will no longer cover food and feed spending.
- Therefore a new legal basis would be needed to ensure that the new proposed budget of €1.891bn over seven years is managed and audited in line with legal requirements and good practice.
- b) Moreover, the move from Heading 2 to Heading 3 will mean that should severe emergencies arise requiring EU financial support, there will legally be no access to the 'Reserve for crises in the agricultural sector'. This access would be crucial to support MSs in the case of a large-scale crisis - such as that on the scale of the Foot and Mouth Disease crisis in 2001 – in which the Veterinary emergency measures (as concerns animal diseases) would not provide the countries concerned with enough financial support to face the situation. It is important to note that the "crisis reserve" under consideration, whose activation requires a complex procedure involving both the European Parliament and the Council, does not offer as much flexibility as the reimbursements allocated to the MSs under the emergency fund, which can be speedily and straightforwardly approved as soon as the outbreak is reported. Therefore, the reserve is not suitable as a replacement for the emergency measures - which ensure prompt intervention when an outbreak occurs - but should be resorted to in order to supplement the emergency measures when they are not sufficient to deal with a very large crisis.
- Both the Commission and the Member States would suffer from the lack of certainty about access to the crisis reserve in a large crisis, especially in the current economic climate.
- c) The current legislative framework is not fully compliant with the Financial Regulation and implementing rules applicable to the general budget of the European Communities.
- Therefore an alignment to the provision of Title VI (grants) by means of the proposed financial regulation covering the food and feed spending is needed.
- d) The provisions regarding the various financial provisions supporting food and feed safety, animal health, plant health and official controls are currently found in a number of different legislative instruments, some having a very old legal base, such as Council Decision 2009/470/EC, which is a re-cast of Council Decision 90/424/EEC.
- This in itself can be confusing and unwieldy for MSs seeking to understand the legislation, with associated administrative burden.
- e) Aside from the context of the MFF and the current disparate legal framework, there is also the problem of the changing sectorial legislation. The current package being worked on will make

certain changes to animal health, plant health, PRM and official controls legislation, some of them very significant.

- Without the according changes to the financial provisions, they will remain unaligned to the new objectives and measures in the policy legislation.

2.2.2. Driver 2 – Operational framework: The existing financial management tools are not optimal

Problems:

- Lack of clarity in eligible measures for funding and their costs
 - Complex administrative arrangements
 - Inefficient allocation of available resources
- a) Current standards expect the Commission to be able to explain clearly and transparently what the EU budget is for and how it will be used, and the current legislation does not fully meet this criteria. Following the revision of the MFF, all budgets should be better aligned with it in order that they can be better managed using programme methods.
- The food and feed financial budgets are not currently time limited and would not sufficiently align with these new requirements.
- b) At present, many of the administrative arrangements for gaining programme approval and funding reimbursement are overly complex. For example, there are around 140 Commission decisions required annually to approve reimbursement decisions associated with the veterinary programmes. In addition, several of the programmes are worth very little, many less than €50,000.
- This takes a significant amount of time, effort and bureaucracy. Moreover, it is doubtful whether the time and effort put into administering tiny programmes outweighs the benefits gained from co-financing.
- c) The financial provisions at present do not set the most clear and consistent objectives and performance indicators to evaluate the cost-effectiveness of EU measures implemented within the food and feed policy.
- This means that the food and feed spending cannot always be consistently assessed, prioritised and improved.
- d) The definition of eligible measures and associated costs are not as clear and simple as they could be. In particular, eligible measures and funding rates are scattered across different regulations. For example, for the Plant Health Emergency measures and the Emergency Veterinary Fund, a 2012 internal audit report recommended that they be clarified and simplified.
- These factors contribute to the over-complexity of the system
- e) The current lack of consistency in funding rates presents Member States with a great deal of uncertainty when planning programmes. For example, for the veterinary and emergency programmes, the compensation rate for slaughtered animals was 50% for most diseases, 60% for FMD, whereas other measures had no fixed rate and varied over time. Plant health measures had a basic rate of 50% but with the possibility of derogation which meant that certain procedures could be funded at higher rates. For example, the pinewood nematode programme in Portugal was funded at 75%.
- This situation is unsettling and difficult to deal with, and is likely to create an additional administrative burden for MSs; therefore it could be rationalised by means of a harmonised approach.
- f) A recent survey of MSs representatives found that the multiannual and annual programme planning framework is regarded as burdensome. The annual cycle of plan preparation, appraisal, approval, adoption and reporting is resource-intensive and involves a high degree of year-on-year repetition. In addition, there is a general lack of visibility and clarity in Member States' medium term programme objectives, and some perceived imprecision in the criteria used to evaluate plans at EU level.

2.2.3. Driver 3 – Policy framework: Current tools are not sufficiently focused to guarantee the achievement of food safety objectives

Problems:

- Sub-optimal implementation of individual policies and risk of not fully achieving overall policy objectives

DG Health and Consumers internal audits and reports, as well as the impact assessments carried out for the individual policy areas, have identified a few issues relating to the existing framework that could be improved to better support policy objectives.

The plant health law impact assessment identified that an increased EU financial support for plant health would pay back several times over in wider economic benefits. This included direct support for surveillance and associated measures; and the expansion of the scope of the EU Reference Laboratories to include plant health work. In addition, the official controls impact assessment concluded that there was a similar case to be made for expanding the scope of the Better Training for Safer Food initiative.

While at an aggregate level, the EU programmes have offered good value for money, the Commission could better formalise the process of evaluating and approving MS programme plans (which has already started to happen but could be improved further). Member States themselves when consulted stated that funding criteria, data management and payment processing were the three areas where they most wanted to see changes to the current model of veterinary programmes. By their very nature, veterinary programmes are long term investments.

All of these factors link to problems listed under the financial driver (2.2.2), and ought to be consistently reflected in the legislation. For instance, the lack of a clear and consistent set of objectives and indicators means that the programmes which benefit from EU co-financing are at risk of under-achieving compared to the objectives which are set out for the policy areas, and resources being spent in a sub-optimal way.

2.3 Who is affected by the current policy?

The current financial framework primarily affects Member States and their competent authorities, as they are the direct beneficiaries of the financial support. As thoroughly presented within each IA of the "Healthier Animals and Plants for a Safer Food Chain Package", there is also a wide range of indirect impacts linked to the EU measures implemented under the food safety policy, affecting the following categories of stakeholders:

- stakeholders involved in keeping live animals and in the production of, trade in, and import or export of live animals, animal products and products of animal origin, non-commercial animal keepers and holdings such as pet owners, zoos, backyard farmers, and hobby farmers;
- farmers, growers, traders in agriculture, horticulture, forestry, the wood industries, wood packaging material industries, logistics industries and industry and trade at large;
- breeders of plant varieties, PRM suppliers and users;
- business operators within the food chain;
- landscape managers, citizens, environmental NGOs and other parties interested in the conservation of the natural environment, landscape and public and private green;
- trading partners and competent authorities in third countries as they have to comply with the EU's import conditions for live animals, animal products and products of animal origin, the EU provisions and pay for export controls and issuance of phytosanitary certificates, and have to perform controls prior to export to the EU;
- veterinarians, both official (state) or private, other veterinary professionals, technicians and the wider veterinary industries;
- consumers both in the EU and outside the EU, as they are the ultimate beneficiaries of measures to ensure the safety and quality of the food chain.

2.4 How would the problems evolve, all things being equal?

The current financial framework would become problematic to manage by the start of 2014 because of the following factors.

Linked to the first set of problems, the primary difficulty would be the absence of a legal base covering the food and feed expenditure after its move from Heading 2 to Heading 3, and allowing it to be controlled and managed. In addition, there would be no legal base for access to the 'reserve for crisis in the agricultural sector' in the case of large crises. In addition, the financial framework will not be fully compliant with the Financial Regulation, notably with Title VI (grants).

As concerns the second set of problems, the lack of clarity regarding eligible measures and the objectives and indicators for the framework would continue to jeopardise the correct monitoring and evaluation of the measures implemented and hamper the effective prioritisation and planning of future expenditure.

Linked to the third set, other minor problems identified through various evaluations, including those in the impact assessments, will continue.

2.5 International dimension

International governance

EU membership of international bodies and its commitment to international agreements, such as the OIE Health Code, the International Plant Protection Convention, the WTO Sanitary and Phytosanitary Agreement and the OECD seed scheme, also ensures that the EU is responsible for maintaining an adequate legal framework consistent with international standards, guidelines and recommendations.

Third Countries

Another international dimension is the possibility of spending limited and targeted EU feed and food budgets in programmes in third countries. This has been done in the past, where a clear case can be made that the programmes would not be otherwise developed, and there is a clear benefit for the EU. This should continue to be the case in the new MFF. For example, rabies control in bordering countries to the EU is usually managed by the neighbouring EU MS in order to ensure compliance with the overall rabies measures, and ensure a buffer zone between the remaining infected areas and EU territory, and so reduce the risk of incursions.

The Importance of Trade

However, the most important international dimension is undoubtedly the value of the EU's production and the importance of trade. The production value at basic price for crop output in the Union in 2011 was €205 billion and for animal output €156 billion.

The EU is the world's largest exporter and importer of food and drink products. In 2010, EU27 food and beverages imports were worth €78 billion, and exports €73 billion.

The EU27 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, but a surplus of 6 million tonnes for beverages. These figures explain how important it is for the EU economy to encourage certain importing countries to meet the EU safety standards for food and feed, notably by means of the BTSF programme.

The EU is the world's largest exporter of PRM with an estimated export value of €4.4 billion representing roughly 60% of the total worldwide PRM export value of €7.7 billion.

Included in these overall figures, in 2010 the EU exported €1.5 billion of live animals, €6.6 billion of meat, €8 billion of dairy products and birds' eggs, €2.9 billion of fish, €9.5 billion of cereals, €8.8 billion of vegetables and fruit and €2.9 of feeding stuff for animals.

The EU's ability to export to third countries relies on its continued reputation of high production standards and added value in EU goods compared to those produced outside Europe. As regards imports, it is essential that all products on the EU market covered by Union food safety legislation are safe. This can only be achieved by a reliable and trusted official controls system which ensures that the relevant EU safety and quality standards are consistently enforced and corresponding expectations from trade partners met (for EU exports) and that goods arriving from third countries offer adequate guarantees of meeting equivalent safety levels (for EU imports).

The various EU initiatives under the auspices of the food safety budget contribute to ensuring that MSs can continue to trade animals and animal products effectively and with as few restrictions as possible. This is an important contribution to the EU's economic recovery.

The impact on trade in the case of disease outbreaks is demonstrated by a couple of very recent case studies:

Schmallenberg virus

The Schmallenberg virus (SBV) is an example of how the appearance of an "unknown" virus and diseased animals have the potential to greatly impact on trade and how a quick reaction from the EU was needed to minimise this impact.

In November 2011 Germany isolated (for the first time in the EU) a new virus that was identified as belonging to the family *Orthobunyavirus*, serogroup *Simbu*. It was given the name "Schmallenberg", after the first place where it was found. Later, the virus was also confirmed in the Netherlands, Belgium, Germany, United Kingdom, France, Luxembourg, Italy, Spain, Denmark, Poland and Austria. From early February, several trading partners (e.g. US and Russian Federation) started taking temporary protective measures including trade restrictions and requested additional guarantees for certain commodities (i.e. live animals, semen and embryos,) awaiting further scientific knowledge before resuming trade.

The Commission together with the MS identified the priorities and areas for which additional information was urgently needed to establish disease control measures. Some of the affected MS started to carry out scientific studies to improve knowledge about this virus and requested EU financial support. The Commission was able to very quickly allocate almost €3m to support 7 Member States to carry out 14 scientific studies to gather further information on the virus. (Commission Decision 2012/349/EU).

As a result of this, it has been confirmed that SBV has a very minor impact on livestock production, the risk of infection to humans from direct contact or products is negligible. Since then, some countries have already lifted trade restrictions, and the EU is in the process of agreeing with others to do the same.

E-Coli

The 2011 outbreak of e-coli, primarily in Germany, demonstrates the impact of a loss of consumer confidence and trade restrictions when an outbreak occurs. Although not a direct animal disease or plant disease or pest, the direct parallels with a possible outbreak in one of those areas are evident, especially those with serious effects on humans.

From May to July 2011, a major outbreak due to the contamination of sprouted seeds by Shiga toxin-producing *Escherichia coli* (STEC) O104:H4 occurred in clusters in the north of Germany and in the Bordeaux region in France. The outbreak started in Germany at the beginning of May and reached a peak on 22 May 2011. It ultimately led to 4010 cases, including 55 deaths.

As soon as the first cases were notified by Germany, the Commission launched appropriate emergency procedures. The European Commission coordinated the response to the outbreak at EU level and was assisted by the ECDC, and the European Food Safety Authority (EFSA). The EU reference laboratory (EURL) for *Escherichia coli* (*E. coli*) played a crucial role in the identification and management of the outbreak; providing risk assessment, advice in preventative measures, exchange of best practice in treatment, the development of a much quicker method for detection, and other epidemiological assistance.

The losses for farmers in the fruit & vegetable sector were estimated to be at least **€812m** in the first 2 weeks alone (source: Copa-Cogeca). In addition a temporary export ban of vegetables to Russia occurred, constituting an annual value of **€600m**. The Commission supported the sector with exceptional measures on market intervention with a total value of **€227m**. This was a previously unforeseen burden on the EU budget. Such measures concerned the products most directly affected by the crisis, i.e. tomatoes, cucumbers, lettuces and certain endives, courgettes and sweet peppers. Sales dropped significantly as consumers stopped buying these vegetables because of uncertainty as to the source of the outbreak, and recommendations not to consume these products raw.

Following the confirmation of the source of the outbreak and its control, trade restrictions were subsequently lifted and consumer confidence has largely been restored.

2.6 The right and justification for EU action

The EU has the right to act in all of these areas, but not exclusive competence. MSs are also free to take their own measures regarding the financial support of animal health, plant health, official controls or feed and food objectives, provided that they do not interfere with other EU regulations, such as those governing the internal market and State Aid.

2.6.1. Treaty basis

There are a number of relevant treaty articles:

- **Article 43** provides the basis for the EU legislative measures on the Common Agricultural Policy. The objectives of that policy are to increase agricultural productivity, to ensure a fair standard of living for the agricultural community, to stabilise markets, to assure the availability of supplies and to ensure that supplies reach consumers at reasonable prices. The Lisbon Treaty qualifies agriculture as shared competence between the EU and its Member States. It is obvious, however, that to a very large extent all fields of agricultural activity as well as ancillary activities upstream and downstream, have been regulated at the EU level. This means that legislation is predominantly a role for the institutions of the European Union.
- **Article 114** provides the legal basis for the establishment and functioning of the internal market and the approximation of provisions laid down by the law, regulation or administrative actions in this respect.
- **Article 168** on health protection refers to the protection of human health from all causes that may damage it, including those related to animal health. The legal basis for veterinary and plant health measures directly aimed at protecting public health were adopted under the co-decision procedure as a result of this article.
- **Article 191** states as the objectives of EU environment policy the preservation of the environment, the prudent and rational use of natural resources as well as promoting measures at international level to deal with environmental problems.

2.6.2. Subsidiarity Test

2.6.2.1. Necessity test - Why can the objectives not be achieved by MSs?

In very general terms, good animal health, plant health, food safety and feed safety generates not only private benefits for the stakeholders concerned, but is a public good with wider societal benefits.

This is particularly true for the spread of diseases and pests. Co-operation in management and control measures is virtually always essential to limiting and defeating the problem. Diseases and pests do not respect national borders, and can easily spread across them. Where there is a risk of this happening, or a case of it having happened, MSs must act together, using similar or identical control and management measures, in order to have an impact on the disease. Reflecting this approach, EU legislation has introduced harmonised rules which apply to all MSs.

In addition, coordination at EU level allows for cheaper action on EU priorities, making it more effective and less expensive than actions by individual MSs. Both animal diseases and plant pests are independently mobile and cross-border effects can occur not only through intra-EU movement of commodities but also via natural spread; therefore they need to be addressed comprehensively. Inaction in one MS may result in spread to others. Third country trade partners might also implement restrictions on imports from the EU as a whole if an outbreak or safety problem in one of the MSs is not properly eradicated or resolved.

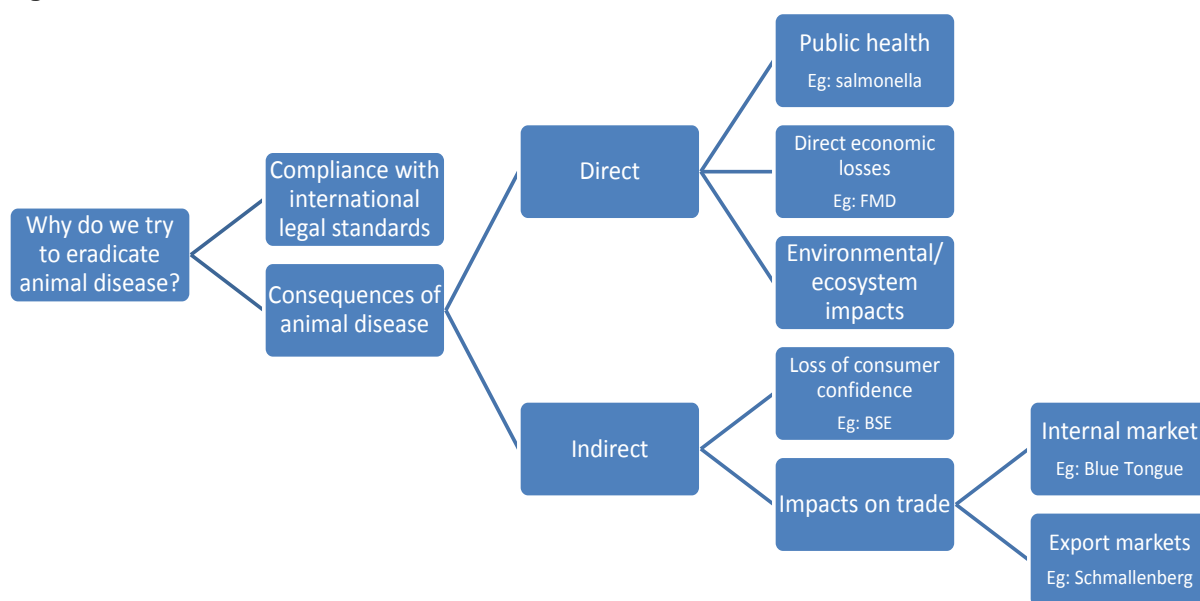
2.6.2.2. Added value test - Can objectives be better achieved by the EU?

The specific added value of EU financing or co-financing is that it provides incentives to MSs to put in place and support eradication and surveillance actions which are in the long-term interest of the Union as a whole. Large-scale eradication actions by MSs, including emergency measures could be difficult without EU support in view of the large costs incurred by the individual MS to the benefit of the EU, even if the overall cost/benefit for the Union as a whole would be clearly positive. This requires solidarity between MSs in sharing the costs and burden. If there were no measures at all at EU level, 27 systems instead of one would be in place. This would pose significant obstacles to movement on the internal market and would likely increase the financial burden associated with controls on health and quality.

But why support eradication and emergency actions in the first place? There are a number of reasons why the EU intervenes to support better and safer food and feed, including reducing animal and plant disease. For example, this flow diagram (Figure 1) shows the various reasons why intervention is considered relevant and important for animal diseases, and gives some idea of the possible impacts if they are left alone. Different diseases have different impacts and profiles, and there are different reasons why we might intervene. For example, although salmonella will cause some direct economic losses for operators, the primary reasons for controlling it are because of its direct threat to public health, and the indirect impact on trade if serious or prolonged outbreaks occur. On the other hand, a disease like Foot and Mouth is epidemic by nature, spreading extremely quickly and requiring immediate control measures. The primary reasons for controlling it are that it causes direct and potentially enormous economic loss to the farmer through natural losses and culling for control; and lower production output should the disease be uncontrolled and animals recover. Its occurrence will provoke serious and immediate trade embargos.

The specific added value of the EU co-financing of the plant health regime is that it provides incentives to MS who put in place eradication and surveillance actions which are in the long-term interest of the Union as a whole. Large-scale eradication actions by MS for outbreaks could be difficult without EU support in view of the large costs incurred by the individual MS to the benefit of the EU, even if the overall cost/benefit for the Union as a whole would be clearly positive. This requires solidarity between MS in sharing the costs and burden. The current example of the pine wood nematode outbreaks in Portugal and Spain demonstrates that EU plant health co-financing budget is crucial to implementing the eradication and containment measures which cause damage to Portuguese and Spanish forestry, however are essential to protect forestry in the other 25 MSs. The impact assessment for the plant health review specifically addressed the Union added value of expenditures in this area and concluded that increased investment in this area would result in significant overall long-term savings for the Union.

Figure 1



The benefits of EU rules for the prevention, notification, control and eradication of plant pests and animal diseases have been demonstrated, respectively, by the appearance of plant pests and occurrence of animal disease outbreaks in recent times. The response to these crises, examples of which are provided in the Animal Health Law and Plant Health Law impact assessments, showed the EU's capability to react quickly, limiting the spread of pests and diseases and minimising their impacts. This was largely due to the harmonised approach to controls, including providing financial compensation for losses due to eradication measures. The current system also enables the development of sustainable surveillance and monitoring programmes by providing co-financing at EU level.

For example, a 2011 report⁴ undertaken by the Food Chain Evaluation Consortium (FCEC) in conjunction with three independent consultants, which looked at the outcome of the EU co-financed animal disease eradication and monitoring programmes, concluded that, "the programmes continue to play a crucial role in the effective management of the targeted animal diseases [...] this [...] offers clear net economic benefits to the relevant sectors and stakeholders, as well as the protection of consumers and public health."

The EURLs are also a key part of co-ordinated EU action. The shared resource enables MSs to rely on shared and consistent best practice being developed across MSs. This ensures that a consistent approach is taken to all aspects of the scientific support of food safety objectives. For example, during the e-coli outbreak in 2011 mentioned above, the EURL was crucial to developing a faster detection method, providing risk assessments, advice on preventative measures, and exchange of best practice in treatment; as well as other epidemiological assistance. Given the cross-border nature of this outbreak, a co-ordinated approach was essential to both detecting and eliminating the outbreak, and to limiting the number of cases and loss of life.

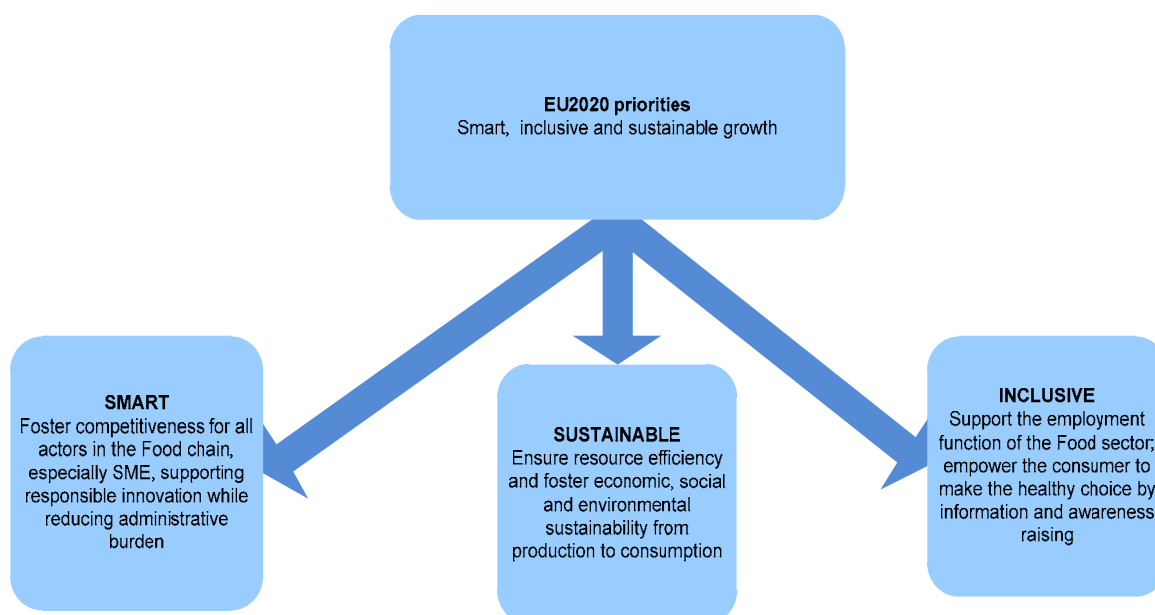
Overall, the approach followed at EU level to financially support activities under the food and feed policy meets the expectations of all interested parties in the MSs. The satisfaction of the public authorities and the private sector stakeholders with the current funding system in this area has been confirmed through the dialogue constantly carried out at EU level, both formally and informally, with these parties.

Section 3: Objectives

3.1 General Objectives

Financial instruments should be part of EU budget interventions in internal policies pursuing the following objectives, as set out in the Commission working paper accompanying the new Multiannual Financial Framework⁵, and with the EU 2020 priorities:

Figure 2: EU2020 priorities for Health and Consumers (SANCO compilation)



⁴http://ec.europa.eu/food/animal/diseases/eradication/docs/fcec_report_ah_eradication_and_monitoring_programmes.pdf

⁵http://ec.europa.eu/budget/library/biblio/documents/fin_fw1420/SEC-868_en.pdf

The general objective of the regulation itself will be:

- Expenditure covered by this Regulation shall aim to ensure a high level of health for humans, animals and plants along the food chain and in related areas and a high level of protection for consumers and the environment while enabling the EU food industry to operate in an environment favouring competitiveness and the creation of jobs.

3.2 Specific objectives

1. To **establish a single, clear and modern legal framework** fit for purpose to manage the food and feed expenditure budget lines, including animal health, plant health and official controls.
2. To **optimise the implementation and the functioning of financial management** instruments.
3. To **support the policy objectives laid out in feed and food legislation** through the effective and efficient distribution of the budget.

3.3 Operational Objectives

1. The modernisation and simplification of the present legal framework has to be achieved through:
 - a. defining a common legal basis, replacing the current multiple legal bases;
 - b. establishing a harmonised legal basis, to cope with the move of food and feed expenditure from Heading 2 (Agriculture) to Heading 3 (Security and Citizenship) of the EU budget;
 - c. ensuring continued access to the "Reserve for crisis in the agriculture sector", to resort to in case of large scale emergencies;
 - d. aligning EU financial instruments in the field of food and feed to the Financial Regulation.
2. The optimisation of the financial management tools will be pursued by:
 - a. simplifying financial management structures and processes, also ensuring that the framework is time limited;
 - b. setting clear objectives and performance indicators;
 - c. clarifying actions eligible for funding or co-financing;
 - d. simplifying and standardising the funding rates, removing ad hoc rates;
3. The support for the policy objectives will be achieved through support in each of the policy areas:
 - a. contributing to a high level of safety of food and other products and of food production systems which may affect safety of food while improving the sustainability of food production;
 - b. contributing to a higher animal health status in the Union and to support the improvement of the welfare of animals;
 - c. contributing to timely detection of plant pests and their eradication where these have entered into the Union;
 - d. contributing to improve the effectiveness, efficiency and reliability of official controls and other activities carried out in view of the effective implementation of and compliance with the Union rules.

The policy objectives of the individual parts of the food and feed legislation, as identified in their individual impact assessments, are laid out in Annex 3.

3.4 Consistency with other EU policies

It is crucial that the proposal currently under consideration also remains consistent with other EU policies. At a high level, this means supporting the objectives of EU 2020 and the Multiannual Financial Framework. Perhaps most importantly, it is crucial that the financial framework supports the economic recovery through promotion of trade and other important economic activity. In other areas, it will be important to ensure that feed and food safety policy supports and complements, and does not overlap or undermine, other EU policies. This is particularly true in the areas of Agriculture and Trade. The new proposals for the Common Agricultural Policy support the same sorts of general objectives as

the current financial regulations in question, but different specific objectives and via different means. It is also crucial that the financial regulation continues to support European trade and is consistent with existing and future trade rules. There is some consideration needed of marine policy, when the financial framework supports the prevention or eradication of diseases affecting aquaculture animals, for example. And it is important to be mindful of the objectives of environmental policies. Lastly, there are strong links between other policies such as public health, animal welfare, and others, which must be co-ordinated with.

Section 4: Policy options

4.1. Option 1: Baseline scenario: No change

No change would involve continuing with the existing set of legislative instruments governing the financial framework. This would mean initially that programmes could continue as now, but from 2014, there would be no legal base for the management and control of the expenditure. If the existing scenario is kept as it is, the 'Reserve for crises in the agricultural sector', needed to cope with large-scale crises for which the ordinary emergency measures are not sufficient, could no longer be resorted to after 2014. Moreover, none of the minor drawbacks identified within the present impact assessment are addressed.

4.2. Option 2: Bring existing legislation into one legislative instrument

Option 2 examines whether it would be possible to keep all existing measures from existing legislation, and bring them together into one regulation, as requested by DG Budget within the discussions on the MFF 2014-2020. This would make the legal provisions consistent with and workable within the new MFF, including making them consistent with the change from Heading 2 (preservation and management of natural resources) to Heading 3 (security and citizenship), and providing the legal basis for its control and management.

However, the existing provisions for financially supporting and co-financing programmes would not materially change.

4.3. Option 3: Single coherent financial programme

Sub-option 3(a): Establish a single coherent financial programme, largely using existing financial provisions, but with some improvements, particularly simplification.

This option envisages, as for option 2, bringing all financial provisions for food and feed together into one regulation. However, rather than keeping all the existing provisions exactly as they are, this option takes the opportunity to ensure that the revision fully meets objectives 1 and 2 by amending the framework to ensure that it is time limited, that it sets clear objectives and indicators, that it identifies eligible actions as well as evaluation criteria, and establishes detailed financial rules. In addition, there are a number of improvements to the current system which would be introduced in this option, including the simplification and harmonisation of co-financing rates, the expansion of certain financing measures to plant health, and better targeting of the scope of the Better Training for Safer Food Programme to also include PRM. In particular, the introduction of a systematic approach to monitoring and evaluation by defining clear objectives accompanied by performance indicators, as mentioned above, would provide evidence on the drivers of cost-effectiveness and critical success factors for food and feed programmes and measures offering better value for money.

Sub-option 3(b): As for sub-option (a) but including the introduction of aspects of Cost and Responsibility Sharing Schemes (CRSS)

Option 3(b) would further develop Option 3(a) by introducing an element of cost and responsibility sharing into the financial regulation. Both the upcoming AHL and PHL put emphasis on the need to explore possibilities of distributing costs and responsibilities more fairly between the EU, the MSs and the private sector. In particular, work has been ongoing for some time in the animal health area to identify whether there are ways in which farmers, animal keepers and MSs could be incentivised to adequately take the responsibility for prevention and best practice management methods, and to

share the costs of outbreaks and epidemics when they do occur. However, in the light of this investigation, there is not enough evidence to suggest that the benefits from introducing this system will outweigh the costs, especially in the short term. The introduction of a CRSS, as assessed with respect to the emergency veterinary fund, was considered not viable in the current climate and not likely to be accepted by MSs and stakeholders for the following reasons:

- it would introduce some administrative complexity, conflicting with the objective of simplification and harmonisation;
- it would require an additional administrative burden to set up the elements of the scheme especially in the start-up phase;
- the contribution required from the private sector risks being unsustainable, particularly in the challenging financial climate.

More details about the investigations conducted in the animal health area are presented in ANNEX 4.

4.4: Option 4: Stop all EU action

It would in theory be possible to stop all EU financial provisions that contribute towards animal health, plant health and food and feed safety, and require MSs to fund their own programmes and activities.

Veterinary programmes

This would leave Member States uncompensated for any veterinary programmes, if they decided to initiate them at all. It is entirely possible that without the incentive to initiate programmes, Member States may stop many of them. It would also provide them with little incentive to comply with EU standards or keep the EU informed.

Emergency measures

In addition, emergency measures would go uncompensated. This would mean that should a serious animal disease outbreak occur, Member States would have to bear management and control burdens themselves.

Plant Health

Plant health measures would also go uncompensated, leaving Member States with no financial contribution for surveillance programmes. There would be no support during periods of emergency.

EU Reference Laboratories

The financing for the EU Reference Laboratories would be removed. Alternative measures such as entirely relying on the private sector to fund and supervise official testing and research, should be taken.

Better Training for Safer Food

Removing the financing for Better Training for Safer Food would mean that there would be no integrated Union-level training available for those working on the front line of official controls.

Option progression logic

The graph in Figure 3 presents the logic of the development of the options presented above, from least action (Option 4) to most action (Option 3.b):

The present Impact Assessment is primarily aimed at exploring possible alternatives in response to the formal requirement from the Secretary General to establish a new common legal basis to control the EU expenditure in the food safety area within the next financial framework. Therefore, neither a scenario where this change to the existing legislation is not made (Option 1), nor a scenario where the entire food safety spend is stopped (Option 4), can be considered as realistic policy alternatives, since they do not address the main purpose of the proposal the present impact assessment examines, i.e. creating a new legal basis complying with the structure of the Budget 2014-2020.

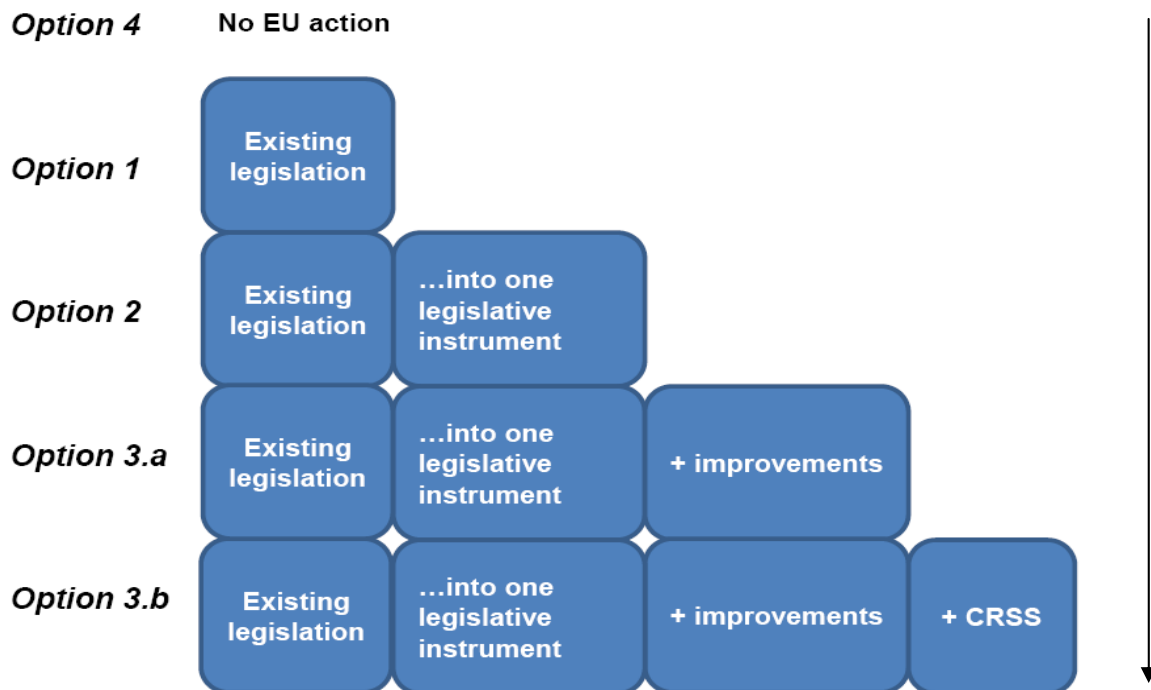
This means that Option 1 and Option 4 can be dismissed without further investigation.

Options 2, 3.a and 3.b, all satisfy this formal requirement missing in Options 1 and 4, and also meet the request from DG Budget to move the existing legislation into a common financial framework covering all food and feed issues.

Moreover, Options 3.a and 3.b introduce a few changes to solve a number of minor problems identified within the present assessment (section 2.2), aimed at modernising the current framework by making it more straightforward, effective and sound.

In addition, Option 3.b envisages an advanced system where the EU, the MSs and the private sector share both the costs and the responsibilities to tackle problems due to animal diseases and plant pests.

Figure 3: Option progression logic



Section 5: Assessment of impacts

As this is strictly a financial regulation, each option will be analysed according to its impact related to the main problems and specific objectives identified earlier in the assessment, which are largely financial or socio-economic impacts, rather than the policy-focused objectives of economic, social and environmental impacts which are traditionally used for policy legislation. The criteria for assessing impacts is broadly related to the achievement of the three specific objectives, and so divided into:

- Administrative and legal impacts
- Financial and management impacts
- Impacts on food safety objectives

5.1: Option 1: Baseline scenario: No change

No change initially means that the current programmes would continue for the next year or so, or new ones be approved on the same basis. Funding for other aspects such as EURLs would continue as now. There is unlikely to be any significant impact on the ground during that time. However, as noted in section 2, the current financial framework risks becoming unmanageable by the start of 2014, as it will no longer be legally consistent with the new MFF which is due to be introduced then, and will have no legal basis for financial management or controls.

5.1.1: Administrative and legal impacts

The financial framework for food safety will no longer be legally supported, because of the move from heading 2 of the MFF to heading 3. The lack of management and audit controls means that the

framework risks being legally non-compliant. This has a potentially huge impact on the Commission and Member States who rely on the co-financing to help fund programmes and activities.

Administrative burden

At present, the complexity of the current system (e.g. lack of harmonisation, fragmentation of the legal basis) creates administrative burden for stakeholders to understand the legislation, and by the start of 2014, will prove very burdensome due to the lack of legal base for controls and management. It is extremely difficult to quantify this burden as some of the consequences of this legal issue are as yet unclear, but it has the potential to be large.

Access to crisis reserve

The impact of the move of the food safety budget lines from Heading 2 to Heading 3 of the MFF leaves a number of legal questions. But the main potential problem is access to the crisis reserve. Although there has not been a serious epidemic outbreak for several years, there is always the potential for MSs to be hit with a debilitating disease or pest, especially with climate change potentially bringing changing conditions for the nurture of vectors or diseases that have not been found in Europe before. The possibility of access to the crisis reserve is an absolutely essential part of last-resort disease control. Without it, MSs would be left to fend for themselves in the face of serious economic losses, as well as the possible associated problems of food safety, public health and food security. In the current economic climate, MSs are likely to find this even harder than usual to bear.

5.1.2: Financial and management impacts

Management control

Setting aside the problems that are inevitably going to arise when there is no legal basis for the control and management of the finances, the use of available resources will continue to be sub-optimal in the short term. The need for better management and evaluation of programmes, particularly the veterinary programmes (by far the largest amount of spend), has already been identified. This will enable MSs to better identify which measures work most effectively against which diseases. Continuing with the current system would mean not reforming the requirements for better evaluation and according ability to modify programmes to make them more effective, therefore inevitably continuing with sub-optimal and perhaps ineffective programmes.

In the longer term, the lack of any legal controls and management after the adoption of the MFF means a complete lack of requirements to assess and monitor programmes, and so no value for money can be guaranteed (if indeed any programmes were able to be continued or approved).

Impacts on/Sustainability of Public budgets

Assuming that around the same rough scale of programmes continue to be co-financed as currently, initially there would be no change to public budgets. However, the legal and administrative uncertainty if the legislation is not reformed to align with the new MFF means that far fewer programmes would be able to be funded. While this might initially save money from public budgets, the expected impacts from removing any prevention and management programmes are high. And if more pests and diseases begin to develop due to the lack of preventative programmes, there would be no guaranteed finances available to help Member States cope with emergency measures. The increase in both animal and plant disease, and the corresponding impacts on food safety, public health, and food security, is likely to ultimately cost much more to public budgets. However, this is extremely difficult to quantify in any meaningful way, as there is no available data assessing the impact of partially or totally removing prevention and control programmes.

Nevertheless, the impact of a serious outbreak can be devastating. To give an idea of the possible scale, the Animal Health Law impact assessment quoted the costs of some recent major crises:

- **BSE** (1996-1997): for UK only, GBP£3.5 billion (0.5% of GDP). The disease also caused a serious fall in consumer confidence across the whole EU and long-term large-scale trade embargos.
- **FMD** (2001-2002): for UK only, GBP£10-12 billion (1.2% of GDP) – i.e. between about €16bn and €19bn - mainly in agriculture / food chain (30%) and tourism (50%). For this outbreak, the EU co-financed €386.7m under the emergency measures to cover part of the direct costs incurred, that is about 3.5% of the total estimated (direct and indirect) losses.

- **Avian flu in the Netherlands (2003):** 30 million birds and direct economic costs of more than €150 million.

In the Plant Health Law Impact Assessment, examples were given of major pest incursions which have already threatened agricultural and forestry production, as well as the natural environment.

- ***Xanthomonas axonopodis* pv. *citri* (citrus canker):** following its introduction into Florida, the US authorities have spent €800 million in their fight against the bacterium. The production value of citrus in the EU, where the pest could cause huge damage, is about €3.9 billion.
- Mortality of western Canada's pine forests due to the **mountain pine beetle (*Dendroctonus ponderosae*)** outbreaks currently approaches 80% and reversed these vast forests from carbon sink to carbon source. Scandinavian pine forests are still free from the pest but are equally susceptible (FCEC, 2011).

5.1.3: Impacts on food safety objectives

Plant and Animal Health

For plant health, the impact assessment shows that the increasing influx of new harmful organisms cannot be adequately stopped without expanding the scope of Union financial support to measures that are not receiving such support at present (surveys for new organisms and priority organisms; compensation to operators for losses from eradication measures). This option was considered unacceptable by the majority of the stakeholders as well as by the Member States.

In addition, should the animal disease veterinary programmes have funding reduced or removed due to the legal problem of lack of controls and management, the frequency and seriousness of animal disease outbreaks may increase. This is particularly the case as the lack of co-financing programmes gives little incentives for MSs to finance them themselves. The potential problems with then reimbursing MSs for emergency spend may also be extremely serious. Member States (and potentially farmers or other individuals and businesses affected) may well have to bear significant and unanticipated financial burdens.

In the long term, the EU will have no legal control over the finances granted to Member States, seriously risking major falls in prevention activity, and therefore putting the whole EU at risk of more animal and plant disease outbreaks. In addition, in the case of an outbreak, there would be no legal recourse to the crisis reserve. This would mean that any serious outbreaks above the budget already reserved would not be reimbursed from EU funds. Therefore, incidents such as those quoted above would be dealt with by Member States alone, with no reimbursement, at a time when many are struggling with recession and budgetary deficit.

5.2: Option 2: Bring existing legislation into one legislative instrument

This option would only partially achieve objective 1 as identified in section 3, and would not meet either of the other two objectives identified. From a formal point of view, the establishment of a new legal basis would ensure continuity of the food and feed expenditure after 2014, when the budget line named "food safety" will be implemented under Heading 3 of the EU budget. The coverage of all food and feed expenditure through one single piece of legislation would address, to some extent, objective 1, by promoting simplicity and encouraging better understanding of the legislation. However, without further change to the existing measures, no harmonisation will be achieved and the specific changes envisaged within the sectorial legislation will not be implemented in the financial instrument. Moreover, it would not allow the financial programme to be planned and managed together comprehensively and consistently or set clear objectives and indicators, and it would not set clear and consistent criteria for evaluating eligible actions, or establish detailed financing rules.

5.3: Option 3 (a): establish a single coherent financial programme, largely using existing financial provisions, but with some improvements

5.3.1: Administrative and legal impacts

The simplification of the system and the harmonization of rates is expected to reduce the administrative burden on the Commission and MSs.

Reducing administrative burden: simplification of funding rates

Funding rates would be simplified to provide only three different standard rates, improving transparency and consistency.

- **50%**

Where Union financial aid takes the form of a grant, the amount of the Union financial contribution would be up to **50%** of the eligible costs. Until 2010, this used to be the standard rate for funding veterinary programmes (representing about 75% of the total food and feed expenditure), and it is also commonly used to co-finance most of the other measures in this area.

- **75%**

The standard rate above would be increased to **75%** for cross-border activities coordinated by two or more Member States in order to eradicate diseases or harmful organisms (as co-operation to overcome the technical problems of working together in harmony is essential to the success of the programme), or for Member States whose 2011 gross national income per inhabitant based on EUROSTAT data is less than 90% of the Union average (to encourage the development of programmes by requiring less state funding from those MSs less able to contribute).

- **100%**

Where the control of serious health risks for the Union is involved, where the activities benefitting from Union contribution are specific tasks of particular importance for the Union or when the activities funded are implemented in third countries (for the good of the EU as well as those countries, and where they are unlikely to be otherwise funded), the grant may cover up to **100%** of eligible costs (see below).

The simplification of the rates would provide more simplicity, transparency and consistency across EU measures. This would enable simpler programme development and approvals processes and reduce administrative burden for both the Commission and Member States.

Reducing administrative burden: removing low-value programmes

Another proposition for reducing administrative burden is to remove the possibility of funding programmes with a value of less than €50,000. At present, a number of very small payments are made to Member States for tiny contributions to veterinary programmes. These do not add up to a significant proportion of the budget, and do not carry great importance for eradicating animal disease. Yet the processes of development by MSs and approval and payment by the Commission take a similar amount of time to a very large and significant programme worth millions of Euros. So, removing them introduces the possibility of eliminating a disproportionate administrative burden for both the Commission and the MSs.

Quantitative analysis

The budgetary impact expected from this introduction of standardised rates and removal of low value programmes has been estimated by projecting the new rates onto recent spending.

As above, three standard co-financing rates are envisaged:

- **50%**
 - basic co-financing rate
- **75%**
 - cross-border activities coordinated by two or more MSs to eradicate diseases or harmful organisms
 - measures for MSs whose 2011 gross national income (GNI) per inhabitant based on EUROSTAT data is below 90% of the Union average
- **100%**
 - measures involving the control of serious health risks for the Union.

The introduction of the standard co-financing rate of 50% would have a positive impact on the EU budget.

- The largest proportion of spend is on veterinary programmes, whose basic co-funding rate has been recently increased to 60%, at the request of Member States (on the basis of article 28.2 of Council Decision 2009/470): therefore an appreciable reduction of the amounts funded can be envisaged.
- The implementation of the new scheme would generate an expected decrease also for compensations under the emergency veterinary measures, which are mostly co-financed at 50% exception made for measures for Foot and Mouth disease, currently co-financed at 60%.

- The spending on plant health measures would be limited affected as their current rate is between 40% and 50%.

Further savings are expected thanks to the fact that any measure not exceeding would no longer be eligible for EU co-financing.

On the other hand, an extra expenditure is expected for measures addressing MSs whose 2011 gross national income (GNI) per inhabitant (in current prices) is below 90% of the Union average: this is likely to partly counterbalance the reduction in the food safety budget due to the introduction of a standard rate of 50% and to the non-eligibility for co-financing for measures below €50,000, as presented above.

Lastly, measures which are currently totally financed or co-financed at higher rates, such as the purchase of vaccines under emergency measures (100%) and the programmes for rabies (75%) and TSE (100%) would not be affected by the changes described above.

Taking all this into account, the application of the new standardised rates to the profile of the expenditure committed in 2011 would have meant:

- for the veterinary programmes, a decrease in expenditures amounting to 13million euro
- for the emergency veterinary measures, an extra-expenditure of about 350,000 euro
- for the plant health measures, an extra-expenditure of less than 7million euro

Overall, the proposed rate system - applied to the items above - would have generated annual budgetary savings on the food safety budget of more than 6million euro.

Streamlining administration across different policies

The financial support for plant health is proposed to be more strongly aligned with animal health as regards procedures and processes. This introduces the possibility of streamlining administration in both the Commission and MSs. This impact is extremely difficult to quantify due to the different arrangements in each MS and the very varied potential for any improvement, and the impact for the Commission is likely to be greater than for MSs.

Reduction in Commission decisions

One major expected change is that the legal requirements for the processes to approve and reimburse programmes in the eradication, monitoring and control programmes and the emergency measures would be simplified. Commission decisions will not have to be taken for every single reimbursement in the administrative process, as now; but a new system introduced with a simpler internal approval process. The c.140 Commission decisions taken each year regarding the veterinary programmes will be reduced to a single decision approving the priorities for funding. The emergency programmes will also be reduced to one decision per outbreak, with no formal reimbursement decisions necessary. This will significantly reduce administrative burden in terms of staff time in the Commission and the Member States. This is also likely to speed up payments to Member States.

5.3.2: Financial and Management Impacts

Use of available resources

Financial management tools will be improved under this reform. By setting clearer objectives and indicators for programmes, and following up evaluations more thoroughly, the veterinary programmes in particular are likely to be much more effective, by tailoring the programme according to the findings of what the most effective actions are for tackling certain kinds of disease. In particular, the disease monitoring and evaluation tool provided for in the Animal Health Law will enable a scientific and evidential base as the foundation for decision-making on the distribution of resources for the promotion of animal health. It is extremely difficult to quantify the impact of these particular changes as the impacts are indirect and their scale is very uncertain. Nevertheless, we can be sure that they will be positive compared to the baseline scenario.

Impacts on/sustainability of public budgets

The overall MFF budget has already been proposed. So, there is virtually no impact on the Commission's budget compared to the baseline scenario. For the financial impact on MSs, there is also little change envisaged. If anything, there will be a reduction in their financial burden. The changes to the co-financing rates should reduce their financial burden. The other administrative burden reductions are also likely to save them money.

5.3.3: Impacts on Food Safety Objectives

Better training on and enforcement of food safety

The review of the official food and feed controls Regulation will strengthen the legal base of the Better Training for Safer Food (BTSF) initiative, make its scope more coherent and improve its efficiency and effectiveness. This would promote further a better understanding of all kinds of plant health, animal health, official controls and food and feed safety legislation and enforcement in MSs and beyond the EU. Very preliminary results of an ongoing general evaluation undertaken with training participants and competent authorities show that 69% of participants consider the programme has improved the quality of their work, 41% consider it has improved their efficiency and 41% consider it has improved the guidance given to front line staff. The greatest impact was stated to have been on border controls and the management of border control posts. The changes proposed will have an impact that is extremely difficult to quantify. The cost, however, is small, and the effects will undoubtedly be positive.

Plant Health

Option 3a will better support the achievement of plant health objectives compared to the baseline option. The impacts of changing this situation were examined in the sector impact assessments and found to be positive. Thus, the plant health law and official controls proposals will put forward the possibility of setting up EURLs in the areas of plant health and supporting these financially from the EU budget; as well as the expansion of EU Reference Centres to PRM. In addition, financial support would be available to all MSs to upgrade plant health surveillance and to reinforce eradication and containment. This would introduce incentives for MSs and operators to be more vigilant, immediately notifying issues and taking early action. This would substantially limit the influx, establishment and spread of new harmful organisms into and within the EU, with a significant positive impact on productivity and profit of growers and foresters and competitiveness with third countries. Risks of trade restrictions from third countries from EU outbreaks of internationally regulated harmful organisms would be substantially mitigated. The annual costs of EU reference laboratories for plant health have been estimated in the PLH IA as €1.5m. It is anticipated that the benefits of this annual €1.5m will far outweigh the costs, but are extremely difficult to quantify.

Animal Health

The better and more efficient use of resources and the increased consistency between animal and plant health measures should lead to a reduction in the occurrence of animal diseases, and therefore a positive impact on animal health objectives. No major changes are proposed to the actual measures which are funded through veterinary programmes and emergency programmes, but simpler and more effective administrative processes and better analysis of the effectiveness and efficiency of programmes should lead to improved animal health. This is almost impossible to quantify or measure as the impacts are indirect and scale uncertain, but a general tendency in the positive direction is self-evident.

More specifically, changes to be put forward in the new Animal Health Law proposal will promote more systematic appraisal of animal diseases, allowing them to be listed for particular measures and prioritised in a transparent fashion, supported by scientific evidence and objective risk assessment. This will support the better implementation of financial support by ensuring that only diseases which are of relevance to the EU and deserve financial support actually receive it. As for emergency measures, the list of animal diseases established may be amended in order to include also diseases which are likely to constitute a new threat for the Union in terms of impact on human health, animal health or welfare, or agricultural or aquaculture productions. The established list of animal diseases and zoonoses under the veterinary programmes may be amended too, taking into account the situation of animal diseases having a significant impact on livestock production or trade, the development of zoonoses which pose a threat to humans, or new scientific or epidemiological development.

5.4: Option 3 (b): Introduction of aspects of Cost and Responsibility Sharing Schemes (CRSS)

Being a development of Option 3(a), impacts already described as for that policy alternative can be mostly kept on board when assessing Option 3(b). The additional CRSS element introduced by this option either entail extra impacts or modify the expected outcomes of Option 3(a). Therefore, the assessment below is largely drawn with reference to impacts envisaged for Option 3(a).

5.4.1: Administrative and legal impacts

Operating costs and conduct of and administrative burden on businesses, including SMEs

The operating costs of and the administrative burden on businesses could be expected to rise in the short term as they will be required to comply with a more advanced system requiring the introduction of additional components of cost and responsibility sharing. There is likely to be an increase in administrative complexity with the introduction of this system.

Challenges of implementation

The implementation of a CRSS system is politically controversial, and is unlikely to be easy or straightforward to introduce.

5.4.2: Financial and Management Impacts

Use of available resources

Option 3(b) envisages a participatory approach when public authorities, at both EU and MSs levels, share with the private sector the burden of losses incurred as well as the responsibilities of running the system. This involvement of the private sector in managing the financial instruments entails an increased engagement towards efficiency which is expected, particularly in the long-term, to maximise the use of available resources.

Impacts on/Sustainability of Public budgets

Since the primary sector will be asked to contribute to the system by sharing costs associated with animal diseases and plant pests, there will be a direct reduction in the budgets of public authorities; moreover, an indirect longer-term reduction in budgets is also expected, through reduced disease outbreaks resulting from increased attention to prevention.

5.4.3: Impacts on food safety objectives

Public Health

Because of the expected reduction in both size and occurrence of plant pests and animal diseases, we can assert that the only impact on public health and safety is the likely consequential trend of a reduced risk to public health and safety. Therefore, its knock-on effects on the food chain, included the risk of loss of consumers' confidence, would also be expected to reduce.

Plant and Animal Health

This Option envisages a system which will incentivise all players involved to reduce the occurrence of pests/diseases as much as possible: since public and private parts jointly bear the losses, they all have an economic stake in preventing/early detecting crises; moreover, the CRSS provide them with specific incentives to invest in the implementation of preventive measures and improving and spreading best practice. Benefits deriving from this system are expected to consolidate in the mid-long run.

Experience from Australia for plant health shows that the introduction of cost and responsibility sharing schemes takes a long period to introduce (in Australia, 10 years). Short-term introduction is likely therefore not to be feasible.

5.4.4: Final considerations on economic/social impacts

The assessment conducted in the frame of emergency measures to make up for losses due to animal and plant disease does acknowledge that a CRSS system is complicated, and that the likelihood of its being acceptable to MSs and to stakeholders is small, even if in the long term, it may reduce the impacts of animal diseases and plant pests. Therefore, the introduction of a CRSS system would defeat the objectives of clarity and simplicity. In addition, the current financial climate makes it more difficult politically and culturally for MSs and stakeholders to accept a larger share of the financial burden, even if the overall burden from outbreaks and pests reduces in the long term. As it is, there is not enough evidence to suggest that the benefits from introducing this system will outweigh the costs. It is possible that this area may be reviewed again in the future.

5.5: Option 4: Stop all EU Action

This option has been discarded without being analysed in great detail. It is self-evident that it would meet none of the objectives set out in Section 3. Rather than considering the impacts in terms of the objectives, as with the other options, the overall impact of stopping each main aspect of food safety funding has been assessed as follows:

Veterinary programmes

There would be two main impacts should funding for veterinary programmes be discontinued entirely. The first would be on the existing programmes. Discontinuing existing funding risks leaving no programmes running which are aimed at tackling existing endemic diseases. Many of these are long-term programmes that are aimed at eradicating diseases which are difficult or very slow to wipe out. For example, bovine tuberculosis is a slow-spreading disease which may lie hidden without clinical symptoms in infected animals for a long period of time, but while that animal is still infectious. To stop a veterinary programme and therefore remove all testing and surveillance in an infected area would almost inevitably lead to slow but undetected spread throughout and between herds, both nationally and internationally, depending on trade patterns. It is unlikely that MSs would continue to fund programmes by themselves, either to the same extent, or at all; especially in the current economic climate. This risks jeopardising the achievements of the investments that have already been made (see case studies in Annex 2). In addition, there would be little incentive for MSs to inform the EU of the health situation in their own countries, meaning no co-ordinated information or action would be available or possible at trans-national level. The approaches taken to different diseases may diverge too far to tackle disease well.

Ultimately this would have a major impact on economic losses and on trade restrictions. It affects both diseases which are still endemic in the EU, but also those which are now exotic. Once spread over a wider area, endemic disease is even harder to detect, control and eradicate; whereas diseases which have already been eradicated, or which are new and emerging, would risk being reintroduced. For example, Bluetongue has been a great success story, tackled by EU co-financed emergency measures and veterinary programmes. In 2007 BTV-8 appeared in northern Europe for the first time. In 2008, there were over 45,000 cases. Through a combination of measures, including widespread vaccination, the disease has not appeared at all in 2012. However, were surveillance to stop and vaccination to be discontinued, the disease could re-emerge given the right climatic conditions, and spread again, causing serious economic losses and widespread trade disruption in the EU economy. This is particularly the case because of the global warming and the changing climate, which is slowly bringing conditions more favourable to certain diseases, like Bluetongue.

Emergency measures

Emergency measures are the other side of the same coin. In the current economic climate, leaving MSs with no EU-level financial support for veterinary programmes means they are more likely to experience incursions and outbreaks. The lack of financial support with emergency measures therefore means they will be less able to cope with them well; and the lack of reimbursement in incursion or outbreak scenarios may well seriously damage a MS's economy. For example, the Foot and Mouth Disease outbreak in Bulgaria in 2011 was quickly identified and eradicated with co-ordination and co-financing provided at EU level, and it is unlikely that it would have been eradicated as quickly should the EU-level support not have been available. In addition, leaving those individuals and businesses who are currently compensated with no compensation in a crisis scenario is likely to seriously damage the rural economy in emergencies, putting farmers and other operators out of business.

Plant Health Measures

Plant health measures are not currently funded to the same extent as animal health measures. However, the plant health law impact assessment clearly demonstrated the justification for increased funding for plant health measures – the benefits of funding plant health measures clearly outweigh the costs of no action (or maintaining the baseline scenario). Thus, we can extrapolate that stopping all action on plant health measures will have significant long-term costs.

EU Reference Laboratories

Stopping any funding for the EU Reference Laboratories would have serious impacts. We must assume that all of the food safety scientific support activities, including testing, surveillance, and

developing new techniques and best practice would still go ahead in some way to have any kind of scientific support to maintaining (or improving) food safety, including animal health and plant health. The EURLs are appointed by the Council and are a network of laboratories unique in the world. They develop and harmonise standards for testing across the EU, ensuring a standardisation and consistency that would be incredibly difficult to obtain through contracting to the private sector. The EURLs also provide neutral arbitration in the case of disagreements between MSs, which would be extremely difficult to establish fairly otherwise.

The EU would also have to look carefully about whether penalties or legal fines would be applied for cancelling or not honouring existing contracts for provision with the EURLs.

There are a number of separate reports and analyses that provide evidence that the EU's financial provisions and joint ventures such as the EURLs and the training initiatives add value over and above what MSs can achieve acting alone. Joint action also underpins the successful functioning of the internal market, and prevents operators being unjustifiably discriminated against due to their location.

Better Training for Safer Food

In 2011 alone, 151 BTSF training activities took place, involving some 6,100 participants. Removing all training in this sphere would not have the dramatic effects predicted for the removal of funding for other areas such as the veterinary programmes or emergency measures. However, for a relatively small amount of spend, BTSF offers an easy and effective way to disseminate information on the enforcement of food and feed safety to all Member States and to third countries. To remove this funding would leave a gap in training which is highly unlikely to be filled elsewhere, and risks reducing the knowledge of enforcement officers over time, ultimately impacting negatively on the enforcement of food and feed controls. Two recent evaluations have concluded that BTSF offers good value for money and should continue.

Conclusion

Stopping all EU financial provision would have the potential to seriously threaten food safety, food security, public health and the environment, as well as jeopardising the recovery of the EU economy by seriously damaging the EU's ability to trade in animals and animal products. It is not desirable from a social, economic, political or environmental point of view. It would also have little to no support amongst stakeholders, including MSs. The principle behind the revision of all of the current legislation is to ensure more coherence and simplicity across the board, and taking away any financial provisions to support EU action is simply unimaginable with the identified objectives in mind, and considering the conclusions of the policy IAs. While the methodological tools and models to explicitly quantify the costs and benefits do not (yet) exist, and some work will need to be done on developing them; it is clear that the risks to the EU of taking this action would undoubtedly be higher and the long-term costs would unquestionably outweigh any short-term savings.

Section 6: Comparing the options

It is clear using proportionate impact assessment principles that Option 3(a) is the preferred way forward. It is the only option to meet all three objectives, and with very few (if any) negative impacts, assessed in the table below in terms of absolute variations against Option 1, i.e. the anticipated impacts over the budgetary period 2014-2020 if the current financial framework is not revised.

Table 2: Comparative assessment of impacts

	Option 3(a)	Option 3(b)
Achievement of legal and administrative objectives	+ Reduction of administrative burden on PA and private sector	- Additional administrative burden on MSs and private sector (in the short-term)
Optimising financial management tools	+ Increased efficiency: <ul style="list-style-type: none"> • clearer objectives and indicators 	-/+ Short run – possible decreased efficiency: <ul style="list-style-type: none"> • time needed to familiarise with

	<ul style="list-style-type: none"> longer-term sustainability 	the new system <ul style="list-style-type: none"> lack of acceptability in both MSs and private sector
		+ Long-run: Increased efficiency
Support to achievement of food and feed objectives	+ Increased effectiveness: <ul style="list-style-type: none"> improved consistency among EU policies and with international commitments 	++ Increased effectiveness: <ul style="list-style-type: none"> Additional incentives towards prevention and eradication

Option 3(b) has been dismissed for now – at present, its complicated nature outweighs any long-term positive impacts in the current challenging financial climate. However, in the future, with a changed environment, it may well offer the most appropriate solution to many of the wider and changing problems facing animal and plant health, and could be re-examined.

Section 7: Monitoring and evaluation

7.1: Evaluation Report

By the end of 2018, an evaluation report shall be established by the Commission on the achievement of the objectives of the measures (at the level of results and impacts), the efficiency of the use of resources and its European added value, in view of a decision on the renewal, modification or suspension of the measures. The evaluation shall additionally address the scope for simplification, the continued relevance of all objectives, as well as the contribution of the measures to the Union priorities of smart, sustainable and inclusive growth. It shall take into account evaluation results on the long-term impact of the predecessor measures.

7.2: Ex-post Evaluation

No later than mid-2022 the Commission shall carry out an ex-post evaluation in close cooperation with the Member States and beneficiaries. The ex-post evaluation shall examine the effectiveness and efficiency of feed and food expenditure and its impact.

Both the evaluation report and the ex-post evaluations shall take account of progress against indicators presented in section 7.3 below. The Commission shall communicate the conclusions of these evaluations to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

7.3: Indicators

The evaluations referred to in paragraphs 1 and 2 shall take account of progress against indicators. As reiterated in the present impact assessment, one deficiency affecting the current framework is the lack of a systematic approach to the monitoring and evaluation of the performance of the measures implemented in the frame of the food safety expenditure.

This is the reason why, with a view to revising the current framework, the preferred alternative identified also aims at developing and implementing a sustainable set of objectives and indicators in order to redress this situation.

Referring back to the operational objectives linked to the achievement of food safety objectives, these will be:

- a. to contribute to a high level of safety of food and other products and of food production systems which may affect safety of food while improving the sustainability of food production.

Indicator: reduction of EU cases in humans, linked to food safety or zoonotic diseases.

- b. to contribute to a higher animal health status in the Union and to support the improvement of the welfare of animals;
Indicator: increase of the number of Member States or region thereof free from the animal diseases for which financial contribution is granted over time, and reduction of disease parameters such as incidence, prevalence, number of outbreaks.
- c. to contribute to timely detection of plant pests and their eradication where these have entered into the Union.
Indicator: coverage of the Union territory by survey for pests in those parts where they are considered not to occur, and time and success rate for the eradication of those pests.
- d. to contribute to improve the effectiveness, efficiency and reliability of official controls and other activities carried out in view of the effective implementation of and compliance with the Union rules.
Indicators: favourable trend of the outcome of controls in particular areas of concern carried out and reported by Commission experts in the Member States.

Based on the initial objectives and indicators listed above, a detailed monitoring system shall be developed by DG Health and Consumers in the first months of 2013, with a view to optimising the financial management tools. Its implementation would allow the assessment of the cost-effectiveness of all measures implemented and provide, consequently, evidence for the prioritisation of the future spending in the frame of the food safety policy.

The pilot-system of performance indicators recently created in the context of the Reference Laboratories will represent a starting point experience towards the development and implementation of a systematic approach to monitor and evaluate all food and feed expenditure.

7.4: Communication

The Commission shall communicate the conclusions of these evaluations to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions.

Annex 1:

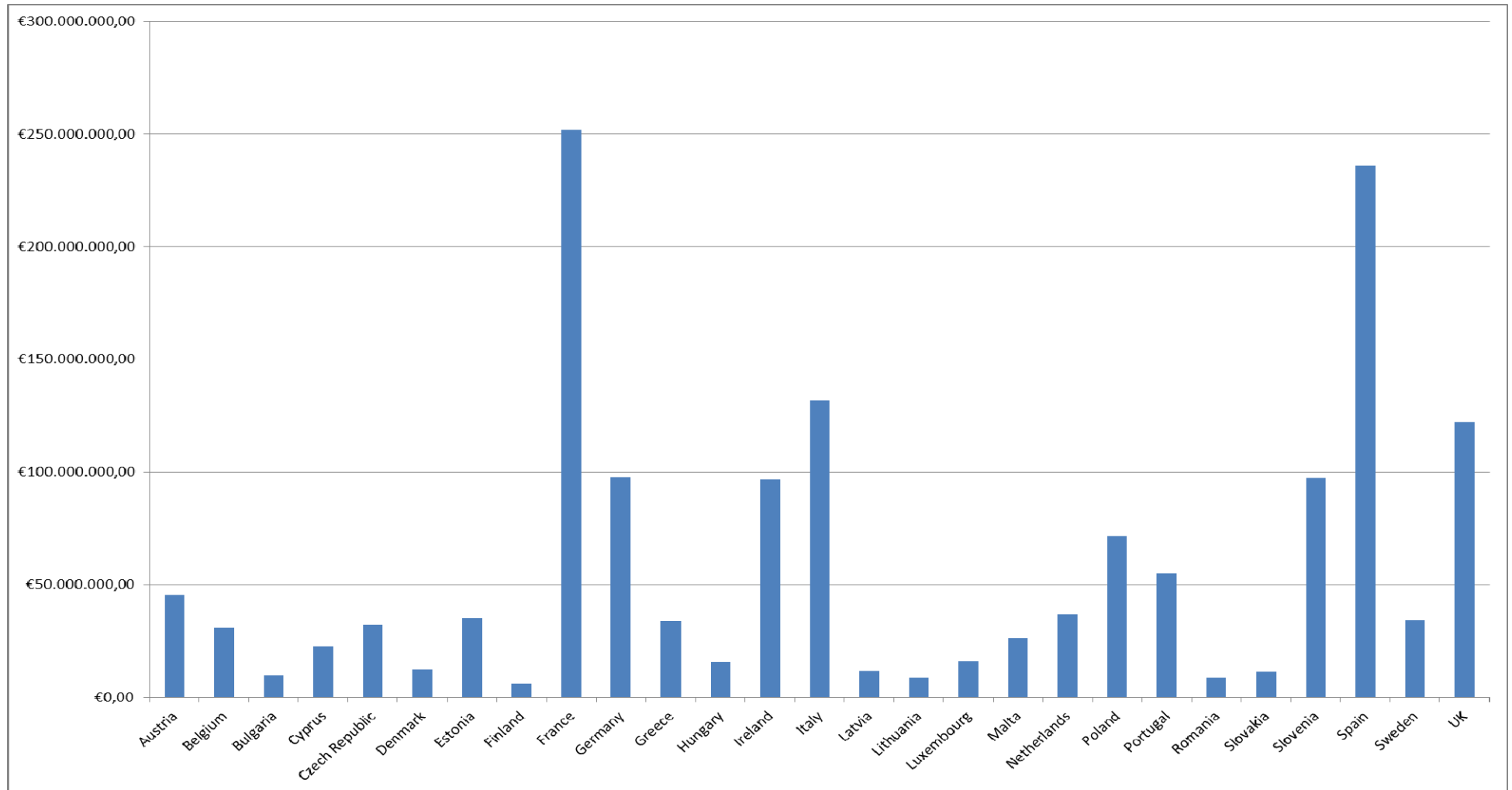
Food Safety Budget 2007-2011

Execution of the Budget for Chapter 17 - Commitments 2007-2011						
Measures	2007	2008	2009	2010	2011	2007-2011
Eradication Programmes	€203.984.156,43	€184.452.356,70	€265.493.595,00	€274.082.000,00	€238.015.000,00	€1.166.027.108,13
Other measures in veterinary, animal welfare, public health	€13.304.888,40	€13.621.935,44	€18.116.450,32	€12.528.635,44	€13.506.114,85	€71.078.024,45
Emergency Fund	€9.460.383,57	€159.985.729,00	€14.095.235,31	€11.967.532,30	€10.053.119,41	€205.561.999,59
Preparatory Action		€4.000.000,00	€4.000.000,00	€2.000.000,00		€10.000.000,00
Plant Health - operational	€1.457.063,19	€5.903.195,51	€16.849.399,94	€8.287.161,00	€21.256.677,24	€53.753.496,88
Food and Feed Control - operational	€16.944.068,66	€21.022.256,19	€25.926.308,23	€30.954.730,80	€29.539.222,00	€124.386.585,88
International affairs	€167.022,67	€166.225,60	€166.225,60	€200.000,00		€699.473,87
Plant Health - administrative	€412.905,00		€300.000,00	€150.160,00	€441.068,44	€1.304.133,44
Food and Feed Expenditure - administrative	€453.750,00	€951.478,10	€674.930,37	€581.369,00	€420.149,23	€3.081.676,70
Pilot Project		€1.000.000,00				€1.000.000,00
Animal Disease Eradication and Emergency Fund - administrative				€211.283,00	€245.072,00	€456.355,00
Administrative Assistance PHEA					€1.100.000,00	€1.100.000,00
Total	€246.184.237,92	€391.103.176,54	€345.622.144,77	€340.962.871,54	€314.576.423,17	€1.638.448.853,94

FOOD SAFETY BUDGET 2005-2011: allocations per MS and evolution over time

	2005	2006	2007	2008	2009	2010	2011	TOTAL 2005-2011
Austria	€2.291.000,00	€2.440.000,00	€4.048.000,00	€8.006.000,00	€9.190.000,00	€10.785.000,00	€8.660.000,00	€45.420.000,00
Belgium	€4.639.000,00	€4.435.000,00	€3.199.000,00	€4.383.000,00	€6.050.000,00	€6.285.000,00	€2.040.000,00	€31.031.000,00
Bulgaria	€0,00	€0,00	€368.000,00	€1.437.400,00	€2.455.000,00	€3.471.000,00	€2.060.000,00	€9.791.400,00
Cyprus	€5.863.000,00	€4.074.000,00	€2.005.000,00	€1.898.000,00	€3.517.000,00	€4.630.000,00	€665.000,00	€22.652.000,00
Czech Republic	€5.746.000,00	€2.920.000,00	€3.071.000,00	€3.213.000,00	€6.460.000,00	€5.655.000,00	€5.240.000,00	€32.305.000,00
Denmark	€2.621.000,00	€2.640.000,00	€2.811.000,00	€2.037.000,00	€610.000,00	€950.000,00	€750.000,00	€12.419.000,00
Estonia	€349.000,00	€1.436.000,00	€1.356.000,00	€1.269.100,00	€9.907.000,00	€12.805.000,00	€8.380.000,00	€35.502.100,00
Finland	€1.615.000,00	€1.251.000,00	€1.064.000,00	€860.000,00	€625.000,00	€205.000,00	€335.000,00	€5.955.000,00
France	€34.770.000,00	€33.070.000,00	€37.237.000,00	€25.005.000,00	€63.470.000,00	€46.580.000,00	€11.650.000,00	€251.782.000,00
Germany	€19.240.000,00	€18.200.000,00	€14.419.000,00	€11.800.000,00	€20.875.000,00	€7.650.000,00	€5.700.000,00	€97.884.000,00
Greece	€3.352.000,00	€3.585.000,00	€2.468.000,00	€2.472.000,00	€6.770.000,00	€7.240.000,00	€8.020.000,00	€33.907.000,00
Hungary	€2.154.000,00	€2.170.000,00	€2.305.000,00	€2.537.000,00	€1.624.000,00	€2.010.000,00	€2.685.000,00	€15.485.000,00
Ireland	€16.307.000,00	€11.850.000,00	€9.109.000,00	€9.558.000,00	€16.760.000,00	€14.790.000,00	€18.205.000,00	€96.579.000,00
Italy	€20.242.000,00	€18.660.000,00	€18.995.000,00	€19.520.000,00	€18.450.000,00	€15.830.000,00	€19.890.000,00	€131.587.000,00
Latvia	€105.000,00	€1.288.000,00	€1.262.000,00	€1.284.100,00	€1.575.000,00	€2.295.000,00	€3.940.000,00	€11.749.100,00
Lithuania	€1.081.000,00	€890.000,00	€1.277.000,00	€1.521.000,00	€686.000,00	€715.000,00	€2.855.000,00	€9.025.000,00
Luxembourg	€220.000,00	€275.000,00	€399.000,00	€4.459.000,00	€2.965.000,00	€4.044.000,00	€3.600.000,00	€15.962.000,00
Malta	€406.000,00	€794.000,00	€1.445.000,00	€3.162.000,00	€5.527.000,00	€7.525.000,00	€7.500.000,00	€26.359.000,00
Netherlands	€6.172.000,00	€6.182.000,00	€10.721.000,00	€7.344.000,00	€2.225.000,00	€2.660.000,00	€1.610.000,00	€36.914.000,00
Poland	€3.615.000,00	€11.833.000,00	€8.236.000,00	€14.541.000,00	€10.340.000,00	€11.875.000,00	€11.115.000,00	€71.555.000,00
Portugal	€5.550.000,00	€5.825.000,00	€13.677.000,00	€8.182.000,00	€7.330.000,00	€7.040.000,00	€7.595.000,00	€55.199.000,00
Romania	€0,00	€0,00	€1.506.000,00	€550.000,00	€1.655.000,00	€2.182.000,00	€3.125.000,00	€9.018.000,00
Slovakia	€1.190.000,00	€1.985.000,00	€1.964.000,00	€1.726.000,00	€2.200.000,00	€1.100.000,00	€1.375.000,00	€11.540.000,00
Slovenia	€14.569.000,00	€12.917.000,00	€13.373.000,00	€12.899.000,00	€10.860.000,00	€12.210.000,00	€20.610.000,00	€97.438.000,00
Spain	€23.654.000,00	€29.185.000,00	€32.325.000,00	€24.406.000,00	€43.600.000,00	€43.380.000,00	€39.300.000,00	€235.850.000,00
Sweden	€5.700.000,00	€7.706.000,00	€8.112.000,00	€5.990.000,00	€3.160.000,00	€2.320.000,00	€1.080.000,00	€34.068.000,00
UK	€16.030.000,00	€8.170.000,00	€6.625.000,00	€6.376.000,00	€8.520.000,00	€38.480.000,00	€38.050.000,00	€122.251.000,00
TOTAL EU27	€197.481.000,00	€193.781.000,00	€203.377.000,00	€186.435.600,00	€267.406.000,00	€274.712.000,00	€236.035.000,00	€1.559.227.600,00

FOOD SAFETY BUDGET 2005-2011: overall allocations per MS



Annex 2: Added Value from EU co-financing: example case studies

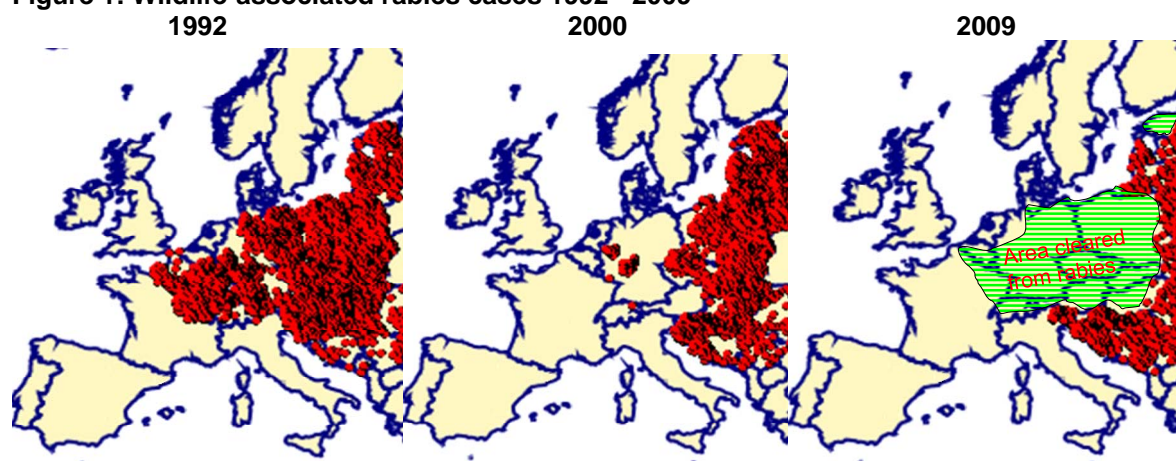
Taking into account the lack of a cost-effectiveness analysis, a continuous evaluation of the programmes co-financed at EU level is nevertheless possible. This evaluation has been conducted in the last few years, based on tangible results of EU action to support the MSs in eradicating, controlling and monitoring certain animal diseases. These studies have shown the overall success of the veterinary programmes but also highlighted some less virtuous stories where particular implementation issues adversely affected the performance of the programme.

Case Study 1: Rabies

Rabies is an infectious zoonosis which may affect all mammalian species. In Europe the main reservoirs for the disease are populations of wild red foxes. The disease is passed through bites or other close contact, and is invariably fatal in humans unless prophylactic treatment is applied immediately after contact. Worldwide rabies is responsible for more than 50,000 reported deaths, mainly in children. Unofficial estimates suggest that including unreported cases, the real figure may be at least double this. Therefore, it is primarily a public health worry (although can also cause direct losses in kept livestock animals). The problem of controlling the disease at its origin (wild animals) has been tackled in recent decades through the spreading of baits containing oral vaccine. Co-ordinated efforts across national borders are essential to its successful eradication, as wild animals can cross borders and re-introduce the disease into an area in which it has been previously eradicated if joint measures are not taken.

The EU has striven to eradicate rabies from its territory since the 1990s. Rabies was previously common across much of Europe (see 1992 map), but concentrated and co-ordinated efforts, co-financed by the EU, led to certain areas, notably France, Belgium, Luxembourg, Austria and much of Germany, being free from rabies by 2000. Further significant progress came in the 2000s, as new Member States from Eastern Europe gained access to EU funding that enabled them to put in place large scale oral vaccination campaigns. This and the importance of the co-financed funding to incentivise effective vaccination programmes led to clearances of whole swathes of central and Eastern Europe by 2009.

Figure 1: Wildlife-associated rabies cases 1992 - 2009



There has been a sustained reduction in spending on rabies in the 1990s and up to 2003. This was thanks to the success of the vaccination campaigns in all the rabies affected then-Member States as oral vaccination was discontinued in cleared areas. Spend on rabies has gone up considerably in recent years, notably since accession of new Member States in 2004, and the increase in co-financing from 50% to 75% in 2010⁶. The cost in real terms, however, is still relatively small. Between 2004 and 2010, only €43m has been spent on EU co-financing.

⁶ The reason for increasing to 75% was the economic difficulties of some MS in securing national funds to maintain oral vaccination until final eradication. Should this happen, the resources spent in previous years are

Figure 2: Number of cases in wildlife and cats and dogs, EU Member States 1994-2009

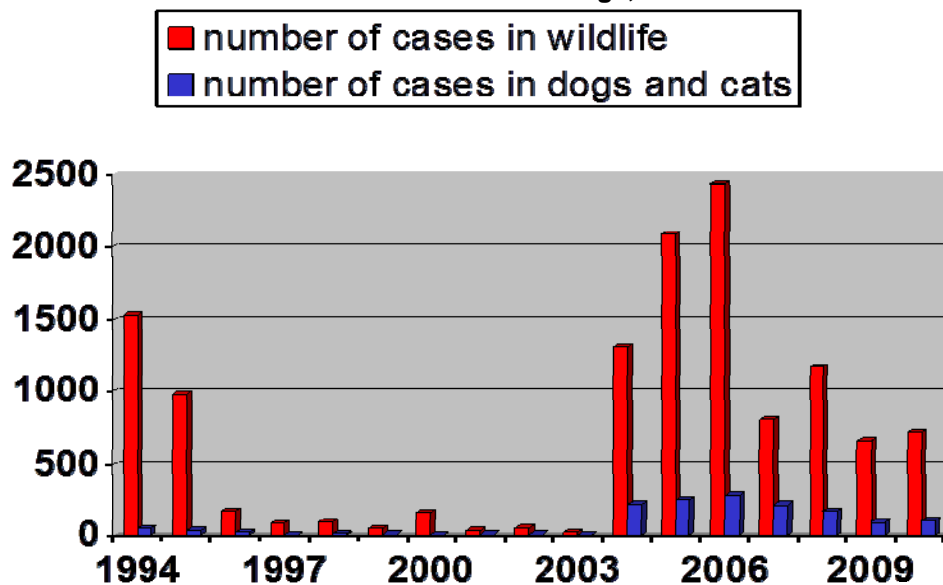
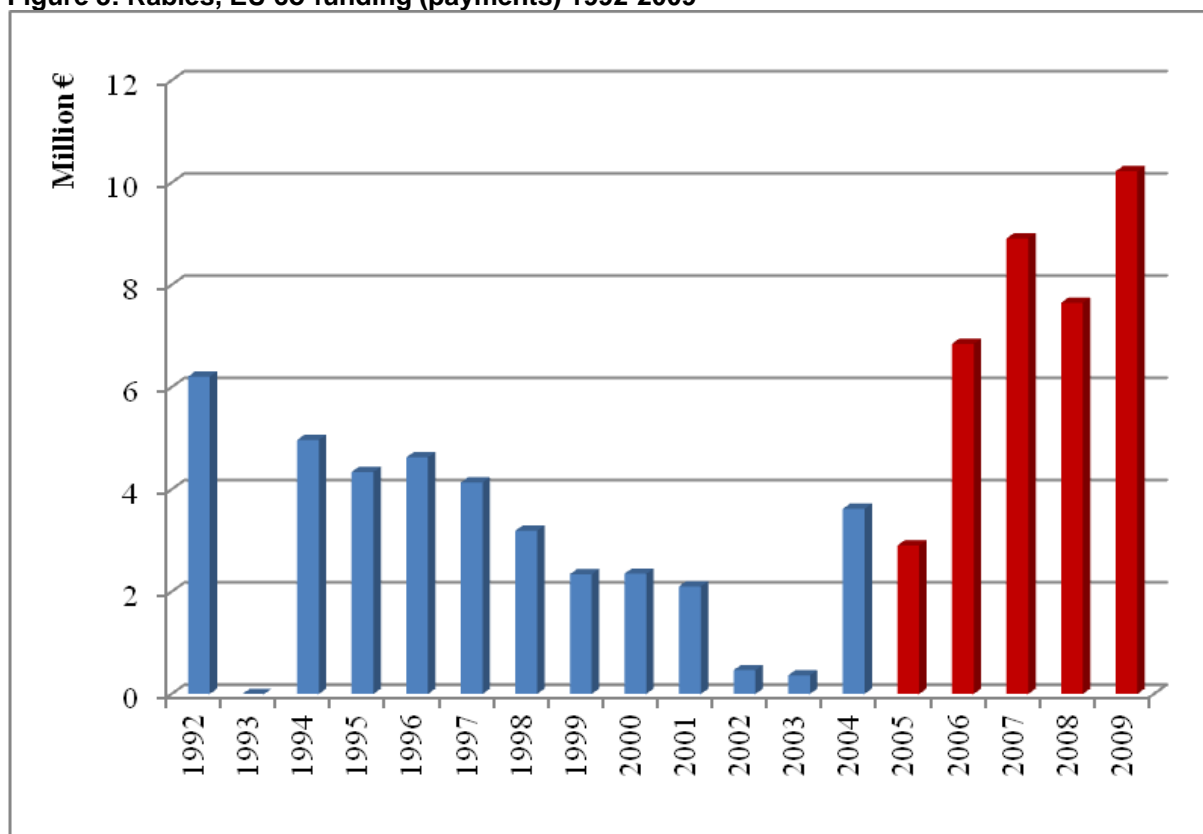


Figure 3: Rabies, EU co-funding (payments) 1992-2009



*Note: data include payments for countries which were non-EU MS at the time: Austria (pre 1995) €255,662, Poland €1,043,832 (pre 2004), and Czech Republic €22,466 (pre 2004); also, Switzerland €45,972.

Source: DG SANCO-based on financial decision 1992-2009

wasted, as interruption of vaccination before eradication enables the disease to quickly spread again. A second reason was to further support MS in the final efforts to achieve eradication

As rabies is primarily a risk in wild animals which can spread across borders unchecked, the EU also co-finances programmes which include some bordering 'buffer zones', where these are not currently funded by the neighbouring country in question. So, for example, the Polish veterinary programme has included some areas of Ukraine and the Latvian and Lithuanian programmes include bordering Belarusian territories. These are funded for the good of the EU as a whole to prevent re-incursions into European territory, threatening European citizens. The spend outside the EU is only a tiny part of the veterinary programmes as a whole.

The effect of the application of oral rabies vaccination in the EU can be understood by the comparing the number of indigenous human cases (deaths) reported in certain neighbouring European third countries with those in the EU in recent decades (Table 2). It is important to note that the two indigenous cases reported in the EU in recent years are both located in Romania, the last Member State to launch EU-funded vaccination campaigns (started in 2011). Most cases in the EU are in fact 'imported' due to people contracting rabies abroad (generally on other continents) where the disease is endemic and only showing symptoms after having returned home.

Table 2: Indigenous cases in the EU and certain other European countries

	2004	2005	2006	2007	2008	2009	2010	2011	2012	Total
Belarus	0	0	0	0	0	0	0	1	1	2
Russian Federation	12	8	2	6	12	10	6	10	1	67
Ukraine	0	0	0	2	2	0	2	0	0	6
EU-27	0	0	0	1	0	0	0	0	1	2

Source: WHO

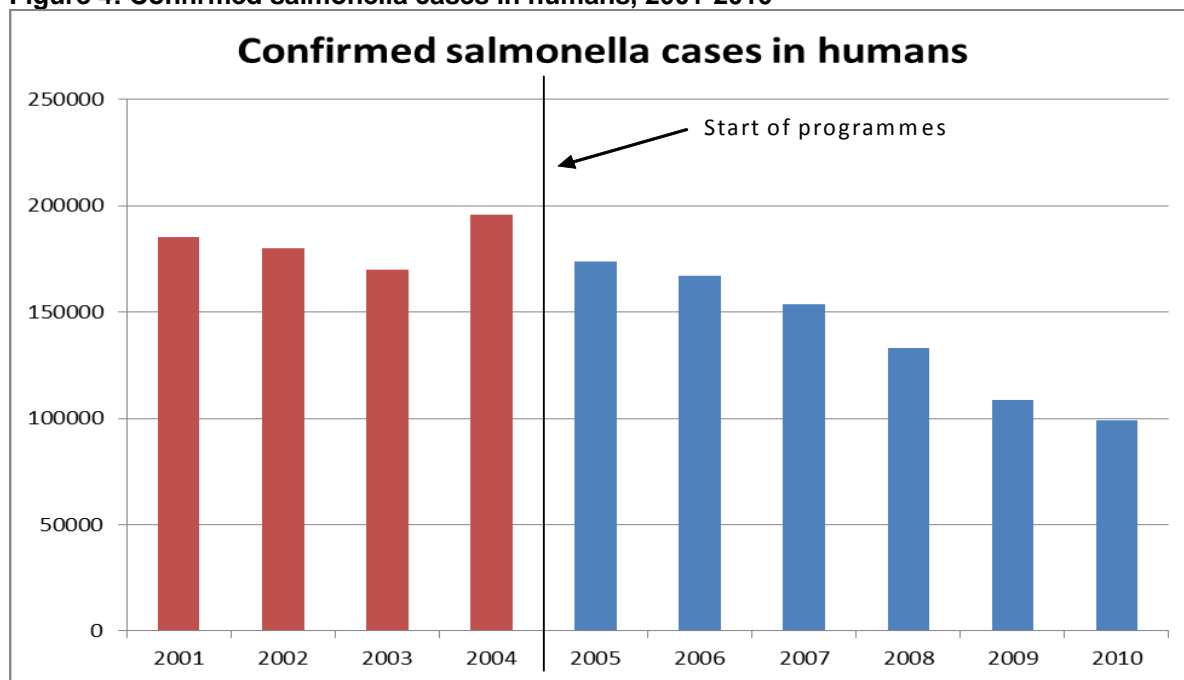
Thus, the EU co-financing is very small compared to the benefits of the eradication of a serious and fatal zoonosis. Apart from the prevented human deaths, a significant saving for a rabies-free country is the reduced need for post-exposure treatment for humans being bitten by animals, which is extremely expensive, and takes a significant period of time to recover (with associated economic losses). Much alternative cost has been saved through the veterinary programmes. In rabies-free countries, this treatment is limited to travellers attacked by animals in infected countries.

Case Study 2: Salmonella

One notable example of the catalytic impact of EU funding is in the tackling of salmonella outbreaks. In 2004, the implementation of mandatory control programmes was introduced. The *salmonella* control programmes are targeted at the most frequent causes of human infections, notably *salmonella Enteritidis* and *salmonella Typhimurium*, which are responsible for about 75% of human infections (2009 data). EU co-financing is given at the rate of 50% for certain defined measures, and totalled under €30m over the period 2004 – 2009.

Epidemiological data since that date clearly shows that there has been a substantial and steady decline in the reported cases in humans across all 27 Member States. The drop is approximately 49% between 2004 and 2010, from 196,000 cases to 99,020. EFSA (the European Food Safety Authority) estimated in 2010 that the overall burden of human salmonellosis in the EU was up to €3bn per year in 2008. Making a simplistic assumption that the cost per case has remained approximately the same over this period (and without adjusting for inflation), we can extrapolate that the savings to the EU economy between 2004 and 2010 have been between a wide range of €131m and €1.96bn. Therefore €30m of EU co-financing (and around €60m of total spend) seems a small price to pay for such an enormous reduction in costs, and demonstrates a clear overall economic benefit, even if the scale is a wide range. And, this is no minor achievement – leaving aside the economic impact of human salmonellosis, which is usually characterised by treatable symptoms; it can be fatal, and so have a devastating personal impact.

Figure 4: Confirmed salmonella cases in humans, 2001-2010



Note: From 2001-2004 data refer to total cases rather than confirmed cases

Case Study 3: BSE

Bovine Spongiform Encephalopathy (BSE) is the bovine form of the disease known as Transmissible Spongiform Encephalopathy (TSE). In Europe, it was first confirmed in the UK in 1987, and a serious epidemic subsequently developed.

BSE is a concern because the balance of evidence suggests that it is zoonosis (leading to the invariably fatal human disease variant Creutzfeldt–Jakob disease or vCJD) transmitted by the consumption of infected bovine products. At one time it was feared that BSE would lead to a serious vCJD epidemic. Although the scale of epidemic once anticipated has not arisen, there have been 173 cases in the UK (as of August 2012), all fatal, and several other cases in the EU; most notably in France (27 cases, all fatal)⁷.

Although the major concern is a public health risk, BSE in cattle causes serious and direct economic losses, and indirect losses through lack of ability to trade. Because the prions associated with BSE are not routinely destroyed by heat, BSE infected cattle products are not safe for human consumption even if cooked, and must be destroyed at high temperatures.

Once the disease became a clear and serious concern, the EU took specific measures to manage and eradicate BSE across its territory. In the UK, the export of beef cattle and bovine products was completely banned, and the beef cattle trade was decimated. Before the ban, in 1995, annual exports of beef of 300,000 tonnes were worth almost GBP£600 million. There was also a substantial trade in live calves from the British dairy herd to the rest of Europe, worth some GBP£70 million per year. This trade completely collapsed when the European Union imposed a ban on all UK exports worldwide as a consequence of the BSE crisis (figures sourced from the Department for Environment, Food and Rural Affairs, UK).

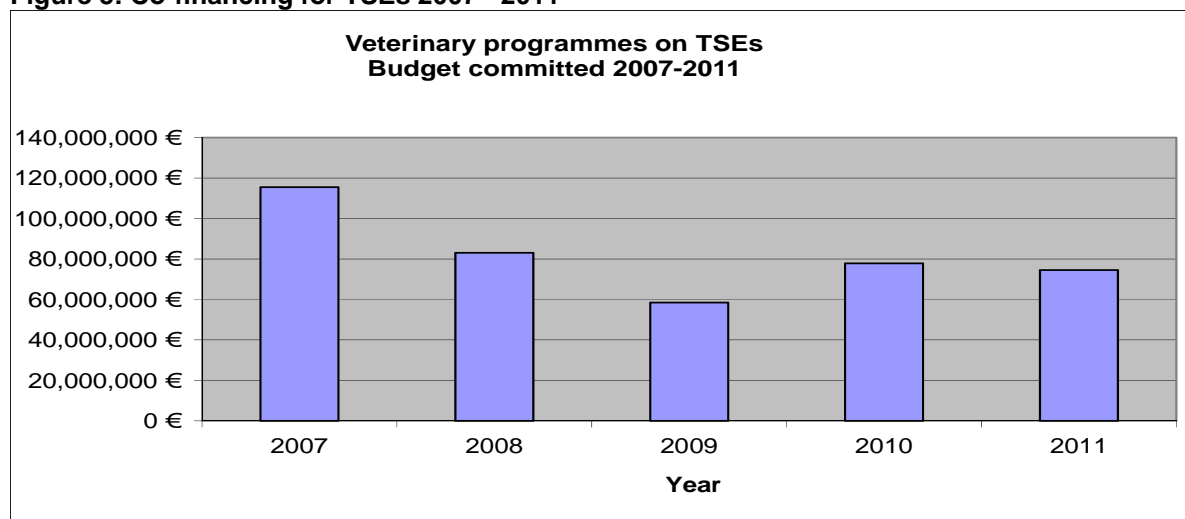
During the epidemic, more than 185,000 BSE cases in cattle were confirmed in the European Union. At the height of the crisis, consumer confidence in the food chain was at an all-time low. In response to this, the European Union implemented a new, comprehensive regulatory framework (the 'food law') to improve EU food safety, ensure a high level of consumer protection and restore and maintain confidence in the EU food supply. In addition, the EU banned the use of animal protein for feeding ruminants, measure that blocked the source of infection to animals.

⁷ National CJD Research & Surveillance Unit (NCJDRSU), University of Edinburgh:
<http://www.cjd.ed.ac.uk/vcjdworld.htm>

The reaction of the EU to this crisis in terms of funding consisted of market measures (handled by DG AGRI) and veterinary measures that included eradication measures (culling of infected or suspected animals) and stringent monitoring measures (testing of all bovines dying on-farm and all bovines slaughtered, before releasing the meat for consumption).

During the period 2005-09, the EU co-financed TSE monitoring and eradication programmes across the EU-27. For the years 2005-2008, the majority (over 80%) of funding was provided for TSE monitoring, a necessary measure to ensure that the disease continues to decline. Nevertheless, the monitoring rules have been significantly relaxed for bovines given the improving and now favourable situation, and the number of tests performed is now significantly lower than previously. The total amount of EU co-financing was €413m.

Figure 5: Co-financing for TSEs 2007 - 2011



In the case of BSE, there has been a dramatic drop in the number of positive cases since the end of the 1990s. During the period 2002-2009, there was an average 35% year-on-year drop for the period; by 2009 only 67 positive cases were found from over 7 million performed tests; in 2010 45 cases from 7.5 million tests; and in 2011 28 cases from 6.3 million tests, implying the disease has almost disappeared.

The key success from the reduction in BSE cases has been the restoration of trade. The UK is a particularly good example, as it was severely hit by the trade ban in 1995. Figure 7 clearly shows the impact of the ban, and the subsequent lifting of it in 2005. UK beef exports since then have grown steadily, since the UK could demonstrate that beef posed negligible risk to humans and so restored consumer confidence.

Figure 6: BSE Cases in the EU 2001-2009

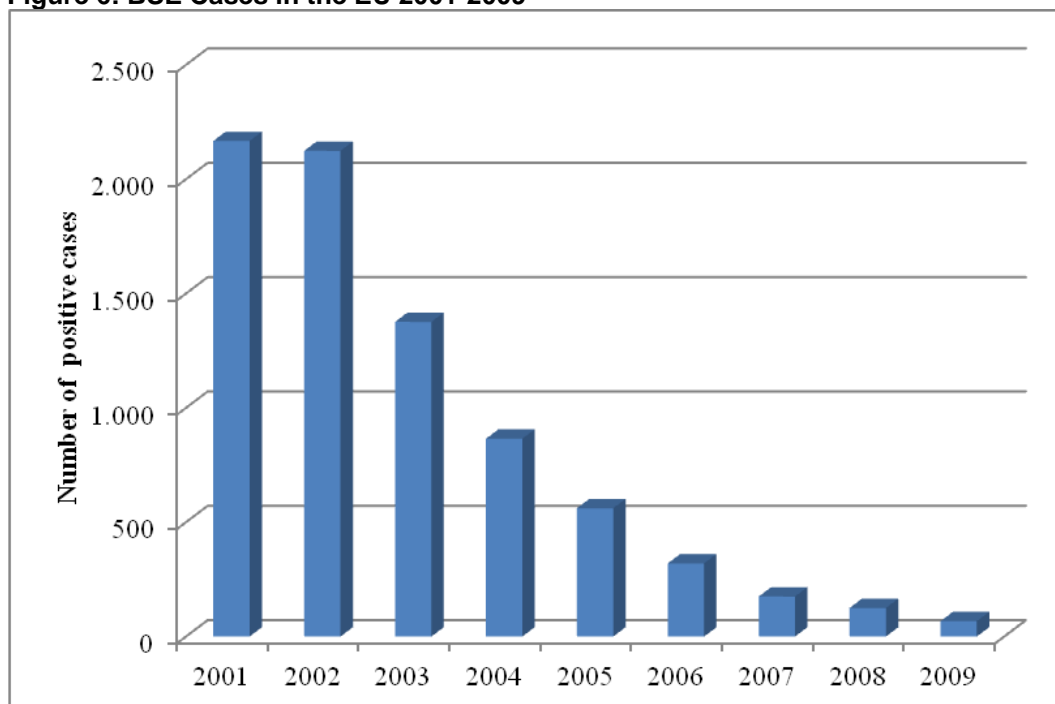


Figure 7: UK fresh bovine meat exports, quantity and value 1985 - 2010



Source: FAOSTAT

Case Study 4: Bovine Tuberculosis

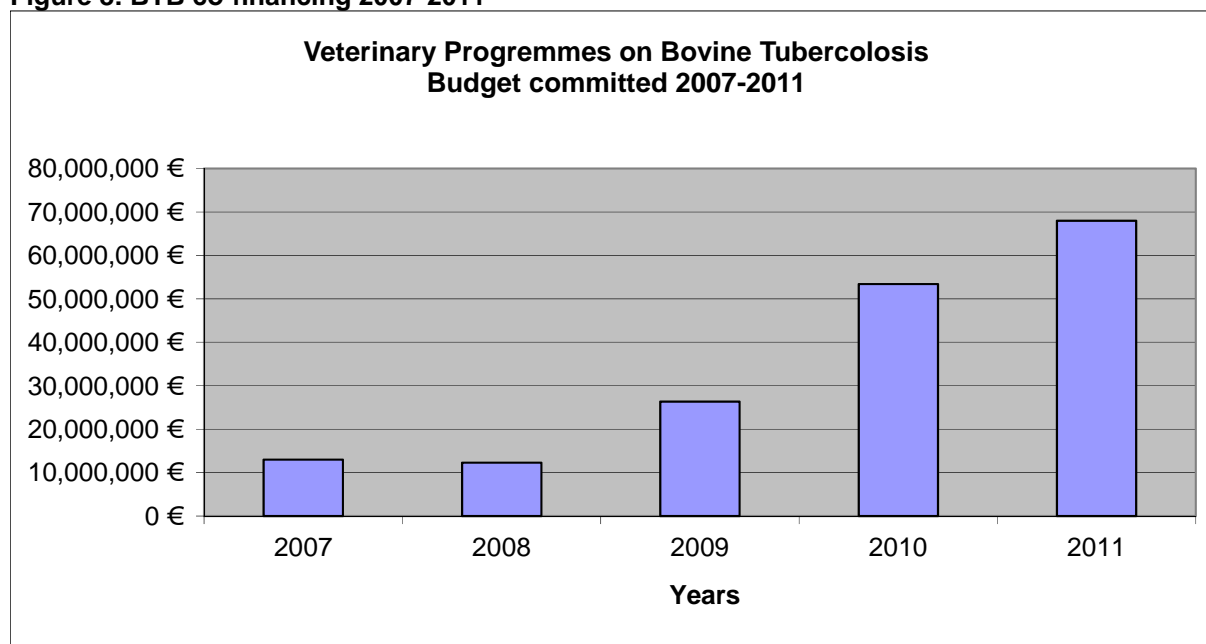
Bovine Tuberculosis is the bovine form of the tuberculosis family of bacteria. It can affect practically all mammals. Until the 1920s when control measures began in developed countries, it was one of the major diseases of domestic animals throughout the world. Today TB remains an important disease of cattle, wild animals, and is a zoonosis (an animal disease which can be transmitted to humans).

BTB has a number of specific characteristics which make it a difficult disease to control without taking long-term and persistent measures. First, the disease can take months or years to develop clinical symptoms, while the animal is nevertheless infectious. Therefore, once established, it can spread through a population undetected if testing is not routinely applied. Second, the disease can often be found in populations of wild animals, which are much more difficult to control. Third, although vaccines are available to prevent BTB, their use is prohibited by EU law. This is primarily because vaccines can interfere with testing for the purposes of detection and elimination. Therefore, testing and culling are the most widely used control measures.

The presence of BTB has a serious impact on trade, and the achievement of 'officially-free status' is a crucial objective of BTB control measures, as this status allows producers to trade freely. Officially-free status can be applied to individual holdings in some cases, but can also be granted to regions or countries.

Although cases are now rare, BTB can also infect humans through the consumption of unpasteurised milk, and very rarely, through direct contact with infected animals through the inhalation of infected droplets.

Figure 8: BTB co-financing 2007-2011



BTB is a slow and difficult disease to tackle, but there are success stories where clear progress can be demonstrated, in part due to EU co-financing.

BTB in Spain

In Spain, the first actions to eradicate bovine TB were taken in the 1950s. In 1965 the government adopted a national plan to combat the disease. Since accession to the EU (1986), programmes for eradication have been accelerated.

Between 1993 and 2009, clear progress can be demonstrated in the reduction of the number of cases.

Figure 9: Bovine TB in Spain, herd prevalence and animal incidence 1993-2009

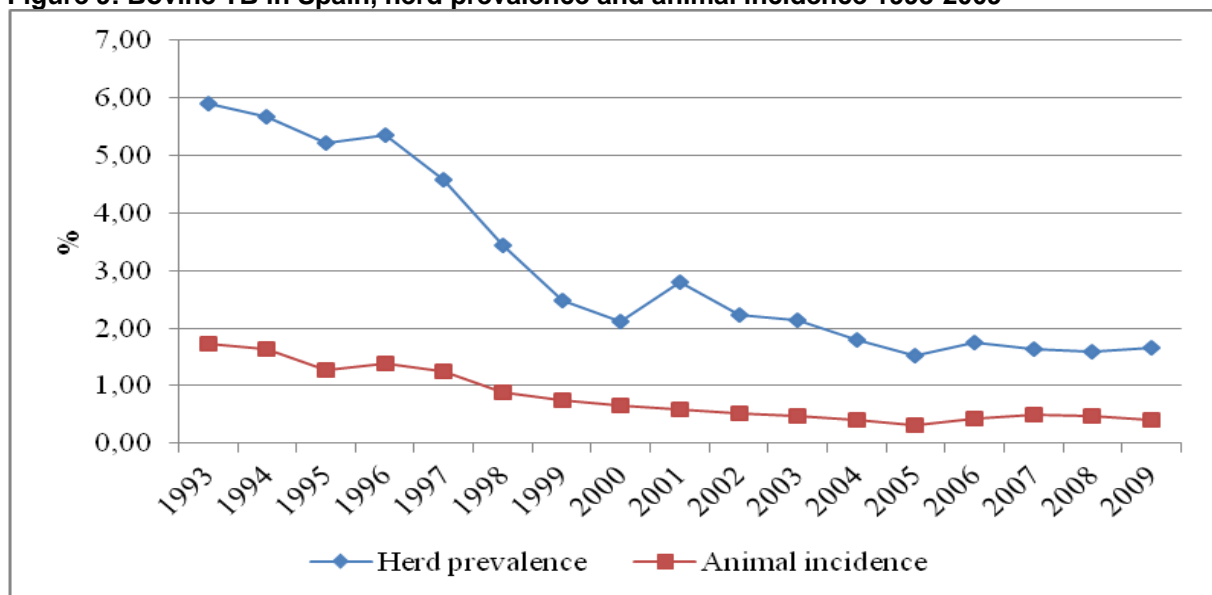
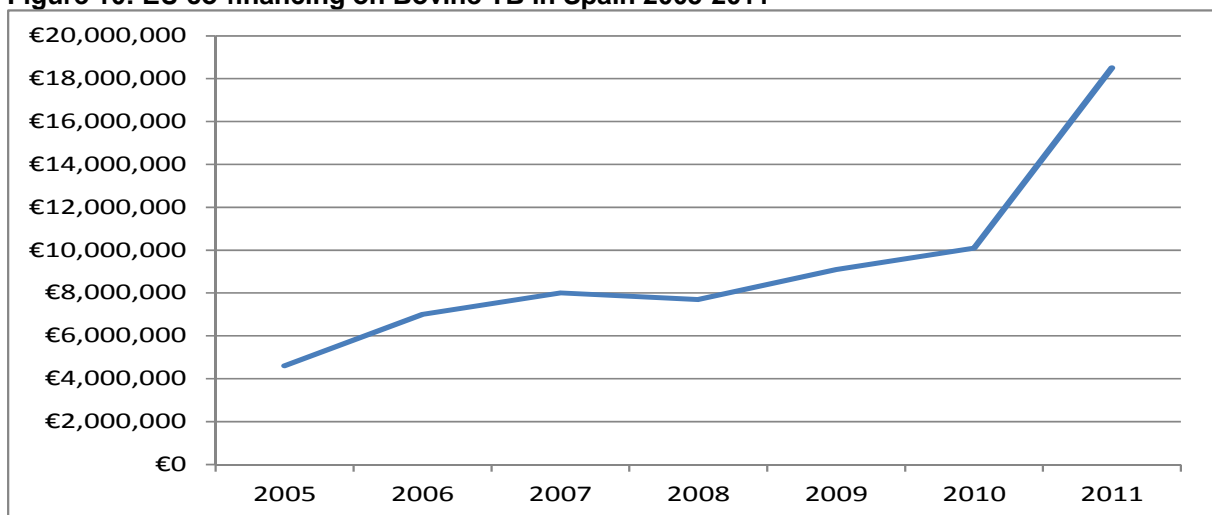


Figure 10: EU co-financing on Bovine TB in Spain 2005-2011



Of course, this success has come through the costs of eradication and control measures. The EU co-financing for BTB in Spain in recent years has increased, although the disease has continued to fall. This is because as the Spanish authorities are winning the battle against TB and seeking to completely eradicate the disease from their territory, nevertheless, there are fewer efficiencies of scale. Control costs therefore tend to rise as you make concerted efforts and get closer to eradication. Nevertheless, once eradicated and declared officially free, measures would reduce to very minimal-cost surveillance in order simply to keep on top of any incursions. And a sense of perspective should be retained as to these costs. While millions of euros have been spent on tackling TB, the costs of not tackling it would be far higher. There would be costs in both direct losses to farmers through losses of animals; but also of the lack of ability to trade. Spain's export trade in live bovines, bovine meat, milk, cheese and butter was worth US\$1.26bn in 2010 alone (equivalent to €947m at 2010 exchange rates) (FAOSTAT), and not tackling bovine TB would impact on this trade very seriously, even wiping it out altogether if the disease were once again to become widespread.

Case Study 5: CSF

Classical swine fever (CSF) is an animal disease affecting domestic pigs and wild boar, of all breeds and ages. It is a highly contagious infection, easily transmitted by direct and indirect contact between pigs, and by materials, swill feeding, trucks, instruments, and humans carrying the virus.

CSF does not infect humans. However, it can cause very significant losses to pig holdings, both due to morbidity and mortality, and because of trade restrictions. Indeed, it is a transboundary disease and the epidemiological situation in one country can affect neighbouring countries, therefore national measures alone tend not to be sufficient to control its spread, especially when outbreaks occur near borders.

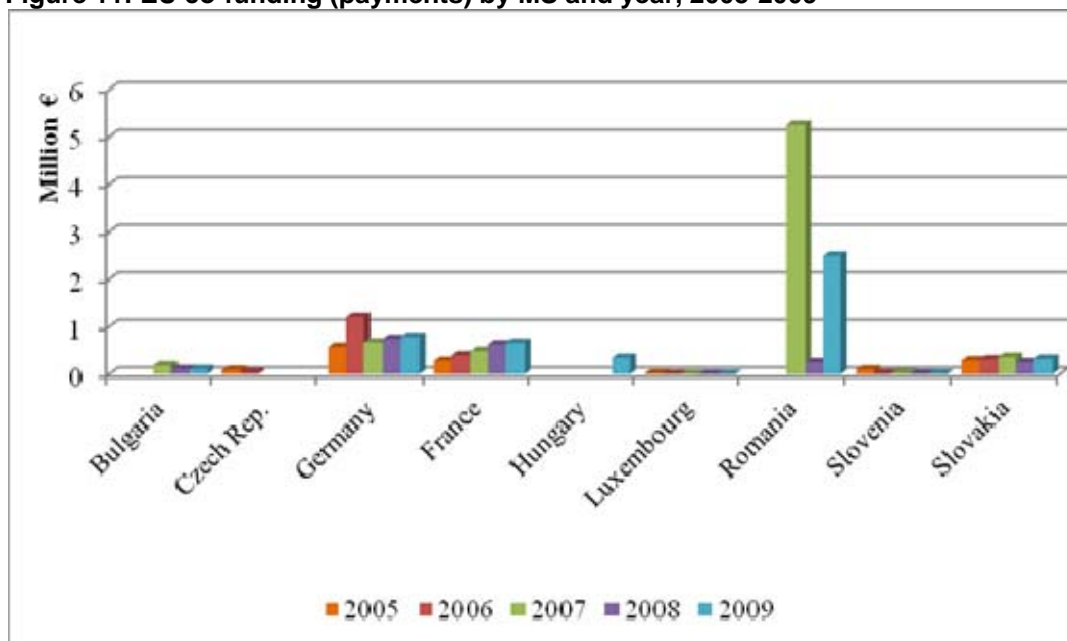
CSF is an example of a highly contagious disease that has been eradicated from most of the EU MS due to stringent vaccination and subsequent prevention and control measures.

Effective vaccines have been available for CSF since the 1980s. Attenuated live vaccines have proven to be the most effective way of reducing disease prevalence by providing quick, long lasting and complete protection. Moreover, vaccination of wild boar has proven to be a tool of increasing importance to control CSF in the environment in Europe over the last 20 years.

Movement control is also crucial in the control of CSF outbreaks, and forms an important element in the contingency plans that all EU Member States have prepared for use in the event of an outbreak.

EU funding for the eradication of CSF over the period 1995-2009 has amounted to €30,207,724. The distribution of payments has been steady throughout the period considered, with the exception of 2007 and 2009. Thanks to the eradication measures and the vaccination policy, by 2004, CSF was eradicated in the majority of EU15 Member States. The increases in 2007 and 2009 were due to the fact that, since 2007, (since their accession to the EU), veterinary programmes have been granted to the new MSs, particularly Romania, where the disease was previously widespread, mainly in the backyard pig population.

Figure 11: EU co-funding (payments) by MS and year, 2005-2009

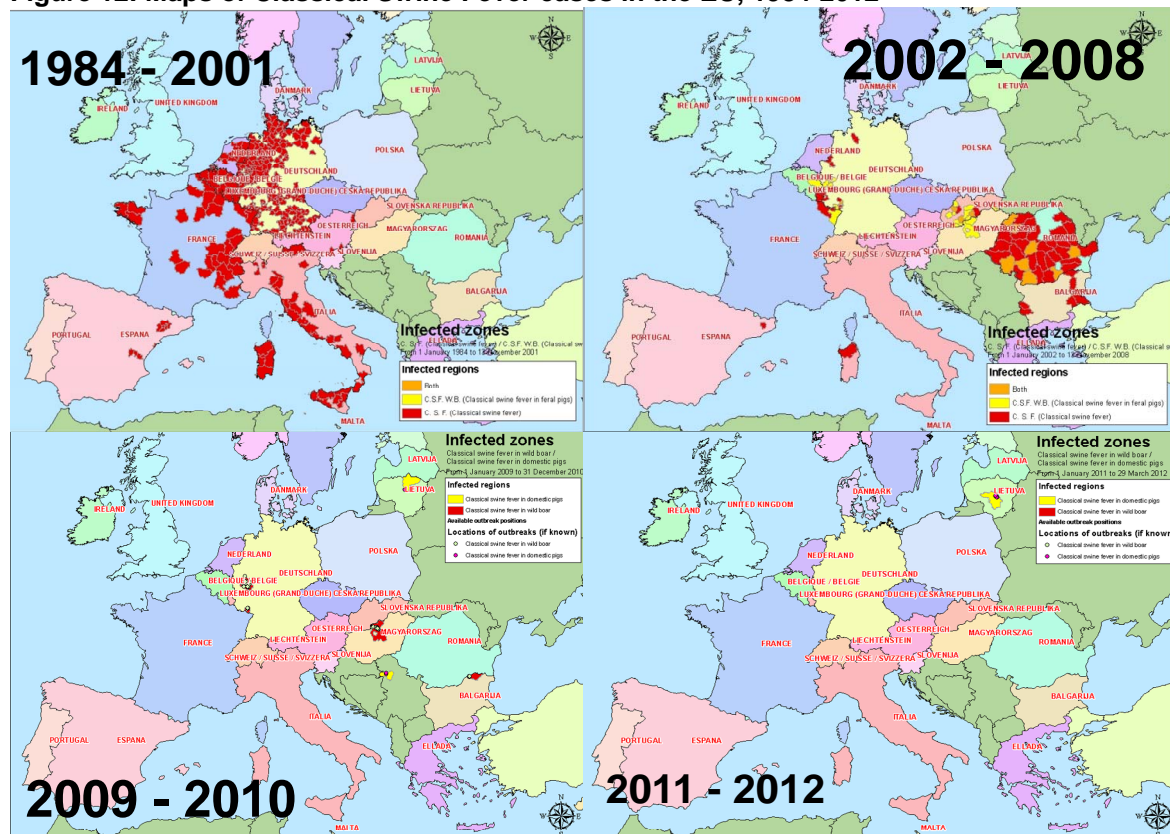


Epidemiological data for these countries indicate that, since 2005, CSF (Belgium, Czech Republic, Slovenia and Luxembourg) incidence in domestic pigs and wild boar has disappeared, or decreased to almost zero (Bulgaria, Germany, France, Hungary, Luxembourg, Romania and Slovakia). The only exceptions were unexpected outbreaks in Romania in 2006/7, but the country has remained free since then.

One of the main positive impacts of the eradication programmes has been the reduction of the CSF incidence in domestic pigs, making it possible to focus on the wildlife reservoir, the wild boar, as source of infection.

The success of the eradication programmes in the EU can be clearly seen through these maps.

Figure 12: Maps of Classical Swine Fever cases in the EU, 1984-2012



Case Study 6: Bovine Brucellosis

Bovine brucellosis is a disease of cattle which is also a zoonosis. If untackled, it causes direct economic losses through spontaneous abortions in cattle, and can be passed onto humans, where it is occasionally fatal. It can be vaccinated against, and there are several success stories of complete eradication to be found within the EU.

From an economic perspective, these success stories have yielded benefits resulting from the avoidance of direct losses for farmers from the cost of morbidity and the cost of reduced production. In terms of the costs of the programmes, the improved health status of the herd has led to a reduction in number and the frequency of sampling as well as in the number of slaughtered animals. One of the main positive impacts of the eradication programmes has also been the removal of barriers to trade, and therefore, the avoidance of indirect losses for operators. As the percentage of accredited holdings increases, the commercial potential of the products increases, and the movement of animals and animal products is facilitated. This is particularly relevant as regards the movement of animals for the purposes of intra-EU trade.

Brucellosis in Ireland

A national brucellosis scheme has been implemented in Ireland since 1966. At the beginning a clearance area was designated, which included the areas of lowest incidence, and a compulsory blood testing programme was introduced, accompanied by a system of ring testing of milk.

Figure 13: Spending on Brucellosis 2007-2011

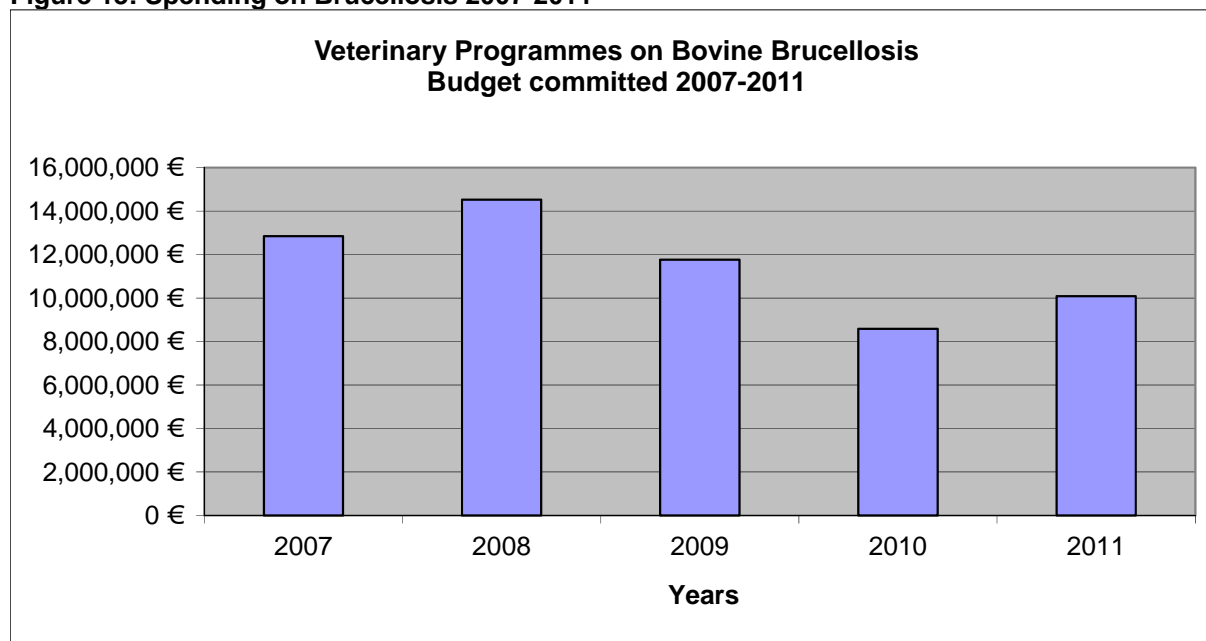
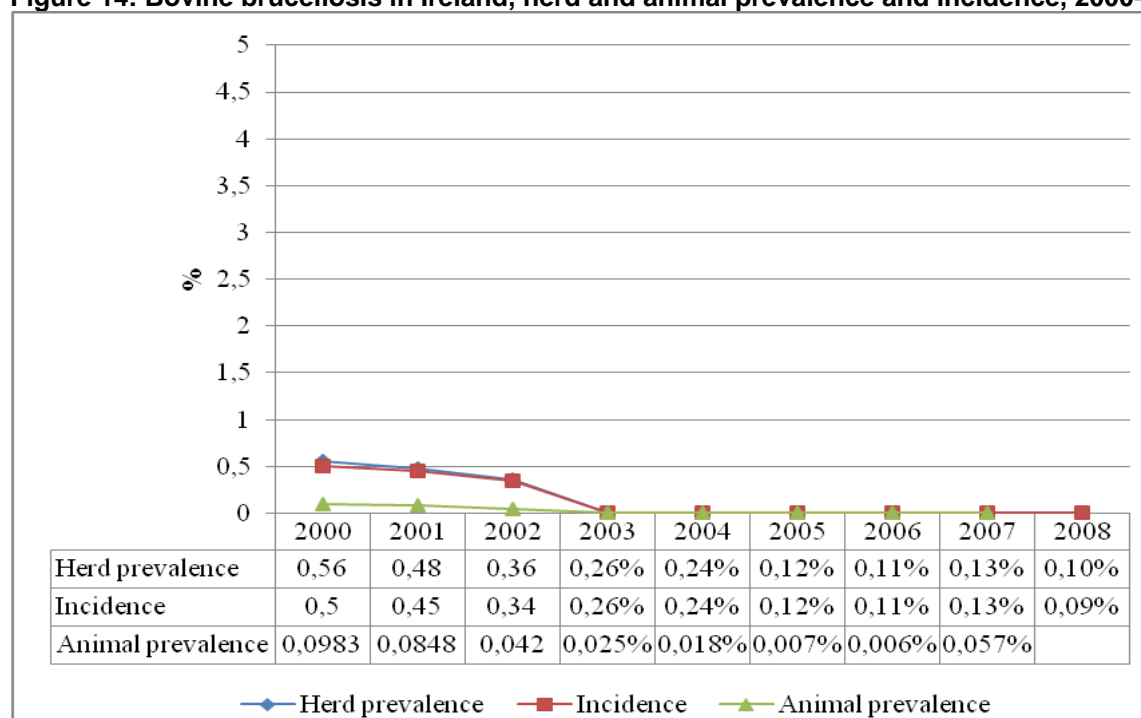


Figure 14: Bovine brucellosis in Ireland, herd and animal prevalence and incidence, 2000-2008



Over the years the clearance area was extended at various stages until it covered the whole country and a general disease-free status was achieved throughout the country by 1986. Measures aimed at achieving eradication of the disease have been maintained since then and the incidence has declined below 0.2% in the period. In the mid-1990s, an increase of the disease incidence was observed, with this being attributed to a temporary accelerated movement pattern of cows, which was prompted by keepers changing the profile of their suckler herds in following the 1992 reform of the CAP. An intensified eradication programme was therefore introduced in the country to deal with this increase in brucellosis levels and this has been improved and continued since then. Since 1998, brucellosis levels have continued to fall and in 2009 Ireland achieved 'Officially Free' status, following three years with no cases.

Since 2001, Irish bovine exports have undergone a good increase. This has undoubtedly been helped by the eradication of brucellosis. Particularly noticeable in Figure 15 is the growth of the export of live bovines, more than a fourfold increase between 2001 and 2010. The declaration of officially free status in 2009 is likely to have been an important contributory factor to the rapid increase of export of live bovines in 2009 and 2010.

Figure 15: Irish live bovine, bovine meat and milk exports 2001-2010 (source: FAOSTAT)



Case Study 7: Avian Influenza

Avian influenza is a form of the influenza virus, and the term as used here refers to the H5N1 strain. It is a zoonosis which can (relatively rarely) be caught through direct contact with birds, although it has little transmissible potential between humans in the H5N1 form. In October 2011, the WHO announced a total of 566 *confirmed* human cases which have resulted in the deaths of 332 people since 2003.

One of the main motivations for carrying out surveillance for avian influenza is the possibility of an evolution of the virus into a more virulent and dangerous form of the disease for humans, and the consequent fear of a pandemic. For example, the 2009 'swine flu' pandemic appears to have mutated from an influenza virus usually affecting pigs, and ultimately led to over 7820 deaths worldwide. However, even this pales in comparison to the 'Spanish flu' pandemic of 1918: a 2005 study estimated that Spanish flu had a global mortality rate of 50-100 million people, or 3-6% of the entire global population. One theory about the origin of the Spanish flu virus is that it originated in poultry (although a non-human mammalian species is also a possibility).

Avian influenza can have significant economic impacts. Outbreaks themselves can be very costly, as demonstrated by the outbreaks in 2003 in Netherlands (€150m of direct economic costs). Outbreaks can also lead to trade restrictions. The disease can affect consumer confidence, and hence market stability of the poultry and egg sectors, as demonstrated by the 2005/06 loss of consumer confidence. The monitoring programmes can help avoid these negative economic impacts through early detection which can reduce the risk of large outbreaks, and by providing assurance to trading partners and consumers.

During the period 2006-09, the EU co-financed avian influenza surveillance programmes in all Member States. The total EU funding over the period amounted to just over €12m. These monitoring programmes were designed to detect AI in both wild and domestic birds.

The surveillance programmes also allow the monitoring of low pathogenic strains which can mutate into high pathogenic strains. For the period 2006-09, the number of wild birds testing positive for low pathogenic AI (LPAI) and other strains of AI has remained relatively steady, while the number of wild birds testing positive for high pathogenic AI (HPAI) has dropped significantly.

Figure 16: Avian influenza, outbreaks in wild birds, 2000-2009

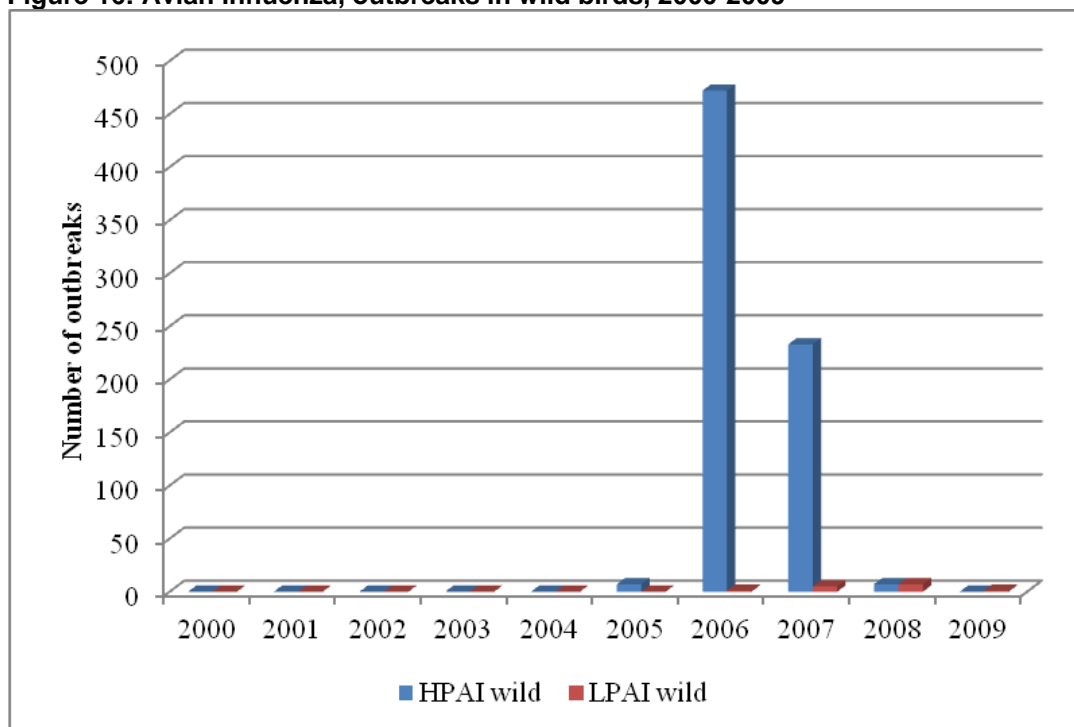
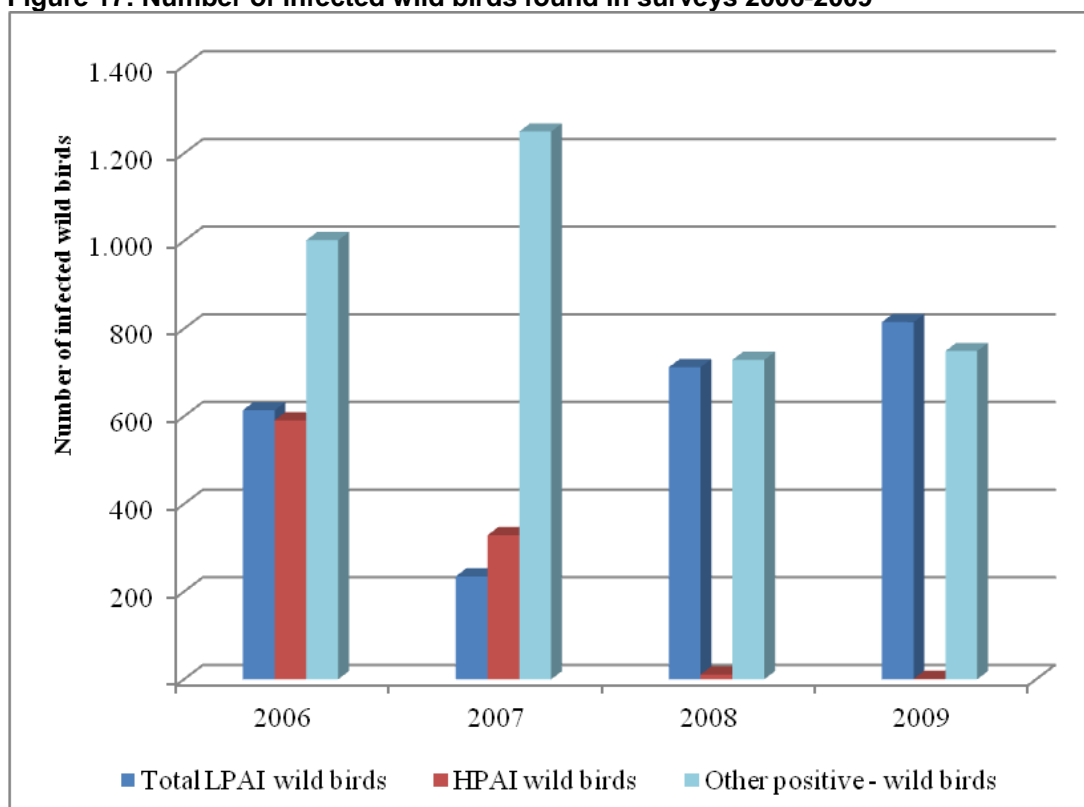


Figure 17: Number of infected wild birds found in surveys 2006-2009



The number of detections does not represent an indicator of the effectiveness of the programme itself. However, the number of detected cases, resulting from the implementation of the survey, indicates the relevance of the programme in maintaining a sound alert system for the disease. This has proven to be an effective mechanism.

There are five main reasons for continuing to survey for avian influenza:

1. The improvement of overall animal health and welfare. While LPAI has a relatively low impact on morbidity and mortality, HPAI can have very dramatic effects.
2. Fewer incidents of avian influenza in birds reduces the risk of the disease in humans, both amongst farmers and the overall population. This is both the case for the H5N1 virus directly infecting humans, but also reduces the possibility of a mutation creating a pandemic in humans (or in other animals important for the food chain or wellbeing of humans).
3. Thirdly, there are strong economic benefits, again particularly from avoiding incidents of avian influenza in domestic birds. In 2003 there was an outbreak of the HPAI H7N7 strain in the Netherlands. This outbreak resulted in the destruction of 30 million birds and direct economic costs of €150m (European Commission, 2006⁸). Similarly, the spread of H5N1 among domestic and wild birds in Romania during 2005 and 2006, i.e. prior to EU accession, has been estimated to have caused losses of around €200m according to Romanian authorities (USDA, 2006). In addition, 325 tonnes of poultry meat is believed to have been destroyed, and 900,000 backyard birds culled.
4. Fourth, the control of avian influenza can have beneficial effects on trade. This is best demonstrated during the 2006 outbreaks of H5N1. Following outbreaks in the EU during 2006, until February 2007, some 73 third countries imposed bans on poultry and egg products from the EU. While most of these bans applied to specific MS with outbreaks, 13 third countries⁹ imposed bans on all poultry meat and egg exports from the EU (independent of whether the Member States had reported an outbreak or not). In 2006 these bans caused significant business disruption for the EU exporting producers. The export value of poultry meat has decreased from €927 in 2005 to €806 in 2006.
5. Fifth, the surveillance programme provides an additional assurance for the public that the disease is being monitored, which has an impact on market stability in this sector.

The effect on consumer confidence can be marked. Research has identified that consumer attitudes towards poultry meat and eggs were closely related to the development of the avian influenza epidemic (see European Commission, 2006; and Magdelaine et al., 2008¹⁰).

Although the majority of consumers had not changed their consumption habits, the survey found that demand for poultry meat was affected (more than the demand for eggs). Specifically, 18% of respondents had reduced consumption of poultry meat, compared to 13% of respondents having reduced their egg consumption. However, the consumption response varied considerably between MS.

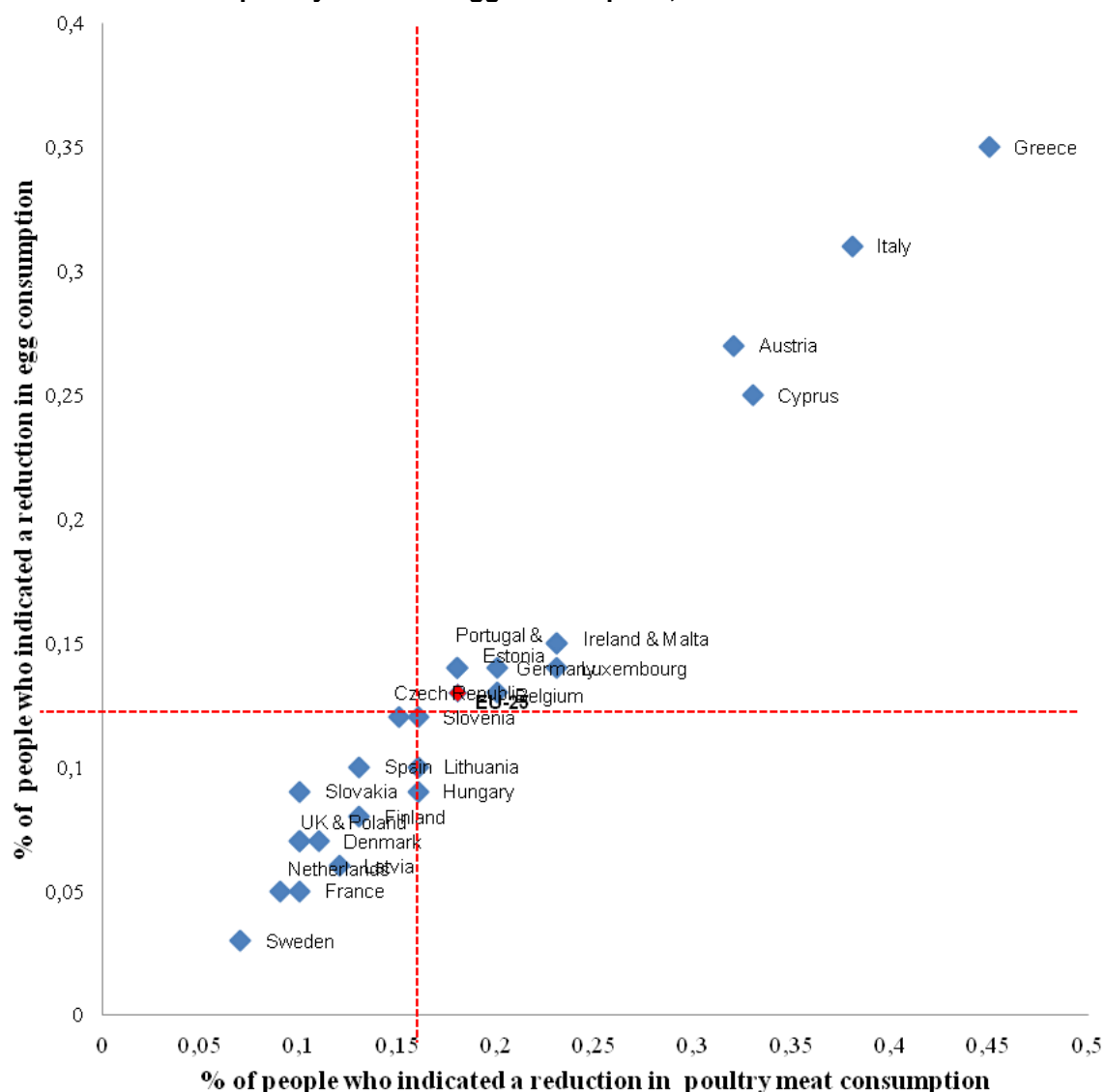
The surveillance programmes have played an important role in the fight against avian influenza by contributing to the early detection of the disease. Early detection allows rapid reaction and effective response by enabling the timely adoption emergency measures to prevent the further spread of the disease. In particular, protection zones can be established around the finding, and control measures can be strengthened. These actions in turn ensure that one incident of avian influenza does not develop into a large scale outbreak which may eventually affect humans. The cross-EU monitoring programmes are a small continued price to pay for this advance warning and security.

⁸ European Commission 2006. Avian Influenza. *Special Eurobarometer 257 – Wave 65.2 –TNS Opinion and Social*. June 2006.

⁹ Angola, Azerbaijan, Cameroon, Chile, Egypt, India, Panama, Papua New Guinea, Senegal, Sierra Leone, Syria, Togo, and United Arab Emirates.

¹⁰ Magdelaine, P., Spess, M.P. and Valceschini, E. 2008 Poultry meat consumption trends in Europe. *World's Poultry Science Journal*. Volume 64, March 2008

Figure 18: Attitudes to poultry meat and egg consumption, 2006



Annex 3: Objectives of individual policy areas

Animal Health

The general objectives of EU animal health policy are outlined in the EU AHS 2007-2013, and are:

- to ensure a high level of public health and food safety by minimising the incidence of biological and chemical risks to humans;
- to promote animal health by preventing/reducing the incidence of animal diseases, and in this way to support farming and the rural economy;
- to improve economic growth/cohesion/competitiveness assuring free circulation of goods and proportionate animal movements;
- to promote farming practices and animal welfare which prevent animal health related threats and minimise environmental impacts in support of the EU Sustainable Development Strategy.

These general objectives demonstrate that the basis for EU action is wider than simply preventing public or animal health problems from arising or ensuring the economic security of farmers. The scope of any new measures will need to encompass not just kept animals (including production animals, animals used for work, sport, recreation or display, companion animals and animals used in research); but also, to an extent, wild animals, where their poor health has the potential to jeopardise any of these objectives.

Plant Health

The overall objectives of the revision of the plant health regime are to ensure an EU plant health regime which:

- Supports the Union's agricultural policy (TFEU Art. 43) and environment policy (TFEU Art. 191) by protective measures against harmful organisms of plants, with prevention at the source as important principle;
- Allows a smooth functioning of the Union's internal market with fair competition (TFEU Art. 114, while respecting the need for a high level of protection of health and the environment, based on scientific facts);
- Contributes to the harmonious development of world trade (TFEU Art. 206, by adopting legislation which complies with the WTO-SPS Agreement).

The intermediate objectives are:

- To ensure that the EU territory remains free from harmful organisms that are not yet present in the Union
- To ensure that the areas affected by harmful organisms with the most severe impacts to the Union (priority organisms) do not increase
- To modernise the regime in terms of governance and incentives
- To ensure adequate support for the regime

Plant Reproductive Material

The general and specific objectives of the PRM revisions are:

- To assure the health and high quality of PRM;
- To provide a single and harmonised regulatory framework which is supportive for innovation and the competitiveness of the European PRM industry;
- To support sustainable agricultural production, biodiversity protection, adaptation to climate change and to contribute to food security and poverty alleviation.
- To ensure a level playing field across the EU through simplified, clarified and harmonised basic rules on fundamental principles presented in an improved legal form;
- To reduce unnecessary costs and administrative burden and to increase flexibility for operators without compromising the general policy objectives;
- To align PRM legislation with other recent Union strategies (plant health law, official controls regulation, agriculture, biodiversity, food security, climate change, bio-based economy);
- To foster innovation in plant breeding, especially in SMEs, in order to improve PRM users' choice and access to a wide diversity of plant varieties adapted to conditions in Europe.

Official Controls

The specific objectives for the revision of the official controls legislation were set with the aim of eliminating the specific obstacles identified during the official controls impact assessment which prevent or hamper the achievement of the general objectives in this area. The specific objectives address two sets of obstacles: those resulting from shortcomings in the design of the official controls' framework and those resulting from the difficulties and inequities in financing of official controls.

Objectives related to the design of the official controls' framework

- Ensure a comprehensive and consistent approach to official controls along the food chain:
 - the system of official controls should be consistent across all food chain sectors avoiding differences which are not justified by the peculiarities of a given sector;
 - this system should provide for all tools necessary to ensure accountability, soundness and effectiveness of the enforcement activities performed in all food chain sectors;
 - this system should avoid duplications and overlaps which result in divergent interpretations and implementation.
- Allow for a more efficient use of national control resources:
 - the system of official controls should require MS to allocate, in all food chain sectors, finite control resources on the basis of the actual risk in order to achieve the most efficient use of such resources.
- Reduce administrative burden and remove unnecessary requirements:
 - unnecessary administrative burden, in particular on MS' CAs, should be eliminated;
 - the system should allow for the necessary flexibility so that important requirements (the accreditation of official laboratories) can be derogated where appropriate.
- Foster closer cooperation between MS to improve official control delivery:
 - the system of official controls should enable swift and effective cooperation, and synergies, among MS' competent authorities (including customs) which are tasked with controls over the food chain.
- Improve transparency:
 - the system of official controls should provide MS with a clear guidance on how a 'high level of transparency' should be ensured so that the European citizens can benefit from the same level of transparency across the EU.

Annex 4: Costs and Responsibility Sharing Scheme in the Animal Health Field (Emergency fund)

CRSS Background

DG Sanco has been going through a long process of analysing the possibility of introducing aspects of cost and responsibility sharing into animal health policy. This has included a 'pre-feasibility study' on options for harmonised cost-sharing schemes in advance of the Animal Health Strategy 2007-2013 published in 2005, a working party of Chief Veterinary Officers (CVOs) in 2008 and a Feasibility Study published in 2011, as well as many other consultations. All of these have been looking at the ways in which losses from animal disease could be financed. A possible option derived from exhaustive recent analysis includes the compulsory introduction of a harmonised cost and responsibility sharing scheme in the form of three complementary aspects.

1. A bonus-malus system to calculate direct losses which are at present compensated by the EU. This envisages changing the co-financing rate for each MS according to whether it had made claims from the emergency fund in the previous year.
2. A public-private partnership scheme to contribute to the compensation of direct losses not currently co-financed by the EU.
3. Coverage of indirect losses (such as loss of business through trade restrictions) through the voluntary introduction of mutual funds or similar insurance-type schemes.

Considering these three aspects, a preferred option was developed which centred on a voluntary approach – no bonus-malus; a voluntary introduction of a public-private partnership; and the positive encouragement of schemes to cover consequential losses. This would be introduced with the door left open to introduce a bonus-malus and/or make the introduction of a public-private partnership scheme compulsory if it was shown to work well.

However, the assessment does acknowledge that:

- this three-part system is complicated, defeating the objectives of clarity and simplicity which are objectives for this IA
 - it creates an additional administrative burden for both authorities and operators
 - the likelihood of its being acceptable to MSs (Bonus-Malus system) and to stakeholders (PPPs) is small
 - even if in the long term, it may reduce the impacts of animal disease, limited advantages can be envisaged in the short term
 - the current financial climate makes it even more difficult politically and culturally for MSs and stakeholders to accept a larger share of the financial burden, even if their overall net burden reduces in the long term.
- moreover, the assessment is not complete for all food and feed expenditure, as it was only conducted in the animal health area.
- As it is, there is not enough evidence to suggest that the benefits from introducing this system will outweigh the costs.

Annex 5: References

Multiannual Financial Framework

- Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions: "A Budget for Europe 2020": http://ec.europa.eu/health/programme/docs/maff-2020_en.pdf
- Commission working paper: A Budget for Europe 2020: The added value of the EU budget http://ec.europa.eu/budget/library/biblio/documents/fin_fw1420/working_paper_added_value_EU_budget_SEC-867_en.pdf
- Commission working paper: A Budget for Europe 2020: the current system of funding, the challenges ahead, the results of stakeholders' consultation and different options on the main horizontal and sectorial issues accompanying the new Multiannual Financial Framework. http://ec.europa.eu/budget/library/biblio/documents/fin_fw1420/SEC-868_en.pdf

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- EU Animal Health Strategy 2007-2013 (AHS) "Prevention is better than cure" http://ec.europa.eu/food/animal/diseases/strategy/docs/animal_health_strategy_en.pdf
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- Evaluation of the Eradication, Monitoring and Control Programmes for Animal Diseases, GHK (interim report)
- Impact Assessment for the Animal Health Law (yet to be published)

Plant Health and PRM

- Evaluation of the Community Plant Health Regime, FCEC, 2010 http://ec.europa.eu/food/plant/plant_health_biosafety/rules/docs/final_report_eval_en.pdf
- Evaluation of the Community *acquis* on the marketing of seed and plant propagating material (S&PM), FCEC, 2008: http://ec.europa.eu/food/plant/plant_propagation_material/review_eu_rules/docs/s_pm_evaluation_finalreport_en.pdf
- Impact Assessment for the Plant Health Law (yet to be published)
- Impact Assessment on PRM (yet to be published)

Better Training for Safer Foods

- Evaluation of the benefits of the Better Training for Safer Foods Programme, GHK (interim report)

European Union Reference Laboratories

- Evaluation of the EU-RLs in the field of food and feed safety and animal health and live animals, FCEC, 2011: http://ec.europa.eu/food/food/controls/reference_laboratories/evaluation_en.htm

Most Relevant Legislation:

- Council Directive 2000/29/EC
- Regulation (EC) No. 882/2004
- Council Decision 2009/470/EC (Council Decision 90/424/EEC)
- Regulation 1205/2005