**Special Report** 

Eradication, control and monitoring programmes to contain animal diseases





**EUROPEAN COURT OF AUDITORS** 12, rue Alcide De Gasperi 1615 Luxembourg **LUXEMBOURG** 

Tel. +352 4398-1

Enquiries: eca.europa.eu/en/Pages/ContactForm.aspx Website: eca.europa.eu Twitter: @EUAuditorsECA

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## **Special Report** | **Eradication**, **control** and monitoring programmes to contain animal diseases

(pursuant to Article 287(4), second subparagraph, TFEU)

Audit team 02

The ECA's special reports set out the results of its performance and compliance audits of specific budgetary areas or management topics. The ECA selects and designs these audit tasks to be of maximum impact by considering the risks to performance or compliance, the level of income or spending involved, forthcoming developments and political and public interest.

This performance audit was produced by Audit Chamber I — headed by ECA Member Augustyn Kubik — which specialises in preservation and management of natural resources spending areas. The audit was led by ECA Member Bettina Jakobsen, supported by the Head of her private office, Katja Mattfolk, and Kim Storup, Attaché; Colm Friel, Principal Manager; Armando do Jogo, Head of Task; Xavier Demarche, Manuel Dias, Andreas Dürrwanger, Oana Dumitrescu, Laure Gatter, Mary Kerrigan, Joanna Kokot, Michela Lanzutti, Joachim Otto, Lucia Rosca and Anna Zalega, auditors.



From left to right: K. Mattfolk, A. do Jogo, C. Friel, B. Jakobsen, X. Demarche.

Contents 03

Paragraph

	Glossary and abbreviations					
I–X	Executive summary					
1–17	Introduction					
1–2	Treatment of animal diseases					
3-4	The EU's animal health strategy					
5–9	Animal disease eradication, control and monitoring programmes					
10-12	Cooperation with countries outside the EU					
13–17	Main roles and responsibilities					
18–23	Audit scope and approach					
24-60	Audit observations					
26-33	While the Commission's approach for the eradication, control and monitoring of animal diseases has generally been sound,					
34–36	and Member State programmes were generally well designed and implemented,					
37–47	the cost-effectiveness of the programmes is difficult to determine,					
48-60	and there remains scope for improvement.					
61–72	Conclusions and recommendations					
	Annex I — Animal disease information					
	Annex II — Main responsibilities					

**Reply of the Commission** 

# Glossary and abbreviations

**ADNS**: Animal Disease Notification System

**BSE**: Bovine spongiform encephalopathy

**BT**: Bluetongue

**CAC**: Codex Alimentarius Commission

**ECDC**: European Centre for Disease Prevention and Control

**EFSA**: European Food Safety Authority

FAO: Food and Agriculture Organisation of the United Nations

**FVO**: Food and Veterinary Office

**Incidence and prevalence**: The incidence of a disease is the disease occurrence in a defined population over a designated time period (number of new cases). The prevalence of a disease is the disease presence in a defined population in a designated time (actual number of cases).

**OIE**: World Organisation for Animal Health

PAFF: Standing Committee on Plants, Animals, Food and Feed

TB: Bovine tuberculosis

**Traces**: TRAde Control and Expert System

TSE: Transmissible spongiform encephalopathies

WAHIS: World Animal Health Information System

WHO: World Health Organisation

**Zoonosis**: Disease or infection that can be transmitted directly or indirectly between animals and humans.

Animal health has a direct impact on public health, because of food safety issues, and because some animal-borne diseases are transmissible to humans. Furthermore animal disease outbreaks can trigger significant economic costs, through loss of internal EU and export markets, and the direct cost of disease control on the EU and Member State budgets.

Animal diseases can spread rapidly, and across borders. The EU has an active animal health policy and finances Member States' programmes to eradicate, control, and monitor certain animal diseases. These programmes involved EU funding of 1.3 billion euro between 2009 and 2014 and cover actions such as animal vaccination, testing, and compensation for slaughtered animals. Depending on the type of disease, eradication is a complex exercise and can take many years. Therefore, there needs to be a sound approach at EU level, with appropriate programmes implemented by the Member States.

#### Ш

The Court examined whether the eradication, control and monitoring programmes adequately contained animal diseases, by assessing the approach taken by the Commission, and Member States' programme design and implementation. The Court also examined whether the cost-effectiveness of programmes was adequately considered.

#### IV

Overall the Court concluded that the animal disease programmes we examined adequately contained animal diseases. However, as disease outbreaks can always occur the Commission and the Member States should continue to be vigilant.

#### V

We concluded that the approach taken by the Commission was generally sound, and was supported by good technical advice, risk analysis, and a mechanism for prioritising resources. The Commission provided guidance and facilitated coordination of Member States' efforts, and established minimum performance criteria to be met by Member State programmes. There have been some notable successes, for example, decreases in cases of bovine spongiform encephalopathy (BSE) in cattle, salmonella in poultry, and rabies in wildlife.

#### VI

We concluded that Member State programmes we examined were generally well designed and implemented, and that Member States had adequate systems to identify animal disease outbreaks and facilitate their eradication.

#### VII

Nevertheless, the cost-effectiveness of programmes is difficult to determine, due to the lack of available models for such analysis. There were examples of insufficiently controlled programmes by the Member States or unreasonably high costs. In some cases in Italy, the amounts paid in compensation to farmers, or the payment reduction imposed by the Commission, provided limited incentive to encourage effective biosecurity measures and the implementation of corrective measures.

#### VIII

We noted some specific areas with scope for improvement. The exchange of epidemiological information and the ready access to historic results could be better supported by the relevant information systems, but was in the process of being improved. The audit also found that some programmes should better specify the actions and controls to be implemented.

#### IX

While our assessment of the implementation of specific veterinary programmes was overall positive, the eradication of bovine brucellosis and tuberculosis, and ovine and caprine brucellosis, posed continuing challenges in some Member States. We found that the EU approach for considering diseases in wildlife should be complemented, notably for tuberculosis, and that the lack of certain vaccines can be detrimental to programme effectiveness.

#### X

The Court recommends that the Commission should:

- (a) facilitate the exchange of epidemiological information between Member States;
- (b) examine whether the existing set of indicators should be updated to provide better information on veterinary control activities and the cost-effectiveness of programmes;
- (c) systematically include, when relevant, the wildlife aspect in the veterinary programmes;
- (d) support the availability of vaccines for use by the Member States when epidemically justified.

Introduction 07

#### Treatment of animal diseases

#### 01

Animal health directly impacts public health, because some animal diseases are transmissible to humans, and because of food safety issues. Good animal health is also a basic requirement for the EU's food industry. For many years therefore, the EU has enforced an extensive set of measures to protect animal health. The cost of dealing with emergencies and diseases, if existing measures do not function correctly, can be significant, with loss of internal EU and export markets, costs of disease control on the EU and Member State budgets, and costs to Member State health systems for treating zoonotic diseases (diseases transmissible to humans). The foot and mouth disease outbreak of 2001 which started in the UK but spread to other countries, is estimated to have cost up to 12 billion euros. The BSE crisis of the 1990s, which was also concentrated in the UK, cost over 3 billion euros in the UK alone and significantly decreased both the volumes and prices of EU beef exports. In recent years, no outbreak has arisen which has led to such significant costs.

#### 02

The type and incidence of animal diseases vary across the EU, depending on factors which include climate, farm types, veterinary practices, and animal movements. Some of the main animal diseases are described in *Annex I*. Moreover, recent outbreaks of African swine fever (Estonia, Latvia, Lithuania and Poland), avian influenza (Germany and Netherlands) or bluetongue (spreading from North Africa and affecting mainly Greece, Spain, Italy, Portugal) all spread quickly across borders. Some animal diseases can spread rapidly (see for example the case of bluetongue in *Figure 1*) if not quickly detected and effectively treated. Effective veterinary measures contribute to the prevention of such highly contagious diseases, and the avoidance of the necessity for emergency measures.

#### The EU's animal health strategy

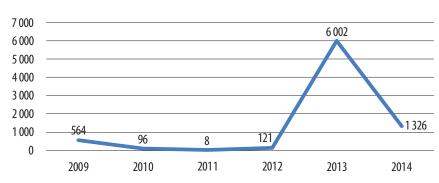
#### 03

The EU's animal health legislative framework is complex. It involves hundreds of pieces of legislation, some of them adopted as far back as 1964. A systematic EU approach to animal disease eradication, control and monitoring was first introduced for some diseases in 1977<sup>1</sup>. From 2009, the Council's Decision<sup>2</sup> on expenditure in the veterinary field, replaced in 2014<sup>3</sup>, sets out the framework for these programmes. The EU's Animal Health Strategy<sup>4</sup> established goals related to health, economic issues, and farming practices as well as an action plan to achieve them. See **Box 1** for details.

- 1 Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle (OJ L 145, 13.6.1977, p. 44).
- 2 Council Decision 2009/470/EC of 25 May 2009 on expenditure in the veterinary field (OJ L 155, 18.6.2009, p. 30).
- Regulation (EU) No 652/2014 of the European Parliament and of the Council of 15 May 2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material, amending Council Directives 98/56/EC, 2000/29/ EC and 2008/90/EC Regulations (EC) No 178/2002, (EC) No 882/2004 and (EC) No 396/2005 of the European Parliament and of the Council, Directive 2009/128/EC of the European Parliament and of the Council and Regulation (EC) No 1107/2009 of the European Parliament and of the Council and repealing Council Decisions 66/399/EEC, 76/894/EEC and 2009/470/EC (OJ L 189, 27.6.2014, p. 1).
- 4 COM(2007) 539 final of 19 September 2007 'A new Animal Health Strategy for the European Union (2007-2013) where "prevention is better than cure" '.

Box,

### Number of outbreaks of bluetongue serotype BTV-1 in the EU



Source: European Commission, DG Health and Food Safety.

#### **EU Animal Health Strategy**

The EU Animal Health Strategy 2007-2013 sets out EU goals and actions. This strategy has four main goals:

- 1. To ensure a high level of public health and food safety by minimising the incidence of biological and chemical risks to humans.
- 2. To promote animal health by preventing/reducing the incidence of animal diseases, and in this way to support farming and the rural economy.
- 3. To improve economic growth/cohesion/competitiveness, assuring free circulation of goods and proportionate animal movements.
- 4. 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 goals were implemented by an action plan of four pillars:

- 1. Prioritisation of EU intervention.
- 2. The EU animal health framework.
- 3. Prevention, surveillance and preparedness.
- 4. Science, innovation and research.

Introduction 09

#### 04

The Commission (DG Health and Food Safety) is responsible for risk management concerning animal diseases. Member States and EU specialised agencies — the European Food Safety Authority (EFSA) and the European Centre for Disease Prevention and Control (ECDC) — are responsible for risk assessment. Since 1982, the EU has had a notification system to prevent the spread of certain contagious diseases. Member States are required to notify the Commission of an outbreak using the Animal Disease Notification System<sup>5</sup> (ADNS) as well as its eradication for certain contagious diseases, so as to prevent their spread in EU livestock.

5 Introduced by Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community (OJ L 378, 31.12.1982, p. 58).

## Animal disease eradication, control and monitoring programmes

#### 05

The cost of dealing with previous disease outbreaks, together with the risk of dealing with future outbreaks of existing or emerging diseases, demonstrate the importance of the EU's veterinary measures. The EU funds Member State veterinary programmes for a number of diseases and zoonoses (see **Box 2**), under the first pillar of the Animal Health Strategy. The objectives of these programmes are:

- to progressively eliminate animal diseases and to implement disease monitoring measures in the Member States and the EU as a whole;
- to ensure a high level of animal health, public health and consumer protection;
- to guarantee a high level of protection of both animal health and public health, to encourage the improvement of the productivity of the livestock sector and to contribute to the economic sustainability of the sectors directly or indirectly affected by an animal disease outbreak.

## 30x 2

#### **Eradication, control and monitoring programmes**

**Eradication programmes**: The aim is the biological extinction of an animal disease or zoonosis, finally resulting in a free or 'officially free' status of the territory according to Union legislation (e.g. bovine tuberculosis).

**Control programmes**: The aim is to maintain the prevalence of an animal disease or zoonosis below sanitary acceptable levels (e.g. salmonella).

**Surveillance/monitoring**: The aim is to collect and record data in defined populations in order to assess the epidemiological evolution of the disease (e.g. avian influenza).

Source: Commission Decision 2008/341/EC.

These programmes are categorised as eradication, control, or surveillance programmes, and cover a wide range of measures including vaccination, testing of animals and compensation for slaughtering or culling.

#### 07

Over the period 2009-2014, the EU budget dedicated 1.3 billion euros for these programmes (see *Table 1*), which forms the bulk of expenditure under the EU food safety budget. The EU financial contribution is usually at the rate of 50 % of the cost incurred by the Member States, up to a maximum amount. Animal diseases and zoonoses which are eligible for EU financial contribution are listed in Annex I to Council's 2009 Decision and from 2014 in Annex II to Regulation (EU) No 652/2014.

## EU commitments to programme costs for the period 2009-2014 by disease (million euro)

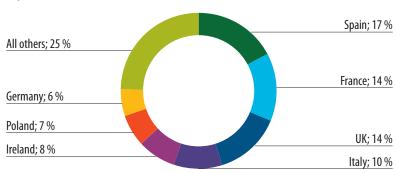
Programme	2009	2010	2011	2012	2013	2014	2009-2014	%
African swine fever	0.1	0.1	0.2	0.9	1.1	0.1	2.3	0.2 %
Aujesky's disease	2.8	2.3	0.0	0.0	0.0	0.0	5.2	0.4 %
Avian influenza	4.9	4.9	3.5	2.7	2.7	2.6	21.3	1.6 %
Bluetongue	112.0	68.2	13.4	3.7	2.5	3.8	203.5	15.4 %
Bovine brucellosis	11.8	8.6	10.1	8.0	7.3	10.3	56.0	4.2 %
Bovine tuberculosis	26.3	53.4	67.9	70.7	63.9	64.2	346.4	26.2 %
Brucellosis melitensis	9.0	7.7	15.9	15.4	15.3	16.2	79.4	6.0 %
Classical swine fever	5.1	4.3	3.7	3.4	3.0	2.6	22.1	1.7 %
Leucosis (EBL)	3.0	2.4	0.0	0.0	0.0	0.0	5.3	0.4 %
Rabies	11.7	15.7	20.9	23.4	19.9	20.4	112.0	8.5 %
Salmonellosis	18.6	24.4	25.1	19.2	19.2	21.2	127.8	9.7 %
Swine vesicular disease	0.5	0.3	0.7	0.9	1.1	0.8	4.3	0.3 %
TSE, BSE and scrapie	61.5	81.8	74.6	54.3	38.9	24.0	335.0	25.4 %
Total	267.4	274.1	236.0	202.3	174.9	166.1	1 320.8	100.0 %
Annual budget as percentage of total budget for the period	20.2 %	20.8 %	17.9 %	15.3 %	13.2 %	12.6 %	100.0 %	

Source: DG Health and Food Safety.

Over 50 % of costs are concentrated in four countries (Spain, France, Italy and the United Kingdom) (see *Figure 2*).

## Figure 2

### Level of programme costs for the period 2009-2014 by Member State



Source: DG Health and Food Safety.

#### 09

In practice, it can be very difficult to eradicate animal diseases. For example, bovine tuberculosis and brucellosis have not yet been eradicated in several Member States, although efforts to control or eradicate them have been in place for more than 50 years. The EU started funding programmes to eradicate these diseases in the 1970s, at which time some Member States already had their own national programmes for many years. *Table 2* shows that it can take decades to acquire an 'officially disease free' status, despite the efforts of Member States and the Commission, and continuing scientific and technical advances. Some countries have however been quicker than others. The continuing presence of such diseases leads to recurring expenditure from the EU budget on the eradication programmes.

#### The eradication of diseases is a lengthy process

	Bovine tuberculosis			Bovine brucellosis			
Member State	First EU-funded programme	Recognition of disease officially free status	Number of years to be- come officially disease free <sup>a</sup>	First EU-funded programme	Recognition of disease officially free status	Number of years to be- come officially disease free <sup>a</sup>	
Ireland	1978⁵	Still not disease free		1978	2009	31	
Spain	1987	Still not disease free		1987	Still not disease free		
France	1978	2001	23	1978	2005	27	
Italy	1980	Still not disease free <sup>c</sup>		1980	Still not disease free <sup>c</sup>		
Poland	2004	2009	5 <sup>d</sup>	2004	2009	5 <sup>d</sup>	
Romania	No EU-funded programmes	Still not disease free <sup>e</sup>		No EU-funded progi	rammes, and recognised disease free in 2014		
UK	2000 <sup>f</sup>	Still not disease free		1978	2015	37	

- <sup>a</sup> Not counting previous national programmes, which have been implemented in most countries for decades before EU funding was first received.
- b First EU-funded programme is in 1978, but EU funding stopped in 2004, and started again in 2009.
- Many of the regions are now officially free.
- d When the EU co-funded programmes started in 2004, the herd prevalence rate was only 0.052 % for TB, and 0.005 % for bovine brucellosis.
- <sup>e</sup> Herd prevalence is insignificant.
- First EU-funded programme is in 2000, but EU funding stopped in 2004, and started again in 2010.

Source: Commission decisions to fund eradication programmes, and to recognise officially free status, for the audited Member States.

#### **Cooperation with countries outside the EU**

#### 10

The OIE, the World Organisation for Animal Health, in its 2014 guidelines for animal disease control, highlights the importance of international cooperation and indicates that where possible, countries should act on a regional basis to harmonise disease control programmes. This is important as diseases can be carried across borders, particularly by wildlife. There is no provision in the regulations for the Commission to directly finance veterinary programmes outside the EU. However, Member States can agree veterinary actions (such as vaccination campaigns in a border strip) directly with neighbouring non-EU countries and include the related costs as sub-programmes of their veterinary programmes financed by the Commission.

Introduction 13

#### 11

Concerning the rabies programmes, in 2015 there were four sub-programmes performed in non-EU countries: Russia (part of the Finnish programme), Belarus (part of the Latvian and Lithuanian programmes) and Ukraine (part of the Polish programme since 2012). A further five were at the planning stage: Russia (part of the Estonian programme), Ukraine (part of the Hungarian programme), Moldavia (part of the Romanian programme), Bosnia and Herzegovina (part of the Croatian programme) and Belarus (part of the Polish programme). Given the complexity of the various bilateral relationships, ensuring sufficient cooperation for effective implementation of sub-programmes outside the EU can be a challenge.

6 Commission
Decision 2008/341/EC of
25 April 2008 laying down
Community criteria for
national programmes for the
eradication, control and
monitoring of certain animal
diseases and zoonoses
(OJ L 115, 29.4.2008, p. 44).

#### 12

The Commission has taken other measures to harmonise disease control programmes with non-EU countries. DG Neighbourhood and Enlargement Negotiations and DG Health and Food Safety launched an Instrument for Pre Accession project in 2011 to provide support for the control and eradication of animal diseases (e.g. rabies and classical swine fever) in seven beneficiary countries of the western Balkans: Albania, Bosnia and Herzegovina, Croatia, the Former Yugoslav Republic of Macedonia, Montenegro, Serbia and Kosovo. Approximately 100 million euros were available for the project.

#### Main roles and responsibilities

#### 13

The Commission (DG Health and Food Safety) manages the ADNS and coordinates emergency measures in the event of an outbreak of a contagious animal disease. The Commission implements veterinary programme expenditures under direct management. DG Health and Food Safety's Food and Veterinary Office (FVO) verifies that EU requirements for the safety and quality of food, and veterinary measures are being satisfied.

#### 14

A Commission Decision from 2008<sup>6</sup> sets out the criteria for Member State programmes in order to be approved for EU funding. It provides that in the Member States, the programmes shall be under the control of the central veterinary authority. Programmes should contain targets, with yearly interim targets if the programme is multiannual; and appropriate indicators (such as incidence and prevalence) should be established and reported on. The detailed implementation and management of the programmes, including any sharing of responsibilities between the public and private sector, is a Member State competence.

Introduction 14

#### 15

Member States may submit their proposals for programmes to the Commission by 31 May<sup>7</sup> of the previous year. These programmes can be set up as annual or multiannual programmes. The majority of programmes are annual.

#### 16

The Commission assesses the quality of Member States' proposed programmes using established criteria, and, when epidemically justified, encourages coordination between bordering Member States. Since 2013, the Commission has used expert assistance for this assessment process. The list of programmes is presented to the Member States at the Standing Committee on Plants, Animals, Food and Feed (PAFF). The Commission adjusts the funding allocation for different diseases and Member States each year based on its assessment of evolving needs. Any changes are discussed with the Member States through the PAFF. The Commission's assessment is based on data submitted by Member States, FVO reports, financial audit reports, and results of a specific Task Force composed of Member State experts. More details of the main responsibilities are set out in *Annex II*.

#### 17

A Commission Decision from 2008<sup>8</sup> defines standard reporting requirements, including templates and reporting schedules, to be used by the Member States for reporting to the Commission. During the implementation of the programmes the Member States send an intermediate report which is assessed by the Commission and may result in an amendment of the programme targets and costs, and a real-location of financial resources between programmes. Final reports and payment applications have to be submitted to the Commission by 30 April of the following year including the assessment of the results achieved and a detailed account of expenditure incurred.

- 7 Article 12 of Regulation (EU) No 652/2014.
- 8 Commission
  Decision 2008/940/EC of
  21 October 2008 laying down
  standard reporting
  requirements for national
  programmes for the
  eradication, control and
  monitoring of certain animal
  diseases and zoonoses
  co-financed by the
  Community (OJ L 335,
  13.12.2008, p. 61).

# Audit scope and approach

#### 18

The audit examined whether the animal disease eradication, control and monitoring programmes adequately contain animal diseases.

#### 19

The detailed questions were:

- (i) Did the Commission have an appropriate approach for the eradication, control and monitoring of animal diseases?
- (ii) Did Member States design and implement appropriate programmes to eradicate, control and monitor animal diseases?
- (iii) Did the programmes adequately consider cost-effectiveness?

#### 20

The audit work was performed at the Commission (DG Health and Food Safety) and in seven Member States (Ireland, Spain, France, Italy, Poland<sup>9</sup>, Romania and the United Kingdom), which together represent 72 % of total expenditure, and a variety of different diseases<sup>10</sup>. The views of the organisations of the main stakeholder groups (farmers, veterinary services and laboratories), and an expert panel organised by the Court, were also obtained.

#### 21

The audit examined the Commission's procedures used to define the strategy and to approve annual and multiannual national programmes submitted by the Member States. This included an examination of relevant opinions and communications from the Commission services (including the FVO), regulatory committees (PAFF, Task Force) agencies (EFSA), and expert reviews initiated by the Commission.

#### 22

In addition to the above programmes, the EU also funds emergency measures to deal with serious outbreaks of animal diseases. The audit did not examine these measures as expenditure represents around 10 % of expenditure on the eradication, control and monitoring programmes.

- 9 In Poland, the audit work was carried out jointly with the Polish Supreme Audit Office.
- 10 A total of 24 Member State programmes were examined for the following diseases:
  Bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis, transmissible spongiform encephalopathies, bluetongue, rabies, classical and African swine fever, avian influenza, and zoonotic salmonella. Background information on these diseases is included in *Annex I*.

The audit at Member State level examined national strategies for the eradication, control and monitoring of animal diseases, the criteria used by Member States to develop programmes, and how the programmes are implemented in practice. Member States' competent veterinary authorities, and relevant regional authorities, were visited. The audit included substantive testing in order to check if the funded actions were carried out as planned and costs were reasonable.

According to the OIE<sup>11</sup>, the desired goal of a disease control programme should be defined from the outset. While eradication has traditionally been the goal for many disease control programmes, this is not always achievable. Specific objectives and indicators leading to the success of the programme should be established. *Figure 3* presents steps for the establishment of a disease control programme.

11 OIE, 'Guidelines for Animal Disease Control', 2014.

## Figure 3

#### Steps for establishing a disease control programme



Source: OIE Guidelines for Animal Disease Control, 2014.

#### 25

Given the complex and heterogeneous situation concerning animal diseases in the EU, it is important that the Commission applies a sound framework for prioritising its funding efforts, coordinating Member State efforts, providing guidance and facilitating best practices. This should include appropriate reporting on performance.

## While the Commission's approach for the eradication, control and monitoring of animal diseases has generally been sound,

#### 26

The audit identified that the Commission's approach for the eradication, control and monitoring of zoonoses and other animal diseases was generally sound and was supported by appropriate technical advice and risk analysis to deal with evolving risks/outbreaks.

#### 27

The EU's animal health policy is well developed, with rules for identification, traceability, welfare, outbreaks and sanitary checks. This is also essential for facilitating trade. However, the current EU animal health legislative framework involves almost 50 basic directives and regulations and some 400 items of secondary legislation, some of them adopted as early as 1964. This complex legislative tapestry is scheduled to be consolidated and replaced by a new Animal Health Law<sup>12</sup>, for which a political agreement was reached in June 2015. From 2007, EU eradication, monitoring and control programmes were part of the EU Animal Health Strategy, which expired in 2013 and has not yet been replaced — pending the adoption of the new Animal Health Law.

#### 28

Overall, we considered the Commission's approach based on funding of priority eradication, control and monitoring programmes at Member State level reasonable. The framework for directing resources to animal disease programmes is based on annual assessments by the Commission of funding priorities (considering issues such as public health impact, production losses, and trade issues), which were discussed with Member State experts. The Commission also has a sound system for assessing the quality of the programmes proposed by Member States, which involves the use of comprehensive assessment criteria covering such aspects as the clarity of programme objectives and management, the historical evolution of the targeted disease, the scientific justification and the efficiency of proposed measures. The criteria for prioritising resources between diseases were not sufficiently developed for the audited programmes. However, with the adoption of an approach to multiannual work programmes for 2016-2017 and the related Commission guidance, this prioritisation is being gradually improved.

12 COM(2013) 260 final of 6 May 2013 'Proposal for a regulation of the European Parliament and of the Council on Animal Health'. The proposal covers terrestrial and aquatic animals and consists of requirements for disease prevention; disease awareness; biosecurity; traceability of animals; surveillance and disease control and eradication; and emergency measures. It foresees a review of the current identification rules for horses and others species for which specific requirements do not currently exist. It also plans for a coherent vaccination policy in the EU, with a framework for antigen, vaccine and diagnostics banks at EU level. On 1 June 2015, the European Parliament and the Council reached political agreement on this proposal.

#### 29

Animal diseases are not restricted by country borders. Disease can be spread by movements of both farmed and wild animals, as well as other vectors. Programmes would therefore be strengthened by good coordination between countries when epidemically justified. There is, however, no legal requirement for Member States to submit coordinated programmes, nor to work together in their implementation.

#### 30

We found that overall, the Commission provides appropriate guidance to, and facilitates coordination between Member States:

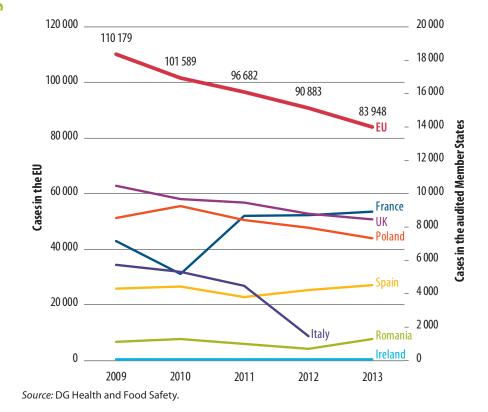
- There are regular contacts between the Commission and Member States at the Standing Committee on Plants, Animals, Food and Feed<sup>13</sup> and meetings of Member State Chief Veterinary Officers.
- Task Forces<sup>14</sup> bring together Member State experts in specific diseases and make recommendations to improve veterinary programmes.
- The Commission uses external experts to review proposed programmes on the basis of comprehensive assessment criteria.
- The Commission's Food and Veterinary Office performs audits in Member States.
- The Animal Disease Notification System enables disease outbreaks to be quickly notified.
- EU reference laboratories<sup>15</sup> work to standardise and improve methodologies.
- The Commission provides training courses<sup>16</sup> to Member State officials.
- From 2014, DG Health and Food Safety provided guidance on the use of a new online application, and the standard formats to be used by Member States, required by the regulations, ensure a certain harmonisation and quality.

- 13 At least one meeting of the Standing Committee on Plants, Animals, Food and Feed (PAFF Committee) is organised every month, where the Member States and the Commission discuss veterinary issues, including the outcome of the veterinary programmes.
- 14 A plenary meeting of the Task Force on the eradication of animal diseases is held once a year, where all the Member States are invited to participate; additional specific working groups on specific diseases are organised regularly and meet several times every year (e.g. sub-group on salmonella).
- 15 The mission of each EU reference laboratory is to standardise methodologies at EU level, to coordinate with Member States as regards diagnostic methods, to organise comparative trials, and to organise annual workshops for national reference laboratories where the experts of the Member States can network, update their knowledge and share information and best practices.
- 16 Better training for safer food (BTSF).

The existence of an EU co-financing framework provides added incentives for the Member States to eradicate animal diseases including zoonosis and there have been some notable successes. It has also led to a positive impact on the human health situation, with resulting cost savings. For example, EFSA estimated<sup>17</sup> in 2012 that the overall economic burden of human salmonellosis could be as high as 3 billion euros a year. In recent years the number of cases has decreased significantly, as shown in *Figure 4*. EFSA has concluded<sup>18</sup> that this reduction is mainly the result of successful Member State salmonella disease control programmes in fowl (*Gallus gallus*), which have reduced the occurrence of salmonella in eggs.

- 17 Source: EFSA factsheet on salmonella.
- 18 EFSA/ECDC EU summary report on zoonoses, zoonotic agents and food-borne outbreaks, 2012. The amount of 3 billion euros is the upper level of the estimate.

### **Zoonotic salmonella** — **Number of human cases in the EU and audited Member States**



#### 32

Another example is rabies where between 2005 and 2014, the total number of rabies cases at EU level has decreased very significantly from 3 708 cases to 305 in the EU-28.

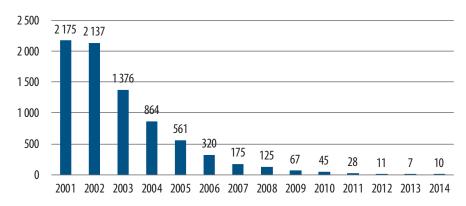
19 These are the animal tissues most at risk of harbouring the infectious agent, and include for example brains and the spinal cord. See *Annex I* for more details on BSE.

#### 33

The measures implemented by the Commission to eradicate BSE in the EU has been particularly successful. The number of BSE cases reduced from more than 2 000 cases in 2001, to 10 in 2014, as indicated in *Figure 5*. The main measures taken include the removal of Specified Risk Material<sup>19</sup> from feed and food chains; a ban on feeding mammalian meat and bone meal to cattle, sheep and goats; and the testing of millions of cattle each year. The frequent updates of legislation in the latest years and research funding have led to a more limited and better targeted testing for BSE. The Commission coordinates well at international level and in particular with the OIE, concerning the categorisation of Member States on the geographical BSE risk level. The programmes for the eradication of bovine tuberculosis also follow a long-term approach, with the trend of disease prevalence decreasing in most Member States. These two diseases represent approximately half of EU programme expenditure (see *Table 1*).

## Figure 5

#### Number of BSE cases in the EU



Source: DG Health and Food Safety.

## and Member State programmes were generally well designed and implemented,

#### 34

Member States are responsible for preparing their eradication, control and monitoring programmes, which address their specific priorities concerning animal diseases based on appropriate indicators. In most cases, Member States have years of experience in dealing with the different animal diseases. The Commission can request, but not force, Member States to propose programmes as well as to change their strategy. Furthermore, when an outbreak posing a risk of cross-border infection occurs, Member States are obliged to implement specific measures provided by the sectorial legislation, whether or not these measures are co-financed by the EU.

#### 35

Member State programmes must meet the minimum criteria established<sup>20</sup> by the Commission in order to be eligible for Community funding. These criteria require the programmes to contain information on, inter alia, objectives, duration, targets, indicators (e.g. disease incidence and prevalence), animal testing, vaccination, and administration. The complexity of the programmes is closely linked to the epidemiological characteristic of the disease concerned. Programmes can comprise a wide range of measures such as: a comprehensive surveillance regime, blood sampling, specific measures for identification of reactors<sup>21</sup>, post-mortem examination, laboratory analysis, compensation schemes for farmers, wildlife surveillance, and computerised systems for the testing and disease management.

#### 36

The Court found that Member States' programmes we examined are generally well designed and adapted to the epidemiological situation. Approved programmes complied with the required criteria, usually described well the measures to be taken, followed the Commission's standard templates, and generally led to positive results (see *Box 3*). The Member States have adequate systems in place to identify animal disease outbreaks in livestock and to facilitate their eradication. The EU TRAde Control and Expert System (Traces) for animal identification and movement control is well-developed and facilitates disease control.

- 20 Decision 2008/341/EC.
- 21 A reactor is an infected animal that responds positively to a test for the disease.

#### A good performance by a Member State programme

TSE programmes are implemented and co-funded by the EU in all Member States and received a large part of the EU funding for veterinary programmes during the audited period (see *Table 1*).

In Ireland, the programme received a total of 17 million euros from 2009 to 2014. While EU funds have been reduced from 4.7 million euros in 2010 to 0.8 million euros in 2014, good performance has been achieved, in particular due to:

- Active and passive surveillance systems aimed at detecting BSE cases.
- o If a case of the disease is identified, epidemiological investigations are carried out and cohort and progeny animals are slaughtered.
- Prohibition of feeding products of animal origin to farmed animals.

In 2014, there were no cases of BSE in Ireland. This compares with three cases in 2012 and 2011, and the peak of over 400 cases in the 1990s.

## the cost-effectiveness of the programmes is difficult to determine,

#### **37**

The Council Decision<sup>22</sup> on veterinary expenditure required the Commission to report to the European Parliament and the Council every 4 years, on the animal health situation and cost-effectiveness of the implementation of veterinary programmes.

#### 38

OIE<sup>23</sup> guidance provides that the decision on the most appropriate intervention options should take into account cost–benefit considerations as well as zoonotic potential and the likelihood of success of a particular set of disease control measures.

- 22 Article 41 Decision 2009/470/ EC.
- 23 OIE, 'Guidelines for animal disease control', May 2014.

#### 39

As indicated in *Table 1*, the yearly direct cost to the EU budget of veterinary programmes is of the order of 200 million euros per year. In addition to this, Member States spend a greater amount, to cover both their share of the costs of the funded programmes, and other veterinary action they have determined to be necessary. Furthermore farmers and the food sector bear costs linked to veterinary expenses, herd replacement, reduced production, animal movement restrictions, and lost markets. The potential benefits of programmes can be grouped in two main categories<sup>24</sup>:

- The improvement of both public and animal health: reducing disease prevalence/incidence; safeguarding public health (in the case of zoonosis); and fulfilling their role as a key disease prevention/management tool in the context of the EU Animal Health Strategy.
- Benefits in economic terms for the EU as whole: protecting the value of the sector; contributing to market stability; ensuring safe trade; increasing extra-EU trade; and reducing human health costs.

#### 40

In implementing the EU budget, the Commission has to follow the principles of sound financial management<sup>25</sup>, and funded actions should be economical, efficient and effective. This implies that the programme results should be justifiable related to their costs. The Court recognises that it is very difficult in practice to monetise the health benefits deriving from animal health policy, particularly for zoonoses, where the main benefit is the avoidance of human infection and in some cases the saving of lives.

### There is a lack of available models to assess the cost-effectiveness of eradication programmes

#### 41

The audit noted a lack of available models and economic indicators to allow the Commission to perform a cost-effectiveness analysis of proposed programmes, and consequently the Commission does not perform such an analysis. In its most recent report (2014) on the animal health situation and cost-effectiveness of veterinary programmes, which was required by the underlying Council Decision, the Commission provided information on costs and results. The Commission recognised in this report that there was a need to better demonstrate the cost-effectiveness of veterinary expenditure.

- 24 From conclusions of 2014 Report from the Commission to the European Parliament and the Council on the outcome of the EU co-financed programmes.
- 25 Article 30 of Regulation (EC, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002 (OJ L 298 of 26.10.2012, p. 1).

In practice, the information contained in the approved programmes and subsequent implementation reports provide detailed information on costs, and also indicators related to activities and performance. While most of the costs (sampling, labs analysis, salary of veterinarians, costs for compensation, etc.) and the qualitative benefit (public health, enhanced export opportunity, etc.) were indicated in programmes, there was a lack of available models and information to assess the cost-effectiveness of financed activities. For example, the EU reaction to the BSE crisis saved lives, contributed to better food safety, improved the quality of controls, and restored consumer confidence — but the cost-effectiveness of the programme cannot be assessed.

#### 43

We also examined whether there was evidence that the costs incurred by the audited programmes were reasonable. The audit noted certain cases, previously identified by the Commission, where some costs were unreasonably high, or not sufficiently controlled by Member States, as illustrated in **Box 4**. In these cases remedial action has been taken by the Commission.

#### Insufficiently controlled actions or high costs

- 1. In Poland, the vaccines used in the annual rabies eradication programmes were purchased at regional level. Between 2002 and 2009 the number of detected cases of rabies in the fox population reduced very significantly, from 884 to 6. However, in 2010 and 2011 the number of detected cases rose rapidly again, to 117 and 103 respectively. These were concentrated in the Małopolska and Podkarpackie regions. The average price of one of the vaccines purchased in Poland for use on wild foxes from 2011 to 2013 was significantly higher than the average price paid in the EU, although the volumes of vaccines supplied to Poland were also the highest in the EU (over 10 million doses each year). Given the economies of scale this does not appear logical. The Commission applied financial reductions and requested the Polish authorities to take action to reduce excessive vaccine prices, notably by organising a single national call for tenders.
- 2. In Romania, the national authorities did not correctly control the implementation of the contracts for the aerial distribution of rabies vaccines for use on wild foxes in 2013 and an insufficient number of vaccines were distributed. Furthermore, the national authorities did not take sufficient samples to test the effectiveness of the vaccination campaign (procedures were improved in 2014). As a consequence, the Commission did not reimburse the vaccination campaign.

Box 4

### In some cases amounts paid in compensation or payment reductions imposed had limited incentive effect

#### 44

The compensation payable to farmers for animals destroyed under disease eradication programmes is required by the legislation not to exceed the market value for healthy animals<sup>26</sup>. This aims at setting a fair compensation level; discouraging fraud; and encouraging the participation of farmers in the programme. However, the EU legislation does not specify how market prices should determine compensation payable; this is determined by Member States in the specific legislation. For example, there is no requirement for Member States to base compensation amounts on the Community scales for the classification of carcasses and their associated prices<sup>27</sup>. Overcompensation may discourage the effective implementation of biosecurity measures.

#### 45

In Italy, the levels of compensation paid for animals destroyed under veterinary programmes were sometimes higher than market prices for healthy animals. For example, in 2012, farmers received an average of 87 euros and up to 111 euros for each sheep destroyed under eradication programmes; but the average market price for carcasses from healthy slaughtered sheep at the time was less than 60 euros<sup>28</sup>. In cases where compensation exceeded the market price, the detection of animal diseases on a farm can be regarded as a windfall opportunity to restock the herd. Furthermore, farmers who might otherwise have valued a 'disease free' status may be discouraged from implementing effective biosecurity measures.

#### 46

In the UK, compensation payable for cattle in England is based on average market prices from the previous month. Compensation for cattle in Northern Ireland and Wales is based on individual valuations which generally lead to higher levels of compensation than in England, and which may discourage farmers from implementing effective biosecurity measures.

#### 47

Following an unfavourable assessment of the technical results of the bovine and ovine brucellosis eradication programmes in a region of Italy (Sicily), the Commission imposed payment reductions of over 7 million euros for the years 2005 to 2012. In 2011, the entire brucellosis programme in Sicily was declared ineligible because of non-performance of a vaccination plan. However, by applying the national system of allocation of resources between the regions, the Italian authorities did not pass on this level of reduction to the regional authorities in Sicily, but rather shared it across all Italian regions (the majority of which had implemented the eradication programme properly). Thus, there was a limited incentive for the authorities in Sicily to improve veterinary measures.

- 26 Article 11 of Regulation (EU) No 652/2014.
- 27 Commission Regulation (EC) No 1249/2008 of 10 December 2008 laying down detailed rules on the implementation of the Community scales for the classification of beef, pig and sheep carcases and the reporting of prices thereof (OJ L 337, 16.12.2008, p. 3).
- 28 European Commission (DG Agriculture and Rural Development, Statistics on agricultural markets 2014: http://ec.europa.eu/ agriculture/ markets-and-prices/ market-statistics/ index\_en.htm).

#### and there remains scope for improvement.

#### 48

The following paragraphs set out areas where we consider that there is scope for improvement to the Commission's approach and to the Member State programmes.

### Animal disease notification and exchange of related information

#### 49

Europe's Animal Disease Notification System (ADNS) is designed to notify standard information on disease outbreaks. It was not designed to have epidemiological management features or to provide historical information and analyse data. It therefore provides little added value when compared with the OIE's World Animal Health Information System (WAHIS), which all Member States are required to use. These two systems both provide information about the number and location of new outbreaks, but there is no interface between them allowing for an automatic exchange of information. In order to better manage animal health threats, Member States have developed their own information systems dealing with epidemiological data. There is, however, not a common system to facilitate the exchange of information and a better coordination of control activities between Member States.

#### **50**

Since 2012, a joint project between the Commission and OIE has worked on linking the ADNS and WAHIS systems with a common interface called Animal Disease Information System (ADIS)<sup>29</sup>.

29 Report on the analysis of ADNS (version 1.4) in the framework of the development of the informatics prototype of an Animal Disease Information System (ADIS) for the European Union aligned with the OIE-WAHIS/WAHID interface: 'For more in depth analysis, reference data such as the number of holdings and animals present in a region are lacking. For more in depth spatial and temporal analysis, additional data, such as the location of all epidemiological units present would be necessary. In order to be more relevant tool for disease management or as a decision tool, additional information would be necessary on disease management measures ... The list of 'Species' values in ADNS contains the major farming animal species and only the generic denomination 'wild species'. It seems reasonable to extend the request for data on the method of diagnosis to all diseases ...'

#### Performance and management information

#### 51

A Commission Decision from 2008<sup>30</sup> sets programme output indicators, which Member States are obliged to report on. In addition, the Commission established a methodology to set performance indicators, which requires Member States to improve their performance in terms of disease prevalence/incidence by a minimum percentage over a specified period. Furthermore, the Commission developed an extensive set of indicators<sup>31</sup> (over 100) which Member States should use. These include output or activity-related indicators, such as the number of animals vaccinated and tests carried out; and also indicators linked to results such as changes in rates of incidence or prevalence. While recognising that there is already an extensive set of indicators, we consider that there is some scope for further improvement, particularly relating to the technical implementation of the programmes<sup>32</sup>. No economic indicators are included that would allow an analysis of the cost-effectiveness of proposed programmes (see paragraphs 41 and 42).

#### **52**

The Commission requires Member States to follow a standard template when drafting their veterinary programmes. This includes information on the evolution of the disease in recent years. In addition one of the criteria used by the Commission (see paragraph 28) to assess draft programmes concerns the quality of the data on disease evolution over the last 5 years. We noted that while such historical data was available in most cases, for three of the 24 Member State programmes concerned by the audit, the Commission's independent evaluators identified that recent draft programmes did not contain enough satisfactory historical information<sup>33</sup>. In these cases, the relevant information was requested by the Commission and provided by the Member States concerned. At the time of the audit the Commission was developing an information system to allow the ready retrieval and analysis of historical information from previous Member State programmes, and introduced a standard electronic reporting system for Member States to send key documents<sup>34</sup> relating to their veterinary programmes<sup>35</sup>. These developments should facilitate the future analysis of programmes.

- 30 Commission
  Decision 2008/940/EC,
  replaced by Commission
  Implementing
  Decision 2014/288/EU of
  12 May 2014 as regards the
  standard reporting
  requirements for national
  programmes for the
  eradication, control and
  monitoring of certain animal
  diseases and zoonoses
  co-financed by the Union and
  repealing Decision 2008/940/
  EC (OJ L 147, 17.5.2014, p. 88).
- 31 Commission document WD SANCO/12915/2012.
- 32 For example, time intervals between testing, the proportion of outbreaks where the source of the infection was identified; for brucellosis, tracking of herds without a herd test, percentage of vaccinated animals within farms and proportion of vaccinated farms; indicators related to training, cost and capacity of veterinary services; for ovine and caprine brucellosis, genotyping results of the strain of brucella.
- 33 This was the case for the proposed UK bovine tuberculosis programme 2015; the proposed Spanish bluetongue programme 2015, and the proposed Italian bluetongue programme 2014.
- 34 Notably draft programmes, intermediate reports, final reports and payment requests.
- 35 Commission Implementing Decision 2014/288/EU.

#### Presentation of veterinary controls in programmes

#### 53

Overall most programmes justified the measures to be taken and the results to be achieved. However, we consider that veterinary measures would benefit from being better described in some programmes as well as the actions taken following FVO recommendations and Task Force advice. In two of the 24 Member State programmes concerned by the audit, the Commission's independent evaluators made similar remarks<sup>36</sup>.

#### Programmes where progress is slow

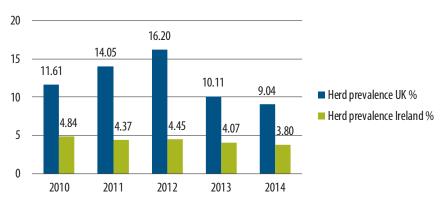
#### 54

The eradication programmes for some diseases in certain Member States last decades (see paragraph 9). While decreasing, the prevalence of bovine tuberculosis in the UK and Ireland is still relatively high (see *Figure 6*) compared to other Member States<sup>37</sup>. In the UK, an increase since 2013 of the tuberculosis testing frequency in low incidence areas from once every 4 years to once a year has led to a higher detection of cases. However, there are still significant challenges inherent to the tuberculosis eradication programme in the UK, with a very high incidence in some regions.

- 36 Italy bluetongue programme for 2014; Ireland bovine tuberculosis 2014.
- 37 In 2014, the herd prevalence of bovine tuberculosis in the UK, Ireland, Spain and Italy was 9.04 %, 3.8 %, 1.72 % and 0.81 % respectively. France and Poland are officially free of the disease, and prevalence in Romania is insignificant.

## Figure 6

#### **Bovine tuberculosis in Ireland and UK**



Source: DG Health and Food Safety.

#### **55**

In Italy, ovine and caprine brucellosis are difficult to eradicate due to a lack of full cooperation from farmers in some regions. The generous compensation scheme (see paragraph 45) may also be a factor. However, prevalence at national level is falling, and had reached 1.2 % in 2014, compared with 3.7 % in 2008. Over the same period, prevalence in Sicily decreased from 11.9 % to 3.4 %.

#### 56

We note that the Commission, in its 2014 report<sup>38</sup> to Parliament and Council on the outcome of EU co-financed veterinary programmes, also noted that the results achieved by the UK bovine tuberculosis programme and the Italian brucellosis programmes were a cause of concern. The Court also recognises that the Commission encourages Member States to take action in such cases through the follow up of recommendations made by the Task Force and the FVO.

#### The approach to treating wildlife

#### **57**

Direct or indirect contacts between wildlife and domesticated animals can lead to the spread of disease, or complicate the effective implementation of animal disease programmes. For example, rabies can be spread from wild foxes, and bovine tuberculosis can be spread by badgers, boar and deer. There are several OIE publications<sup>39</sup> on the monitoring of wildlife diseases, as well as a related international agreement on disease notification. While the purchase of rabies vaccines for wildlife is included in Member State programmes, the EU does not have a specific approach to combat tuberculosis in wildlife.

#### 58

There are no legislative provisions at EU level for tuberculosis eradication in animal species other than cattle (e.g. wild goats, and other wildlife). In particular, in the UK, badgers are protected by national legislation which may complicate the effective implementation of the bovine tuberculosis eradication programme.

- 38 COM(2014) 115 final of 5 March 2014 'Report from the Commission to the European Parliament and the Council on the outcome of the EU co-financed programmes for the eradication, control and monitoring of animal diseases and zoonosis over the period of 2005-2011', section 3.3.
- 39 OIE, 'Training manual on wildlife diseases and surveillance', 2010.

#### The availability of certain vaccines

#### **59**

According to the OIE<sup>40</sup>, the ready availability of suitable veterinary vaccines and antigens is essential for animal health programmes<sup>41</sup>. There are a number of EU initiatives and research projects aimed at detecting emerging viruses and promoting the availability of vaccines<sup>42</sup>. Depending on the disease, there may be very few, if any, suitable vaccines available for use in the EU. However, vaccination is one of the essential tools available to implement an effective 'prevention is better than cure' approach. The reasons why vaccines are not always available are complex. Recent research has tended to show that<sup>43</sup> besides the technical difficulties in their development, there is insufficient financial interest for the pharmaceutical industry to seek authorisation to use certain vaccines in the EU. **Box 5** illustrates some practical difficulties caused by a lack of suitable vaccines.

- 40 OIE, 'Manual of diagnostic tests and vaccines for terrestrial animals', 2014.
- 41 OIE, 'Guidelines for animal disease control', May 2014.
- 42 For example, the EU's research funds have supported projects for the development of vaccines against tuberculosis (NEWTBVAC), brucellosis (BRU-VAC) and classical swine fever (CSFV-GODIVA).
- 43 Videnova, K. and Mackay, D.K.J., 'Availability of vaccines against major animal diseases in the European Union'.

#### 60

At European level, there is no legal framework for the joint procurement of vaccines, nor a general bank of vaccine stocks. The process to purchase vaccines following a call for tenders by Member States can take several months, and in the meantime the virus may continue to spread into the animal population. We noted that the new Animal Health Law currently under discussion by the legislative authorities would widen the Commission's capacity to establish vaccine banks.

## Box 5

#### Difficulties caused by a lack of suitable vaccines

There are over 20 variants (serotypes) of the bluetongue virus (an insect-borne, viral disease of ruminants).

In Italy, six variants have been identified. No polyvalent vaccines (effective against several strains of the virus) are currently recognised in the EU. It is therefore difficult in such cases to envisage the use of vaccines.

In France, during the bluetongue crisis of 2008, there were limited stocks of the vaccine. The French authorities therefore had to procure extra supplies urgently. This was both expensive and time consuming, and the national authorities considered that the 520 cases of bluetongue detected in Ile et Villaine may have been avoided if vaccines had been available sooner.

At the time of the first bluetongue outbreak serotype S4 in Spain (Extremadura region), not enough vaccine against this serotype was available. Hence, the vaccination campaign was postponed to the following year in order to restrain the disease during the next possible viral propagation period.

# Conclusions and recommendations

#### 61

Animal diseases cause significant economic costs and are a risk to both animal and human health. Diseases can spread across borders, and previous disease outbreaks have cost billions of euros. The EU therefore aims to protect animal health and funds Member States' programmes to eradicate, control and monitor specific animal diseases. These programmes cover actions such as sampling, laboratory analysis, compensation payments for destroyed animals, and vaccination campaigns. EU expenditure has been decreasing in recent years, and no major crisis comparable to the foot and mouth disease outbreak of 2001 has occurred recently. However, the EU needs to be prepared to deal with future crises, and it can take many years for eradication programmes to result in a disease-free status.

#### 62

The audit examined whether the animal disease eradication, control and monitoring programmes adequately contain animal diseases. This involved examining whether the Commission's approach was appropriate; whether Member States designed and implemented appropriate programmes, and whether the cost-effectiveness of programmes was adequately considered.

#### 63

Overall the Court concluded that the animal disease programmes we examined adequately contained animal diseases. However, as disease outbreaks can always occur the Commission and the Member States should continue to be vigilant.

#### 64

The Commission's strategy for the animal disease programmes was generally sound: Commission actions were supported by good technical advice; there was a well-developed policy for animal health; and there was an established framework for prioritising budget resources on priority programmes. The approach taken to eradicate BSE has been particularly successful. Other good examples are the reduction in cases of zoonotic salmonella and rabies. The underlying legislation remained complex, and the prioritisation of funding between diseases was being gradually improved (paragraphs 26 to 33).

#### 65

We found that Member States programmes were generally well designed and implemented. Programmes met the required criteria, and Member States had adequate systems to identify animal disease outbreaks and facilitate their eradication (paragraphs 34 to 36).

We found that while the Commission was required to report on the cost-effectiveness of veterinary programmes to the European Parliament and Council, there is a lack of suitable models to do so. Approved programmes and subsequent implementation reports provide information on costs and results, but the cost-effectiveness of programmes is difficult to determine (paragraphs 37 to 42).

#### 67

Concerning costs, the audit noted examples of insufficiently controlled or unreasonably high costs, which were previously identified by the Commission. In some cases in Italy, the amounts paid in compensation to farmers, or the payment reduction imposed by the Commission, had a limited incentive effect to encourage effective biosecurity measures and the implementation of corrective measures (paragraphs 43 to 47).

#### 68

We identified some specific areas with scope for improvement. The exchange of epidemiological information between Member States could be better supported by information systems (paragraphs 49 and 50).

#### **69**

The Commission established a detailed set of minimum programme output indicators to be used by the Member States. We found that the information relating to veterinary measures, as well as follow-up action to earlier recommendations by the FVO and Task Force could be better described in some Member State programmes. At the time of the audit, there was not always sufficient readily available historical information on the evolution of diseases. However, a database to record technical programme indicators was being developed, and the Commission had introduced a new electronic reporting system (paragraphs 51 to 53).

#### **70**

We noted some programmes where progress was slow: notably the eradication of bovine tuberculosis in the UK and Ireland, and ovine and caprine brucellosis in the south of Italy (paragraphs 54 to 56).

Wildlife can spread disease in domestic animals (and indeed people) and therefore needs to be considered when developing an approach to animal health and the funding of animal disease programmes. We found that the EU approach for considering diseases in wildlife should be complemented, notably for tuberculosis (paragraphs 57 and 58).

#### **72**

Vaccines are a key tool for certain eradication programmes. The Court noted that depending on the disease, there may be few, if any, suitable vaccines. In particular, we found that the lack of vaccines to treat bluetongue adversely affected programmes in Italy, France and Spain. Furthermore, at the time of the audit, there was no legal framework for the joint procurement of vaccines, nor a general bank of vaccine stocks at European level (paragraphs 59 and 60).

#### Recommendations

In order to further improve the eradication, control and monitoring of animal diseases, the Commission should:

- (a) facilitate the exchange of epidemiological information between Member States;
- (b) examine whether the existing set of indicators should be updated to provide better information on veterinary control activities and the cost-effectiveness of programmes;
- (c) systematically include, when relevant, the wildlife aspect in the veterinary programmes;
- (d) support the availability of vaccines for use by the Member States when epidemically justified.

This report was adopted by Chamber I, headed by Mr Augustyn KUBIK, Member of the Court of Auditors, in Luxembourg at its meeting of 3 February 2016.

For the Court of Auditors

vica.

Vítor Manuel da SILVA CALDEIRA

President

# **Animal disease information**

	What is it?	How does it spread?	What is the public health risk?	What are the clinical signs?	How is it diagnosed?	How can it be prevented or controlled?
Avian influenza	Avian influenza (AI), caused by the influenza virus Type'A', can affect several species of food producing birds (chickens, turkeys, quails, guinea fowl, etc.), as well as pet birds and wild birds with some strains resulting in high mortality rates. The virus has also been isolated from mammalian species including humans, rats and mice, weasels and ferrets, pigs, cats, tigers and dogs.	Several factors can contribute to the spread of Al viruses including globalisation and international trade (legally and illegally), marketing practices (live bird markets), farming practices and the presence of the viruses in wild birds. Al viruses can be spread through direct contact with secretions from infected birds, especially faeces or through contaminated feed, water, equipment and clothing.	While Al is primarily a bird disease, it can cross from birds to humans. Al viruses are highly species-specific, but have, on rare occasions, crossed the species barrier to infect humans. Transmission to humans has occurred when there is close contact with infected birds or heavily contaminated environments.	In the mild form, signs of illness may be expressed only as ruffled feathers, reduced egg production, or mild effects on the respiratory system. In the severe form of the disease, the virus not only affects the respiratory tract, as in the mild form, but also invades multiple organs and tissues that can result in massive internal haemorrhaging.	Al may be suspected on the basis of clinical signs and events leading to the disease. Laboratory tests are required to confirm the diagnosis.	Around the world, surveillance measures have been put in place to detect the presence of infection in poultry according to OIE standards for the surveillance of AI.
African swine fever	African swine fever (ASF) is a highly contagious haemorrhagic disease of pigs, warthogs, European wild boar and American wild pigs. All age groups are equally susceptible. With high virulence forms of the virus, ASF is characterised by high fever, loss of appetite, haemorrhages in the skin and internal organs, and death in 2-10 days on average. Mortality rates may be as high as 100 %.	The warthog can serve as a natural reservoir of the virus without sign of disease. Spread from this reservoir is via the soft tick Ornithodoros moubata. The tick will ingest the virus when taking a blood meal and then pass it on when feeding on susceptible animals. Biting flies and ticks, contaminated premises, vehicles, equipment or clothing can also spread the virus to susceptible animals.	ASF is not a human health threat.	The severity and distribution of the lesions also vary according to virulence of the virus. Severe cases of the disease are characterised by high fever and death in 2-10 days on average. The mortality rate can be as high as 100 %. Other clinical signs may include loss of appetite, depression, redness of the skin of the ears, abdomen, and legs, respiratory distress, vomiting, bleeding from the nose or rectum and sometimes diarrhoea. Abortion may be the first event seen in an outbreak.	ASF may be suspected based on clinical signs and confirmation must be made through prescribed laboratory tests, particularly to differentiate this disease from classical swine fever (CSF).	There is no published treatment or vaccine for ASF. All successful eradication programmes have involved the rapid diagnosis, slaughter and disposal of all animals on infected premises, thorough cleaning and disinfection, movement controls and surveillance.

What are the clinical How is it How can it be prevented or signs? diagnosed?	The disease is signs until she aborts.  There may be such as abortions, but confirmation is borrioms, infertility, isidne and through services in the importance of with prescribed to abortions, infertility.
What is the public What are the health risk?	Brucellosis is a zoonosis highly infectious for humans causing a disease often called undulant fever or Malta fever. Symptoms in humans include intermittent or irregular fever, headache, weakness, of the testicles in mal profuse sweating, and occasionally the including the liver and spleen may also occur. Veterinarians, farmers, and abattoir workers are vulneretention of placenta, able to infection as stillbirth or birth of under the infection as stillbirth or birth of under the infection as stillbirth or birth of under the infection as a stillbirth or birth of under the infection as stillbirth or birth of birth of under the infection as stillbirth or birth of
How does it spread?	Brucellosis is a zoonosis highly infectious for human causing a disease when the animal aborts or materia are found in the bacteria are found in the emironment for several animal in emist, particularly in colomost to other animals which become infected by ingesting the bacteria. The bacteria also colonise the udder and contaminate the milk. Brucellosis is an important disease in wildlife, they handle infected infecting feral pigs, bison,
What is it?	Brucellosis is a contagious disease of livestochwith significant be conomic impact. The disease is caused by a various bacteria of the family brucella, which tend to infect a specific animal species. The however, most species of brucella are able to brinfect other animal process as well. It affects the cattle, swine, sheep and the goats, camels, equines, in infect other ruminants.
	Brucellosis

	What is it?	How does it spread?	What is the public health risk?	What are the clinical signs?	How is it diagnosed?	How can it be prevented or controlled?
Bluetongue	Bluetongue (BT) is a non-contagious, viral disease affecting domestic and wild ruminants (primarily sheep and including cattle, goats, buffalo, antelope, deer, elk and camels) that is transmitted by insects, particularly biting midges of the Culicoides species. The virus which causes BT is identified as a member of the Reoviridae family. Twenty-four (24) different serotypes have been identified and the ability of each strain to cause disease varies considerably. In highly susceptible sheep, morbidity can be as high as 100 %.	The insect vector is the key to transmission of BT virus between animals. Vectors are infected with BT virus after ingesting blood from infected animals. Without the vector, the disease cannot spread from animal to animal.	There is no public health risk associated with BT.	In infected sheep, clinical signs vary and can include fever, haemorrhages and ulcerations of the oral and nasal tissue; profuse diarrhoea, vomiting, pneumonia; 'blue' tongue as a result of cyanosis (rare); pregnant ewes may abort.	BT may be suspected based on typical clinical signs, prevalence of required insect vectors and particularly in areas where the disease is endemic. Laboratory tests are required to confirm the diagnosis.	In endemic areas, sentinel monitoring programmes actively sample animals in sentinel herds to monitor for presence of the virus. Vaccination is used as the most effective and practical measure to minimise losses related to the disease and to potentially interrupt the cycle from infected animal to vector. It is essential to use a vaccine designed to provide protection against the specific strain (or strains) of virus of concern in a particular area.
Bovine tuberculosis	Bovine tuberculosis (TB) is a chronic disease of animals caused by a bacteria called Mycobacterium bovis, (M. bovis) which is close- ly related to the bacteria that cause human and avian tuberculosis. This disease can affect practically all mammals, causing a general state of illness, coughing and eventual death.	The disease is contagious and spread by contact with infected domestic and wild animals. The usual route of infection is by inhaling infected droplets which are expelled from the lungs by coughing. Calves and humans can also become infected by ingesting raw milk from infected cows.	Humans can be infected both by drinking raw milk from infected cattle, or by inhaling infective droplets. It is estimated in some countries that up to 10 percent of human tuberculosis is due to bovine TB.	TB usually has a prolonged course, and symptoms take months or years to appear. The usual clinical signs include: weakness, loss of appetite, weight-loss, fluctuating fever, intermittent hackling cough, diarrhoea, large prominent lymph nodes.	The standard method for detection of TB is the tuberculin test, where a small amount of antipen is injected into the skin, and the immune reaction is measured. Definitive diagnosis is made by growing the bacteria in the laboratory, a process that takes at least 8 weeks.	The standard control measure applied to TB is test and slaughter. Disease eradication programmes consisting of post mortem meat inspection, intensive surveillance including on-farm visits, systematic individual testing of cattle and removal of infected and incontact animals as well as movement controls have been very successful in reducing or eliminating the disease. Pasteurisation of milk of infected animals to a temperature sufficient to kill the bacteria has prevented the spread of disease in humans.

How can it be prevented or controlled?	largeted surveillance of occurrences of clinical neurological disease; transparency in reporting findings of BSE; safeguards on importation of live ruminant species and their products, in accordance with the OIE Terrestrial Code; removal of specified risk material (SRM) (brain, spinal column) during slaughter and processing of carcasses; prohibit the inclusion of SRM in animal feeds, thus removing potentially contaminated material from the food chain; humane destruction of all suspected and susceptible animals exposed to contaminated feed; appropriate disposal of carcasses and all animal products; livestock identification to enable effective surveillance and tracing of suspected livestock.
How can it b	Targeted surveillance of occurrences of clinical neur logical disease; transparent in reporting findings of BSE safeguards on importation of live ruminant species an their products, in accordan with the OIE Terrestrial Cod removal of specified risk material (SRM) (brain, spin. column) during slaughter and processing of carcasses prohibit the inclusion of SR in animal feeds, thus removing potentially contaminat material from the food chal humane destruction of all suspected and susceptible animals exposed to contaminated feed; appropriat disposal of carcasses and al animal products; livestock identification to enable efficient surveillance and tracin of suspected livestock.
How is it diagnosed?	BSE may be suspected based on clinical signs. Diagnosis can only be confirmed by microscopic examination of brain tissues.
What are the clinical signs?	Since the average time between an animal's infection with the prion and the onset of clinical signs normally ranges from 4 to 5 years, clinical signs of BSE are found in adult animals. Symptoms may last for a period of 2 to 6 months before the animal dies.
What is the public health risk?	There are indications that variant Creutzfeldt-Jakob disease in humans could be caused by the consumption of beef products contaminated by infected nervous tissue or medical devices manufactured from infected animal tissues.  Milk and milk products are considered safe.
How does it spread?	Scientists believe that the spread of this disease in cattle is caused by feeding rendered material from infected cattle. The prion is resistant to commercial inactivation procedures such as heat, which means that it may not be completely destroyed in the rendering process.
What is it?	BSE is a progressive, fatal disease of the nervous system of cattle. The disease has a long incubation period of 4 to 5 years and there is currently no treatment or vaccine for the disease. BSE is one of a group of diseases known as transmissible spongiform encephalopathy (TSE). Other TSEs include scrapie in sheep, chronic wasting disease (CWD) in deer and elk, and Creutzfeldt-Jakob disease in humans. BSE, like other TSEs, is characterised by the presence of an abnormal infectious protein called a prion in nervous tissue. The subsequent spongy degeneration of the brain results in severe and fatal
	Bovine spongiform encephalopa- thy (BSE)

	What is it?	How does it spread?	What is the public health risk?	What are the clinical signs?	How is it diagnosed?	How can it be prevented or controlled?
Classical swine Fever	Classical swine fever (CSF), also known as hog cholera, is a contagious viral disease of domestic and wild swine. It is caused by a virus of the genus Pestivirus of the family Flaviviridae, which is closely related to the viruses that cause bovine viral diarrhoea in cattle and border disease in sheep. There is only one serotype of CSF virus (CSFV).	The most common method of transmission is through direct contact between healthy swine and those infected with CSF virus. The virus is shed in saliva, nasal secretions, urine, and faces. Contact with contaminated vehicles, pens, feed, or clothing may spread the disease. Animals that are chronic carriers of the disease (persistently infected) may show no clinical signs of illness but may shed the virus in their feces. Offspring of infected sows can become infected in the uterus, and can shed the virus for months. It has been proven that in parts of Europe, the wild boar population may play a role in the epidemiology of the disease.	Humans are not affected by this virus. Swine are the only species known to be susceptible.	In the acute form of the disease, in all age groups, there is fever, huddling of sick animals, loss of appetite, dullness, weakness, conjunctivitis, constipation followed by diarrhoea, and an unsteady gait. Several days after the onset of clinical signs, the ears, abdomen and inner thighs may show a purple discoloration. Animals with acute disease die within 1-2 weeks. Severe cases of the disease appear very similar to African swine fever.	Because the clinical signs are not exclusive to CSF, and vary widely, laboratory tests are required to detect antibodies or the virus itself.	Treatment is not attempted. In areas where the disease is endemic, vaccination can prevent the spread of the disease. As the disease is brought under control, vaccination ceases, with continued surveillance. In disease—free areas, a stamping out policy is applied consisting of early detection, movement control, proper disposal of carcasses, and cleaning and disinfection. This policy has led to the elimination of CSF from North America, and much of western Europe.

How can it be prevented or controlled?	In countries where the disease is endemic, measures are implemented to address and reduce the risk of infection in susceptible populations (wildlife, stray and domestic animals) and create a buffer between the animal source of the disease and humans: Vaccination programmes for domestic animals, wildlife rabies control programmes including vaccination (trap/vaccinate/release or delivery of oral vaccines).
How can it	In countries whe is endemic, mea implemented to reduce the risk conscipling to wildlife, stray a animals) and crebetween the an of the disease an Vaccination progenestic anima rabies control princluding vaccin vaccinate/releas of oral vaccines)
How is it diagnosed?	The disease may be suspected based on clinical signs, however, laboratory tests are required to confirm the diagnosis. Samples diagnosis. Samples sent to competent laboratories for diagnosis.
What are the clinical signs?	Clinical signs of rabies in animals will vary depending on the effect of the virus on the brain. Typical signs include sudden behavioural changes and progressive paralysis leading to death. In some cases, however, an animal may die rapidly without demonstrating significant clinical signs. In humans, early signs. can include fever or headache. As the disease progresses, symptoms may include confusion, depression, sleepiness, agitation or paralysis of the face, throat and neck. Death generally results from progressive paralysis.
What is the public health risk?	Rabies is regarded as one of the most important zoonotic diseases in the world (a disease which primarily affects animals, but can cause disease in humans).  Any encounter with a domestic or wild animal where a bite is received must be investigated. Rabid wild animals lose their natural fear of humans, increasing the risk of encounter. Clinical signs in animals such as excessive salivation, choking or gagging can lead humans to unknowingly risk infection while examining inside the mouth of dogs and livestock searching for a foreign body or attempting to administer medication with bare hands. It is important to immediately wash any bite wound or exposed surface with soap and water and report the incident to a doctor or hospital emergency department.
How does it spread?	Rabies is transmitted through the saliva of an infected animal. Infection occurs primarily via bite wounds, or infected saliva entering an open cut or wound or mucous membrane, such as those in the mouth, nasal cavity or eyes. Infection through inhalation of the virus has been documented, for example, in the environment of a densely populated bat cave. The virus has been documently site for a period of time before travelling along the nerves to the brain. In the brain, the virus multiplies quickly, resulting in clinical signs. The virus then moves from the brain along nerves to the salivary glands. The period of time before clinical signs appear in an infected animal can vary depending on the strain of virus and entry point. It is thus important to realise that the disease can be transmitted via the saliva of an infected animal to other animals and humans before the onset of clinical signs of the disease in the infected animal.
What is it?	Rabies is a viral disease that affects the central nervous system of warm-blooded animals, including humans. The disease has a long incubation period (6 months) and symptoms may take several weeks to appear affer infection. However, once symptoms appear, rabies is always fatal in animals.
	Rabies

	What is it?	How does it spread?	What is the public health risk?	What are the clinical signs?	How is it diagnosed?	How can it be prevented or controlled?
Salmonella	Salmonella is a bacterium that can cause an illness called salmonel- losis in humans. Salmonella is commonly found in the intestines of healthy birds and mammals. In foods, it is most frequently found lineggs and raw meat from pigs, turkeys and chickens.	It can spread to humans through contaminated foods. Safe handling of raw meat and other raw food ingredients, thorough cooking and good kitchen hygiene can prevent or reduce the risk posed by contaminated food.	Salmonellosis is a zoonosis: a disease or infection that can be transmitted directly or indirectly between animals and humans. If it infects the bloodstream it can be life-threatening.	The usual symptoms of human salmonellosis include fever, diarrhoea and abdominal cramps. The symptoms of salmonella in fowl include ruffled feathers, thirst, reluctance to move, and yellow diarrhoea.	The disease in fowl may be suspected based on clinical signs, however laboratory tests are required to confirm the diagnosis.	A coordinated approach by all EU actors on zoonotic diseases have helped reduce human cases of salmonellosis in the EU by almost one half over 5 years (2004-2009). In 2003, the EU set up an extended control programme for zoonoses, considering Salmonella as a priority. Enhanced salmonella control programmes in poultry were implemented in all EU Member States. Targets were set for the reduction of salmonella in poultry flocks (e.g. laying hens, broilers, turkeys) and pigs. Restrictions were also imposed on the trade of products from infected flocks.

Source: OIE and EFSA.

## **Main responsibilities**

## 01

The Commission (DG Health and Food Safety) is responsible for coordinating, assessing and approving Member States' draft national programmes and providing the financial support for them under direct management. The responsible directorate for veterinary measures is Directorate G — Veterinary and International affairs.

# 02

A Task Force, operating since 2000, provides expert guidance for disease eradication to the Member States. It is composed of representatives from Member States and the Commission, and has subgroups for the main animal diseases. The Task Force and its subgroups provide an opportunity to share best practice between Member State experts and the Commission. Following subgroup meetings, the Task Force makes specific recommendations to improve Member State programmes. The Task Force meets in plenary session each year.

# 03

DG Health and Food Safety manages the Animal Disease Notification System ('ADNS') and coordinates emergency measures in the event of an outbreak of a contagious animal disease. In addition, DG Health and Food Safety manages the 'Traces' system which notifies, certifies and monitors imports, exports and intra-EU cross-border trade in animals and certain animal products.

# 04

The ADNS is an electronic notification system designed to register and document the evolution of the situation of important infectious animal diseases. It aims to ensure the immediate notification of 'alert' messages as well as detailed information about outbreaks of animal diseases in Member States and other countries that are connected to the system. Data is input at country level. The Commission correlates data and transmits the information on primary and secondary outbreaks to the veterinary authorities of the Member States on a daily basis. This enables the veterinary authorities in Member States to assess risks and take necessary actions.

# 05

The FVO is Directorate F of DG Health and Food Safety. Its main task is to verify that the requirements of Community legislation on the safety and quality of food, veterinary and phytosanitary products are being satisfied. It performs audits in the 28 Member States and in third countries exporting or seeking to export to the EU. It is composed of veterinary professionals, and its inspection/audit tasks are part of an annual work programme that is drawn up on the basis of risk analysis. Its work includes systems evaluations and substantive testing. Each audit results in a report that contains conclusions and recommendations. Auditees are invited to submit an action plan covering all findings of deficiencies. The implementation of this plan is evaluated and monitored. The FVO publishes its audit reports and a summary annual report on DG Health and Food Safety's website.

# 06

Member States carry out the actual administration and implementation of the programmes through the relevant national authority. In case of federal or decentralised states, the implementation may be devolved to local level (e.g. in Great Britain responsibility is at county level; in Germany responsibility lies with the *Länder*). A single application for reimbursement and the final report are presented by each Member State to the Commission.

# 07

Member States are responsible for the management of their programmes, and the Commission is formally informed of actions taken in the annual report and cost claim.

# 08

The PAFF is composed of representatives from EU governments. The Committee's mandate covers general animal health risks and the entire food supply chain from the farm to fork. It is chaired by a European Commission representative. The Commission may consult the relevant committee on measures it is planning to adopt. The Committee can then deliver an opinion on the Commission's work.

# 09

EFSA is responsible for evaluating food safety risks and notifying them to the Commission. It is not responsible for risk management. It works closely with national authorities and provides scientific advice on matters linked to food safety. Its scientific advice is an important source of information about risks and an essential element in designing the Commission's approach to risk management. In terms of animal diseases it is mainly involved in the scientific studies of the disease eradication. Furthermore, it might be consulted in case of emergency measures during a serious outbreak.

# 10

Other organisations, notably the ECDC, the OIE and the Codex Alimentarius Commission (CAC), set up by the Food and Agriculture Organisation of the United Nations (FAO) and the World Health Organisation (WHO) assess matters related to human and animal health.

# **Executive summary**

#### VII

The Commission wishes to point to the vast amount of evidence of the overall cost–benefit of veterinary programmes, for example, the avoidance of human infection and in some cases the saving of lives. No models are available, not even at international level, to analyse cost-effectiveness of the programmes due to their specific nature.

The Commission agrees that overcompensation by a Member State might limit the incentive to apply effective biosecurity measures. However, the Commission does not consider that there is evidence that such cases actually occurred extensively.

As regards the payment reduction imposed by the Commission, the Commission wishes to clarify that it falls solely under the competence of the Member State to share, according to the national rules, the financial penalties applied by the Commission.

### VIII

The Commission continues to further develop its existing IT tools to better support the Member States' programmes.

#### IX

The Commission has a specific approach adapted to each disease. Wildlife is included when epidemically justified, as it is the case for avian influenza, classical swine fever, African swine fever, rabies. The Commission agrees that more consideration is needed for bovine tuberculosis with targeted measures for wildlife, taking into account the environment (for example, badger population which is an issue in the UK but not on the continent); other species maybe relevant in other Member States, such as deer.

#### X (a)

The Commission accepts this recommendation.

#### X (b)

The Commission accepts this recommendation.

#### X (c)

The Commission accepts to ensure that Member States systematically include, when relevant, the wildlife aspect in their veterinary programmes.

#### X(d)

The Commission accepts this recommendation.

## Introduction

#### 05

From 2007, EU veterinary programmes were considered one of the possible policy instruments to be employed under the comprehensive EU Animal Health Strategy.

#### 09

For some animal diseases, eradication can be a lengthy process due to the specificity of the disease. However, bovine tuberculosis and bovine brucellosis had been eradicated in most of the Member States. In those Member States where the disease is still present, several regions are already officially free. The difficulty to eradicate some animal diseases entails recurring expenditure from the EU budget for the veterinary programmes.

### **Audit observations**

#### 27

From 2007, EU veterinary programmes were considered one of the possible policy instruments to be employed under the comprehensive EU Animal Health Strategy.

#### 41

The Commission underlines that models to analyse the cost-effectiveness of the measures taken have not yet been developed, not even at international level. At the same time, the Commission points to the vast amount of evidence of the overall cost-benefit of veterinary programmes, for example, the avoidance of human infection and in some cases the saving of lives.

## Box 4 — Insufficiently controlled actions or high costs

- 1. The first single national call for tender launched by the Polish authorities for 2015 at the request of the Commission showed the desired effect: average vaccine prices dropped by half.
- 2. The issue in Romania is an example where the Commission detected the non-compliance and reacted immediately by refusing to reimburse the costs of the programme. The Commission requested Romania to take a number of remedial actions. In order to verify that the Romanian authorities had taken appropriate measures, the Food Veterinary Office (a Directorate of DG Health and Food Safety) carried out an audit on the 2014 rabies programme in Romania. Since then, Romania has implemented corrective actions as requested by the Commission.

#### 44

The Commission agrees that there is 'no requirement for Member States to base compensation amounts on the Community scales for the classification of carcasses'. This is due to the fact that the grid only refers to meat animals ready for commercial slaughtering. The animals slaughtered during veterinary programmes are quite often breeding animals or animals too young for commercial slaughtering. Thus, a grid is often not applicable.

The Commission underlines that farmers face a variety of consequences when not applying proper biosecurity measures. In case of an outbreak, a farmer has to bear costs that are not compensated, such as economic disadvantages due to animal movement restrictions, loss of animal production, loss of commercial reputation, additional cost for restocking, cleaning and disinfection. These costs could outweigh a possible overcompensation.

**Reply of the Commission** 

#### 45

The Commission points to the difficulties in comparing market prices with compensation values (see Commission's reply to paragraph 44). In Italy compensation rates in case of diseases are regulated in detail by law<sup>1</sup>.

Moreover, the statistics on agricultural markets quoted by the Court do not refer to market prices of healthy live animals but to market prices for sheep meat.

Financial audits carried out by the Commission on veterinary programmes in Italy concluded that the compensation rates were in line with the eligible value.

### 46

The Food Veterinary Office carried out an audit on the tuberculosis eradication programme of the UK<sup>2</sup> and found that in Wales the Tuberculosis (Wales) Order includes measures to link compensation to best farming practice, including appropriate biosecurity measures.

#### 47

The Commission is of the opinion that it applied the appropriate corrective measures taking into account the detected deficiencies in the national programme. It falls solely under the competence of the Member State to share, according to the national rules, the financial penalties applied by the Commission.

#### 51

The Commission agrees and intends to review together with the Member States which additional indicators could be useful for the assessment of the technical implementation of the programmes. However, as regards cost effectiveness the Commission will, together with the Member States, examine the possibility of identifying suitable indicators in relation to cost-effectiveness specific to the veterinary programmes.

#### 55

The Commission points to its financial audits carried out on veterinary programmes in Italy, which concluded that the compensation paid by Italy was eligible, and that its recommendation on compensation levels was being addressed (see also Commission's replies to paragraphs 44 and 45). There is no evidence that there was a link between compensation and delays in eradication in Italy.

#### 57

The Commission has a strategy for surveillance, monitoring and control adapted to each disease. Wildlife is included when epidemically justified, for example, avian influenza, classical swine fever, African swine fever, rabies. The Commission agrees that more consideration is needed for bovine tuberculosis with targeted measures for wildlife, taking into account the environment (for example, badger population which is an issue in the UK but not on the continent); other species might be relevant in other Member States, such as deer.

<sup>1</sup> Reference; 'art.6 della legge 28 maggio 1981, n. 296 e' (last modification decree 11 August 2015).

 $<sup>2\</sup>quad DG\ Health\ and\ Food\ Safety,\ FVO\ audit\ report\ 'United\ Kingdom\ 2011-6057',\ http://ec.europa.eu/food/fvo/audit\_reports/index.cfm$ 

# Common Commission's reply to paragraphs 59 and 60

The Commission underlines that vaccine/antigen banks have already been put in place for two diseases, namely foot and mouth disease and classical swine fever. This was done based — where relevant — on a risk analysis of the strains most likely to occur in Europe.

### **Conclusions and recommendations**

#### 66

While no models are available, not even at international level, to analyse cost-effectiveness of the programmes, the Commission wishes to point to the vast amount of evidence of the overall cost-benefit of veterinary programmes, for example, the avoidance of human infection and in some cases the saving of lives.

#### 67

The Commission agrees that overcompensation by a Member State might limit the incentive to apply effective biosecurity measures. However, the Commission does not consider that there is evidence that such cases actually occurred extensively. The Commission is of the opinion that it applied the appropriate corrective measures taking into account the detected deficiencies in the national programmes. It falls solely under the competence of the Member State to share, according to the national rules, the financial penalties applied by the Commission.

#### 69

The Commission underlines that the information was available before the end of the Commission's evaluation exercise as the three Member States concerned provided the missing historical information further to the Commission's request. Given that only three out of 24 Member States were concerned, the Commission considers this an isolated case.

#### 70

For some animal diseases, eradication can be a lengthy process due to the specificity of the disease. This is typically the case for tuberculosis and brucellosis.

#### 71

The Commission has a strategy for surveillance, monitoring and control adapted to each disease. Wildlife is included when epidemically justified, for example, avian influenza, classical swine fever, African swine fever, rabies. The Commission agrees that more consideration is needed for bovine tuberculosis with targeted measures for wildlife, taking into account the environment (for example, badger population which is an issue in the UK but not on the continent); other species might be relevant in other Member States, such as deer.

#### 72

The Commission underlines that vaccine/antigen banks have already been put in place for two diseases, namely foot and mouth disease and classical swine fever. This was done based — where relevant — on a risk analysis of the strains most likely to occur in Europe.

Reply of the Commission 48

### **Recommendations**

- (a) The Commission accepts this recommendation.
- (b) The Commission accepts this recommendation.
- (c) The Commission accepts to ensure that Member States systematically include, when relevant, the wildlife aspect in their veterinary programmes.
- (d) The Commission accepts this recommendation.

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Animal diseases can spread rapidly, causing significant economic costs and are a risk to both animal and human health. The EU has an active animal health policy and finances Member States' programmes to eradicate, control, and monitor certain animal diseases. The Court examined these programmes and concluded that the Commission's approach and Member State programmes were generally sound. There have been several success stories but eradication is a complex exercise and can take many years. However, there remains scope for improvement. We make recommendations to the Commission concerning the exchange of epidemiological information between Member States; the indicators used for veterinary control activities and cost-effectiveness; how wildlife is treated and the availability of vaccines.

