EUROPEAN
COMMISSION

Brussels, 6.5.2013
SWD(2013) 161 final

COMMISSION STAFF WORKING DOCUMENT

IMPACT ASSESSMENT

Accompanying the document

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on Animal Health

{COM(2013) 260 final}
{SWD(2013) 160 final}

1. Procedural issues and consultation of interested parties

The proposal for action on the EU animal health policy is the result of a long series of considered analyses.

In 2004, the Commission launched an independent evaluation to assess the performance of the Community Animal Health Policy (CAHP)[1] over the previous decade and its coherence with other EU policy interventions. The aim was to identify elements of the CAHP which could be further improved and to propose options to achieve these improvements. The summary of the key messages of the CAHP evaluation is attached at Annex II, and also discussed in further detail below.

Among other things, the CAHP evaluation recommended that a single strategy for animal health be developed to prevent piecemeal and crisis-driven development of policy. The EU Animal Health Strategy 2007-2013 (AHS) "Prevention is better than cure" was the result[2].

The AHS provides for the adoption of a "single regulatory framework for animal health with a greater focus on incentives than penalties, consistent with other EU policies and converging to international standards" and which will "define and integrate common principles and requirements of existing legislation". In their reaction to the Commission Communication on the new Strategy, the European Parliament[3], the Council[4] and the European Economic and Social Committee[5] welcomed this initiative. Subsequently, the Action Plan for the implementation of the Strategy[6] confirmed that "the main objective of the Strategy is the development of an EU Animal Health Law (AHL)".

From the very start of the process, key stakeholders, Member States (MS) Competent Authorities (CA), international organisations and trading partners have been closely involved and have played a crucial role in the discussion. In addition, economic and social stakeholders such as European associations with an interest in animal health and welfare and the interested public have been consulted on a number of occasions in accordance with the Commission's standards for consultation.

This exercise represents a considerable contribution to the so-called "fitness check" of the food safety and health policy and legislation.

At the same time, it reflects the priorities of Smart Regulation[7] by aiming to simplify the existing legal framework while reflecting stakeholders' expectations in reducing administrative burdens.

And finally, it reflects Commission priorities such as the smart growth objective of the Europe 2020 strategy[8] by helping the sector to become more resilient due to active prevention measures and risk management.

---

1 http://ec.europa.eu/food/animal/diseases/strategy/cahpeval_en.htm
2 http://ec.europa.eu/food/animal/diseases/strategy/index_en.htm
3 *EP Resolution 2007/2260(INI)*
4 *Doc.15481/07 ADD 1*
5 *NAT/376 – EU Animal Health Strategy*
6 COM (2008) 545 final, http://ec.europa.eu/food/animal/diseases/strategy/documents_en.htm
7 COM(2010) 543 final "Smart Regulation in the European Union"
8 COM(2010) 2020 "Europe 2020 - A strategy for smart, sustainable and inclusive growth"

This Impact Assessment (IA) follows the structure given in the Commission's IA guidelines[9]. It aims to consider the economic, social and environmental aspects of EU policy on animal health in an integrated and proportionate way.

1.1. Consultation of Member States' Experts

CA of the MS have been involved in the preparation of this initiative from an early stage.

Preparatory work started in the frame of the expert working group meetings of the Chief Veterinary Officers of the MS (CVOs). Several working groups were created (in the so-called Adelbrecht process) in order to obtain guidance from the CVOs on the implementation of the new AHS. Commission officials also participated in the working groups. The conclusions of the various working groups on issues such as prioritization of EU intervention and categorization of animal diseases, biosecurity and the use of the veterinary fund are publicly available.[10]

As a continuation of this work, several seminars were organised by the EU presidencies to discuss major issues related to the AHL proposal. These led to the adoption of the set of CVO Conclusions on biosecurity and incentives for prevention (October 2009)[11] and on animal disease surveillance systems (April 2010)[12].

Furthermore, as explained in greater detail under point 1.3, representatives of several MS formed part of the AHL Steering Group.

MS have been updated regularly by the Commission on the development of the AHL during both the Council and Commission CVO meetings and the Standing Committee of the Food Chain and Animal Health (SCOFCAH).

1.2. Animal Health Advisory Committee

The Animal Health Advisory Committee was created as a working group of the Advisory Group on the Food Chain and Animal and Plant Health[13]. It is chaired by a Commission representative, with the special participation of three representatives of CVOs from three MS (the past, present and future Presidencies). The list of other key stakeholders is publicly available[14] as are the agendas, the presentations, the summaries and the participants for each meeting[15].

A consultation and regular update on the progress of the work was provided at numerous meetings of this Committee[16] in order to ascertain stakeholders' perceptions of the issues identified, to collect views about the possible options to solve them and to sound out stakeholders on the likely acceptability of the various options.

---

9 SEC(2009)92 of 15 January 2009

10 http://ec.europa.eu/food/animal/diseases/strategy/pillars/action_en.htm, under point 3.1, 5 and 17 respectively

11 15000/2/09 REV2, http://register.consilium.europa.eu/pdf/en/09/st15/st15000-re02.en09.pdf

12 9547/10, http://register.consilium.europa.eu/pdf/en/10/st09/st09547.en10.pdf

13 Article 4.2 of Commission Decision 2004/613/EC of 6 August 2004

14 http://ec.europa.eu/food/animal/diseases/strategy/participants_en.htm

15 http://ec.europa.eu/food/animal/diseases/strategy/animal_health_advisory_committee_en.htm

16 19 May 2008, 3 November 2008, 6 March, 15 June, 29 September 2009, 8 February, 18 June 2010, 14 February 2011

Ad hoc bilateral meetings were held with the representatives of the specific sectors likely to be affected, including key associations (see summary of chronology of main exchanges in Annex III).

1.3. Animal Health Law Stakeholder Steering Group

An AHL Stakeholder Steering Group was set up to assist the Commission Services during the impact assessment process. Its assistance was particularly important in the definition of problems.

This group comprised experts from national veterinary authorities, experts from international organizations and other interested stakeholders.

In particular, delegates from the national veterinary authorities of Germany, Italy, Hungary, Denmark, the United Kingdom, Belgium, Sweden, Slovenia, Lithuania, Finland, the Netherlands, France and Switzerland participated, as well as delegates from the following international, economic or non-governmental organisations: COPA-COGECA (European farmers and European agri-cooperatives), OIE (World Organization for Animal Health), UECBV (European Livestock and Meat Trading Union), FVE (Federation of Veterinarians of Europe), FESASS (European Federation for Animal Health and Sanitary Security), IFAH-Europe (International Federation for Animal Health Europe), FEAP (Federation of European Aquaculture Producers), AVEC (Association of Poultry Processors and Poultry Trade in the EU countries), Vier Pfoten (Four Paws international).

The steering group had 4 meetings during the first part of 2009, and working papers were used during the meetings to focus on and consider particular factors.[17] The work of the steering group is summarised in a document entitled "Problem identification during the creation of the AHL" which can be found in Annex IV.

1.4. Inter-Service Steering Group (ISSG)

Given the crosscutting nature of the issues concerned, the Commission set up an ISSG to provide specialised input and to bring a wider perspective to the process.

Five meetings of the ISSG were held (31 October 2008, 10 February 2009, 9 July 2009, 5 July 2010, 14 April 2011) in order to obtain other services' views about the issues identified, the possible options and likely impacts in addition to a formal 'Consultation Inter-Service' (CIS) on the AHL consultation document in August / September 2009.

The following services were invited: SG, SJ, AGRI, COMP, ENTR, ENV, RTD, MARKT, MARE, OLAF, TRADE, RELEX, ELARG. As far as possible, the comments expressed by the various DGs represented at the five meetings have been taken into account in this document.

1.5. General on-line consultation

A general consultation addressed to the general public, stakeholders, MS and third countries was carried out from 23 October to 31 December 2009 via an online Interactive Policy

[17] http://ec.europa.eu/food/animal/diseases/strategy/pillars/action_steering_group_en.htm. Meetings held on 18 February, 25 March, 19 May and 3 July.

Making tool.[18] The outcome of this consultation was used as part of the analysis of impacts. The statistics and a summary of the main findings are available at Annex V.

1.6. Consultation of competent authorities of MS and the industry on administrative burdens

Two questionnaires were developed in order to collect readily available data on administrative burdens and administrative costs for the competent authorities and the operators.[19] Data on compliance costs incurred by operators when implementing current EU animal health legislation and data concerning the expected potential impact of the proposal on administrative burdens for enterprises and competent authorities were also requested in the questionnaires.

Where relevant, the results of this consultation have been used to analyse the impacts of the different proposed options and to identify opportunities for cost reduction.

1.7. Other opportunities used for consultation

EU producers of semen, ova and embryos were the target of a separate questionnaire for gathering data to compare possible options for animal health rules for intra-EU trade. The submitted data was used to assess the impacts of the different options identified. An ad-hoc meeting between the Commission services and the RepVet group of COPA-COGECA was organised to explain the different possible options in order to facilitate answering the questionnaire. The results of that questionnaire can be found in Annex VI.

A task force of experts assisted the Commission in the development of an expert paper[20] on EU vaccine/antigen banks for major animal diseases (such as foot and mouth disease, classical swine fever etc.). Based on that work a questionnaire on emergency vaccination policy prepared by Commission services was addressed to the EU CVOs. The analysis of the replies can be found in Annex VII (part 2).[21]

In addition to the discussions at CVO level, special emphasis was given to the concept of surveillance and its introduction in the new AHL during the Task Force for Animal Disease Surveillance (TFADS). This Task Force was created in November 2008 to support the MS and the Commission services. Two meetings of this expert group, which took place on 16-17 December 2009 and 17-18 May 2010, reflected on the ways in which surveillance should be introduced in the new AHL. This provided expertise and experience on animal disease surveillance in the context of animal disease management, and summaries of the meetings can be found here: http://ec.europa.eu/food/animal/diseases/surveillance/index_en.htm. In addition, the Spanish Presidency held a seminar on animal disease surveillance as part of the Working Party of Chief Veterinary Officers.

1.8. IAB opinion

The draft IA report was discussed at the meeting of the IAB on 13 July 2011. Following this meeting the board issued an opinion on the draft IA emphasising four main points to be addressed in the final version of the IA report.

---

18 http://ec.europa.eu/food/animal/diseases/strategy/pillars/consultation_process_en.htm

19 http://ec.europa.eu/food/animal/diseases/strategy/pillars/consultation_process_en.htm. Addressees had the possibility to respond from 19 December 2009 to 15 March 2010

20 http://ec.europa.eu/food/animal/diseases/strategy/pillars/antigen-vaccine-banks-task-force_en.htm

21 SANCO/7117/2010

These four main points have been addressed in this revised version of the IA as follows:

(1) Strengthen the evidence regarding the seriousness of problems:

- The background of evaluation of existing law and development of strategy is now more clearly explained in the first paragraph to the IA.

- More extensive explanations are now given on the problems generated by the lack of a single and fully coherent EU legal framework.

- A summary of the key findings of the CAHP evaluation has now been annexed to the IA (new Annex II) to better explain the background to the development of the AH strategy, the thinking behind the AHL and the stakeholders views collected in this exercise.

- The summary of the main findings of the stakeholder consultation is now annexed to the IA rather than a reference made to a web-link (new Annex V).

- The results from the stakeholder consultation have now also been referred to in each relevant problem identified; including showing how many would support a change in the existing legislation. Examples have also been added of particular problems highlighted by the AHL steering group.

- In Point 2.2.1., a paragraph has now been added to explain who is affected by regulatory over-complexity and how.

(2) Clarify what each option involves and add a simplification only option:

- A new 'simplification only' option 2 has been added in sections 4 and 5 and explanations are given for why this is not a viable option.

- A new point 4.6 has been introduced to explain more clearly the new elements that would be introduced by each option.

- Changes have been made to the legislation table (now Annex IX), to outline more precisely the changes planned in the new legislation. In this new Annex IX an introductory chapter has also been added to explain the key new elements of the future AHL, in accordance with options 4 and 5. Some details are also provided to outline the elements of the existing legislation and map them onto the new AHL and/or the delegated and implementing acts that should follow it, although full details cannot be provided at this stage.

- A new Annex X has been introduced showing the structure of the new AHL in accordance with options 4 and 5.

(3) Present adequate information regarding vaccination issues:

- The current EU approach to vaccination has been explained and assessed in new Part 1 of Annex VII.

- The conclusions of this assessment are presented in the main text of the IA.

(4) Properly assess administrative burden arising from familiarisation activities:

- In point 5.4.1. and 5.5.1., a short explanation has been provided why familiarisation costs for the new AH framework law have not been quantified by the Standard Cost Model (SCM) but rather identified as being part of the business-as-usual costs for business and competent authorities alike, given the individual and different natures of animal diseases and subsequent frequent adaptations of the legal framework.

The IA executive summary has been changed accordingly to reflect the changes of the main report. In addition, this version of the IA includes several improvements to better respond to the IA Quality Checklist for IAB Opinion.

The Impact Assessment was re-submitted to the IAB in September 2011 with these amendments made. Some further changes were requested by the IAB and have been addressed as follows:

(1) Clarify what the preferred option involves in terms of non-commercial actors, biosecurity and future Impact Assessments.

- More analysis has been made in section 5.4.1 of the impact of option 4 on non-commercial actors, particularly in economic impacts.

- Option labels in the Annex XI on biosecurity have been changed for clarity, and the options linked back specifically to options in the main text.

- A set of sub-options in table 4.1 has been removed where its impacts have not been separately analysed.

- A paragraph has been added at the start of Annex IX to give examples of where further impact assessments might be required.

(2) Present further evidence regarding the seriousness of particular problems.

- An FVE report has been cited as evidence around the lack of consistency in training for veterinarians in section 2.2.1.5.

- Some more explanation of the problems faced in regulatory over-complexity has been made in section 2.2.1.6, using Food and Veterinary Office (FVO) reports as evidence.

(3) Consistently describe vaccination options

- The main text of the report has been linked more explicitly to Annex VII on vaccination, particularly in table 4.1 in section 1.

- The option labels in Annex VII have been changed to provide more clarity and for ease of linkage with the main text.

- Annex VII has more analysis of stakeholder views and the need for subsidiarity.

(4) Better explain administrative burden analysis

- The impacts of new information obligations have been covered more explicitly in section 5.4.1 in examining the analysis of economic impacts of the preferred option 4.

(D) Procedure and presentation

- A sentence has been added at the end of section 7 to cover the proposed evaluation timetable.

2. Policy context, problems identified, and subsidiarity

2.1. Background and context

2.1.1. Nature and size of the sectors concerned

Across the EU, the farming sector is the largest user of animals with at least 2 billion birds (chickens, laying hens, turkeys, etc.) and 334 million mammals (pigs, sheep, goats, cattle, fur animals, etc.). There are 13.7 million animal holdings in the EU.[22]

The value of livestock farming output in the EU is €149 billion[23] of which pigs and poultry (subject to specific EU provisions) represent 38% (i.e. €57.6 billion). Animal output value represents 41% of the overall agricultural output (€363 billion in 2008).

According to Eurostat, total aquaculture production in the European Union (EU-27) in 2005 was 1,272,455 tonnes (live weight). This includes production of crustaceans, molluscs, and finfish[24]. The total value of production is estimated as €3,159bn.

Pet animals represent the second largest type or usage of animals, by number, in the EU. There are around 120 million dogs and cats, and approximately 35 million pet birds. The annual value of cat and dog sales in the EU is estimated at €1.3 billion and the sector is estimated to generate direct employment of 300,000 persons, including 32,000 dog breeders.

Many fewer animals are used for experimentation (pharmaceutical and cosmetic industries and public research bodies): around 12 million animals in the EU, of which most are rodents. There are between 2,000 and 3,000 zoos in the EU and there are an estimated 800,000 captive wild animals. The fur farming sector also farms a significant number of animals, covering about 7,200 farmers and producing around 32 million pelts per year[25]. No reliable data could be obtained for circuses or other activities such as animals used in sports, shows, etc.

EU intervention is currently focused primarily on the prevention and control of major transmissible diseases that can have significant health and economic impacts at EU level. Animal diseases do not recognize borders and present a constant threat to all of the sectors above. They pose a direct risk to animal and often public health, but also can have other negative but indirect impacts, such as economic or social effects. The unpredictable occurrence and behaviour of animal disease epidemics and the still insufficient reliability of modelling studies, despite the recent progress made in this field, makes forecasting their frequency and impact very difficult.

The impacts of an animal disease outbreak can vary widely due to a variety of factors including the epidemiological characteristics of the disease, the structure of the sectors affected and the nature of the control measures imposed. These impacts can include negative effects for animal and human health, costs to livestock farmers and related industries of dealing with disease and of business disruption, public sector costs of eradication and monitoring, and changes in consumption patterns. Often, disease outbreaks also have significant impacts on international trade of animals and animal products. Finally, many

[22] Data from Eurostat 2007, Number of farms and heads by economic size of farm (ESU):. http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-AF-07-001/EN/KS-AF-07-001-EN.PDF

[23] Data 2008 from the evaluation report.

[24] Finfish is the aggregate term for freshwater, diadromous and marine fish

[25] Data from European Fur Breeders Association, Annual Report 2010

animal diseases also affect wild animals, and may have detrimental effects on wild animal populations. Thus they can have a negative environmental impact, for example, on biodiversity.

Some of the consequence of past animal health crises have been used to illustrate the potential scale of the impacts of animal disease outbreaks.

- **BSE** (1996-1997): for UK only, GBP£3.5 billion (0.5% of GDP). The disease also caused a serious fall in consumer confidence across the whole EU and the deaths of more than 200 people in the last 15 years.

- **FMD** (2001-2002): for UK only, GBP£10-12 billion (1.2% of GDP) mainly in agriculture / food chain (30%) and tourism (50%).

- **SARS** (2003): (cost of lost GDP: US$18bn in East and Southeast Asia (0.6% of GDP) (Asian Development Bank); estimated global economic impact US$30bn (World Health Organisation, 2003). Around 800 people ultimately died from the illness.

- **Avian flu in the Netherlands** (2003): 30 million birds and direct economic costs of more than €150 million. A veterinarian died due to this disease.

The EU emergency fund[26] makes financial contributions to MS during animal disease outbreaks[27]. It would usually make a contribution of 50% (with the remaining 50% covered by the MS) of the direct costs to animal keepers for certain specified diseases. Table 1.1 below sets out contributions since 2000. As shown, the total amount paid since 2000 is just over €1 billion. However, it should be noted that of this, €664 million (63% of total) was paid between 2002-2005 in relation to Foot and Mouth outbreaks in 2001.

Table 1.1: EU Emergency Fund Payments by Disease from 2000-2010

Year of Payment	Payments in €m						
	Avian Influenza	Bluetongue - disease, surveillance & vaccination	Classical swine fever	FMD	Newcastle disease	Other Diseases	Grand Total
2000	13.79		47.05				60.84
2001	17.00	0.73	6.28				24.01
2002		11.46	11.42	400.44	0.42	0.57	424.32
2003	4.76	0.47	1.78	67.82			74.84
2004	55.92	4.14	8.92	78.73	1.00		148.71
2005	18.23	2.65	4.16	119.96	0.65		145.64
2006	0.05	0.10	1.63				1.78
2007	1.00	4.27	5.00		0.22	1.20	11.69

[26] 2009/470/EC: Council Decision of 25 May 2009 on expenditure in the veterinary field (Codified version), *OJ L 155, 18.6.2009, p. 30–45*

[27] The way the EU supports the control and eradication of animal disease outbreaks is not addressed in this document as it is the subject of a separate piece of work to revise Council Decision 2009/470/EC.

2008	8.65	51.00	3.32	0.46	0.14		63.56
2009	3.90	36.36	0.04		0.36		40.66
2010	1.27	31.75	0.02	0.72		17.18	50.94
Grand Total	**124.57**	**142.93**	**89.63**	**668.14**	**2.79**	**18.95**	**1,046.99**

Animals must fulfil specific animal health conditions when they are moved between MS or imported from third countries. Indeed there are areas within the EU with different health statuses (for example, freedom from certain animal diseases). These conditions ensure that animals do not pose any risk during movement and they are moved only to an area of equal or lower health status than their place of origin. The conditions are attested by official veterinary certificates accompanying the consignment of the animals from their origin to their destination.

These specific rules for movements are sometimes considered burdensome, especially in the case of frequent cross-border movements between two adjacent MSs with a similar or identical health status. The most often cited examples of movements of this kind are those of pigs and poultry between Germany and the Netherlands; cattle between France, Belgium and Luxembourg; animals for slaughter between Austria and Germany; and cattle, pigs and sheep between Ireland and Northern Ireland (in the UK). More detailed analysis (along with some assessment of policy options referred to in Section 4 later) is available in Annex VIII.

2.1.2. Overview of legislative framework and ongoing developments

The current EU animal health legislative framework involves almost 50 basic directives and regulations, some of them adopted as early as 1964. The veterinary *acquis communautaire* now covers more than 400 acts:

- c. 50 basic acts that lay down horizontal and vertical principles of animal health which apply to intra-Community trade, imports, disease eradication, veterinary controls, notification of diseases and financial support of terrestrial and aquatic animal. A provisional list of legislation expected to be affected by the new legal framework is attached in Annex IX;

- c. 200 acts of general application that lay down implementing rules such as the ones that specify lists of third countries, or the rules on veterinary certification;

- c. 200 acts of special application that lay down more specific provisions such as rules on protection or transitional measures.

This set of animal health legislation interacts with the current legal framework on animal welfare, food safety, public health, animal nutrition, veterinary medicinal products, environmental protection, official controls, the Common Fisheries Policy (CFP) and the Common Agricultural Policy (CAP). A new proposal would need to successfully interlink with all these sets of legislation, especially with Regulation (EC) No. 882/2004[28], so as to increase consistency for official controls (checks) related to animal health.

[28] On official controls to ensure the verification of compliance with *inter alia* animal health rules, OJ No L 165, 1 p. 30.04.2004

For the aquatic sector, Directive 2006/88/EC was adopted in 2006, bringing together disease control and trade provisions (intra-EU movements and import). This amalgamation was a new concept, which has proven to work fairly successfully, so no policy changes are being proposed in this area. Therefore, this Impact Assessment largely focuses on policies relating to terrestrial animals.

2.2. Problem definition

As noted in Section 1 above, problems with the existing animal health framework and suggestions for improvements to it have been identified in a number of fora. Subsequent to the evaluation of the CAHP and the development of the EU AHS 2007-2013, stakeholders and competent authorities of the MS were then further asked to identify problems with current legislation on animal health in the scope of the AHL Steering Group. The replies served as a basis to develop the "Annotated agenda for a wide stakeholder consultation" in which stakeholders were asked to raise any issues of concern as regards current legislation on animal health. The summary of this consultation is available at Annex V.

The CAHP Evaluation and the stakeholders' consultation broadly agreed that the current system functioned well, however a number of issues were identified that could be improved. Some relate to the general policy approach whilst others relate to specific legal acts or diseases. Some of these issues should be addressed by stakeholders as part of their responsibility to prevent animal diseases, but others relate to the responsibilities of the EU and of CA.

As the AHS recommends that the AHL should be a general horizontal legislative framework, **this impact assessment focuses on the main problems identified in the general policy approach**. Some of the more specific problems identified during the wide stakeholders' consultation have been used in this impact assessment as examples of the general problems. Others will be addressed, if needed, in subsequent legislative proposals and impact assessments – see Annex IX for more details.

As noted above, a summary of the key messages from the CAHP is available at Annex II; however the main thematic issues identified **during the CAHP evaluation** were:

- ***The high complexity of the current CAHP***

- ***The lack of an overall strategy***

- ***An insufficient focus on disease prevention, with a particular focus on the need for increased biosecurity.***

A specific policy issue was also identified both in the evaluation and in the consultation with stakeholders in the framework of the AHL preparatory work:

- ***Issues related to intra-EU trade in live animals.***

These trade issues cut across the general problems identified in the first three bullets. As such, further more specific analysis was carried out on intra-EU trade, which is presented in overview in section 5 and in detail in Annex VIII.

2.2.1. High Complexity of the current CAHP

As described above, current EU animal health legislation is very complex, with over 400 pieces of legislation, but no single horizontal law containing the overarching principles, main objectives and tools of animal health policy. This means that legal measures are spread among very many different pieces of legislation with different subject matters, including a mixture of horizontal and vertical issues, trade (intra-EU and international), disease control measures and specific safeguard measures.

Within the current framework there are not always clear links to other relevant legislation, and there can be a lack of consistency and transparency across the various existing animal health legislation. The existing veterinary legislation and policies were widely perceived to be very complex by stakeholders across the board during the evaluation of the CAHP.

The high complexity of the current system means it can be difficult for stakeholders (whether CA, veterinary professionals or farmers and operators 'on the ground') to understand their roles and responsibilities. Since this complexity and lack of clarity are caused by the shortcomings of the existing legal framework, they cannot be adequately mitigated by means of training or other familiarisation exercises only. Consequently, the current complexity has the potential to jeopardise the achievement of the EU's animal health objectives.

All the specific problems identified below within the overall problem of 'high complexity of the current CAHP' relate to the implementation of the current legislation, with the exception of the lack of rules on professional qualifications and training for official veterinarians (see 2.2.1.5), which relates to a lack of legislation.

2.2.1.1. Large number of pieces of EU animal health legislation

Driver: Large number of pieces of EU animal health legislation but no single horizontal law.

Problem: Potential high administrative burden for stakeholders to understand legislation.

The absence of a single horizontal act containing the overarching principles means that obligations are scattered in different legal acts. This can mean that the rules can be unclear or difficult to comprehend for animal keepers and owners. They may need to consult many different pieces of legislation or consult a specialist before they can fulfil their obligations. Some obligations are laid down in legislation dealing with disease outbreaks which could be outside their day-to-day areas of activity. There can also be a lack of clarity about the relationship between animal health legislation and other pillars of legislation. So it can potentially be difficult for stakeholders to fully comprehend their roles and responsibilities in the current animal health framework. Nevertheless, this situation can vary between MS according to the manner in which they have transposed directives, with some potentially offering more coherence than others.

Nevertheless, it is clear that the time spent by animal keepers and operators familiarising themselves with their statutory obligations represents an administrative burden. This could be through the time spent by operators reading legislation (or more likely guidance about the legislation), or the cost of consulting legal experts. When aggregated across the several million animal keepers, operators and related business operators in the EU, this is clearly a considerable administrative burden.

2.2.1.2. Responsibilities and obligations of animal keepers and owners are not always clearly spelled out

Driver: Existing roles and responsibilities differ across existing legislation and in many cases are not clearly laid down and consequently interpreted differently in different MS.

Problems: Animal keepers' legal responsibilities as they are expressed in the current legal framework do not reflect the totality of the role of keepers and operators in animal disease prevention and management. Differences in responsibilities between MS may lead to varying costs of complying with obligations between keepers in different MS.

Animal keepers and owners, especially farmers, are well placed to prevent and detect animal diseases, but they can also contribute to the frequency and scale of disease outbreaks. Current EU and/or national legislation already sets certain obligations for animal keepers and owners, such as:

– notifying the keeping or possession of animals,

– notifying the relevant authority of the presence or suspected presence of certain diseases without delay,

– providing regular care for and supervision of the animals,

– handling animals with a certain standard of care,

– reporting the dispatch and/or arrival of animal consignments,

– keeping records and registers and providing for the identification and traceability of animals,

– having a baseline knowledge of animal diseases and how to prevent them.

Most of these obligations are laid down in Directives and Decisions which are then transposed by MS, but some others are not regulated at EU level. For example, there are currently very few mechanisms at EU level which actively involve animal keepers in the rapid notification of suspected animal disease or on-farm preventive measures, but many of these types of mechanism exist at national or regional levels.

The current framework creates a particular problem. Because many of the obligations are in Directives, they can be transposed into MS legislation differently. MS sometimes interpret the obligations in different ways so there are disparities in obligations related to animal health for animal keepers and owners between MS. These inconsistencies between MS mean that the responsibilities of animal keepers vary across the EU, which can alter the costs of complying with legislation. This in turn leads to an uneven playing field for livestock keepers in different MS in relation to the cost and responsibilities of national animal health requirements.

During the stakeholder consultation, there was wide support for clarifying these responsibilities, with 78.4% of respondents replying 'agree' or 'strongly agree' to the proposal to clearly setting out obligations of animal keepers/owners/operators. In particular many of the stakeholders stressed the need to establish obligations for operators as well as for animal keepers. The impacts on small farmers have to be taken into consideration. Furthermore, the

third countries replying to the questionnaire stressed that these obligations should not be imposed on third country operators.

2.2.1.3 Rules for commercial farming do not always apply in a proportionate manner to non-commercial animal keeping

Driver: To establish better consistency and proportionality to address risk posed by non-commercial animal keeping.

Problem: Non-commercial animal keeping usually entails a different kind and level of disease risk compared to industrial farming and the administrative burdens imposed on non-commercial animal keeping is not always proportionate to the level of disease risk.

During the consultations, concerns were raised that surveillance and disease control measures are applied identically to both commercial and non-commercial holdings (such as hobby and backyard holdings). The necessity of the current application of measures to non-commercial farming (such as for example the obligation to identify and register certain animals and the holding registration), was questioned, given the different levels of risk that they pose.

To ensure appropriate animal health in the EU and for effective prevention and control of animal disease, at least a basic level of control measures need to be applied to both categories of holdings as they can both be affected by disease and become a source of wider infection. In some circumstances, non-commercial holdings can pose a lower risk of spreading diseases compared to industrial holdings: for example, because of fewer movements, less contact with other animals (especially with industrially farmed animals), animals being kept in smaller groups and more contact between the keepers and the animals (see studies on the spread of Avian Influenza). On the other hand there are circumstances where high numbers of small non-commercial holdings can present a potentially major risk of spreading diseases to industrial farming. An example of this might be small-scale pig production. The risk of disease can arise from potentially lower biosecurity levels in such holdings such as increased wildlife contact, less supervised movement control, swill feeding, uncontrolled disposal of carcasses, etc.

Current practices also raise some questions about intra-EU movements, specifically whether different conditions should be applied to commercial and non-commercial movements. Some species of animals are considered not to represent a high risk for spreading animal diseases, or are kept or bred in certain particular and well controlled biologically secure conditions (for example, laboratories, zoos, circuses etc.). Pet animals are often moved in a different context, that is to say, they move in accompanying their owners on their journeys. So they have little contact with farmed (or in fact any other) animals and the risk of spreading disease is much lower. However, the movements do need to be somewhat traceable and controllable in case of disease outbreaks posing risks to animal or human health.

The stakeholder consultation showed a high level of support for the Commission's approach for differentiated rules for commercial and non-commercial movements, providing possibilities for risk based exemptions on a case-by case basis (74.5% of respondents agreed or strongly agreed with the suggested approach). However, a certain extent of uneasiness was observed as a significant percentage of respondents argued that changes could lead to an increased risk of animal disease spread and possible outbreaks. (for full details see 2.8 in Annex V).

2.2.1.4. Unclear definition of the role of veterinary services including the tasks and duties of official veterinarians, and other veterinary practitioners.

Driver: Inconsistency in the role of veterinary services across existing EU legislation.

Problems: Legal uncertainty about roles of veterinary services, possible conflicts of interest and limits to the development of veterinary networks.

EU legislation (such as Council Directive 90/425/EEC, Regulation (EC) No 882/2004, Council Directive 64/432/EEC, and Regulation (EC) 854/2004) gives different definitions of 'competent authority', 'official veterinarian', 'approved veterinarian' and 'official auxiliary'. This lack of legal clarity has paved the way for different interpretations by the MS, and an uncertainty about the roles of the various segments of veterinary services during animal disease outbreaks.

For example, the majority of MSs' veterinary practitioners or technicians are authorised to perform a range of official veterinary activities, including sampling (for example, in the cases of brucellosis, tuberculosis, Aujeszky's disease and the tuberculosis skin test), vaccination (for example, for Bluetongue) and also some clear-cut official controls, such as regular hygiene checks on dairy farms, or health checks of animals prior to intra-EU trade dispatch. In other MS, official tasks such as these are only performed by official veterinarians.

The steering group consultation also raised concerns that a veterinary practitioner might face a 'conflict of interest' when certifying animals in his or her care; for example if carrying out work as an official veterinarian but also undertaking private veterinary work, perhaps for the same client.

Different roles for veterinary services across the EU could limit veterinary coordination and the development of networks for the surveillance, prevention, early detection, control and notification of disease.

At the same time, all MS are members of the World Organisation for Animal Health (OIE). The OIE Terrestrial and Aquatic Animal Health Codes provide existing frameworks to which EU rules should be aligned in order to ensure that MS are fulfilling their obligations as OIE members, which, amongst other positive benefits, facilitates trade with third countries. The Terrestrial Animal Health Code defines the concept of 'Veterinary Services' as the governmental and non-governmental organisations that implement animal health and welfare measures and other standards and recommendations in the two OIE codes in the territory. The Veterinary Services are under the overall control and direction of the Veterinary Authority. Private sector veterinary organisations, veterinarians, veterinary paraprofessionals or aquatic animal health professionals are therefore included in Veterinary Services and they are normally accredited or approved by the Veterinary Authority to deliver the delegated functions. The tasks of veterinary services include many programming and management activities, including international certification, and particularly the organisation of a veterinary network for the prevention, control and notification of disease outbreaks. International trade in animals, animal products and products of animal origin is based on international (OIE) standards, where the first step in fulfilling import conditions is a successful evaluation of the veterinary services in a given potential exporting country. Without that evaluation, health certification is not reliable and export is therefore not possible under OIE rules.

However, it has to be noted that in aquaculture, apiculture and some other animal categories (such as animals used in scientific experiments) control activities may be carried out not only by veterinarians but by other professions and services. In this regard, international standards and recommendations set in the OIE Terrestrial and Aquatic Codes have to be taken into account.

This variety in the structure of differing veterinary services, their relationships nationally, intra-EU and internationally, and the differences in their roles and responsibilities, adds to the complexity of the current context. During the stakeholder consultation, 81.7% of respondents agreed with the suggestion to clarify the tasks and duties of official veterinarians and veterinary practitioners (for full details see 2.3 in Annex V). Stakeholders are of the view that there is a need to clarify and harmonise certain veterinary tasks EU-wide. This is in particular valid for "export certification" and international trade.

2.2.1.5. Lack of rules on the professional qualifications and training for official and approved veterinarians

Driver: Diverging national standards for qualification and training for official and approved veterinarians.

Problem: Differences between levels of health protection across MS due to the differences in veterinary qualifications, ongoing training and professional development.

Official, approved and authorised veterinarians need in-depth and regularly updated knowledge and skills to perform official tasks and official controls adequately. This knowledge will be gained first through undergraduate veterinary education and then by postgraduate studies and/or vocational training. Differences in these qualifications between MS mean that there can be differing levels of health protection and impartiality throughout the EU.

The Federation of Veterinarians of Europe (FVE) and the European Association of Establishments for Veterinary Education (EAEVE) run an evaluation system of veterinary schools in MSs with a view to providing an independent and fair accreditation system. The latest published evaluation, in 2009, concluded that while many veterinary schools in the EU are world-class, some 16% are at one or more points inadequate[29]. This variability in education can lead to inconsistency in the knowledge of those who qualify as vets.

Regulation (EC) No 882/2004 already envisages appropriate and, as necessary, additional training for staff performing official control tasks. In addition, there are specific provisions on the professional qualifications and continuing education of official veterinarians, but this is limited to those responsible for fresh meat controls in establishments covered by Regulation (EC) No 854/2004. These provisions may need to be extended to other areas of competence of official veterinarians to ensure that official tasks are performed in an adequate and uniform way throughout the EU. At the same time it has to be noted that in aquaculture, apiculture and some other animal categories (i.e. experimental animals), control activities may be carried out not only by veterinarians but by other professions and services. This would have to be taken into account as necessary in defining the required qualifications and ongoing professional development.

29 http://www.fve.org/news/position_papers/education/060_oie_education%20_conference_october_2009_presentation_jvaarten.pdf

During the stakeholder consultation, there was wide support for extending the requirements for professional qualification and for veterinary training for officials veterinarians in all areas, and to those authorised to perform official tasks in the field of animal health, with 81.0% of respondents replying 'agree' or 'strongly agree'. Many supported a broader harmonised EU approach for all those that perform official tasks; this includes not only veterinarians but also other professionals. On the other hand, others warn that MS already have continuous professional developments for veterinarians in place and that additional regulation at EU level is unnecessary. If training is to be introduced, it should be output / target oriented towards proper enforcement and should not generate unnecessary costs. (for full details see 2.4 in Annex V).

2.2.1.6. Specific animal health conditions relating to imports are difficult to understand, and apply

Driver: Animal health conditions on imports are unclear and difficult to apply.

Problem: Administrative burden for third countries, importers and competent authorities to understand and comply with conditions.

Animal health import requirements for live animals, animal products and products of animal origin are based on the need to prevent the introduction of animal diseases into the EU. These specific requirements are scattered in different pieces of legislation and sometimes within the texts of import certificates instead of the legal act itself.

This makes the rules difficult to understand and apply for competent authorities and business operators in MS and third countries. For example, the Food and Veterinary Office (FVO) has regularly made recommendations to MS to improve their import controls. Many of the issues causing the recommendations appear to arise from misunderstandings due to a lack of clarity rather than wilful disregard. In addition, the complexity adds an administrative burden to operators, who can find it difficult to establish what the requirements for import actually are. The introduction of basic animal health requirements would reduce the administrative familiarisation burden on operators who are running import businesses, and grant more consistency in import policy.

The time spent by the concerned parties understanding animal health import conditions represents an administrative burden for business operators and competent authorities in both MS and third countries which has the potential to be reduced through simplification, harmonisation of the controls, and the introduction of electronic forms.

During the stakeholder consultation, 75.1% of respondents replied 'agree' or 'strongly agree' to the proposals to make the import conditions clearer and simpler. For full details of the proposals see 2.12 and 2.9 in Annex V. Stakeholders especially highlighted the issue of competitiveness: they are of the view that EU operators face stricter standards than international standards. Imports of special animal categories also have to be considered carefully, and exemptions only granted taking into consideration the risks involved (e.g. protected and endangered species, wild animals, etc). They emphasised the need for clear definitions to avoid misunderstanding in import conditions (for example, llamas should not be considered as ruminants).

2.2.2. Lack of a single overall strategy

The final report of the CAHP evaluation highlighted the lack of a single general approach behind the CAHP measures. Instead, the CAHP was perceived to be a patchwork of specific measures and actions, with insufficient clarity in its overall direction. The setting of priorities for the CAHP has consisted of a mixture of longer-term components such as eradication programmes or contingency planning but also of short-term or crisis-driven elements.

Resources, personnel and management attention have tended to follow animal health crises with a reducing focus on the definition and achievement of longer-term strategic objectives. Consequently, this apparent lack of a clear long-term strategy and prioritisation system could lead to sub-optimal prioritisation and allocation of resources.

All of the problems identified below which relate to the lack of a single overall strategy are areas where EU law exists only in piecemeal fashion (for example, relating only to certain diseases); or where there is no existing law.

2.2.2.1. Lack of categorisation and prioritisation of animal disease policy

Driver: Lack of prioritisation of different animal disease control and policy measures.

Problem: Sub-optimal allocation of resources for disease control.

As described above, the CAHP evaluation highlighted the absence of a clear system for prioritising resources for animal health policy interventions, such as categorisation of animal diseases and animal-related threats, (or reliable scientific grounds for such categorisation). This means that resources have sometimes been allocated on short-term, political or crisis-driven grounds, which do not fully reflect evidence based on scientific risk assessments and cost-benefit analysis. The management of less high-profile diseases might therefore be de-prioritised as a consequence. This sub-optimal allocation of resources for disease control under the current system could lead to more negative impacts of animal diseases than if resource allocation were optimally prioritised.

In many cases, the existing legal framework is too rigid and cannot adapt to new developments, including new scientific developments. The AHL Steering Group mentioned certain examples of these problems in their discussions in July 2009, for example: the rules on swine vesicular disease, which they felt to be disproportionate to the risks the disease poses; and protective measures for Newcastle Disease, which they felt to be outdated.

A bluetongue case study is outlined in the box below to illustrate a short term crisis-driven allocation of resources.

Bluetongue disease

Bluetongue is an insect-transmitted disease which appeared in North-Western Europe for the first time ever in summer 2006 when a virus strain, probably originating in sub-Saharan Africa, appeared in the Netherlands. That summer was exceptionally warm and these unusual climatic conditions may have exacerbated the conditions for the virus to flourish. That year 2,000 farms were affected, and in the following year 60,000 farms were affected, from the UK to the Czech Republic. Infections caused high mortality in sheep and goat populations.

In Belgium it is estimated that the mortality rate in 2007 amounted to one sixth of the national sheep and goat population. Economic losses in the Netherlands were estimated at

€130 million in 2006 and 2007. In 2007, a BTV-8 outbreak in France was estimated to cost €1.1 billion. Losses there were largely due to the inability to trade cattle on the international market.

In the EU in 2008, a total of 45,000 outbreaks were reported. That number dropped to 1,118 in 2009 and only 120 in 2010. The success is credited primarily to the vaccination campaigns in the MS. A co-financed EU programme was adopted, initially funded by the "emergency fund", and later by annual programmes in all affected areas. This appears to be the main factor leading to the near-disappearance of the disease in the EU in 2010.

It has been argued that a more preventative approach to Bluetongue could have prevented much of the mortality and costs of the disease that the emergency measures required.

2.2.2.2. Poor coordination of animal disease surveillance

Driver: Lack of coordination between different surveillance systems and actors.

Problem: Sub-optimal use of surveillance to reduce the risk and impact of disease outbreaks.

Animal health surveillance is an essential tool to detect and control animal diseases, to monitor disease trends, to support claims for freedom from disease or infection, to provide data for use in risk analysis, for animal and/or public health purposes, and to substantiate the rationale for sanitary measures. Therefore, surveillance is a key element of any animal health policy that gives priority to a preventive approach, early detection and quick response.

Animal disease surveillance is one of the cornerstones of Pillar 3 of the AHS 2007-2013. Several activities (as noted above in section 1.7) have been carried out to identify the main challenges for surveillance and how they could be addressed:

– The current picture of animal disease surveillance in the EU is rather complex and the purposes or objectives of surveillance systems are not always sufficiently clear in current legislation (for example, there are surveillance systems which are EU harmonised vs. those not harmonised; compulsory vs. voluntary; surveillance in free areas vs. monitoring in not-free areas; EU co-financed vs. not EU co-financed; active vs. passive; farmed animals vs. wildlife and so on). It can therefore be difficult for stakeholders and competent authorities to understand their roles and responsibilities.

– The current surveillance systems may not be sustainable, as they do not necessarily make best use of available resources, nor optimally set priorities; so the affordability, sustainability and communication of surveillance activities need to be addressed. Support and engagement of the veterinary authorities and stakeholders, in particular farmers and trading partners, is essential and should be actively sought.

During the stakeholder consultation, 67.3% of respondents replied 'agree' or 'strongly agree' to the proposals to improve animal health surveillance. Full details are in part 2.6 of Annex V. Stakeholders suggested that the surveillance should be developed in partnership with them. Some have asked for a cautious approach in introducing surveillance network in order not to be too prescriptive.

2.2.2.3. Insufficient harmonisation of EU legislation with international standards

Driver: All MS are members of the OIE, so EU legislation should aim to better align with the existing OIE Health Codes for the sake of consistency with international trade rules and competitiveness of the EU farming industry.

Problem: In certain respects, convergence of standards represents a trade-off with animal health standards, but lack of convergence may lead to lack of competitiveness and even international trade disputes.

MS are members of the OIE and as a result should align their rules to the existing OIE Code. As such the standards of the OIE Health Codes should be reflected in EU legislation. Some current differences in EU legislation and OIE standards are set out in the box below.

The potential problem that arises from these differences is in the difficulty of achieving the optimal balance between aligning with OIE standards and maintaining EU health standards. This amounts to a trade-off between maintaining good relations with third countries, hence maintaining the competitiveness of the EU farming industry and avoiding potential trade disputes; and maintaining current animal health standards within the EU.

During the stakeholder consultation, 82.3% of respondents replied 'agree' or 'strongly agree' to the proposals to aligning EU standards with international standards (while not lowering EU standards) and to promoting EU standards in international fora, particularly the OIE.

Whilst EU trade and import legislation generally reflects OIE standards, sometimes there are differences. For example:

- The OIE only carries out a paper evaluation as the basis for determining disease-free countries or zones. The EU does not consider this sufficient and generally carries out its own on-the-spot inspections before granting its trading partners this status.

- The EU has its own level of protection for certain imports, based on scientific risk assessment, which is often higher than that which can be achieved solely by applying OIE standards or guidelines. An example is that the EU does not accept that the import of bone-in beef from a country carrying out vaccinations against foot and mouth disease is safe, whereas under certain conditions this would be possible under the OIE code.

- The EU can act faster and indeed can be more flexible than the OIE in certain instances, such as in recognising different regions of a country or reinstating disease-free status following a satisfactory outcome of an inspection by the Food and Veterinary Office.

- The definition of certain disease incubation periods or other time intervals and the approaches to evaluating competent authorities for animal health is different in OIE and EU standards.

- There are differences in veterinary roles and standards as highlighted earlier.

- Diagnostic tests in EU legislation do not always mirror the prescribed tests in the OIE manual.

2.2.2.4. Emerging, re-emerging and exotic diseases are not duly considered in current legislation

Driver: Lack of flexibility and appropriate tools to respond to, control and monitor emerging and exotic animal diseases.

Problem: Potential for larger scale and more frequent exotic disease outbreaks.

Public authorities and animal keepers know less about diseases which are not commonly present in the EU (typically known as exotic diseases) or are currently unknown (emerging diseases), than about diseases which are endemic in the EU. This means that MS and the EU have lower preparedness for dealing with outbreaks of exotic or emerging diseases. This can contribute to larger scale outbreaks of exotic diseases than if there was more adequate crisis-preparedness.

General EU measures for the control of certain animal diseases are laid down in Directive 92/119/EEC but these measures refer only to a limited list of emerging and/or exotic diseases for the EU and some of these measures do not prescribe the right tools to deal with certain exotic diseases. The rigidity of current rules limits the possibilities for the EU to play a more proactive role to prevent the spread and introduction of such diseases or to react in the event of a new animal disease. This could lead to delays in taking the appropriate measures to control them. In addition, past crises have shown the need to put in place clear and flexible rules for controlling and monitoring animal diseases that can be adapted to every conceivable situation and to varying regional factors. A good example is that of bluetongue, which was outlined in 2.2.2.1 above. Other examples were highlighted by the AHL Steering Group in their meeting in July 2009 for which they felt the existing legislation is too rigid and the EU relatively unprepared. These included Rift Valley Fever, and the rules for African Horse Sickness.

During the stakeholder consultation, 86.1% of respondents replied 'agree' or 'strongly agree' to the proposals to reflect emerging diseases in the AHL and to update certain disease control directives that are outdated or disproportionate. Full details are available in 2.10 of Annex V.

2.2.3. Insufficient focus on disease prevention

Freedom from animal diseases is widely considered to be a *global public good*, as it protects the health of animals and public health as highlighted in the "One World – One Health" concept developed by the WHO (World Health Organisation), OIE (World Organisation for Animal Health) and FAO (Food and Agriculture Organisation)[30]. Its importance is not limited to the rural economy but impacts on the whole of society. Animal diseases and related control measures can be costly to the livestock sector, and to competent authorities which currently cover most of the costs of crisis response. Additionally, freedom from certain animal diseases is a necessary condition for animals and animal products before they are traded within the EU and with third countries.

While animal health crises will always occur, the CAHP evaluation highlighted the need to focus more on disease prevention and rapid and effective risk management in order to reduce the incidence and scale of animal disease outbreaks. Recent work to put in practice the "One World – One Health" concept clearly show that the emphasis is shifting away from crisis

[30] See *Contributing to One World, One Health, A Strategic Framework for Reducing Risks of Infectious Diseases at the Animal–Human–Ecosystems Interface*, at*:* http://www.oie.int/downld/AVIAN%20INFLUENZA/OWOH/OWOH_14Oct08.pdf.

response to building the systems and capacity to prevent and respond more effectively to future outbreaks of diseases.

The issues identified below are all problems caused by a mixture of both the content and implementation of existing legal powers; and because legal powers to provide an overall coherent view of all animal diseases are lacking.

2.2.3.1. Poor coordination of animal disease surveillance and monitoring

Driver: Lack of coordination between different surveillance systems and actors.

Problem: Sub-optimal use of surveillance to reduce the risk and impact of animal disease outbreaks.

As noted above in 2.2.2.2, surveillance is an essential tool to detect and control animal diseases. Its present sub-optimal use means the EU's ability to prevent disease outbreaks before they occur is not at its full potential. The improvement of surveillance systems is widely supported by stakeholders, as noted above.

2.2.3.2. Insufficient on-farm biosecurity measures to prevent outbreaks on farms and in the farming industry

Driver: Lack of comprehensive rules on farm biosecurity measures to reduce impact of disease outbreaks.

Problem: Inefficient use of biosecurity on-farm and in the farming industry, and increased risk of disease outbreaks.

Farmers (animal keepers in general) are often the best placed persons to prevent and detect animal diseases. Currently, very few mechanisms exist at EU level that actively encourage animal keepers to take preventive disease measures. Mechanisms to achieve on-farm biosecurity at other levels within the EU are mainly voluntary or industry-led schemes, which typically achieve a lower uptake than statutory measures.

The lack of biosecurity measures is driven by two factors:

– Many farmers and animal keepers lack sufficient information about biosecurity measures they could implement. In particular they are unlikely to be aware of the costs of implementing biosecurity measures compared to the benefits of reduced animal diseases. This can lead to farmers implementing fewer biosecurity measures than would be beneficial to them (because the on-farm benefits would exceed the implementation costs). This can lead to a lower level of biosecurity than is optimal and a higher risk of on-farm disease outbreaks.

– With optional or voluntary biosecurity schemes, farmers can choose the level of on-farm biosecurity they implement. Without specific mandates or incentives to take into account the wider benefits (public benefits) of their biosecurity measures, farmers are unlikely to implement additional measures above those that benefit them directly (private benefits). For example, certain measures might reduce the likelihood of disease outbreaks spreading to other farms and therefore lead to an overall lower cost of disease to society as a whole. So farmers implement on-farm biosecurity measures based on the private benefits they receive on their farm, not fully taking into account public benefits to others or to wider

society. This also leads to a lower level of biosecurity than is socially optimal and a higher risk of on-farm disease outbreaks spreading to other farms.

Still very few mechanisms, regulatory or not, exist to rate holdings with respect to their level of biosecurity within the EU. Those mechanisms that do exist do not recognise or assist those who wish to achieve higher than minimum (additional) standards (and may even create an uneven playing field for them). More data and analysis on this issue are available in Annex XI.

During the stakeholder consultation, 75.8% of respondents replied 'agree' or 'strongly agree' to the proposal of a legal framework introducing voluntary biosecurity on farms, and a minimum criteria for biosecurity measures (adapted to local circumstances). Detailed stakeholder views and conclusions are presented in Points 2.5. and 3.5 of Annex V.

2.2.3.3. Applicability and acceptability of the current vaccination strategy for control of animal diseases

Driver: The willingness of MS and stakeholders to use vaccination as a tool to control animal disease outbreaks, which is often linked to the availability and reliability of vaccines and differentiating diagnostic tests.

Problem: Sub-optimal level of use of vaccination for major animal diseases, increasing the impact of animal disease outbreaks, when they occur.

The use of vaccination to control major epidemic diseases has been the subject of very intense debate in the EU in the last twenty years. The main reasons why vaccination is not often applied by MS are the poor availability of certain vaccines and associated DIVA[31] tests; concern over potential trade blocks (of imports of vaccinated animals and/or products of vaccinated animals) by third countries; and consumer perception in the EU.

Nevertheless, it is widely agreed that in many cases vaccination could be used as a means of preventing animal diseases. But more importantly, vaccination could also be the best means of preventing and minimising negative impacts of animal diseases once they occur by preventing further spread of disease. The principle 'vaccination is better than unnecessary culling' was agreed during the creation of the AHS and its Action Plan.[32] In order to address the issue of availability of vaccines**,** a task force of experts was created to assist the Commission in the development of an expert policy paper[33] on EU vaccine/antigen banks for major animal diseases. The main conclusions reached in this process were:

– For most of the relevant infectious diseases, existing legislation regarding emerging vaccination should be amended so that vaccination becomes a more realistic and viable option in the event of a crisis.

---

31 Differentiating Infected from Vaccinated Animals

32 The European Parliament (*EP Resolution 2007/2260(INI)), the Council (Doc.15481/07 ADD 1) and the European Economic and Social Committee (NAT/376 – EU Animal Health Strategy) and stakeholders*

33 The summary of the paper produced by this group of experts was presented to the delegates of Member States during the SCFCAH meeting on 3 May 2010.
http://ec.europa.eu/food/animal/diseases/strategy/pillars/antigen-vaccine-banks-task-force_en.htm
DG SANCO consulted the Chief Veterinary Officers of the EU Member States in charge of implementing animal health legislation on the use of vaccination as a control tool for major epidemic diseases.

– The mechanisms of accessing the vaccines/diagnostics have to be clarified. A procedure should be established to assure guaranteed supply.

A detailed analysis of vaccination policy and further data are presented in Part 1 of Annex VII. Stakeholders' views concerning vaccination are collated in Point 2.15 of Annex V. As referred to previously, the questionnaire and a summary of the outcome of this consultation with the CVOs can be found in Part 2 of Annex VII to this document.

This approach is widely supported by stakeholders – there is wide agreement that vaccination should be used in a flexible way, taking into account its advantages and disadvantages and encouraged where it is strategically sensible to do so.

2.2.3.4. No consistent provisions for training on animal health for people dealing with animals

Driver: Animal keepers often have a lack of access to information and training on animal health.

Problem: Potential for sub-optimal on-farm animal health measures to prevent and control animal diseases, with increased potential for disease outbreaks.

Current EU legislation focuses on training for people dealing with or handling animals in dealers' premises, assembly centres and during transport. However, there are no provisions for training of people dealing with animals at farm level in order to achieve a higher level of awareness of the potential health, social and economical impacts that animal diseases might have and the measures that they themselves can implement to prevent them. This potential lack of awareness can lead to poor implementation of the rules, and the risk of animal health and welfare problems, such as late reporting of animal disease outbreaks. This can result in measures for controlling the diseases being delayed and therefore have an increased impact.

During the stakeholder consultation, a voluntary approach to better training was regarded as the most adequate solution by the majority of stakeholders (see Point 2.2. in Annex V). However, a significant share preferred that training should be compulsory in the AHL, expressing at the same time concerns on funding. The importance of flexibility to adapt provisions to differing circumstances was highlighted by a majority of stakeholders.

2.2.4. Rules for intra-EU trade of live terrestrial animals are sub-optimal

Whilst the previously described problems fit under the thematic headings, the steering group highlighted problems with intra-EU trade that fell under several of these different categories. Therefore rather than addressing these thematically, the issues related to trade have been grouped together. The issues here are areas where the existing law is not optimal, but any proposals for better coherence would not necessarily expand the EU's powers further.

2.2.4.1. Current animal health rules for intra-EU trade

Driver: Current animal health rules for intra-EU trade for live terrestrial animals are not always proportionate to the animal health risks posed by movements.

Problem: Current rules limit the single market for live terrestrial animals, and the administrative burden for traders and competent authorities is not always proportionate to the level of animal health risk posed by different types of movements.

Current animal health provisions for commercial movements of live terrestrial animals between MS are largely based on the "intra-EU trade" concept. Under this approach, before live terrestrial animals are moved between MS they must fulfil certain animal health requirements established in the EU legislation. Veterinary checks and examination are required to ensure the animal meets these requirements and a certificate is issued before the movement is allowed. A notification of the movement must be made in national identification and registration databases and into the TRACES[34] system.

The current EU legislation allows MS to maintain, to a certain extent, animal health rules on national movements in live animals, provided that these national rules comply with the relevant provisions on the control of diseases that are regulated at EU level.

The current system with different requirements for movements within the MS to that across MS does not fit well with the concept of the single market. Although border veterinary checks between MS were abolished long ago and certain certification rules for the EU movements are more straightforward than those for international trade; the movements system still contains different market approaches to trade within MS than for trade across MS.

Furthermore, this system was criticised during the CAHP evaluation for being complicated, expensive for operators and burdensome from an administrative perspective for operators and competent authorities, and because this administrative burden was not proportionate to the health risks posed by such movements. This is most obviously the case for movements of animals between two MS with an identical health status (in an extreme example, even movements across a border between holdings of the same owner, or cross-border transhumance) and movements of animals for direct slaughter. These are largely known in the EU, for example between Germany and the Netherlands; Belgium and Luxembourg; Austria and Germany; in the island of Ireland; Slovenia and Austria; France and Italy; the special case of moving reindeer between Finland and Sweden; and many others. In these cases, an argument can be made that the health status guarantees for the relevant animals may not need to be so demanding.

However, in some cases the measures may be proportionate to the animal health risk posed, for example when animals or their products are moved between holdings or zones of a different health status, or for specific categories of animals, where a health status is of particular or specific relevance and where appropriate health guarantees have to be provided.

A balanced solution ought to be sought for the health risks involved in a particular movement, reducing some complexity of the procedures and costs attached to it and preserving a transparent and simple system that can be easily applied in practice. More data, a special analysis and examples on this issue are available in Annex VIII.

2.2.4.2. Duplication of procedures and electronic certification

Driver: Lack of harmonisation of procedures and certification for intra-EU movements.

Problem: Current system is difficult to use and unclear, with a high administrative burden for users through duplication of procedures.

[34] TRACES is the intra-trade system for cross-border trade in animals. TRACES allows the competent authorities of the different Member States to inform each other of cross-border movements of animal submitted to veterinary certification.

The diverse information systems on animal health within the EU and in the international framework (TRACES and ADNS in the EU; WAHIS-WAHID for the OIE; and national databases for animal identification and registration) sometimes create multiplication of effort for MS, as the same notification has to be entered in several databases. In addition, despite the high number of information systems, they do not provide information fit for purpose for EU and MS risk managers to support decision making on disease prevention and control measures.

Furthermore, electronic certification could be considered as an option to simplify veterinary procedures greatly. The TRACES system could enable electronic certification and so simplify the process, but a legal basis for doing this is currently lacking.

The collection, processing and use of information on animal health does not function optimally and does not deliver its full potential value.

For example, the CAHP evaluation recommended exploring further the possibility of developing integrated electronic systems that could lead to better traceability and a reduction of administrative burdens for operators. However, there would be considerable technical and other difficulties to be overcome. Prior to proceeding, such integration efforts would have to be subject of a detailed technical feasibility study/impact assessment, as there are risks in integrating the electronic systems for EU procedures applied in animal movement (e.g. data overload, security issues) that require further technical analysis.

2.2.4.3. Concept of compartmentalisation is not widely recognised in EU law

Driver: Compartments used in some production systems are not widely recognised in EU law.

Problem: Legislation does not reflect lower disease risks of compartments, so compartmentalisation is not well incentivised in the current legal framework.

In the context of better biosecurity a new concept of "compartmentalisation" was developed at international level and described in the OIE Health Codes. A compartment is a group of one or more animal establishments which are subject to a common biosecurity management system, with a distinct health status for a specific disease or diseases which require surveillance. These control and biosecurity measures are usually applied to facilitate international trade.

In practical terms this implies that a compartment might be considered as a homogeneous production unit with respect to health status, veterinary control measures and trade, as all establishments in the compartment have the same distinct status, which is known throughout the compartment.

This concept has not been introduced into the EU legislation except in Directive 2005/94/EC related to the measures for Avian Influenza, and Directive 2006/88/EC related to aquaculture animals. It could also be extended to other diseases and used by the MS for the purposes of international and intra-EU trade, and for better control and eradication of animal diseases.

There is currently a lack of legal powers to provide an overall coherent approach for compartmentalisation for all relevant diseases.

2.3. Who is affected by the current policy?

The current policy and the issues associated with it as identified above particularly affect stakeholders involved in keeping live animals and in the production of, trade in, and import or export of live animals, animal products and products of animal origin. Non-commercial animal keepers and holdings such as pet owners, zoos, backyard farmers, and hobby farmers are also affected.

Under present legislation, animal keepers have a degree of responsibility for prevention and control of animal diseases. In general, non-professional animal keepers usually have a lower level of biosecurity and awareness of hazardous practices compared to the professional sector.

Competent authorities in the MS in charge of implementing and controlling the implementation of animal health rules are also a set of key stakeholders.

Trading partners and competent authorities in third countries are affected by the EU's import conditions for live animals, animal products and products of animal origin.

Veterinarians, both official (state) or private, other veterinary professionals, technicians and the wider veterinary industries also play a key role in the delivery of EU animal health policy.

2.4. The right and justification for EU action

2.4.1. Treaty basis

Articles 43, 114 and 168 of the Treaty on the Functioning of the European Union (TFEU) provide the legal basis for the EU legislative measures on animal health, as they are an essential part of EU agricultural, public health and consumer protection, trade and single market policy.

- **Article 43** provides the basis for the EU legislative measures on the Common Agricultural Policy. This article also became the basis for veterinary legislation as the CAHP is considered from a legal perspective to be part of the Common Agricultural Policy, so adopting the same legislative and administrative procedures.

- **Article 114** provides the legal basis for the establishment and functioning of the internal market and the approximation of provisions laid down by the law, regulation or administrative actions in this respect.

- **Article 168** on health protection refers to the protection of human health from all causes that may damage it, including those related to animal health. The legal basis for veterinary and plant health measures directly aimed at protecting public health were adopted under the co-decision procedure as a result of this article.

2.4.2. Subsidiarity test

Necessity test - Why can the objectives not be achieved by MS?

In very general terms, good animal health generates not only private benefits for the particular animal keepers and owners concerned with individual animals, but is a public good with wider societal benefits. The transmissible nature of many animal diseases means that a common approach, rather than a series of individual actions, is likely to have the greatest overall benefits.

The value of a harmonised EU approach to the control of major transmissible diseases has been confirmed by judgements of the Court of Justice and by reports of the Court of Auditors, the farming, agricultural and food industries, the European Parliament, and other stakeholders; with the Commission's role in policy making becoming increasingly accepted both within the EU and internationally.

Veterinary legislation at EU level has led to harmonised rules which apply to all MS and has replaced a complex web of national and regional rules. This harmonisation has helped to reduce the administrative burden for operators, traders, veterinarians and veterinary-related industries.

A harmonised animal health policy has played a key role in the establishment of the single market, facilitating intra-EU trade in animals and animal products (meat, milk, etc.) by setting up harmonised animal health conditions and promoting the success of the CAP. The development of harmonised EU animal health standards has progressed in parallel with the development of intra-EU trade and trade with third countries.

The necessity of continued EU level action is demonstrated by the fact that if MS were to introduce national rules including possible restrictive measures in the event of an animal disease outbreak, serious disruption would likely occur to trade in animals, animal products and products of animal origin as well as to related agricultural and industrial activities such as farming and slaughter. This could also have consequent effects on exports of live animals due to the credibility of EU measures in third countries being jeopardised, while in the long run the EU would lose the power to negotiate at international level.

Animal disease outbreaks that have occurred in the past have shown that MS may be subject to internal pressures which might not allow them to adopt the most effective disease control measures. This problem occurs particularly when certain outbreak scenarios are not provided for in EU legislation. In this situation, there could be increased spread of animal disease and additional costs and losses for the farming, agricultural and food industries as well as costs for MS and the EU.

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

The benefits of harmonised rules for the prevention, notification, control and eradication of animal diseases at EU level have been demonstrated during animal disease outbreaks in recent times. The response to these crises showed the EU's capability to react quickly, limiting the spread of diseases and minimising their impacts. This was largely due to the harmonised approach to disease control, including providing financial compensation for the losses on farms due to disease eradication measures. The current system also enables the development of sustainable surveillance and monitoring programmes by providing co-financing at the EU level. In the past, the EU harmonised approach to disease control has enabled the EU to defend the interests of its MSs on the international scene. For example, the EU has been able to negotiate the regionalisation approach for disease control measures with several third countries on many occasions. This approach looks at the evidence for where diseases actually occur, treating regions individually according to risk, not simply a single country or territory as a disease-ridden or disease-free block. This has meant that in the case of a disease outbreak in a part of the EU, other parts of the EU have been able to continue to trade without restrictions with third countries. These benefits of these negotiations could not have been achieved without the EU acting as a coherent block.

The main tools that have enabled the achievement of the benefits mentioned above are:

- The establishment of an enhanced system for animal identification and traceability and of TRACES,

- The functioning of the Animal Disease Notification System (ADNS),

- Veterinary Fund expenditure.

Furthermore, the AHL envisages the introduction of a disease categorisation and prioritisation exercise for evaluating the value of EU intervention in relation to animal diseases and related threats. This exercise would categorise animal diseases according to their impact on the economy, trade, human health, society, animal welfare and the environment. It would also take into account the feasibility of implementing successful control measures. Categorisation is a risk management exercise which would be compulsory prior to determining:

– whether a disease should be dealt with at the EU level, by MS and/or at the private level;

– if at EU level, the nature of EU intervention (such as legislation, enforcement regulation, eradication, awareness, training, cooperation or research).

The AHL aims to establish a general framework for the prevention, control and eradication of animal diseases. This framework will be built on outcome-based rules, avoiding over-prescriptiveness, and leaving room for MS to regulate or set more detailed legislation when necessary, so providing for the flexibility to adapt the rules to national, regional or local circumstances.

On the other hand, rules on trade must necessarily have a certain level of detail and precision to reduce the risk of different implementation practices by operators and competent authorities and subsequent distortion of competition and possible reduction in the coherence of the approach to tackling disease.

Boundary test - Impact on other geographical areas and other policy areas

Trans-boundary animal diseases are a permanent threat for livestock keepers and MS as they can have major economic implications for both the private and public sectors. They can easily spread from one country to another and can reach pandemic proportions. Wild animals can play an important epidemiological role in the transmission of animal diseases and their movements are extremely difficult to control or restrict between MS (for example, the spread of avian influenza through wild birds). Global trade and movements of people and goods increase the risk of rapid disease spread over greater distances. For this reason control measures and harmonised surveillance systems are needed at EU level. Past evidence of cases where MS failed to control the spread of the disease (in the absence of an EU-wide framework) show that such cases may lead to significant cross-border impacts in terms of animal health and possibly also public health.

The EU, as the largest global importer of food and animal feed, needs to protect itself against the possible introduction of exotic animal diseases and public health risks through the trade in live animals and animal products. The EU has harmonised rules for imports of live animals and animal products. Their objective is to make sure that the same principles for import are applied in all MS in order to prevent animals carrying transmissible diseases that are dangerous for livestock or humans from entering EU territory.

All types of micro-organisms (viruses, bacteria, parasites) causing animal diseases are covered by this impact assessment. Invasive alien species other than micro-organisms, but also causing diseases are not covered by this impact assessment. This issue is currently being assessed by DG Environment and will be addressed separately to the envisaged animal health law's scope of animal health and pathogens. DG Sanco has worked closely with DG Environment to ensure a joined-up approach.

The new AHS for the EU endorses the concept of the OIE and the World Bank of animal health as a "global public good", which means that good animal health benefits everyone. It accepts that the functioning of animal health services should be a public investment priority. The implementation of the strategy requires public authorities in the EU to take a common approach. Furthermore, the roles and responsibilities of all actors have to be clear and consistently enforced throughout the EU for the sake of better prevention of animal diseases.

In light of these different elements, EU action is justified, as it is clear that MS cannot achieve this satisfactorily acting alone and that the EU would achieve a consistent approach more effectively and efficiently.

3. Objectives

Having established in section 2 above that there are a number of aspects of EU animal health policy that could be improved, and that the EU has both the basis to act and can add value by doing so, we now turn to the objectives of what animal health policy is actually trying to achieve.

The EU as a whole is working towards the agreed objectives of Europe 2020[35]. Animal health objectives should uphold these crucial overarching objectives by reducing the risk of the negative economic, social (including public health) and environmental impacts of poor animal health or animal disease outbreaks; and consequently by supporting the economic security and success of animal keepers, particularly farmers.

It is worth reiterating here that animal health objectives do not stand in isolation. Good animal health is a critical factor in ensuring the viability and sustainability of the internal market; and particularly of the food sector, which is the largest single economic sector in the EU. There is inevitably overlap and interaction with other areas of policy, such as animal welfare, food safety, animal nutrition, veterinary medicines, and official controls, but also with wider agricultural and environmental issues.

3.1. General objectives

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

- to ensure a high level of public health and food safety by minimising the incidence of biological and chemical risks to humans;

- to promote animal health by preventing/reducing the incidence of animal diseases, and in this way to support farming and the rural economy;

- to improve economic growth/cohesion/competitiveness assuring free circulation of goods and proportionate animal movements;

- to promote farming practices and animal welfare which prevent animal health related threats and minimise environmental impacts in support of the EU Sustainable Development Strategy.

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

[35] http://ec.europa.eu/europe2020/index_en.htm

3.2. Specific objectives

The specific objectives of the new legislation are:

– to establish a single, simplified, transparent and clear regulatory framework that sets out systematically the objectives, scope and principles of the regulatory intervention; based on good governance and compliant with international (e.g. OIE) standards; focusing on long-term preventative measures and working together with all relevant stakeholders;

– to introduce overarching general principles allowing a simplified legal framework in order to be prepared for the new challenges, i.e. to enable quick reaction in case of emerging diseases; whilst ensuring the same quality of reaction as provided for in current legislation.

– to ensure consistency amongst the horizontal principles of the legislation in the field of animal health, animal welfare and food safety policies as well as broader EU policies on climate change and sustainability;

- to reduce the economic and social impact of animal diseases on public health, animal welfare, economy and society as far as possible by enhancing disease awareness, preparedness, surveillance and emergency response systems at national and EU level;
- to ensure the smooth functioning of the internal market of animals and animal products, with a high level of protection of animal health and public health and supporting the objectives of Europe 2020.

3.3. Operational objectives:

- to integrate the new prevention-driven and incentive-oriented approach into the core of animal health policy;
- to provide for a clear and balanced distribution of roles and responsibilities between competent authorities, EU institutions, the farming sector, animal owners and others;
- to introduce disease categorization as the basis for EU intervention;
- to provide for effective mechanisms for a rapid response to disease events, including new challenges, such as emerging diseases;
- to ensure effective emergency preparedness and early response to animal diseases threats and zoonoses, including use of vaccines as appropriate;
- to introduce simplified procedures, wherever possible for technical and other reasons, taking into account the specificity of small farmers and micro businesses;
- to ensure that the new legal framework provides enough flexibility to adapt smoothly to future scientific and technological developments;
- to reduce the risk of trade disruption by seeking an appropriate level of convergence with relevant international standards, while ensuring a firm commitment to high standards of animal health.

4. Options

In order to solve the problems identified and achieve the above-mentioned operational objectives, we have considered four policy options below. It is worth noting here that the development of any new measures will need to have taken evidence into account (where it exists), particularly scientific evidence; but also social, economic and ethical considerations.

Option 1: Do nothing (i.e: continue with current policy)

Option 2: Simplification of existing legislation with no major content or policy changes

Option 3: Existing legal framework with more self-regulation

Option 4: A new flexible general legislative framework on animal health issues, based on achieving certain animal health outcomes

Option 5: A new prescriptive legislative framework on animal health issues, based on setting specific processes and standards for animal health policy.

4.1. Option 1 - Do nothing

Current animal health rules would remain, with technical updates and adaptations made as necessary but without a horizontal framework establishing overall strategic objectives. Where possible, existing regulatory tools would be used to tackle problems identified.

4.2. Option 2 – Simplification of existing legislation with no major content or policy changes

This option would enable the bringing together of all the existing Animal Health Legislation into one large piece of legislation, but would not make any significant changes to the content of the legislation itself. Minor changes would only be made as circumstances required, and in order to comply with the Lisbon Treaty. This would slightly improve clarity of the legal framework but would not solve the problems highlighted in the AHS and in Section 2 of this document.

4.3. Option 3 – Existing legal framework with more self-regulation

This option would complement the current animal health policy and existing legislation with additional initiatives of a non-regulatory nature. Under this option, the use of self-regulation tools[36] such as the drafting of guidelines by the Commission, or by stakeholders with the Commission and/or MS acting as facilitators, would be envisaged in order to cover some of the gaps and inefficiencies of the current animal health legislation. These guidelines would focus on different aspects of day-to-day management at the farm level that may be challenging and would encourage best practice. They would take into account the risks associated with certain types of production and would explain how to contribute to disease prevention and implement more effective biosecurity and surveillance measures. As now, MS would have the ability to regulate certain issues at national level. Legislation would be updated individually as necessary to comply with new requirements (such as the new

[36] Self regulation is defined in the Commission's publication "Better Regulation: Simply Explained" (2006) as "voluntary agreements between private bodies to solve problems by taking commitments between themselves".

decision-making processes following the introduction of the Lisbon Treaty), or with technological developments.

4.4. Option 4 - Flexible general legislative framework on animal health issues (AHL)

Under this option, a new legal framework would set out the principles and objectives for animal health policy required to achieve desired **outcomes**. The outcomes, such as certain animal health and linked public health standards, would be agreed at EU level. However, the framework would be flexible to allow MS to set their own specific rules in certain cases to achieve these outcomes. It envisages that these specific rules would be based on veterinary risk assessment and cost benefit analysis to best suit particular situations in MS.

This general legislative framework of the AHL would not include detailed and specific legislative provisions such as particular disease control measures for specific diseases, specific identification and registration rules for each animal species, or specific measures on movements within the EU for particular species and so on. These specific measures would be laid down at a later stage by means of delegated or implementing acts under the procedure foreseen in Articles 290 and 291 of the TFEU. These acts would be subject to an Impact Assessment where appropriate.

4.5. Option 5 - Prescriptive general legislative framework on animal health issues (AHL)

Under this option, a new comprehensive legal framework would set out the principles and objectives of animal health. This framework would set specific standards for animal health **rules and procedures** which would be required across MS, with little flexibility for MS to adapt the rules to their differing circumstances. In this case the legal framework would be much more prescriptive and detailed but would cover more or less the same or similar content as the previous option.

Like option 4, this general legislative framework of AHL would likely not contain detailed and specific legislative provisions. These rules would be laid down at a later stage by means of delegated or implementing acts under the procedure foreseen in Articles 290 and 291 of the TFEU and subject to an impact assessment where appropriate. A more detailed overview of what could be included in delegated or implementing acts can be found in table IX.1 presented in Annex IX.

4.6. Key elements of the different options

Table 4.1 below shows in more detail how various elements of animal health policy would be implemented under each of options 3, 4 and 5. Options 1 and 2 are not considered as they would not entail changes in policy or approach, and so there would be no substantive changes to these aspects of policy.

Separately, the new elements of a legislative framework under both options 4 and 5 are set out in more detail in Annex IX. The possible structure of the AHL and its empowering provisions is also schematically presented in Annex X.

Under option 4 the legislative framework would set out the desired animal health outcomes with flexibility for MS to set rules and standards appropriate to their situations. Under option 5 the legislative framework would set out the desired animal health standards for animal health policy, which MS will be required to implement.

Table 4.1: Aspects of animal health policy in relation to options 3-5

Aspect of Animal Health Policy	Option 3	Option 4	Option 5
Clarification of owners' obligations	Guidelines clarifying keepers' obligations in existing legislation	Set framework of animal health outcomes for which the keepers' obligations have to be set	All keepers have the same obligations - set to maintain higher health standards
Training for animal keepers	Guidelines about training for keepers	All keepers must be able to provide a particular level of animal health protection, with training if necessary	All keepers must undertake training to achieve a particular level
Clarify vets' responsibilities	Guidelines about vet responsibilities for different types of vet	Vet responsibilities clarified under the basis of not having conflict of interest in light of national organisational structures	All vets have the same responsibilities across EU
Vet training	Guidelines about training of vets performing official controls	Requirement for training for all veterinarians performing official tasks ensures same quality of animal health protection throughout EU	All vets undertake identical training for official tasks
On-farm biosecurity (also see Annex XI)	Guidelines about best on-farm biosecurity practices, incl. information about costs and benefits of each practice	All keepers must introduce a certain level of biosecurity measures to ensure the health of their animals as appropriate for their type of farming and local circumstances.	All keepers must introduce a certain defined set of on-farm biosecurity measures
Prioritise surveillance	Develop non-legislative surveillance strategy/principles for surveillance priority - encourage stakeholders to follow them.	Set basic principles and increase co-ordination of surveillance based on risks and ensuring particular level of animal health protection. Encourage surveillance networks to develop along these principles	Develop EU-wide surveillance system and harmonised surveillance networks

Aspect of Animal Health Policy	Option 3	Option 4	Option 5
Intra-EU trade	No change without altering the legislation. Possible clarification about the use of assembly centres	Allow derogations for certain types of Intra-EU movements in live terrestrial animals based on risk and economic analysis	Move to placing on the market concept for Intra-EU trade in live terrestrial animals
Exotic and emerging diseases	Guidelines about best practice for exotic disease controls, develop non-legislative tools to improve disease preparedness and encourage exotic disease research	Develop legislative tools to improve preparedness and react quickly to exotic disease outbreaks; flexibility for MS to adapt tools to their own conditions	Develop tools to deal and to react to exotic diseases - the same obligations across EU
Categorisation of diseases	Encourage national CAs and stakeholders to use results of disease categorisation tool to prioritise resources between diseases not covered by EU legislation	Categorise diseases (for intervention) at EU level	Categorise diseases (for intervention) at EU and MS level and fix the tool which is used to categorise diseases
Principles for animal health import requirements	Guidelines for importers and TCs clarifying requirements and best practice for imported products	Legislation consolidates and defines animal health standards for imported commodities	Consolidation of criteria into a single transparent document. Allow for higher standards than the international based on risk assessment
Compartmentalisation	Improve information about potential for compartments under existing legislation (poultry for AI, aquaculture)	Extend compartments to more animal diseases and species - compartments have flexibility over which measures they implement as long as an EU defined health status is achieved.	Extend compartments to more animal diseases and species - compartments must comply with defined animal health measures
Align with OIE standards	Possible only with small /partial modifications in current legislation	Alignment where possible, higher standards in EU legislation only allowed on risk and CBA evidence base	Align EU legislation to OIE framework where it doesn't compromise health standards
Non-commercial farming	Encourage best-practice amongst non-commercial farming and develop guidelines for these	Definition and principles for non-commercial farming based on risk outcomes and flexible for MS conditions. Derogations from registration/ movement/ identification requirements for commercial farms where low risk to anima/human health.	Definition and rules set for non-commercial farms harmonised for the EU
Vaccination strategy (also see Annex VII)	Raise awareness about the safety of vaccinated	Legal strategy to harmonise the use of	EU level vaccination strategy, same approach

Aspect of Animal Health Policy	Option 3	Option 4	Option 5
	meat and alter market perception of vaccinated meat (affect the demand side of vaccine disconnect).	vaccines based on their impact on disease control. Options B.i. (providing flexible approach for different diseases of Union concern with EU vaccine bank) and B.ii (without EU vaccine bank) in Annex VII	for use of vaccines across the EU. Options A.i (providing a single vaccination policy for all diseases with EU vaccine bank) and A.ii (without EU vaccine bank) in Annex VII.

Of course, elements of the options could be combined for different policy aspects. For example, a flexible legislative framework could be introduced (option 4) but with encouragement for self-regulation for, say, improved biosecurity measures (following the principle of option 3) and perhaps some specific detailed rules on the face of the law for, say, animal trade and movements (in accordance with the principle of option 5). Other combinations are of course possible.

5. Impact analysis

The analysis below sets out the impacts of the different options. Options 1 (no change) and 2 (simplification only) are briefly analysed and related back to the existing problems already identified in Chapter 2. The reduction in the instance of animal disease is such a crucial outcome that a short introduction on the overall impact on the reduction of animal disease is necessary for each of the options 3-5. The analysis will then look at the economic, social and environmental impacts of each option. As mentioned above, additional analysis on intra-EU trade is also available in Annex VIII, and on biosecurity in Annex XI. The potential effects of changes were felt to be so potentially wide-ranging in these areas that some further scrutiny of the possible impacts was felt necessary.

5.1. Option 1 – No Change

To allow for a proper comparison of the options, Option 1, continuing with current animal health policy, is being used as the policy baseline and the impacts of the other options will be assessed in relation to it.

The no change option has already been specifically rejected by both the impact assessment for the AHS and the CAHP assessment, and would therefore be extremely difficult to justify. No change will mean a continuation of the current EU level approach to tackling animal health issues and the problems identified in Chapter 2.2.

Some illustrations of the possible consequences of 'no change' are set out below and add to the evidence that option 1 is not a desirable approach because of the potentially high-impact consequences of continuing with the current framework. Choosing this option would mean accepting the lack of a coherent, comprehensive approach to the EU's work in the field of animal health. The major objectives and principles of the CAHP, including the protection of animal health and also the associated public health aims would not be achieved. The roles and responsibilities of all actors involved in animal health will continue to lack clarity and there will be an insufficient focus on disease prevention. The EU will have to face the new challenges for animal and public health described in Chapter 2 with the current legal and financial instruments that would not necessarily be fit for purpose. This option will not provide sufficient incentives for farmers and animal keepers to take optimal preventative disease measures. This in turn could lower public opinion of the EU farming industries, which has already been dented in recent crises.

Furthermore, an adaptation of basic acts to the new regulatory procedure on the execution of powers based on the Treaty of Lisbon is necessary. This fact in itself requires at least certain legislative changes in the current animal health legislation and therefore doesn't support the no-change scenario.

In the boxes below we use some hypothetical examples to illustrate the potential impact of this option. The option doesn't promote a effective and pro-active approach to emerging and exotic diseases, or encourage the optimal preventive approaches or categorization of risks. There would be impacts on public health, on consumption, and on trade, as well as economic costs.

Possible consequences of a human influenza pandemic caused by a virus of avian or mammal origin

Influenza viruses are a large family of viruses able to infect many species of birds and mammals, including humans. Wild aquatic birds are the main reservoir of influenza viruses. These viruses may also spread to mammals and adapt to the new hosts. When a new influenza virus able to be transmitted between humans emerges, it may rapidly spread throughout the world causing a human pandemic.

During previous pandemics, great variations have been seen in mortality rates, severity of illness, and patterns of spread. The mortality of the previous century's three pandemics varied enormously, from less than 1 million to some 50 million deaths. One consistent feature reported in all cases, nonetheless, was the rapid surge in the number of fatalities and their exponential increase over a very brief time, often measured in weeks. Most recent estimates indicate that the "Spanish" flu outbreak of 1918 that was caused by a virus of avian origin could have been responsible for the death of 50 million people, or 2.5% of the global population of the time.

The recent fears of a devastating incoming pandemic originated from the emergence of a new avian influenza virus type H5N1 in south-east Asia in the mid 1990s which was capable of infecting and causing disease not only in birds but also in humans (due to bird-to-human transmission). From 2003 this virus began spreading westwards to more than 50 countries in Asia, Europe and Africa. According to data from the WHO, by 3 June 2011, a total of 556 human cases of H5N1 avian influenza had been reported, causing a total of 325 deaths. This represents a high case-fatality rate of 58%.

Several incursions of this virus, mainly due to the spread via migratory birds, also occurred in the EU in 2006-2010, in poultry and other birds. However, the disease was successfully contained and eradicated, thanks to enhanced surveillance and control measures, and no human cases occurred.

However, while the scientific community was mainly focussing on the potential pandemic risk posed by the H5N1 virus, in 2009 the 'swine 'flu' pandemic caused by the H1N1 influenza virus, which included genes of bird, human and pig origin, emerged in Mexico and then spread all over the world (human-to-human transmission). Eventually the pandemic caused by this virus was much less serious than feared at first, although it caused at least 18,000 deaths, with a case fatality rate of 0.03%.

Recently, the H5N1 virus circulating in Egypt – where 145 human cases have been reported in the last years - showed increased ability to bind to human cells, which may indicate an increased pandemic potential. Scientists continue to recommend closely following the evolution of this virus and to intensify the efforts to eradicate it from birds in those countries in Asia and Africa where it is currently endemic.

Pandemics, like the viruses that cause them, are largely unpredictable and it is therefore impossible to predict with any accuracy the origin of the next pandemic and its impact. However, all estimates, from the best-case to the worst-case scenario, show that losses would be very extensive. These consequences might be prevented or their impacts diminished by more effective preventive mechanisms and better tools for rapid response to emerging risks.

Examples of impact of disease outbreaks on trade

- The UK had developed a significant export trade in beef and live cattle during the early 1990s. By 1995, annual exports of beef of 300,000 tonnes were worth almost £600 million. There was also a substantial trade in live calves from the British dairy herd to the rest of Europe, worth some £70 million per year. This trade completely collapsed when the European Union imposed a ban on all UK exports worldwide as a consequence of the BSE crisis. (Source: DEFRA)

- In 2003 Classical Swine Fever (CSF) outbreaks in the Netherlands, Belgium, Germany, France and Spain resulted in a drop of 15% in live animal exports (Source: Europa-Agriculture Trade Statistics).

5.2. Option 2 – Simplification of existing legal framework with no significant policy change

Option 2 assumes that there would be a simplification of the existing legal framework, by bringing together the several pieces of existing legislation into one overall piece of legislation but without addressing policy options and developments set out in the AHS.

The benefits associated with this option are solely those from the simplification of the legislation. By bringing together all the existing legislation into one place, there would be some improved simplicity for those stakeholders searching for legislation who weren't already aware where it would be.

However, it is difficult to see how this would actually work in practice. The existing legislation has no single set of principles of overarching coherence and so to put everything in one piece of legislation would lead to a long list of the existing acquis, really achieving very little in the way of genuine simplification.

If option 2 is chosen the EU would run a reputational risk as a key opportunity would be missed to address the deficiencies in the current legislation which have been widely criticised, and the problems due to the lack of a single overall policy (Section 2.2.2.), the insufficient focus on disease prevention (Section 2.2.3.) and the shortcomings of the current rules on intra-EU trade (Section 2.2.4.). Even the problem of the large number of pieces of legislation and complexity of the current legal framework discussed in Section 2.2.1. would not be solved, as any new piece of law is not by definition more coherent unless work is done to identify and set out the principles of the animal health policy and create a new, overarching legal framework.

The approach of option 2 would not solve the problems that have emerged during the evaluation of the CAHP and highlighted by the stakeholders during the recent consultations.

5.3. Option 3 – Existing legal framework with more self-regulation

Self-regulation is defined by the Commission as "voluntary agreements between private bodies to solve problems by taking commitments between themselves". This option is

composed mainly of non-regulatory actions that will be carried out with the resources currently available and will not create additional administrative burdens. These actions would include the Commission and/or MS either developing guidance and best practice to improve animal health measures or encouraging stakeholders to do so. These would be complementary to the existing animal health legal framework and would aim to achieve better prevention of animal diseases.

In general terms, offering guidance and promoting best practices for animal health measures will make animal keepers and other actors in the food chain better informed about animal health measures and disease risks and so take more responsibility for their actions. If animal keepers are more aware of best practices for preventing diseases, they are more likely to implement measures, such as biosecurity and surveillance, which would be worthwhile for them in terms of reducing the frequency and impact of animal diseases.

However, these actions will not be mandated. They rely on the willingness of stakeholders to develop guidance in the first place; and the co-operation of animal keepers in voluntarily following this guidance, under circumstances where it may not always be in their direct interest to do so. Therefore the actual effects of this option being put into practice are very uncertain, ranging from no change at all at one end to a potentially fairly positive impact at the other. Nevertheless, even if some significantly positive self-regulatory schemes were to get successfully underway, working within the existing legal framework would be likely to prove challenging.

As part of this option, we can assume that certain legislative changes would be necessary (for example, to align with the new co-decision requirements as agreed under the Lisbon Treaty, or because of technological developments). However, these would be carried out individually for each piece of legislation rather than trying to coherently combine them into a new overarching framework as envisaged in options 4 and 5.

If we assume that some change takes place under option 3, there should be a reduction in the scale and frequency of animal disease outbreaks. This is largely because increased guidance and information is likely to improve understanding and take-up of preventative disease measures.

The likely reduction in the scale and frequency of animal disease outbreaks is due to:

- The clarification of owners' obligations – keepers are more likely to understand their obligations and comply with them.
- The increased likelihood of additional training being taken by animal keepers.
- The increase in understanding of biosecurity and keepers' likely take-up of best practice in biosecurity.
- The increase in understanding of the importance of surveillance and better individual surveillance measures being taken.
- Better information sharing about emerging and exotic diseases and their possible impacts.
- Encouraging better information-sharing and best practice among non-commercial farmers.

- Increased take-up of vaccination where appropriate.

However, as mentioned above, under self-regulation there would be no mandates or incentives for stakeholders to implement best practices recommended in guidelines (if guidelines are developed at all). This means that each stakeholder is only likely to improve his animal health practices when it is worthwhile for him as an individual to do so – i.e. the projected reduction in the costs of animal disease to the individual stakeholder is higher than the costs of implementing preventative measures. They have no incentive to consider the wider benefits of reduction in animal disease, for example benefits to other stakeholders, competent authorities, consumers and rural economies. Therefore, the improvement in animal health practices would be lower than required to reduce the impact of animal diseases by the socially optimal amount, and there is a smaller reduction in animal diseases compared to using mandates or incentives.

It is very difficult to accurately quantify this reduction in animal disease outbreaks, as the scale and frequency of disease outbreaks depend on an extremely complex set of factors, on top of the aforementioned uncertainties inherent in this option.

Furthermore it needs to be mentioned that an adaptation of basic acts to the new regulatory procedure on the execution of powers based on the Treaty of Lisbon is necessary. This fact in itself requires at least certain legislative changes to the current animal health legislation.

5.3.1. Economic impacts

Assuming that some action towards self-regulation does happen, the possible economic impacts of option 3 divide into two aspects:

- the impacts on farming and the rural economy; and
- the impact on the promotion of growth and cohesion within the EU.

Of these, the first (the impacts on farming and the rural economy) would largely be positive impacts. The reduction in the scale and frequency of animal disease outbreaks that option 3 could be expected to deliver will have positive ramifications in several areas. It is impossible to quantify these savings but there will be benefits to:

- The farming sector, through:
    - Direct financial benefits of reduced disease instance
    - Benefits through simplification of administrative burdens (although this is initially partially offset by extra costs of adjusting to any new system and developing guidance)
    - Development of new, more efficient practices
- Wider food chain stakeholders, particularly assembly centres; transporters and dealers; slaughterhouses; and food processing companies.
- The rural economy, particularly through possible improved rural employment opportunities and benefits to rural tourism (or rather, fewer disbenefits because of the lack of movement restrictions or other stigma associated with disease outbreaks).

With respect to the promotion of growth and cohesion within the EU, there might be some positive impacts from clarifying the use of assembly centres for live movements, which may enhance intra-EU trade. However, there will be some initial negative impacts from familiarising and implementing any new guidelines. Because of the uncertainty of whether and how these factors would be implemented under self-regulation, and their complex interaction, it is difficult to say whether the overall positive economic impact of any measures would outweigh the familiarisation and implementation costs.

5.3.2. Social Impacts

The social impacts of any positive self-regulation measures stem directly from the aforementioned potential reduction in animal disease instances. Any reduction in animal disease would consequently reduce any associated public health risks. So the impact (if any) is positive, but indirect and impossible to quantify.

5.3.3. Environmental impacts

First, the best practice guidelines envisaged in option 3 are likely to include aspects related to appropriate environmental management of the farm, especially regarding the use of veterinary medicinal products and better hygiene (management of slurry, etc) to minimise the environmental impact of farming practices. Therefore, if these guidelines are in fact developed, we can assume a positive environmental impact from the effects of improved environmental management.

Assuming that there is a reduced instance of animal disease outbreaks, we can extrapolate several other positive environmental impacts. However, as noted previously, this is an assumption that is uncertain and impossible to quantify. Nevertheless, the likely positive impacts include the below.

Animal diseases found in kept animals can have negative impacts on wildlife (for example, the impact of avian flu on wild birds). Thus reducing the incidence of such diseases should have a two-fold beneficial effect; both in the reduction of wildlife disease and the protection of biodiversity, and subsequent reduction of the risk of diseased wildlife re-infecting kept animals and even humans. Guidelines on best practices should also help farmers to better understand the importance of their role in interacting with and protecting wildlife and biodiversity.

Reduced animal disease instance would also lead to fewer health-related welfare problems, thereby overall improving animal welfare. In addition, if new guidelines promote better use of vaccination, this will also have a preventative effect on both animal diseases and also the associated welfare problems.

We can also assume that biosecurity guidelines would be included in any self-regulatory guidance scheme. It is very difficult to predict what the environmental impacts of improved biosecurity measures would be. On the one hand, we have already identified the positive environmental impacts from the lower instance of animal disease outbreaks. On the other hand, increased biosecurity measures might include the increased use of disinfectants or chemicals which could potentially have harmful effects on the surrounding environment.

5.4. Option 4 – flexible general legislative framework for animal health issues

Option 4 covers a new flexible general legislative framework as envisaged in the AHS. This is expected to have more definite and deeper impacts than option 3 because it will enable

legislative changes in animal health policy, which option 3 cannot bring about. It will also mandate certain aspects of animal health policy which option 3 only makes voluntary. And although it potentially has similar outcomes to option 5 in terms of animal health; it offers greater flexibility and subsequently a potentially lower administrative burden. As noted previously, Table 4.1 and Annex IX show in more detail which measures option 4 would specifically entail. However, the longer-term impacts of option 4 cannot be fully quantified at present because many of the specific rules of a general framework law on animal health will be developed subsequent to the law's introduction. Nevertheless, some general points about the overall direction of travel, and whether its effects are likely to be positive or negative, can be made in respect of its economic, social and environmental impacts.

5.4.1. Economic impacts

The economic impacts of option 4 are expected to be largely positive.

First, there are the benefits expected from reduced disease instance. These are much as outlined in 5.3.1, but because option 4 would have more definite and deeper outcomes, and is expected to have a greater impact in any case, we can say that the impacts from prevention of animal diseases would be of a similar nature, but more pronounced. However, for the reasons outlined above, it is very difficult to quantify them any further than in relative terms.

Overall, resources will be better targeted according to risk, saving time and money. This is true of surveillance, where a more risk-based approach will be encouraged; and contingency planning and categorisation/prioritisation of diseases where legislative tools will be developed to improve readiness for disease outbreaks in accordance with their risk of actually occurring.

A vaccination strategy will be developed to harmonise the use of vaccines based on their impact on disease control. The safety of products of animal origin from vaccinated animals could be emphasised to encourage the industry to increase use of vaccines, when relevant and possible. This would likely have positive economic impacts in the reduction of the instance of animal disease and all the associated impacts mentioned elsewhere in this analysis. However, there would still exist certain barriers to trade with countries who do not wish to import meat from vaccinated animals due to negative consumer perception and/or associated risks of spreading disease, so this may have a negative economic impact.

An impact of option 4 which needs some further analysis is that of administrative burden. Undoubtedly there would be some negative economic impact from the initial administrative burden of familiarisation with the new legislative framework for farmers and other animal keepers as well as competent authorities. However, due to the very nature of animal disease, regular updates of valid rules are standard procedure which means that one-off familiarisation costs are likely to be limited and integrated into business-as-usual costs (see feature box below).

As regards to the costs of familiarisation with new legislation, due to the very nature of animal diseases and continuously evolving legislation, these are largely part of business-as-usual costs. However, a special effort might be needed for CA to adequately manage the implementation of new legislation. In order to support MS in this task, while generating EU added value by fostering experience exchange, the Commission services maintain the 'Better Training for Safer Food' initiative[37] to train and advice officials in MS and third countries on EU requirements.

[37] Council Regulation (EC) No 882/2004 Art. 51

A practical example is the training on zoonoses which was provided in 2009 and 2010 for more than 300 Member States' officials, focusing on microbiological criteria and the control of zoonoses, with a total cost of just over €2m for the two years.

Ongoing training activities should only be adapted to the needs deriving from the adoption of the new legislative framework.

Nevertheless, in the long term, the more coherent strategic framework should make more sense to those learning about their obligations for the first time (for example, for new entrants to farming). Overall and in the long term, it is fair to assume that a flexible and outcome-based framework will impose a lower administrative burden on farming and related industries and animal keepers than the prescriptive framework of option 5. This is because its inherent flexibility means obligations and requirements could be tailored to national or regional circumstances, enabling MSs to adapt any administrative obligations to that which is only strictly necessary according to a reasonable assessment of risk.

However, this could lead to them setting lighter touch regulation, or fewer requirements than at EU level, because they do not wish to impose higher burdens than other MSs thereby placing their livestock industry at a competitive disadvantage. In addition, they might not fully consider the impacts of diseases on other MS when deciding level of controls – so they implement fewer controls that would be optimal for the EU as a whole (taking into account the full costs of disease spread).

There are two examples that were felt particularly important to analyse in more detail: biosecurity and trade. With respect to biosecurity, a questionnaire was carried out to seek the views of relevant stakeholders about the level of burden that the possible introduction of biosecurity plans would bring. The results are shown in detail in Annex XI and demonstrate mixed views. While many stakeholders thought that biosecurity plans would represent overall cost savings, others thought that they would impose too many costs. These mixed views suggest that the possibility of option 4, allowing MSs to introduce biosecurity plans if they felt it beneficial, would be the best option for all parties. More will be said about this in the analysis relating to option 5 below.

Intra-EU trade in animals was the other issue to be looked at in more detail, as it might be particularly affected. Under option 4, possible derogations to remove the burden of health certification could be introduced in a combination of the AHL itself and secondary legislation. Nevertheless, derogations would refer to specific sectors or types of movements, and so for each category of movement which is allowed derogation, a full individual risk and economic assessment would need to be carried out.

However, it is possible to estimate the unit saving per consignment if a particular derogation for health certification was introduced. The overview of the administrative burden at present is available in Annex VIII. The unit reduction in administrative burden is set out in Table 5.2 below following the Standard Cost Model template. The administrative burden saving to operators is estimated to be €120 per consignment sent, and the saving to the competent authority estimated at €128. These are based on the time estimates received from the administrative burden questionnaires during the consultation period and are estimates of the savings related to removing certification for particular procedures which are considered low risk, for example, moving animals for slaughter.

For illustrative purposes, the following table applies the unit cost saving to different types of movements to illustrate the potential annual reduction in administrative burden that could be

realised if various derogations were introduced. They are based on the annual number of consignments sent between MS from information in TRACES. As derogations would usually be introduced in a secondary level of legislation these benefits would not be immediately realised when the AHL was adopted, but they are indicative of the direction of travel proposed.

Table 5.2: Illustrative reduction in administrative burden saving for different categories of movements, based on movement figures in 2009. Savings figures represent estimated annual cost savings.

		Number of Consignments	Savings to Operator	Savings to Competent Authority	Total Savings
Bovine - direct to slaughter		**16,939**	**2,036,068 €**	**2,170, 733 €**	**4,206,801 €**
Bovine - all slaughter		28,314	3,403,343 €	3,628,439 €	7,031,782 €
Bovine - all movements w/out assembly centre		92,618	11,132,684 €	11,868,997 €	23,001,680 €
All species - movements less than 3 hours		**115,726**	**13,910,265 €**	**14,830,287 €**	**28,740,552 €**
All species - less than 3 hours and to slaughter		68,052	8,179,850 €	8,720,864 €	16,900,714 €
All movements to slaughter		**321,838**	**38,684,928 €**	**41,243,540 €**	**79,928,467 €**
Of which:	Bovine	28,314	3,403,343 €	3,628,439 €	7,031,782 €
	Equine	3,537	425,147 €	453,267 €	878,414 €
	Goats	621	74,644 €	79,581 €	154,225 €
	Poultry	52,364	6,294,153 €	6,710,447 €	13,004,599 €
	Sheep	8,721	1,048,264 €	1,117,596 €	2,165,860 €
	Swine	78,691	9,458,658 €	10,084,252 €	19,542,910 €

There would also be other economic impacts. The law would introduce some obligations to acquire particular knowledge for all veterinarians performing official tasks across the EU. Therefore it would be easier for vets to move around between MS to perform official tasks. This has both economic and social impacts, as it would improve the flexibility of the vet labour market in responding to supply and demand peaks and troughs (especially in times of animal disease outbreaks, when a great deal of veterinary resource may be needed in a particular place).

Unpublished data from the Federation of Veterinarians of Europe (FVE)[38] in 2010 shows that the total number of veterinarians in the 27 EU MS is 187,175. Of this number, around 25,000 work in the public veterinary services. However, it is worth noting that a large proportion of veterinarians working in private or general practice (around 112,000) also carry out some official public tasks as official or authorised veterinarians. All these categories of veterinarians will be affected to some extent by the changes described above.

The obligation to have a basic knowledge of animal health matters would not generally be over and above what is expected in good practice. Therefore, veterinarians and the vast

[38] FVE: Interim report on veterinary demography, 2010 - unpublished

majority of commercial farmers would not expect to be affected by this requirement, as their training and education, working experience and/or acquired knowledge would be sufficient to meet the basic requirements. These measures will concentrate on improving the knowledge of those carrying out activities which represent a higher health risk (such as assembly operations), and new entrants. It should also require those (relatively few) individuals who present health risks through lack of knowledge and bad practice to improve their standards. Those who would be affected are exactly those who pose the most risk, so this obligation is proportionate and sensible for disease prevention.

It is not envisaged that this measure would impose significant or disproportionate economic impacts on non-commercial farmers or other keepers of animals. While they will be required to have some basic knowledge about animal health where appropriate, it will not be over and above what good practice would dictate. In line with the risk-based approach of the framework, pet animals are proposed to be exempt from the requirements for registration, approval, record-keeping and register-keeping; movement certification where their movements are non-commercial; and in some cases, the requirements for import into the Union. As well as pets, other small-scale and low-risk situations would or could be granted derogations from requirements such as registration of premises, movement certification and identification requirements. In some cases, MS would be able to decide at what level these derogations would apply, ensuring that local contexts were taken into account.

Thus this option aims to achieve the optimum balance between reducing disease risk, but minimising costs and adapting to local circumstances.

5.4.2. Social Impacts

As noted above, there should be a slightly positive social effect with respect to the flexibility of the veterinary labour market and in particular, some benefits from achieving a consistently safe standard across the EU in animals and animal products.

5.4.3. Environmental impacts

Assuming that there is a reduced instance of animal disease outbreaks, we can extrapolate several other positive environmental impacts. However, as noted previously, this is an assumption that is uncertain and impossible to quantify. We can nevertheless assume that the flexible AHL will have a greater impact on animal disease than option 3, and the likely positive impacts include the below.

First, a better structured vaccination policy, setting up a flexible legal framework for vaccination, will provide the possibility of different approaches to be used for different diseases under different circumstances. The AHL will give the possibility to animal keepers to use vaccination for all diseases, and promote the vaccination option whenever feasible. For diseases relevant for Union intervention the AHL will take a flexible approach by choosing the best option to address a particular disease in particular circumstances on a case by case basis; for example, by allowing either a general preventive vaccination, introducing compulsory vaccination, or providing for emergency vaccination only, etc). For more details see Annex VII.

Reduced animal disease instance would also lead to fewer health-related welfare problems, thereby in overall terms improving animal welfare. In addition, if new guidelines promote better use of vaccination, this will also have a preventative effect on both animal diseases but also the associated welfare problems.

We can also assume that improved biosecurity would be encouraged in some form in a flexible manner. It is very difficult to predict what the environmental impacts of improved biosecurity measures would be. On the one hand, we have already identified the positive environmental impacts from the lower instance of animal disease outbreaks. On the other hand, increased biosecurity measures might include the increased use of disinfectants or chemicals which could have harmful effects on the surrounding environment. More stringent biosecurity measures can, however, have negative impacts on animal welfare. For example, housing pigs or poultry indoors all year round could have negative welfare impacts.

All the above could also result in better overall health of animals, which would contribute to the reduced use of antimicrobial agents in animals and thus indirectly, reducing the level of antimicrobial resistant microorganisms in animals.

As with option 3, the reduction of the incidence of animal disease should have a two-fold beneficial effect on wildlife, through the reduction in animal disease in wildlife, the associated health and welfare benefits and the protection of biodiversity; and the subsequent reduction of the risk of diseased wildlife re-infecting kept animals and even humans.

5.5. Option 5 – prescriptive general legislative framework for animal health issues

Option 5 is a prescriptive legal framework setting out specific requirements for animal health. More details about the measures that option 5 would entail are available in Table 4.1 above.

Analysis of the impacts of option 5 does come up against some of the same problems as with the other options; namely, that it is a wide-ranging legislative proposal with many different aspects. Most of the details will be covered in delegated or implementing legislation and cannot be fully described in this impact assessment. Those specific proposals with significant anticipated impacts are likely to undergo their own specific impact assessment before introduction. In this assessment, while the general direction of travel can be extrapolated, the specific levels at which certain requirements would be set are as yet impossible to develop and assess.

Option 5 is likely to lead to a significant reduction in the instance of animal disease in the EU. This has the associated benefits already described in options 3 and 4. However, option 5 is likely to have a significant administrative burden. In addition, more prescriptive rules are liable to become obsolete much more quickly with environmental and technological changes as they are less flexible. The main focus in the assessment of this option is to determine whether the projected reduction in disease is worth the associated implementation and ongoing costs, including the potential administrative burden.

5.5.1. Economic impacts

Option 5 should entail a reduction in animal disease, but as for the other options, this is extremely difficult to quantify. It is difficult to assert with any confidence that requiring the same standards across the board, as in option 5, will have a better or worse effect than a well-executed risk-based approach, as in option 4. It depends at what level resources are applied and standards are set. However, one could assert that (assuming the same level of resources applied to each option) a good risk-based application of resources, with riskier areas assigned more time and attention; will have a more beneficial effect than a uniform standard applied across the board, with riskier and less risky areas assigned a similar level of resources.

As with option 4, if option 5 were to be introduced, there would be a transitional administrative burden associated with animal keepers and competent authorities familiarising themselves with the new legislation. However, and as for option 4, due to the very nature of animal disease, regular updates of valid rules are standard procedure, which means that one-off familiarisation costs are likely to be negligible and integrated into business-as-usual costs. Also, over time, and particularly for those new to animal keeping, a more coherent framework should be easier to understand compared with option 1 (no change).

Nevertheless, option 5 envisages very comprehensive training for farmers, even those who have many years of experience. This would be an enormous administrative burden for the farmers themselves. If the MSs were obliged to provide or source the training, it would also be a massive burden for them.

We can very roughly extrapolate a range for the potential administrative burden of providing training.

We will assume that training is required by many farm personnel working with animals. There are 16.4m persons who work regularly on farm holdings (Eurostat). If we assume that 45-55% of these farmers work with animals at some point, we get a figure of 7.4-9.0m persons. Of these farm personnel working with animals, we might assume that 20-40% would be exempted because of previous education, professional development or training, or 'grandfather rights'. This would leave a range of 4.4m - 7.2m people requiring training. We will also assume that every person will have one day's training and we can assume that a day's training costs €200-400 per person to put on.

So total administrative burden (number of people x cost per person) is estimated to be in the range of €886m - €2.89bn. This ignores the costs of lost labour to those taking the training, and the cost of developing it and setting it up.

So even if it were possible to use existing mechanisms for training delivery such as the Farm Advisory Service[39], this is an enormous sum and would be very difficult to justify imposing on MSs unless there were very significant benefits expected. As it is, although some benefits would likely arise, it is virtually impossible to demonstrate that the added value of this extent of training would be in the region of billions of euros.

In addition, the lack of flexibility in the ability of animal keepers to implement differing measures for differing circumstances would likely mean that in many cases, keepers would be implementing measures very unlikely to benefit them or their neighbours, perhaps measures altogether unnecessary. Some animal keepers such as 'hobby' or backyard keepers, and perhaps even those with family pets, would also have to accept a new administrative burden.

The administrative burden for MSs is potentially very large with this option. The size of the burden would depend on exactly how it were to be implemented, but if there were requirements for MSs to provide training for animal keepers; as well as developing, administering and enforcing new animal health measures in biosecurity and surveillance; the burdens would be very significant. For example, the specific analysis of the possible administrative burden on MSs with respect to possible biosecurity requirements was carried out through a questionnaire to the MSs, as mentioned above, and the full results can be seen

[39] As outlined in Art 12 of Council Regulation (EC) No 73/2009 of 19 January 2009 establishing common rules for direct support schemes for farmers under the common agricultural policy and establishing certain support schemes for farmers

in Annex XI. The questionnaire results show mixed opinions among stakeholders. While some felt that biosecurity plans would be beneficial overall, others felt that the costs involved would be disproportionate. Therefore, on the basis of these results, it would be difficult to justify imposing biosecurity plans as an obligatory requirement for all relevant holdings and operators in all MSs.

On the positive side, the new prescriptive law would likely remove some of the obstacles to animal movements, promoting a more harmonised single market. However, with a prescriptive and comprehensive system of movements there are likely to be 'winners' and 'losers' among those who are differently affected by the new requirements, some of whom will benefit economically, but some who will bear additional costs (see also Table VIII.2 and Figure VIII.2 of Annex VIII). There will also be a positive economic impact from a more harmonised veterinary expertise. If vets are required to undergo identical training for official tasks, this will promote their free movement and, as with option 4, enable the supply of vets to better follow peaks and troughs in demand according to circumstances such as disease outbreaks. More detail on this is below in the social impacts.

5.5.2. Social impacts

The prescriptive legislative framework will set out the knowledge and skills which must be attained in the professional qualifications and training for official and approved veterinarians at EU level. Ensuring that veterinarians have the same knowledge and skills throughout the EU will make it easier for official and approved veterinarians to work in other MS without compromising health standards. Additionally, as these veterinarians all acquire more comparable knowledge and skills, this will improve the functioning of the veterinary labour market as it will reduce the barriers to veterinarians moving between MS. As noted in option 4, most veterinarians would be affected to some degree, and a large proportion of them work full time in public veterinary services or do some public veterinary work.

5.5.3. Environmental impacts

There should largely be positive health and environmental impacts from the implementation of option 5, very similar to those outlined in option 4. On the one hand, more mandated actions might be expected to produce more positive environmental impacts of the kind outlined in relation to option 4. However, the increased rigidity of option 5 may mean that measures are less adaptable to particular environmental circumstances, perhaps leading to some negative environmental impacts. It is very difficult to assess even the relative direction of travel here, let alone to quantify the expected impacts.

This is also relevant for possible vaccination policy options, which would in this option envisage a single vaccination policy for all diseases. This option is considered in a detailed evaluation in Annex VII and assessed as not realistic.

6. How do the options compare?

Below in Table 6.1 is a general summary analysis of options 3-5 against the suggested assessment criteria of effectiveness, efficiency, and coherence with overarching EU objectives, strategies and priorities. Options 1 and 2 are not considered here because they self-evidently do not meet the objectives set out in Section 3.

Table 6.1: Comparison of Options 3-5

Objectives	Option 3	Option 4	Option 5
Effectiveness	Option 3 has a range of outcomes from no change compared to the baseline, to a relatively significant self-regulatory system. Its effectiveness in relation to achieving the objectives is therefore more likely to be positive than negative. +	Option 4 is likely to be effective in achieving or working towards these objectives. +	Option 5 is likely to be effective in achieving or working towards these objectives, but may be less likely to maintain this effectiveness in the long term because of its lack of flexibility. +
Efficiency	Its efficiency depends on the amount of resources devoted to getting a self-regulatory system up and running. However, it will not require time consuming regulatory change. +/-	The flexible framework will require limited familiarisation costs; because this will mainly be undertaken within already existing training networks (e.g. BTSF, etc).It is likely to be more understandable and efficient in the longer term for stakeholders, both animal keepers and MS. ++	Option 5 is likely to require more administrative burden to familiarise and implement. While it will allow for more coherence in the legislation and may lead to an overall benefit, the lack of flexibility means that as circumstances change, more resource will be required to change the legislation. +
Coherence with EU objectives	It would not achieve the objectives set out in the EU AHS of bringing together all AH legislation under one framework. -	Would achieve the EU AH strategy goal of bringing together all AH legislation into a coherent and flexible framework. Is in line with flexible approach taken elsewhere and is most likely to achieve the operational objectives in section 3. ++	Would achieve the EU AH strategy goal of a single legislative framework but the lack of flexibility means it is less likely to achieve some of the operational objectives as it is less able to be adapted to changing circumstances in the future. +

Overall, option 4 seems to be the option most likely to deliver a good level of effectiveness, efficiency and coherence with EU objectives. It should achieve the main objectives of delivering the clarity and coherence of an overall strategy and framework, but leaving flexibility to allow for particular circumstances in particular MS or regions, and to adapt to

rapidly changing circumstances. Therefore, it is also the option which best respects the principles of subsidiarity and proportionality. Option 3, while offering more continuity with the present context, simply lacks any guarantee of positive outcomes, and retains the existing confusing myriad of legislation. Option 5 would deliver the objective of simplicity with an overarching strategy and framework, but is likely to be too rigid to adapt successfully to differing circumstances across the Union and changes in the long term, so potentially undermining its own objectives.

The beauty of option 4 is in its flexibility. As noted previously, the nature of the overarching enabling framework means that it is possible for certain specific policy measures to use the tools outlined in general terms in options 3 or 5. The tools of option 3 (some self-regulatory schemes or elements) could be introduced or encouraged if a particular issue was felt to be unnecessary or inappropriate to be specifically covered in legislation The more prescriptive legislative framework described in option 5 could be introduced for particular issues, species or diseases under delegated or implementing legislation under the flexible legislative framework if more detailed measures were necessary or appropriate.

7. How will the option implemented be assessed?

The option implemented will need to achieve, or clearly work positively towards achieving, the objectives set out in Section 3.

The AHS sums up the purpose of performance indicators well: **"Simple and reliable performance indicators** will help to measure progress towards the strategy's goals, guide policy, inform priorities, target resources and focus discussion […] They will cover both hard indicators of animal health (e.g. disease prevalence, number of animals culled due to disease) and softer indicators tracking the confidence, expectations and perceptions of European citizens. It must be recognised that uncertainties and unforeseeable events may affect achievement of the performance indicators."

It is very difficult to prescribe a set of precise indicators here that will definitively show that such a wide-ranging initiative such as the AHL has succeeded in its objectives; and additionally that any improvement in the indicators is directly attributable to the AHL. This is partly because of the complexity of the interlinked measures and their effects; and partly because the objectives could be completely undermined by external events out of the direct control of the EU or its MSs. Not only are there peaks and troughs in certain indicators (such as animal disease outbreaks) that might not be indicative of the direct effects of the AH Law; there are also other wider factors (for example, political or economic issues either within or outside the EU) that may affect the general direction of travel in some indicators.

Nevertheless, a series of measurements over a fairly generous timeframe should give an indication of the general direction of travel. Those indicators could be, as the strategy says, hard indicators or soft indicators. Examples of hard indicators of success are:

- the proportion of EU veterinary expenditure for eradication and monitoring measures compared to costs of emergency measures (data from emergency veterinary fund);

- restrictions (number of areas x length of restrictions) due to outbreaks of regulated notifiable diseases (data from ADNS/ADIS);

- the number of large scale disease outbreaks and of animals culled due to eradication measures (data from emergency veterinary fund);

- overall costs and losses for the EU, MS and farmers and other stakeholders due to animal disease outbreaks

- animal consignments moved across borders under the simplified regime;

- the number of training sessions taken up by animal keepers, especially farmers.

Several 'soft' perception indicators could be developed around the objectives outlined in section 3, particularly the operational objectives. These would need to cover the perceptions of the relevant stakeholders about the success or otherwise of each objective – sometimes a wide range of stakeholders, sometimes more narrow. For a genuinely useful indicator, a baseline would need to be taken either before or at the moment that the AHL is implemented, and comparisons in perceptions taken at future points in time.

As noted above, this impact assessment is necessarily a wide-ranging overview. When specific secondary legislative measures are introduced, more specific impact assessments will need to be completed, and as part of this, much more specific indicators for each measure.

It is envisaged that an evaluation should take place around five years after the implementation of the AHL, and the results will be made available for future decision-making.

ANNEX I Glossary of technical terms and abbreviations

ADIS	Animal Disease Information System
ADNS	Animal Disease Notification System
AGRI	EU Commission's Directorate General for Agriculture and Rural Development
AHAC	Animal Health Advisory Committee
AHL	Animal Health Law
AHS	Animal Health Strategy 2007-2013
AI	Avian Influenza
ASF	African Swine Fever
AVEC	Association of Poultry Processors and Poultry Trade in the EU countries
BSE	Bovine Spongiform Encephalopathy
BT	Bluetongue disease
CA	Competent Authority
CAP	Common Agricultural Policy
CAHP	Community Animal Health Policy
CBA	Cost Benefit Analysis
CLITRAVI	Liaison Centre for the Meat Processing Industry in the European Union
Compartment	an animal subpopulation contained in one or more establishments under a common biosecurity management system with a distinct health status with respect to a specific disease or diseases for which required surveillance, control and biosecurity measures have been applied for the purpose of international trade
COPA-COGECA	European farmer and agri-cooperatives organisation
CSF	Classical Swine Fever
CVO	Chief Veterinary Officer
DEFRA	Department for Environment, Food and Rural Affairs, United Kingdom
DG	Directorate General
EAZA	European Association of Zoos and Aquaria
EFBA	European Fur Breeders' Association
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENTR	EU Commission's Directorate General for Enterprise and Industry
ENV	EU Commission's Directorate General for Environment
EUROSTAT	The statistical office of the European Union
FAO	Food and Agriculture Organisation
FEAP	Federation of European Aquaculture Producers
FEDIAF	European Pet Food Industry Federation

FESASS	European Federation for Animal Health and Sanitary Security
FMD	Foot and Mouth Disease
FVE	Federation of Veterinarians of Europe
FVO	Food and Veterinary Office
HPAI	Highly Pathogenic Avian Influenza
IA	Impact Assessment
IAB	Impact Assessment Board
IFAH - Europe	International Federation for Animal health Europe
Intra-EU trade	Movements of animal and products between EU Member States
ISSG	Inter-Service Steering Group
LPAI	Low Pathogenic Avian Influenza
LS /SJ	The European Commission's Legal Service
MS	Member State / Member States
NCD	Newcastle Disease
OIE	World Organisation for Animal Health
OIE PVS	The OIE Tool for the Evaluation of Performance of Veterinary Services
OLAF	European Anti-Fraud Office
RepVet group	Veterinarians representing sectors of artificial insemination of their respective MS (in the framework of COPA-COGECA)
RTD	EU Commission's Directorate General for Research and Innovation
SANCO	EU Commission's Directorate General for Health and Consumers
SARS	Severe Acute Respiratory Syndrome caused by Corona virus
SCFCAH	Standing Committee of the Food Chain and Animal Health
SG	European Commission Secretariat-General
SVD	Swine Vesicular Disease
TFADS	Task Force for Animal Disease Surveillance
TFEU	Treaty on the Functioning of the European Union
TRADE	EU Commission's Directorate General for Trade
TRACES	Trade Control and Expert System of the EU
The Treaty	Treaty on European Union
UECBV	The European Livestock And Meat Trading Union
Vier Pfoten	For Paws international
WAHIS-WAHID	World Animal Health Information System and World Animal Health Information Database
WHO	World Health Organisation
WTO	World Trade Organisation
WTO-SPS	World Trade Organisation - Sanitary & Phytosanitary Agreement

ANNEX II Key Messages from the evaluation of the Community Animal Health Policy (CAHP)

The following key points have emerged from this evaluation:

1. Over the time period reviewed by this evaluation (1995-2004), the Community Animal Health Policy (CAHP) has become increasingly successful in terms of achieving the outcomes it is seeking to pursue. Although policy improvements were mainly stimulated by the need to respond to some major crises that occurred in the Community during this period, the results can be considered to have been positive. Thus, for example, there has been a considerable reduction over time in the prevalence of a significant number of animal diseases and a considerably better structured response to crises. Following the CSF, FMD and AI crises all relevant "vertical" legislation on the control of these diseases was revised and updated, taking into account the lessons learnt, including those on vaccination and contingency planning. It is also an achievement that over time the Commission's role in respect of the policy has come to be increasingly widely accepted both within the EU and internationally.

2. This having been said, until now the policy has consisted of a series of interrelated policy actions/actors at institutional and civil society level operating under a large umbrella of legislation and formal/informal networks but without a definition of strategy for the whole and limited assessment of the success of actions taken in terms of review and feedback on performance. The evaluation has demonstrated the need to develop a clear and transparent strategy accompanied by a communication strategy which improves stakeholder engagement and involvement in decision-making. In addition, future actions need to be informed by a review of the achievement of outcomes in relation to past actions.

3. The evaluation has highlighted the many linkages inherent in the policy e.g. between what happens in third countries, what happens at EU borders and what actions are taken to secure animal health status within the EU. In future better consistency between actions to improve animal health and welfare in the EU and international competitiveness could be achieved by pursuing simplified rules and better regulation and carrying out impact assessments before introducing new legislation.

4. Subsidiarity aspects have been a key theme underlying the various policy areas covered by this evaluation. With principles and rules laid down at EU level but implemented by Member States, enforcement issues have often been identified as a key parameter in allowing flexibility at MS/regional/local level while the Commission's role is crucial in guaranteeing that a common approach and standards apply across the Community.

5. In terms of strategic focus, while it is clear that crises will always recur, the evaluation has highlighted the need to move towards a policy which is more focused on effective risk management/disease prevention. This can be achieved via better risk based targeting of funding (using cost effectiveness and cost benefit analysis), measures and incentives at all levels as well as early detection of exotic and new/emerging disease threats. This involves better prioritisation of actions relating to disease eradication and surveillance, research and development, controls on illegal entry of potentially risk

carrying materials but also more generally creating a stronger culture of bio-security at all levels.

6. Following analysis undertaken in particular under Part II of this evaluation, a key component in the creation of such a culture of bio-security would be the introduction of a harmonised framework for cost and responsibility sharing. This could be structured so as to allow implementation in line with subsidiarity at Member State and regional level. A key component of such a cost and responsibility sharing framework as well as the idea of better overall prioritisation of actions would be the introduction of a disease classification system. This would allow greater focus on those diseases which can be considered to have high 'EU relevance' in terms of the need for coordinated action at EU level due to their potential impact on human health and potential supra-national/supra-regional economic impact.

7. More specific actions which could be considered for the future would include:
   - Further alignment of EU rules more closely with OIE guidelines and standards;
   - A gradual move towards integrated electronic identification and certification procedures for intra-Community trade;
   - The streamlining of texts going through the Standing Committee procedures;
   - Providing specific support for bio-security measures at farm level via existing funds;
   - Providing specific support to third countries to assist them in upgrading their animal health status to meet EU and international (OIE) requirements;
   - Negotiating export conditions at Community level;
   - Targeting illegal (commercial) imports/fraud.

A preliminary assessment of the advantages/disadvantages, feasibility, stakeholder acceptance and needs for further assessment has also been undertaken for each of these actions.

The full CAHP evaluation and supporting documents are available at: http://ec.europa.eu/food/animal/diseases/strategy/final_report_en.htm

ANNEX III Summary of chronology of main exchanges with representatives of specific sectors likely to be affected by the new AH Law

No	Action	Time
(1)	Stakeholders' Steering group (1st meeting)	18 February 2009
(2)	Animal Health Advisory Committee meeting	6 March 2009
(3)	Stakeholders' Steering group (2nd meeting)	25 March 2009
(4)	Stakeholders' Steering group (3rd meeting)	19 May 2009
(5)	FESSAS (Fédération Européenne pour la Santé Animale et la Sécurité Sanitaire) general assembly	12 June 2009
(6)	Animal Health Advisory Committee meeting	15 June 2009
(7)	Stakeholders' Steering group (4th meeting)	3 July 2009
(8)	CVO meeting	3 September 2009
(9)	Special Advisory Committee meeting (Consultation kick-off)	29 September 2009
(10)	Informal CVO meeting, Jonkoping, Sweden	21-23 October 2009
(11)	Animal Health Advisory Committee meeting	9 November 2009
(12)	CVO meeting	10 November 2009
(13)	Thorough stakeholders consultation in the frame of the preparation of the impact assessment	23 October to 31December 2009
(14)	FVE (Federation of Veterinarians of Europe) - General Assembly	13 November 2009
(15)	DG AGRI – Advisory group on beekeeping	18 November 2009
(16)	Administrative burden/costs and compliance cost questionnaires for CA and operators – informal consultation with the members of ISSG	20 November to 3 December
(17)	Meeting: Veterinary education – DG Markt, DG EAC	23 November 2009
(18)	Administrative burden/costs and compliance cost questionnaires – sent to the MS and stakeholders	5 December 2009
(19)	CVO meeting	8 December 2009
(20)	Fédération Nationale des groupements de défense sanitaire	9 December 2009
(21)	COPA–COGECA (Comité des organisations professionnelles agricoles - Confédération générale de la coopération agricole) working party on animal health and welfare	9 December 2009
(22)	Task Force Animal Disease Surveillance: surveillance in general	17 December 2009

(23)	CVO meeting	14 January 2010
(24)	Animal Health Advisory Committee meeting (if and as necessary, depending on progress)	8 February 2010
(25)	Rencontre avec les éleveurs de l'Aisne 02, France	15 January 2010
(26)	Meeting veterinary education: EAC	15 February 2010
(27)	DG AGRI - Simplification WG with MS experts	23 March 2010
(28)	Informal CVO meeting – Sevilla, Spain	13-15 April, 2010
(29)	Meeting FESSAS	22 April 2010
(30)	Intra-SANCO meeting	10 May 2010
(31)	Task Force Animal Disease Surveillance: surveillance in the EU AHL	17-18 May 2010
(32)	COPA–COGECA working party on animal health and welfare	19 May 2010
(33)	COPA –COGECA RepVet meeting	19 May 2010
(34)	CVO meeting	16 June 2010
(35)	Inter-Service steering group meeting	5 July 2010
(36)	Animal Health Advisory Committee meeting	18 June 2010
(37)	Rep Vet meeting and EU AI Vets conference	15-16 September 2010
(38)	COPA-COGECA – Export working group	10 October 2010
(39)	Meeting COPA-COGECA working party on animal health and welfare	4 November 2010
(40)	AHL WG meeting with EU MS, Switzerland, Norway and Iceland	10 December 2010
(41)	Council WG on bee health	1 February 2011
(42)	AHL WG meeting with EU MS, Switzerland, Norway and Iceland	4 February 2011
(43)	Animal Health Advisory Committee meeting	17 February 2011
(44)	CVO meeting	18 February 2011
(45)	AHL WG meeting with EU MS, Switzerland, Norway and Iceland	4 March 2011
(46)	Commission CVO meeting	22 March 2011
(47)	COPA-COGECA working party on animal health and welfare	30 March 2011

Minutes of these meeting, consultation results, summaries, conclusions and presentations used to steer the discussions are available upon request.

ANNEX IV Summary document of the stakeholders' steering group: "Problem identification during the creation of the animal health law"

EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate D – Animal Health and Welfare
D1 - Animal Health and Standing Committees

Brussels 03/07/2009

WORKING DOCUMENT

on

PROBLEM IDENTIFICATION DURING THE CREATION OF THE ANIMAL HEALTH LAW (point 4 of the Programming document[40] of the Animal Health Strategy 2007-2013)

Steering Group on the EU Animal Health Law
Brussels, 3 July 2009

This document does not necessarily represent the views of the Commission Services

[40] http://ec.europa.eu/food/animal/diseases/strategy/pillars/action_en.htm

Problem identification (group)	Problem definition	Objectives/Solutions (following the discussion of the SG)	Relevance for the AHL/Remarks
Complexity of the legislation	Current legislation is composed of 60 basic legal acts and more than 400 implementing acts and safeguard rules.	To establish a horizontal act containing the general principles, main objectives, and tools.	Yes
	In the absence of a horizontal legal act the legislation is scattered among many legal measures with a different subject-matter, a mixture of horizontal and vertical issues including trade (intra-Community and international), disease control measures and specific safeguard measures.	To merge common provisions scattered through different Directives To clarify links with other legislation	
Burdensome implementation	Identification, Registration and Traceability systems are often perceived as too burdensome, costly	To establish a reliable system for food producing animals based on the risks for human and animal health and not only on grounds of costs Costs borne by all beneficiaries not only livestock owners (measures considered as Global Public Good).	Yes No for detailed provisions
	Bovine identification system is too complex and resource-demanding (notification obligations, documents, finances).	Bovine identification simplification	AHS Action plan: Steering group on electronic identification of bovine animals.
	Disease control and preventive measures currently applied to hobby and /or backyard farms might be too restrictive but on the other hand, these measures might be necessary in order to address risks.	To clarify a need for the differentiation or unification of disease control measures on commercial and non-commercial farming to address risks in a proper way.	Yes
	Current animal health rules for zoo's and circus' animals require the registration of the movements of these animals inside a country.	To clarify the scope the rules of identification and registration of certain categories of animals	Yes

Problem identification (group)	Problem definition	Objectives/Solutions (following the discussion of the SG)	Relevance for the AHL/Remarks
Unclear responsibilities	There are several existing databases and computerised systems (TRACES, I+R, ADNS) which are not interconnected and require different notification processes, which often leads to duplications and unnecessary burden.	Need for alignment of ADIS with the OIE database - WAHIS/WAHID as Regional Core System. Integration national I&R databases and TRACES. To verify the possibilities for unified I&R system (EU 27), and possible links linked to the animal health information system (long term).	Yes Steering group on ADIS Steering group on Electronic certification and Inter-operability of bovine databases
	No unified legal basis for TRACES (outdated, originating from ANIMO and SHIFT).	To provide for an appropriate legal base for TRACES and TRACES procedures.	Yes No - for detailed provisions.
	Need to modernise and simplify certification	Electronic certificates possibly in TRACES To simplify wording in the certificates as far as possible.	Yes AHS Action plan: Steering group on electronic certification
	Responsibilities of the competent authorities not always clear (control obligations)	To clarify the roles and responsibilities of different actors as regards official controls and other supervision or testing activities not directly linked to the verification of compliance with the existing legislation.	Yes (see also part on convergence with international standards: Veterinary services to be considered as a Global Public Good).
	The role and the tasks of the approved veterinarians need to be to be clarified in relation to the official controls (Regulation (EC) No. 882/2004).	Clarify and adjust the roles of official veterinarians, approved veterinarians and other official control bodies covering the full scope of the animal health law.	Yes

Problem identification (group)	Problem definition	Objectives/Solutions (following the discussion of the SG)	Relevance for the AHL/Remarks
	Need for a better and clearer coordination between different surveillance systems and actors.	To establish a better surveillance network where the roles of all actors are clear in order to achieve an effective preparedness for control and eradication of animal diseases.	Yes
	The responsibilities of animal keepers/farmers/owners/operators/animal transporters/dealers and veterinarians are not clear.	The roles and responsibilities of all actors need to be clarified.	Yes
	The role of NGOs and farmers associations is not clear.	To clarify the role of NGOs, industry associations.	Yes
	EFSA's role is not clear as regards animal health and welfare.	To define EFSA's role as regards animal health and welfare risk analysis.	Yes
Rigidity of legislation to adapt to new circumstances and developments, including scientific developments	Legislation is too rigid to be adapted to scientific developments and new circumstances.	Legislative instrument to establish general principles to be directly applicable, while specific control rules should be easily modifiable (comitology).	Yes No - for detailed provisions.
	Flexibility for appropriate urgent response in case of disease outbreaks has to be at least maintained.		
	Provisions of the bluetongue directive do not reflect the current health situation and this result in spread of the disease.	Revision of the rules for control and eradication o bluetongue.	Yes - for general provisions.
	Rules on Swine Vesicular Disease are disproportionate to the risk.	Set proportionate rules for SVD.	Yes – for general provisions. Prioritisation exercise
	Protective measures for NCD are outdated (Directive 92/66/EEC)	Set new and updated rules for NCD	Yes - for general provisions
	Procedure for standardisation of used laboratory tests is too complicated.	To simplify procedures for standardisation as far as possible, use of diagnostic manuals and ISO references OIE and Codex (CCMAS) references.	Yes – for general provisions
	Certain rules for intra-Community trade are inflexible	Trade facilitation mechanisms and	Yes

Problem identification (group)	Problem definition	Objectives/Solutions (following the discussion of the SG)	Relevance for the AHL/Remarks
	and difficult to implement.	cross-border facilitation: reduced controls for trade between territories with the same health status, possibilities to supply certain categories of animals cross-border, surveillance, I+R rules, biosecurity.	
	There is a need to clarify the use of bilateral agreements for intra-Community trade in order to ensure a proper functioning of the Single Market.	Clarification of the use of bilateral agreements.	Yes
	Need of import certificate for animals accompanying their owners and for certain products for personal consumption in all cases even if they do not pose any risk.	The obligations for import certificates and possibilities for derogation to the general rule to be set in the AHL.	Yes – for general provisions Directives 2002/99/EC and 92/65/EEC
	Directive 92/65/EEC is "unworkable": trade conditions for many animal species are not clear or not useful and create unnecessary administrative burden.	Directive 92/65/EEC to be improved radically.	Yes - for general provisions
Limited convergence with the international standards (See also part on "Unclear responsibilities")	Current legislation does not recognize Veterinary services as a public good in line with the OIE provisions	To set provisions on: - Staff resources - Coordination/cooperation between the CA - Training or guidelines for vet. Services - Definition and distribution of responsibilities	Yes OIE Chapter 3.1., 3.2., OIE PVS Tool (Evaluation of veterinary services).
Duplications, overlaps, inconsistencies with other policy areas	Need to review the categories of animals for intra-Community trade (especially Bov, Ov, Sus and equidae) as they are not consistent with the import rules (and the OIE).	To review the categories of animals for intra-Community trade to make them consistent with the international trade rules and standards where relevant.	Yes No – for detailed provisions
	The concept of what is considered as" trade" and the definition of "non-commercial movement" are not clear.	Concepts as "trade" and "non-commercial" movement to be clarified.	Yes

Problem identification (group) exist (such as zoonoses, animal nutrition, animal welfare, official control regulation.)	Problem definition	Objectives/Solutions (following the discussion of the SG)	Relevance for the AHL/Remarks
	Provisions for intra-Community trade and import of equidae are inconsistent. (Directive 90/426/EEC).	Amend the provisions for intra-Community trade and imports of equidae.	Yes No – for detailed provisions
	Rules for movements of pet animals younger than 3 months are not harmonised There are no rules for pet animals others than dogs, cats and birds	Revision of the rules for the movement of pet animals to better adapt them to the risks.	No Regulation (EC) No. 998/2003
	Biosecurity needs to be applied as a preventive tool and not only when an outbreak occurs	- Possible application of HACCP - principles system for biosecurity on-farms - Biosecurity guidelines on EU level - To encourage the drafting and application of biosecurity guidelines at MS/regional/other levels.	Yes
	Need to provide incentives for prevention of animal diseases.	To provide incentives for the adoption of biosecurity and other preventive measures, financial incentives, trade incentives, reduced number of controls.	Yes
	The concept of compartment is currently only applicable to the poultry sector as regards Avian influenza.	Introduction of the concept of compartment for other diseases/species.	Yes
Prevention-driven approach	Early detection of animal diseases and the current surveillance network needs to be improved	Animal keepers (including hobby keepers) need to be registered and to implement preventive measures including surveillance adapted to their activities.	Yes
		Compulsory veterinary supervision of holdings/herds.	

Problem identification (group)	Problem definition	Objectives/Solutions (following the discussion of the SG)	Relevance for the AHL/Remarks
	Need to put in place a clear vaccination strategy for the different diseases.	- Vaccination as a possible tool - vaccination strategies - exit strategies	Yes (general principles) Remark: Task force on the reinforcement of the EU antigen/vaccine banks
	Sufficient rendering capacity is not always available for crisis events	Ensure sufficient rendering capacity for crisis events, so that dead animals are not buried or burned, in order to efficiently prevent the spread of diseases.	No Provision included in the new regulatory proposal for animal by-products
	Epidemiological unit and the definition of holding are not clearly set in the EU legislation.	Epidemiological unit to be clearly defined (align to the OIE Code definition)	Yes
	Current legislation allows moving around sick bee-colonies.	To amend rules in order to prevent further spread of bees' diseases	Yes - for general provisions
	Emerging diseases not properly addressed – in particular Rift Valley Fever (Directive 92/119/EEC) and rules for AHS.	Emerging diseases should be reflected	Yes - for general provisions Prioritisation exercise
	Other diseases as PRRS, E. multilocularis, Gyrodactilus salaries are not properly addressed in the current rules for control and eradication.	To assess the need to address other diseases.	No – with the exception of general principles. Prioritisation of diseases
	The re-grouping of animals in assembly centres may pose a threat for the spread of animal diseases.	To explore options in order to address this potential risk.	Yes No – for detailed provisions
	The system of identification of companion animals is not harmonised and is not compulsory for all species and this might lead to animal health and welfare	The relevance of identification of companion animals needs to be highlighted from different perspectives	Yes

Problem identification (group)	Problem definition	Objectives/Solutions (following the discussion of the SG)	Relevance for the AHL/Remarks
	threats (including illegal trade).	(animal health, animal welfare, public health and illegal trade).	
	Provisions for the certification of game birds are unclear, disease surveillance programmes for some of the diseases need to be evaluated (Directive 90/539/EEC).	Provisions of Directive 90/539/EEC to be revised	Yes No – for detailed provisions
	Need to minimize opportunities for mistakes and fraud in the certification process.	Certificates reflecting clearly the trade conditions and clear adequate items that could be honestly signed by a veterinarian	Yes No – for detailed provisions
	Un-availability of Veterinary medicines due to insufficient markets (minor uses/ minor species)	DG ENTR	No (DG ENTR)
	Public interest of having reliable vaccines and diagnostic tools		
	Need for DIVA vaccines to deal with different animal diseases		
	Misuse of veterinary medicines can trigger the appearance/spread of antimicrobial resistant organisms.	Promoting responsible use of antimicrobials	Yes
	Rules for imports of pathogens including aquatic animals' pathogens are not harmonised.	To harmonize provisions for imports of pathogens. Directive 92/118/EEC	Yes No – for detailed provisions
	Rules for imports and trade of reptiles and amphibians and trade of deer/ other ruminants are not harmonized. (Directive 92/65).	Review provisions of to better adapt them to risks.	Yes No – for detailed provisions

Problem identification (group)	Problem definition	Objectives/Solutions (following the discussion of the SG)	Relevance for the AHL/Remarks
	There are no common horizontal rules and standards on basic knowledge on animal health for people dealing with animals.	To establish rules or training for the persons involved with animals. To promote/encourage training To raise awareness of the need to have appropriate training programmes.	Yes For official control staff: 882/2004 For veterinarians: Decision 90/424/EEC
Others	No specific provisions on the qualifications of official and/or approved veterinarians in the field of animal health / animal welfare (Rules governing the qualifications of official veterinarians already exist in the Regulation (EC) No. 854/2004 for the veterinary public health)	To set rules governing the qualifications of official veterinarians in the field of animal health / animal welfare similar to those already existing in the Regulation (EC) No. 854/2004	Yes

ANNEX V Summary of Consultation Responses

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Animal health and welfare
Animal health and standing committees

Working document on the

"Annotated agenda

for stakeholders' consultation"

Summary of the consultation questionnaire on the new EU Animal Health Law
Brussels, March 2010

This document does not necessarily represent the views of the Commission Services

Please note that this document has been established for information and consultation purposes only. It has not been adopted or in any way approved by the European Commission and should not be regarded as representative of the Commission Services either. The European Commission does not guarantee the accuracy of the information provided, nor does it accept responsibility for any use made thereof.

1. Introduction

The wide stakeholders' consultation on possible approaches for the new Animal Health Law (AHL) included 14 major issues that were collected by the Commission in previous discussions with the AHL Stakeholders' steering group.

The consultation document "Annotated agenda for wide Stakeholders' consultation was presented to the Animal Health Advisory Committee on 29 September, 2009.

This document was published on the Commission website and was available through the Commission's IPM tool (Interactive Policy Making) as of 23 October 2010 until the end of 2009. The consultation was concluded at the end of 2009 / beginning of 2010.

During this period the Commission received 153 responses. Structure of responding entities is presented in Table 1.

Comments presented below are summarised regardless of the fact whether they were made by the participants of the consultation that have supported Commission's preliminary approach or rejected it.

Status of submitting entity: -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)	
An economic/business operator	17		(11.1%)	(11.1%)
An organisation	110		(71.9%)	(71.9%)
Other (please specify)	26		(17%)	(17%)

If an organisation, nature thereof: -single choice reply- (compulsory)

	Number of requested records	Requested records (110)	% of total number records (153)	
EU national veterinary authority	7	(6.4%)		(4.6%)
Other national veterinary authority	6	(5.5%)		(3.9%)
International organisation	4	(3.6%)		(2.6%)
Industry organisation on EU level	13	(11.8%)		(8.5%)
Industry organisation on national level	23	(20.9%)		(15%)
Non-governmental organisation EU level	12	(10.9%)		(7.8%)
Non-govt. organisation national level	28		(25.5%)	(18.3%)
Other organisation (please specify)	17		(15.5%)	(11.1%)

2. Results of the consultation

Results and summary of different questions are presented in the following points

2.1. Responsibilities and obligations of animal keepers and owners

- Proposed approach for comments

The Community Animal Health Law would clearly set out the obligations of animal keepers/owners/operators and those would be applied equally in all Member States.

- Statistics

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	45	(29.4%)	(29.4%)
Agree	75	(49%)	(49%)
Neutral	9	(5.9%)	(5.9%)
Disagree	15	(9.8%)	(9.8%)
Strongly disagree	4	(2.6%)	(2.6%)
Not relevant	1	(0.7%)	(0.7%)
No opinion	4	(2.6%)	(2.6%)

- Comments

Rules:

- To establish the roles and responsibilities of the operators in a Regulation would allow for more clear and practical rules, will help to limit/prevent actions under political pressure and will establish a level of playing field for operators in the EU ensuring a smooth functioning of the internal market as the animal health policy will be implemented in a uniform way across the EU.

- A Directive establishing general principles to be applied equally in the MS would be better option as it provides for greater flexibility to adapt it to different circumstances in the Member States (different species and production systems, economic needs, territorial needs need for quick action in case of emerging threats).

- This issue should be left to be regulated by the MS so they can agree the roles and responsibilities in conjunction with their livestock industry. To lay down the roles and responsibilities of the operators at EU level will create an inflexible system.

- The EU should only regulate the aspects that could have an impact at EU level (e.g.: trans-boundary animal diseases). MS should be able to set higher standards than the EU ones.

- There is no need for establishing these rules as current legislation sets clear obligations for operators.

- A licensing system for farmers accredited by experts should be established (linked to knowledge, training, etc).

- Transitional period needs to be provided.

- Responsibilities of operators other than animal keepers such as transport operators, handlers of animals and trader must be defined as well.

- Roles and responsibilities should be defined for all animal owners/keepers (keepers of wild animals, hobby-keepers, etc.)

- Obligations should be output based and not prescriptive. They should be practical, proportionate, and science-based, adapted to different situations in the Member States and should avoid disproportionate burden.

- The roles and responsibilities should be linked to EU compensation after animal disease outbreaks.

- Some disease incursions are out of control of the farmers (e.g. bluetongue virus).

- Animals registered in the national databases should always be linked to a responsible person (owner, keeper).

- When establishing roles and responsibilities of operators it should be specified how they need to liaise with the veterinarians. Operators should be obliged to take appropriate professional advice to manage risks.

- Should be clear that notification of an outbreak will not have negative consequences: encourage early reporting.

- Animal health and animal welfare rules should be separate.

- Coherence with food law needs to be ensured.

- The rules for use and availability of veterinary medicines are also important. Roles and responsibilities should be laid down together with obligations and privileges emerging from them and linked with setting the right conditions to fulfil these responsibilities (scale and intensity of the production, level of biosecurity, disease status and self control measures)

- Third countries replying to the questionnaire highlighted that these obligations should not be imposed to third country operators exporting animals and animal products to the EU.

Impacts:

- The Member States should be responsible for ensuring and demonstrating full implementation (including control of the system and sanctions in case of non-compliance).This could generate administrative burdens and have negative impact in other controls due to lack of resources.

- The consequences for small farmers should be taken into account. Traceability requirements should be adapted to them and simplified, if not they risk disappearing and they play a crucial social role in rural areas. Same considerations apply for hobby holdings.

- The impact would depend on the current situation in the Member States and on the different sectors, on new obligations been introduced or just a clarifying the current ones and also is the fulfilment of these roles and responsibilities would be linked to the EU financial compensation after animal disease outbreaks.

- To clarify the roles and responsibilities of the operators will benefit animal welfare and animal disease control.

Specific sector concerns: Zoos

- The specialized and unique role of zoos must be considered in the AHL (zoo animals are not part of the food chain but part of breeding-conservation programmes). There is a need to clarify when animals kept in zoos would fall under the definition of the animal health law. Implementation of AH legislation for these animals varies considerably amongst the MS and this makes the movement within the EU difficult (transport is rare and not as risky as farmed animals, part of breeding and conservations programmes). Knowledge of applicability at customs level and local level is poor. Negative consequence to these specificities are not taken into account.

2.2. Training on animal health and welfare for people dealing with animals

➢ Proposed approach for comments

The animal health law could introduce the possibility of training people dealing with animals, and give incentives and tools (guidelines) to the Member States for such training. Increased awareness of potential threats related to animal diseases among staff dealing with animals is one of the basic pillars of effective and efficient early detection systems.

➢ Statistics

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	26	(17%)	(17%)
Agree	88	(57.5%)	(57.5%)
Neutral	9	(5.9%)	(5.9%)
Disagree	18	(11.8%)	(11.8%)
Strongly disagree	6	(3.9%)	(3.9%)
Not relevant	1	(0.7%)	(0.7%)
No opinion	5	(3.3%)	(3.3%)

- Comments

Financial issues:

- The impact of training provisions would depend on its funding. The Rural Development Fund is used for this purpose in some MSs. The use of funds from the Better Training for Safer Food programme should be considered.
- Funding and training centres are needed in the MSs.
- Training requirements should be linked to compensation after animal disease outbreaks.
- There should be a compensation of business hours lost due to training for animal keepers.
- Training at work should be possible.
- Cost-effective means to provide training should be explored (webpages, etc)
- There will be no big impacts in the MSs as training systems are already in place.
- An assessment of the availability and quality of training in the Member States (MSs) will need to be carried out.

Target group

- Low motivation of farmers for attending training could be an issue, especially for those with "worst" preventive behaviour.
- Training is needed mainly for non-commercial activities and extensive farming.
- It's necessary to take into account the knowledge that they already have (different level of knowledge, experience and education of the farmers). Experience and "learning by doing" should be recognized.
- Accessibility of training to small farmers, in remote areas needs to be guaranteed (not to discourage them from quitting the activity). Negative social and economic impacts are expected if training requirements and access to training are not adapted to them.
- An important target group for training is the staff working in abattoirs (early detection of animal diseases).
- How to ensure and control training of pet owners, temporary staff?
- Training is needed especially for new farmers.
- Zoo staff is very experienced and qualified. Training is already available for them but more harmonization will be welcomed.

- Stricter rules on training should apply for professional keepers than for non-professional ones.

- Target-groups for training are too large: only for commercial activities. Better not to include animal welfare.

Compulsory Vs voluntary. Level at which training should be regulated.

- Training needs are too specific (depending on the activity, the experience and knowledge of the animal keepers) to be addressed at EU or MS level; it will be better done by the industry.

- Training should be compulsory to ensure equal implementation in the MSs.

- Training should be voluntarily in the first place and after a transitional period should become compulsory.

- Training should be a requisite in order to obtain a compulsory licence to keep animals. Training should be part of a farm assurance scheme including farm visitation scheme.

- Combination of options is suggested: compulsory training plus incentives provided.

- Obligatory provision should be basic and relevant level of awareness (not to detailed obligations).

- Training should be laid down just as an objective in the Animal Health Law and then the MSs will choose the means to attain it.

- The EU should lay down the minimum content of training and then the MSs will decide for whom it will be compulsory.

- Training should be voluntary to allow for flexibility to integrate existing mechanisms.

Content

- An important aspect would be the quality and relevance of the training provided as it has to be adapted to the type of activity.

- Farmers need to be aware of the legislative developments and their obligations and of the economic consequences of animal diseases (epidemic and endemic).

- There is a need to reinforce the links/confidence between animal keepers and veterinarians.

- Competence and training are two different things. The frequency of the training and continuous training are important issues to be considered.

- Guidelines should be provided to the MSs.

- Training is not output-based, is expensive and cumbersome. The key issue is to have a well functioning veterinary services and laboratory infrastructure at reasonable prices.

- All training requirements should be coordinated so that animal keepers can combine (animal welfare, animal health…).

2.3. The role of the veterinary services - clarifying the tasks and duties of official veterinarians and private veterinary practitioners

➢ Proposed approach for comments

The basic tasks and responsibilities of official and/or approved veterinarians should be laid down in Regulation (EC) No 882/2004, while specific provisions could be regulated in the animal health law.
The new legal framework should make clear what specific tasks and duties in the field of animal health a veterinary practitioner can undertake as an official/designated/approved veterinarian and under what conditions. This system should be comparable and should not vary between the Member States.

EU legislation should take into account the internationally recognised (OIE) standards for these specific tasks and duties, which enable the EU Member States' international trade to flow smoothly.

➢ Statistics

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	24	(15.7%)	(15.7%)
Agree	101	(66%)	(66%)
Neutral	9	(5.9%)	(5.9%)
Disagree	11	(7.2%)	(7.2%)
Strongly disagree	2	(1.3%)	(1.3%)
Not relevant	1	(0.7%)	(0.7%)
No opinion	5	(3.3%)	(3.3%)

➢ Comments

- There is a widely perceived need to harmonise and clarify certain veterinary tasks EU-wide. This is valid in particular for the "export certification". In general certain tasks are perceived as purely official, while the others have a certain official character (need to remain under authority control) but can be performed by veterinary practitioners.

- Conflict of interest shall be avoided. However, opinions diverge on whether one should achieve that through professional standards and conduct or through the EU or national legislation.

- Certain perceive that MS should have more freedom to organise their services as they wish (principle of subsidiarity). The focus should be given towards an output based and not prescriptive approach.

- Quality standards of the veterinary services should be set - especially in relation to certification scheme.

- Veterinarians are not always perceived to be best placed responsible persons for all animals, especially aquatic animals and apiculture. In addition, certain roles can be trusted to other staff such as technicians, animal keepers.

- One should avoid higher administrative and compliance costs. Higher number of official veterinarians is unlikely; therefore we should aim for an optimal use of all available resources in order to achieve best possible results and ensure the coverage of all areas (including remote areas) with the veterinary services. System should be able to adapt to rural production, small farms.

- New system should take into account possible public-private partnerships as Animal Health Services, which are lately being developed in some countries.

- For international trade compliance with the OIE standards is very important.

2.4. Professional qualifications and training for official and approved veterinarians

➢ Proposed approach for comments

The Animal Health Law would extend the requirements for professional qualifications and for veterinary training to official veterinarians in all areas and to those authorised to perform official tasks in the field of animal health, similar to the existing provisions of Regulation (EC) No 854/2004. Additionally it could provide basic requirements for Continuing Professional Development (CPD) for veterinarians

➢ Statistics

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	34	(22.2%)	(22.2%)
Agree	90	(58.8%)	(58.8%)
Neutral	13	(8.5%)	(8.5%)
Disagree	4	(2.6%)	(2.6%)
Strongly disagree	2	(1.3%)	(1.3%)
Not relevant	1	(0.7%)	(0.7%)
No opinion	9	(5.9%)	(5.9%)

➢ Comments:

- Education and training for veterinarians are very important but should be adapted to the level of public tasks assigned to a professional; for example approved veterinarians don't need the same level of training as the official veterinarians. The

trainings should therefore be output / target oriented towards proper enforcement and shouldn't generate unnecessary costs.

- Basic requirements of the AHL should secure the quality of the veterinary services and acting of veterinary professionals.

- We should aim to establish a harmonised EU approach for all those that perform official tasks and these include besides veterinarians some other professionals, especially linked to certain working areas, as for example aquaculture, apiculture, etc. Training programmes should be flexible and adjusted to specific needs.

- A need for an EU-wide minimum requirements (which should not be too low) for undergraduate and post-graduate training was expressed. However, MS shall have the possibility to deliver this output, and keep the flexibility for its organisation and financing.

- Many MS already have continuous professional developments of veterinarians put in place and for those it seems that the additional regulation at the EU level would be redundant.

- Some are of the view that it is necessary to regulate all steps of veterinary education, including accreditation of the veterinary schools.

- Many participants emphasised that good qualifications of veterinarians are well perceived by the farmers and this strengthens the public opinion on food safety.

2.5. Biosecurity measures to prevent outbreaks on farms and not only deal with them when they occur

➢ Proposed approach for comments:

The Animal Health Strategy aims for preventive and incentive-oriented approaches. Therefore a legal framework should aim for the voluntary introduction of biosecurity measures at farms. The implementation of these measures could be encouraged by providing incentives such as trade-facilitation mechanisms and reducing the number of controls. The animal health law would set the minimum criteria for biosecurity measures, allowing them to be adapted to local circumstances.

➢ Statistics:

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	25	(16.3%)	(16.3%)
Agree	91	(59.5%)	(59.5%)
Neutral	12	(7.8%)	(7.8%)
Disagree	16	(10.5%)	(10.5%)
Strongly disagree	3	(2%)	(2%)
Not relevant	0	(0%)	(0%)

No opinion	6	(3.9%)	(3.9%)

➢ Comments:

Controls

- Reductions of controls plus trade-facilitation mechanisms lead to increased risks.
- Controls should be maintained: to ensure implementation of biosecurity measures.
- Controls need to be reviewed in order to simplify, check of they provide added-value or if they are obsolete and duplicated.

Scope

- Biosecurity should also be applied on transport and holdings other than farms.
- It is also important to manage and reduce the risk at Member States level (import controls strengthened, animal disease eradication programmes, etc.)
- Large commercial farms should apply maximum biosecurity standards and incentives will be provided to them, while small farms and hobby farms should apply minimum standards adapted to their circumstances.
- Small holdings with poor biosecurity represent a high risk.
- These options are not applicable for zoos and aquariums (different risks also: low density, animals do not enter the food chain: different measures needed: ex: visitors). Directive 92/65 is not properly implemented and therefore there are no incentives for zoos applying biosecurity measures.
- Interaction of animals kept on zoos and wild animals are not covered by the Directive 92/65.
- Special status for genetically important livestock (indigenous breeds) should be granted.

Incentives

- At MS level, sanitary actors (veterinarians, administration and professional organizations) should encourage and motivate farmers for the adoption of biosecurity measures, for example by linking biosecurity measures to increased farm profitability and better animal health.
- Incentives such as access to markets are important to ensure effective and wide-spread implementation of minimum standards.
- The objective should be to discourage the transport of animals, not to increase it as this represents a risk for animal health and welfare. Reward should be granted to farms with close-production cycles as they avoid animal movements. Specialization and intensification of farms: increases the development of fast spreading disease (highly pathogen virus)

- Incentives must be conditioned to risk analysis carried out after biosecurity measures are in place.

- An important incentive for the implementation of biosecurity measures would be to exempt from certain restrictions farmers with excellent biosecurity measures in a restricted zone if they did not get the disease. It is also important to grant financial compensation for farms in surveillance/ restricted zones.

- Trade facilitation mechanisms and reduced controls can only be granted if the Competent Authorities have certainty of the correct implementation of biosecurity measures. This will imply reporting requirements from farmers to the competent authorities (increased administrative burden for farmers that has to be compensated with less costs due to reduced controls and saving in acquisition of trade-certificates).

- Financial support from the EU would be needed to implement biosecurity measures. Need also for denial or reduction of compensation in case of disease outbreaks to holdings where biosecurity measures are not adhere to.

Impact

- Rules on biosecurity measure should be designed in partnership with the industry to allow for adaptation to their own circumstances and minimize costs.

- Implementation of biosecurity measures would be an economic burden for farmers. Therefore, rules should be science-based, cost-effective, easy to implement

- Investments will depend on sector/ MS and of the farm status-quo but will be compensated through better animal health and welfare.

- Balance between costs of diseases and investment costs needs to be calculated before implementing biosecurity measures.

- Implementation of biosecurity measures would have benefits day to day and also when outbreaks occur.

- Implementation of biosecurity measures would be a challenge for several structures (veterinary services, farmers) but they are crucial for future development.

Rules

- Efficacy would depend on the definition and content of biosecurity measures (avoid inconsistent, highly variable definitions and insufficient controls).

- Quarantine, testing before introduction of new animals, vectors control are important measures.

- Rules should be outcome-based and not prescriptive.

- Same rules should apply for third country imports.

- Biosecurity measures have to be equally implemented to be effective.

- Role of the veterinary surgeon (advice, recommend which biosecurity measures are more suitable for each holding) should be recognized.
- Important to link with financial issues.
- Biosecurity should not be introduced at the costs of animal welfare (free-range, outdoor keeping, more sterile environment and less contact animal keeper-animals).
- Biosecurity measures should be measurable in order to be able to assess compliance.
- Role of veterinary practitioners should be officially recognized.
- HACCP should be applied for larger farms that will be audited (instead of trade-related controls) .
- Collection and transport of animals can only be done if they come from holdings with similar biosecurity status.
- Surveillance and controls should be risk-based.

Compulsory/voluntary

- Combination of options 2 and 3 is suggested as the best approach by various stakeholders.
- Biosecurity measures should be compulsory (EU minimum standards) and then Member States can impose higher requirements.
- Promoting implementation (soft-regulation) is the best option.
- Biosecurity needs to be adapted to the type of farm (certain level of biosecurity to be obligatory and equally applied in the EU; industry that wants to go further could do it through guidelines (and in this way participation of farmers will be encouraged).
- Assurance systems should be developed in order to ensure and control implementation.
- Training and guidance are better tools than Regulation.
- Should be responsibility of the Member States to develop a non-legislative framework.
- Minimum standards should be mandatory and on top of that voluntary standards with incentives provided.
- Compulsory minimum requirements are inflexible for adapting them to different premises (example: laboratories).
- MS should introduce long-term health management plans, regular visitation of veterinary practitioners for all livestock enterprises.
- Companion and hobby animals should also be taken into account.
- Biosecurity measures should be prerequisite for trade with animals and animal products.

- Implementing a legal framework with few exemptions is better than to establish minimum criteria and unmanageable national guidelines.

- Minimum requirements should be laid down for high-risk holdings (traders, market shows, transport…) taking into account animal density, size of the enterprises or farms.

2.6. Animal disease surveillance needs to be improved

➢ Proposed approach for comments:

Without prejudice to Directive 2003/99/EC as regards zoonoses, the best way to improve animal disease surveillance seems to be to extend the scope and purpose of surveillance networks as set out in Article 14 of Directive 64/432/EEC, which is currently envisaged only for bovine animals and pigs, to other species of terrestrial animals/diseases. Animal keepers (including hobby keepers) would be registered and preventive measures suited to their activities introduced, including surveillance. The new Animal Disease Information System would support this approach by clarifying and facilitating reporting. The introduction of surveillance networks will support the implementation of trade-facilitation mechanisms.

➢ Statistics:

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	19	(12.4%)	(12.4%)
Agree	84	(54.9%)	(54.9%)
Neutral	19	(12.4%)	(12.4%)
Disagree	14	(9.2%)	(9.2%)
Strongly disagree	9	(5.9%)	(5.9%)
Not relevant	1	(0.7%)	(0.7%)
No opinion	7	(4.6%)	(4.6%)

➢ Comments:

In some cases preliminary approach of the Commission to strengthen the surveillance system was supported, but on the other hand there was some diversity of opinions in relation to Commission's option 3 (suggested surveillance network). Many of those supporting the preliminary approach have, instead of option 3, rather chosen options 1 – EU wide compulsory surveillance for certain diseases (in eleven cases) or 4 – to develop soft regulatory approach "guidelines" (in nine cases).

- Proposed approach for surveillance network appears to be too prescriptive, detailed and to a certain extent too authoritative. What we should aim for is robust disease surveillance, providing solid grounds for early warning and detection of diseases.

- There is a perception of a limited applicability for all animal species. Specificities of different production channels and production types should be taken into account, i.e. for hobby farms, backyards, horse keeping, laboratory animals, zoos, fur animals, companion animals, wildlife, endangered species etc.

- Specific disease situation have to be taken into account, partnership with stakeholders established and appropriate consideration taken on the private surveillance.

- Surveillance should be structured in a way that it would provide minimum EU requirements on one hand and open the possibilities for additional provisions in the Member States (basic health statuses and additional health guarantees).

- The purpose and expected outcomes of surveillance should be clearly defined.

- Some consulted prefer to have a soft regulatory approach (option 4)

- Surveillance system should be cost effective and linked to the level of threat of a certain disease (in particular zoonotic agents)

2.7. Intra-Community trade / placing on the market concept

➢ Proposed approach Option 1:

Similarly to the approach already introduced for aquaculture animals in Directive 2006/88/EC, the concept of intra-Community trade in live terrestrial animals would be replaced by the concept 'placing on the market'.

1. Proposed approach Option 2:

Maintain the concept of intra-Community trade as the basis for regulating commercial movements of terrestrial animals between Member States. However, the implementation of enhanced biosecurity measures and surveillance schemes and subsequent trade facilitation mechanisms should, in principle, narrow the gaps between the rules governing intra-Community trade and those on national movements in live terrestrial animals, and eventually make it possible in the long term to move towards a 'placing on the market' system for live terrestrial animals, too.

➢ Statistics:

- Option 1 – placing on the market

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	13	(8.5%)	(8.5%)
Agree	46	(30.1%)	(30.1%)
Neutral	16	(10.5%)	(10.5%)
Disagree	48	(31.4%)	(31.4%)
Strongly disagree	10	(6.5%)	(6.5%)
Not relevant	3	(2%)	(2%)
No opinion	17	(11.1%)	(11.1%)

- Option 2: Intra-Community trade

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	19	(12.4%)	(12.4%)
Agree	53	(34.6%)	(34.6%)
Neutral	27	(17.6%)	(17.6%)
Disagree	25	(16.3%)	(16.3%)
Strongly disagree	6	(3.9%)	(3.9%)
Not relevant	4	(2.6%)	(2.6%)
No opinion	19	(12.4%)	(12.4%)

Comments concerning statistics:

The results from the IPM tool as presented above show separate analysis of the answers received for each of the two options presented in the consultation paper.
However, many replied on both questions with the same answer, as for example: neutral, no opinion, acceptable or unacceptable in both cases. Finally, only 108 of 153 received clearly expressed their view for one or another option and of those 65 opted to keep the Intra-Community trade system and 43 chosen the introduction of placing of the market approach.
From presented data it can be concluded that the views on both approaches are rather divided, but a tendency towards the Intra-Community trade concept.

Additional remarks

- New EU AHL should pave a pathway towards the placing on the market concept but should not introduce it at this stage yet.
- Possible introduction of HACCP-like concepts is not welcomed, has not been proven as a right approach for small holdings and it brings too many costs for operators.
- Certain categories and/or species of animals are perceived as low risk and should therefore in view of consulting parties be exempted from the general movement rules, especially when these animals are kept in controlled environment – for example laboratory animals). For some specific rules would be needed (bees, zoo animals, etc.)
- Differentiation for commercial and non-commercial movements is important.
- EU legislation should lay down minimal health requirements and recognise initiatives for reaching higher biosecurtiy and health standards.

On the placing on the market

- This concept is at this stage perceived as too risky, hazardous, and premature. The animals can not be compared to products of animal origin they involve more health risks.

- There are doubts if the system is feasible for terrestrial animals.
- Problem in certification of specific health provisions especially in terms of export of animals are envisaged.
- Placing on the market concept would suit only certain types of holdings or trade partners; while for the others it would represent a big additional burden, limiting them with the sourcing of animals and national movements.
- Suggested system appears too costly for the majority of holdings across the EU.
- It would be more difficult to apply the placing on the market for terrestrial animals than it was for aquatic animals. Terrestrial animals involve, which consequently leads to more diseases. The system introduced for aquaculture, has already shown deficiencies, which might be even bigger in case of more complex situation on terrestrial side.
- Placing on the market could be introduced by imposing animal health surveillance schemes (including regular veterinary visits on farms), recording, traceability, good hygiene practices and be strongly supported by regionalisation.
- In case of placing on the market, clear provisions should be set for movement of animals from holdings with low health status to those with high health status.
- Placing on the market approach is perceived as beneficial as the holdings will need to comply with higher standards that will bring more advantages to welfare of animals.

2.8. Differentiation or uniformity of trade rules and disease control measures on commercial and non-commercial farming

➢ Proposed approach for comments:

Diseases do not distinguish between different categories of holdings and all holdings might be at risk of getting and spreading disease. The optimal way forward seems to be to apply disease control measures and the same rules on movement for all holdings; however, opportunities for risk-based exemptions on a case-by-case basis might be achievable for certain diseases or animals. The Animal Health Law would need to provide for basic principles on when and how a certain category of animal or product movement can be exempted from the general rule. Detailed provisions should be set in subsequent legislation and made sufficiently flexible and controllable.

➢ Statistics:

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	30	(19.6%)	(19.6%)
Agree	84	(54.9%)	(54.9%)
Neutral	15	(9.8%)	(9.8%)
Disagree	13	(8.5%)	(8.5%)

Strongly disagree	4	(2.6%)	(2.6%)
Not relevant	0	(0%)	(0%)
No opinion	7	(4.6%)	(4.6%)

➢ Comments:

- EU legislation for these categories of animals should allow for stricter Member States rules.
- AHL should not go beyond guidelines and basic principles on when and how a certain category of animals/ products should be subjected to stricter rules.
- Harmonized EU approach is needed.
- This issue should be left to be regulated by the MSs (hobby, zoo, etc). Rules have to be flexible to acknowledge local circumstances.
- Proportionality is vital.
- Definition of commercial and hobby holdings needs to be established (any holding that is part of the food production chain should be considered as commercial). Definition should be sound and enforceable.
- An important issue is who will be responsible to grant the exemptions.
- Risk-evaluation to establish exemptions should be harmonized, acknowledge risk evaluating principles.
- Avoid having at the end a two-tier system.
- Requiring application of derogation case-by-case is too heavy administrative system.
- High administrative burden costs for small/hobby farms, cost beneficial at all levels in the long-run.
- Impacts of differentiating rules: minimum risk for disease spreading, decrease bureaucracy.
- Exemption should be generic, based on the size of the holding, no case-by-case basis, similar to hygiene package.
- Possible adaptation with regard to compartmentalization principle should be considered.
- The EU should clearly state those animals and diseases for which exemptions would apply.
- Specific rules for categories of animals different from farm animals should be provided.
- Certain category of animals could be exempted if they apply self-imposed higher level of biosecurity and health status.
- Hobby-farmers, pet owners: low disease awareness, low knowledge on biosecurity, important to find a relevant, realistic way to include these groups, avoid practical increasing of administrative burden for competent authorities and farmers.

- The new Regulation should contain tools for performing risk-based analysis and surveillance schemes for movements of non-commercial farming.
- To give hobby holdings a formal status, that would place them under the general rules and allow for derogations.

Arguments against differentiation of measures:

- AH rules should apply equally, regardless of whether the animals are kept for commercial or non-commercial purposes.
- Trans-boundary transport of pets can spread pathogens.
- No animals should be exempted from monitoring and surveillance. Zoo, circus and pet animals should be controlled when they are moved (at least randomly).
- Surveillance and monitoring also needed for wild animals.
- Outbreak and spreading of animal diseases in non-commercial holdings could have major implications for commercial ones (establishment of restricted and surveillance zones).
- To differentiate between commercial and non-commercial animals is difficult (hobby farmers often engage in limited commercial activities.
- Horse transport should maintain strict health regulations.

Arguments in favour of differentiation

- More flexible for zoos/hobby animals: not intended for the food chain.
- Ornamental fish, kept in home aquarium should be exempted for general rules.
- Exceptions should apply also to some specific traditional small farms (free-range, organic) in the poultry/eggs sector.
- Contact movements at non-commercial farms are far less than in commercial holdings.
- Laboratory animals represent minimum risk (not traded, confined).
- Differentiation animals for slaughter and other animals: limited risk, deserve to be treated differently.
- Diseases are normally concentrated in commercial holdings.
- Zoos do not represent a risk for agricultural holdings, is the other way around, they are relatively small population of endangered species applying already strict animal health rules. Zoos usually do not exchange animals with agricultural holdings.
- Breeding programmes for endangered species are jeopardized by unclear legislation, lack of uniform application and slow decision-making process: animal exchanges are difficult or

even impossible: compromised welfare conditions and obstruction of conservation initiatives.

- All holdings do not pose the same risks for animal diseases spreading (hosts specificity, opportunities for disease transmission, new animals, transport, stocking densities).
- Some control measures are not suitable for zoo animals (compulsory slaughter is not adequate; vaccination and surveillance are better).
- Indigenous livestock breeds need a special status in the event of disease: if not, negative impact in biodiversity, special breeds will disappear.

2.9. Animal health requirements for trade and import for certain animal species under Directive 92/65/EC

➢ Proposed approach for comments:

The future Animal Health Law should establish clear general rules on trade for these "special" species and categories of animals, and clarify which species could be exempted by special animal health rules, while leaving more specific provision to implementing rules.

➢ Statistics:

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	41	(26.8%)	(26.8%)
Agree	76	(49.7%)	(49.7%)
Neutral	12	(7.8%)	(7.8%)
Disagree	3	(2%)	(2%)
Strongly disagree	2	(1.3%)	(1.3%)
Not relevant	2	(1.3%)	(1.3%)
No opinion	17	(11.1%)	(11.1%)

➢ Comments:

General remarks:

- EU rules for these categories of animals should be consistent with the OIE standards.
- Transit of animals from third country to third country through the EU should be taken into account.
- Traceability of animal movements is a key issue. Use of TRACES for every type of animal movement should be required.
- We have to be careful that the new law does not encourage transport of wild/exotic animals. Conditions for transport should be taken into consideration as well.

- Wild animals need sedation and special handling before moving them and this should also be taken into account when laying down rules.

Risk of "special species" imports:

- A risk-based approach should be followed when establishing rules for these categories of animals.
- Basic rules should apply also for animals not entering the food-chain if they represent a risk to the health of food-producing animals or for food-safety.
- As changes in ecosystems can lead to disease risks, a clear and justified need should be demonstrated for importation of "special species".
- Imports of exotic animals may not have an immediate health risk, but in the long term could have huge consequences.
- Exemptions to the rules have to be as limited as possible: exotic species could be a major reservoir of exotic pathogens and the origin of epizootic disease in the EU animal populations.
- Prevention aspects of animal health legislation should apply to all species.
- This review should not lead to a ban on imports from species already authorised.

Degree of harmonization of the rules:

- Rules should be completely harmonized for these species, including implementing rules, otherwise is not possible to have a harmonized border control and intra-Community trade control system and to avoid market distortion.
- The EU should lay down minimum requirements for these categories of animals and the MS should be able to apply stricter rules based on their animal disease situation.
- Same rules should apply for all MS, but allowing them to review exemptions for certain species if they are considered to be an increased disease-threat.
- Directive 92/65 is not implemented properly by the Member States and this makes movement of animals impossible sometimes and therefore breeding/conservation programmes are endangered. This legal act should be changed from Directive to Regulation. There is a need for uniform implementation of the rules, also targeting movements of zoo animals across MS.
- Basic general rules should apply to all species. MSs starting to import new species should present and discuss this with the rest of the MS. Not only the species but also the conditions for importation should be specified.

Specific sector remarks:

- Important to establish a clear definition of the species to avoid misunderstandings (e.g.: llamas are not ruminants).

- Wild equidae should be accommodated into Directive 92/65. Some species such as the American bison are kept in zoos and also for commercial purposes. Experts should be consulted before laying down rules to avoid problems. Legislation should reflect the correct taxonomy; to treat a whole taxonomic class as if they were domestic animals has no sense.

- Laboratory animals are almost always maintained at a very high health status, which is closely monitored and controlled and therefore exemptions from restrictions should apply for those animals.

- Ornamental fish should have a different status than fish.

- Specific needs of the horse sector should be taken into account. Extent of horse movements is huge compared to exotic pets and zoo animals. All horses shouldn't be treated the same (wild ponies, slaughter horses, competition horses), they have hugely varied health status and disease risks.

- The possibility for bilateral agreements on cross-border movement of certain species as reindeer should however remain possible, but rules on traceability should be laid down to ensure rapid tracing in disease outbreaks.

2.10. Emerging, re-emerging and exotic diseases

➢ Proposed approach for comments:

Emerging diseases should be reflected in the new Animal Health Law and linked to the ongoing exercise to set priorities for EU intervention and categorise diseases. Certain provisions of the current Directive 92/119/EEC can be considered as a basis for developing a solid and concise legal framework for horizontal control principles for emerging, re-emerging and exotic diseases, taking into consideration the OIE rules on notification. The provisions of certain disease control directives that are outdated, disproportionate, not flexible enough or not aligned with international standards should be revised and aligned with general principles to be set out in the Animal Health Law. In addition, some technical adaptations to existing rules in the chapter of simplification will be needed.

➢ Statistics:

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	43	(28.1%)	(28.1%)
Agree	89	(58.2%)	(58.2%)
Neutral	7	(4.6%)	(4.6%)
Disagree	3	(2%)	(2%)
Strongly disagree	0	(0%)	(0%)
Not relevant	0	(0%)	(0%)
No opinion	11	(7.2%)	(7.2%)

➢ Comments:

- Basic EU animal health legislation is too rigid (difficult to change) to accommodate all emerging and re-emerging diseases. Detailed provisions should be flexible and should therefore be laid down in lower level legislation. Strategies to control different types diseases are different and this needs to be taken into account. Member States should have a possibility to introduce national measures for control of specific diseases.

- Framework AHL should provide general rules for different groups of diseases (like vector borne diseases, highly contagious diseases with direct transmission, etc.). It should take into consideration wildlife as a permanent reservoir of disease agents, different exotic animal species and pet animals that might introduce new diseases especially zoonotic agents.

- Definition of emerging diseases should be constructed carefully and can include non-infectious diseases and antimicrobial resistance.

- AHL should include latest scientific knowledge and risk based measures within the EU and in imports.

- AHL disease control rules should align as far as possible with the OIE. Where scientifically justified a higher health status should be set.

- Vaccination policy should be less restrictive and the importance of vaccination strengthened. More emphasis should be given to vaccine development.

- Innovation is important for the animal health sector in particular in developing new diagnostic kits, vaccines. EU should aim for latest diagnostic and vaccination technologies and should influence in this respect international organisations.

- Disease categorisation and prioritisation are very important tools and the result needs to be included in the AHL.

- OIE disease situation information should be introduced into the TRACES system, which can be used as a proper control tool for preventing the introduction of exotic diseases into the EU.

- More passive surveillance should be used for diagnosis of emerging diseases.

2.11. Review and simplification of current rules on identification and registration of animals

➢ Proposed approach for comments:

Current provisions would be essentially confirmed, without lowering current traceability standards. However, basic principles and objectives for identification and registration of animals would be clearly laid down in the Animal Health Law, while specific provisions for different species or categories of animals would be established by Comitology. This would ensure policy coherence, better understanding of the animal owners and more successful enforcement. In the meantime, current legislation would remain in place.

➢ Statistics

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	22	(14.4%)	(14.4%)
Agree	92	(60.1%)	(60.1%)
Neutral	16	(10.5%)	(10.5%)
Disagree	7	(4.6%)	(4.6%)
Strongly disagree	4	(2.6%)	(2.6%)
Not relevant	1	(0.7%)	(0.7%)
No opinion	11	(7.2%)	(7.2%)

➢ Comments:

- The Commission's approach was generally supported. However, only basic principles, objectives and outcomes should be set in the AHL; excluding many detailed provisions or rules for identification.
- Traceability is perceived as an imperative but it can be achievable with different means. Individual identification of all species is not always necessary.
- Identification and registration of pet animals was largely perceived as a necessary step further for animal health and welfare reasons.
- Identification of non-food animals is seen as necessary for these animals might represent a health threat for other animals and humans.
- All elements of identification and registration system (identification mark, documents, and database) are not suitable for all species and categories of animals. Therefore careful consideration should be given to what extent these provisions would apply to all animals like fur animals, bees, aquatic animals, poultry, etc.
- Data collected for identification and registration should be used for other purposes and not only traceability. Identification and registration databases of the member states should be connected within the EU.
- Specificity has to be recognised especially for equidae, where an existing system complying with the international standards for registered horses is already in place. More emphasis should be given to its implementation.
- AHL should give consideration to special animal categories like zoo animals, where an international approach has been created (ISIS system; ZIMS database). Special arrangement for domestic animals kept in zoos is suggested.
- A good balance of efficiency, feasibility and costs should be established.

2.12. Specific animal health conditions relating imports

➢ Proposed approach

Regulation (EC) No 882/2004 provides the legal framework for general import conditions and controls. These provisions would be supplemented by specific import conditions set out in the new animal health law. These rules are to allow appropriate flexibility, while all the technical provisions are to be set in subsequent legislation and in line with the OIE recommendations as far as possible. Flexibility and tailor-made rules based on risk assessment should ensure the desired level of protection, while at the same time reducing the burden for operators.
The Animal Health Law should make explicit the specific principles to be observed when setting import conditions based on animal health concerns (i.e. what animal health grounds warrant the limitation of trade with non-EU countries) and the principle that import conditions must be risk-based and therefore adjustable to the level of risk.
The Animal Health Law should cross-refer to the principles and procedures laid down in Regulation 882/2004 for collecting information on the basis of which import conditions are set and the arrangements for setting general and specific import conditions by sectoral (delegated) legislation.

➢ Statistics:

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	27	(17.6%)	(17.6%)
Agree	88	(57.5%)	(57.5%)
Neutral	18	(11.8%)	(11.8%)
Disagree	6	(3.9%)	(3.9%)
Strongly disagree	0	(0%)	(0%)
Not relevant	0	(0%)	(0%)
No opinion	14	(9.2%)	(9.2%)

➢ Comments:

Rules

- Flexibility is required to allow Member States to apply additional conditions if necessary, based on a scientific risk analysis.
- Principles and procedures should all be the same for all MS and clear for all operators, to avoid delays in animal transport and problems.
- Details on import requirements to be established in bilateral agreements.
- Simplification is welcomed, but without lowering standards while increasing rules for the EU operators.

- All import requirements (specific rules for imports and controls) should be laid down in Regulation 882/2004 to remain a coherent set.
- AHL should lay down main requirements; specific requirements should be left for implementing rules.
- Harmonized procedures and intensity of controls should be the same across al MS.
- Good pre-import testing and monitoring are essential.
- Stakeholders and importers should be consulted to make sure that the conditions are easy to understand and accessible and not "lost" in a complicated legal act dealing with very different range of issues. Simplification should not be only for Competent Authorities, but also for operators.
- List of risks by species and sector is a good start.
- Proper enforcement of the legislation is a key point.
- Efficient identification of imported animals is essential.
- Imports of live animals and animal products are the biggest threat for animal health in the EU.
- Sanctions to MS not complying not implementing the rules, not supporting the veterinary services shall be defined and applied.
- EFSA should be consulted to carry out risk-assessment in relation to imports.

Import conditions and competitiveness of EU business.

- Rules on general import condition should be based first on scientific risk assessment and international standards.
- Import conditions should be similar to the requirements imposed to EU farmers and food business operators by the EU legislation. This may regard the registration, training, surveillance and monitoring: in that way control of disease risks of imports will be improved and will create a level of playing field.
- Community standards are higher than international ones: this means higher costs for EU producers.
- The concepts used for risk analysis in the EU and in third countries are not the same.
- Imported products and animals should comply with the same standards as the EU ones (animal welfare, animal health and food safety, environment).
- Third countries should apply regionalization as the EU does.
- Requirements for internal movements should be equal to import conditions (not having higher standards for intra EU trade than for imports).

Impact

- Simplification of import regulation likely to facilitate border controls and improve AH status in the Community.
- Impact on bilateral trade between MS should be taken into account.

Specific sector needs

- Specificities of the horse sector should be taken into account.
- Occasional imports of zoo animals are needed to ensure long-term genetic variability (conservation/breeding programmes for endangered species). Disease risks should not be extrapolated from domestic to wild animals, experts should be consulted.
- Genetically important livestock should have a special treatment, also in the OIE Code.

2.13. Converegence of the EU legislation with international standards

➢ Proposed approach

In order both to achieve its desired level of protection in relation to imports and fulfil its international obligations the EU should:

- align the EU legislation with the international standards as far as possible (OIE, Codex) while at the same time not lowering its health standards which have already been achieved; and
- promote its standards in the international fora and in particular the OIE, with the aim to ensure the maximum possible convergence between the EU and international standards.

➢ Statistics:

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	43	(28.1%)	(28.1%)
Agree	83	(54.2%)	(54.2%)
Neutral	13	(8.5%)	(8.5%)
Disagree	4	(2.6%)	(2.6%)
Strongly disagree	2	(1.3%)	(1.3%)
Not relevant	0	(0%)	(0%)
No opinion	8	(5.2%)	(5.2%)

- Comments:

- OIE convergence is by the majority welcomed. However, the current EU health standards should not be lowered where the EU has reached higher standard. Only few expressed the need to review current higher EU standards to see if they can be adjusted to a level provided for in international standards.

- When creating new measures, higher standards than the OIE can be introduced only after a risk assessment. In these cases all efforts should be engaged to reach the consensus to modify relevant international standards.

- Moreover some emphasise that the internal EU rules should not be more stringent than the import rules unless specifically justified (if possible with quantitative analysis). The goal of the subsequent requirements should be to minimize risk to acceptable level.

- OIE recommendations focus on outputs (achievements) rather than tools and EU legislation should follow this approach.

- The ones that disagree with the approach mostly stress that the EU has achieved higher health and quality standards in the past. Their perception is that these standards should not be lowered and the EU position not weakened.

- EU influence in the international forums should be more proactive aiming at achieving higher standards at the international level. EU membership is perceived as a beneficial step forward. However, EU can't be too patronising and impose so high standards, which can have negative effects for less developed countries.

- Concept of aligning with international standards should not limit the onset of private standards at a higher level.

- Definitions in the AHL should be in line with the OIE standards.

- In terms of OIE animal welfare constitutes an important element of OIE convergence..

- Emerging diseases presenting threat to biodiversity of animal species are an important element. OIE already follows this approach; co-operation with other international organisations should be considered.

- Responses of countries in case of disease outbreaks should be comparable; EU currently applies much more reasonable measures towards than some countries apply towards the EU.

2.14. The definition of 'epidemiological unit' and 'holding' in EU legislation

- Proposed approach

The Animal Health Law should refine existing concepts of herd and holding and establish cross-links between them. he concept and definition of ‘epidemiological unit’ for animal health purposes is of fundamental importance to taking all measures necessary on biosecurity, registration of animals and their movements, surveillance and definition of the animal health status of the relevant population and, as a consequence, granting incentives for prevention, as highlighted in several points in this document. Therefore, based on these concepts, the Animal Health Law should ensure a coherent and consistent definition of ’epidemiological unit’.

➢ Statistics:

Do you support this preliminary approach? -single choice reply- (compulsory)

	Number of requested records	Requested records (153)	% of total number records (153)
Strongly agree	27	(17.6%)	(17.6%)
Agree	81	(52.9%)	(52.9%)
Neutral	20	(13.1%)	(13.1%)
Disagree	4	(2.6%)	(2.6%)
Strongly disagree	0	(0%)	(0%)
Not relevant	1	(0.7%)	(0.7%)
No opinion	20	(13.1%)	(13.1%)

➢ Comments:

- Epidemiological unit has to be defined for each pathogen.
- The definition of epidemiological unit should be based on the OIE definition to be accepted internationally.
- Work in partnership with the OIE to agree on a definition that suits also EU purposes.
- There should be flexibility in the definition to adapt it to different systems/species. It would be necessary also to define a list of common basic criteria in order to adopt similar approaches for each species, together with the definition of epidemiological unit.
- All relevant terms describing animal populations should be considered when defining epidemiological unit.
- A clear and undisputable definition should be established in the AHL to avoid misunderstandings and problems.
- The new definition should take into account already existing definitions and arrangements in the MS and their particularities.
- It's too difficult to establish a definition that will fit in all cases, is better to rely on barriers to slow down the spreading of diseases and stand-still requirements that are easier to standardise.
- The consequences of establishing this definition have to be assessed carefully (e.g. implications for movement reporting burden that this could have).It is important to identify current patterns of land use within each MS and use this to assess the impacts of moving towards the use of a prescribed definition of a holding.
- To refine the definition of herd and holding is necessary but to define epidemiological unit at EU level is too complicated.
- Pet owners of small number of animals should be excluded from the scope of the definition; otherwise it would be extremely complicated.

- Definition of approved areas in Directive 92/65 may help in order to establish a definition of epidemiological unit.

- Panel of internationally recognized scientists and epidemiologist to find what could be the best possible definition.

- Definition for pet animals is easier than for large commercial holdings that should be registered.

- General rules to exempt certain parts of holdings from restrictions should be laid down in relation to the characteristics of each disease or disease group and specific implementation rules left to the MS.

- One herd per holding and holding becomes epidemiological unit.

- To define epidemiological unit will have no use for animal disease control purposes, as all animals in the holding will have to be killed in case of an outbreak.

2.15. Is there any other issue that you would like to raise or that you feel that should be addressed by the Animal Health Law and that is not included in the document?

General principles:

- A new "general framework law" should be established, with the aim to merge animal health, animal welfare and food safety into a single framework. These three areas can't be separated. Therefore they need to be put together into the same legal text, since they address the same actors and stakeholders (animal keepers, traders, veterinarians, etc.). General food law shall be re-constructed for that purpose.

- AHL shall include general principles, similar to the ones set out in a general food law (Regulation (EC) No. 178/2002).

- AHL shall include veterinary checks regime and prevention principles through controls on permitted imports.

- AHL should contain budgetary / financial questions – emergency funding rules.

- A clear and reactive chain of command of veterinary services needs to be set.

Coherence with other legislation and policies:

- Coherence between animal and public health legislation addressing primary production needs to be drawn up (coherence of animal health certification and providing food chain information). It shall establish a single sending of information and link databases.

- Relation between the AHL, food and feed safety, zoonoses should be established. Monitoring and surveillance schemes in all areas should be adjusted to each other and be comparable.

- AHL should integrate with other Commission activities under the framework of DG AGRI, ENTR, and ENVI.

Relation animal health animal welfare:

- Clear reference and link between animal health and animal welfare needs to be established in the AHL.

- Comprehensive definition of health and welfare should be set out: "freedom of diseases or abnormality and state of wellbeing by meeting physical, physiological and psychological elements.

- Link should be established to protection of laboratory animals.

Focus on prevention:

- Disease prevention is a shared effort of all MS; good implementation and control are needed.

- Focus on prevention should not take away need to focus on eradication. Eradication is a starting point for prevention. Prevention and biosecurity should be promoted as beneficial to farmer in day-to-day life.

One health concept:

- Include "One health" concept – diseases spread from animals to humans and from domestic animals to wildlife and vice versa. This needs to be considered in the legislation.

Vaccination:

- Vaccination policy should be clarified and vaccination should not be prohibited, when it is proved to be effective and it doesn't harm health.

- Vaccination of animals after outbreaks should be more protective; emergency measures and special marking of animal products remain in place for too long period and influence the trade with products of vaccinated animals. This causes unjustifiable economic losses.

- Hobby keepers want to use preventive vaccination to protect their animals and this should be allowed. This same is valid for protection of rare breeds.

- Vaccination should be designated as a strong preventative tool.

- There is no reason for products, which originate from vaccinated animals to be distinguished with special labelling. These products don't constitute public health risks.

- There are considerable differences between health statuses of vaccinated and non-vaccinated areas, which result in trade implications.

- A level of proving of disease freedom after vaccination for creation diseases is too high (for example 100% for FMD, which is un-realistic).

Wildlife:

- Wild animals present health risk and the AHL shall provide the same approach to them as to the commercial animals, in particular in relation to disease control measures (TB testing)

- More attention should be given to wild animals and non-commercial categories of animals.

Horses:

- EU animal health policy is unclear about the status of the horses and doesn't reflect commercial, racing, breeding, sporting and leisure movements of horses.

- Distinction between breeding and registered horses is not needed; only slaughter horses need a different approach.

- Provisions of directive 90/426/EEC to be included into the bilateral trade or veterinary agreements, which would reduce day-to day practical problems and costs, facilitate exchanges and allow flexibility.

Specific animal categories:

- Bees and beekeeping are special areas of expertise. The AHL should also provide legal framework for them, but allowing specific rules at a higher level of detail as a subsequent step.

- Zoo animals and aquatic animals from aquariums need modified arrangements. Movements of those animals do not usually have the nature of commercial movements and animals don't end in food chain. Related to this protection of rare species need to be taken into the consideration. Furthermore, transport of these animals can't be considered as commercial operation.

- Some categories of animals presenting lover health risks per se and some of them leave in controlled environment, these elements should be taken into account accordingly (i.e. fur animals, laboratory animals).

- Amphybians and other "exotic" companion animals have often in the past constituted health risks, especially for humans (salmonella infections) and other animals.

Movements:

- All movements represent risks; therefore national movements should be included in the AHL.

- Animal identification and registration databases should be connected in order to facilitate animal movements across the EU.

- For animal health and welfare reasons movements of animals should be limited to only one assembly operation.

- Rules should be established for gathering of animals at international level like international exhibitions.

Disease control measures:

- An automatic abolishment of emergency measures after a certain period elapses after the outbreak should be introduced into legislation.
- Stand-still requirements for pigs in directive 91/119/EEC should be reviewed.
- The new law should replace detailed rules for disease control, especially those from the Regulation (EC) No. 2005/76, Directive 2005/94/E, 2003/85/EC, 200/75/EC with more general provisions, allowing more flexibility.
- Measures to control Rift Valley Fever have to be put in place.
- Rules for suppression of tuberculosis should be up-dated.

Laboratories and tests:

- More flexibility should be introduced for tests in a framework of directive 90/429 for porcine semen.
- AHL should include provisions to ensure quality of laboratory reagents.

Audits and controls:

- Internal audits should ensure harmonised application of EU rules in the MS.
- Better enforcement measures should be put in place in the AHL.
- More flexibility should be allowed on a level and frequency of controls (example Regulation (EC) No. 1082/2003 – controls on identification of bovine animals).

VMPs and antimicrobial resistance:

- AHL should include chapter on veterinary medicinal products – holistic approach needed.
- Prevention part should include rules for use of antibiotics, with a link to prevent developing of antimicrobial resistance.
- Availability of VMPs, vaccines and biocides should be regulated by the AHL.
- AMB resistance: status of MRSA in MS differs. Continuation of work on eradication and fighting diseases. Facilitating trade only adds to spreading.

Import:

- Import certificates for aquatic animals are too complicated. Signing authorities in third countries can't understand them.

Stakeholders:

- AHL should contain a chapter dealing with the relationship with stakeholders to ensure transparency, easier implementation of legislation across the EU). An instrument similar to the Animal Health Advisory Committee would be advisable.

Private standards:

- New animal health legislation should give room for private quality systems.

3. Conclusions

3.1. Responsibilities and obligations of animal keepers and owners

Results of the consultation show a general support of stakeholders on the proposed approach by the Commission to clarify roles and responsibilities of animal keepers and owners. However, some discrepancies on the degree of harmonisation of this subject were observed. The need to establish obligations also for operators other than animal keepers and owners was highlighted by several stakeholders.

3.2. Training for people dealing with animals

Although the voluntary approach was regarded as the most adequate one by the majority of stakeholders, a significant share would prefer that compulsory training for people dealing with animals is established in the AHL. Concerns on the funding for training activities were expressed by some stakeholders. The majority of stakeholders highlighted the importance to provide flexibility to adapt training provisions to specific circumstances.

3.3. The role of the veterinary services - clarifying the tasks and duties of official veterinarians and private veterinary practitioners

Consultation shows a need to clarify and harmonise certain veterinary tasks EU-wide. This is valid in particular for the "export certification" and international trade. Certain veterinary tasks are perceived as purely official, while the others have a certain official character (need to remain under authority's control) and can be performed by veterinary practitioners, other experts, where relevant (i.e. for aquaculture, apiculture) or other staff, such as technicians. All resources should be used in an optimal way in order to ensure proper territorial coverage and a good quality of veterinary services in line with the OIE provisions.

3.4. Professional qualifications and training for official and approved veterinarians

Education and training for veterinarians are very important but should be flexible, adjusted to specific needs and adapted to the level of public tasks assigned to a professional; approved veterinarians don't need the same level of training as the official veterinarians. These trainings should therefore be output / target oriented towards proper enforcement and shouldn't generate unnecessary costs. Training should be provided also to other professionals responsible for certain working areas with a lack of veterinarians, such as for example aquaculture, apiculture, etc. Many MS already have already introduced continuous professional developments of

veterinarians and for those it seems that the additional regulation at the EU level would be redundant.

3.5. Biosecurity measures to prevent outbreaks on farms and not only deal with them when they occur

Although the voluntary approach was regarded as the most adequate one by the majority of stakeholders, a significant share would prefer that compulsory biosecurity measures are established in the AHL. A combination of options 2 and 3 was suggested as the best approach by various stakeholders. Some stakeholders are against providing trade-facilitation mechanisms as they consider that this would increase animal diseases risk. Discrepancies on the scope for implementation of biosecurity measures and on the level at which this should be regulated were observed.

3.6. Surveillance

There is a substantial support towards the Commission's approach to strengthen the surveillance, however the views on the necessity to introduce surveillance network were more diverged. It seems that even this approach would largely be welcomed but should aim for a robust system for disease surveillance that would be able to adjust to different production types and different diseases. Room for additional provisions and specific solutions at the level of Member States should be preserved, using at the same time, where possible a soft-regulatory approach.

3.7. Intra-Community trade / placing on the market concept

From presented statistical data it can be concluded that the views on both approaches are rather divided, but there is a tendency towards the keeping of Intra-EU trade concept.
The overall feeling is that the new EU AHL should pave a pathway towards the placing on the market but should not yet introduce it at this stage. This concept is perceived as too risky, hazardous, and premature. The animals can not be compared to products of animal origin they involve more health risks. There are doubts if the system is feasible for terrestrial animals as it already shows problems with aquaculture. In addition, it could create further problems related to inability of the certification of specific health provisions for export of animals. A fear exist that placing on the market would suit only certain types of holdings or trade partners; while for the others it would represent a big additional burden, limiting them with the sourcing of animals and national movements. On the other hand the concept is well perceived from the animal welfare perspective, expecting the farms to obtain better conditions for animals.

3.8. Differentiation or uniformity of trade rules and disease control measures on commercial and non-commercial farming

The majority of the replies support differentiation of measures for commercial and non-commercial holdings. However, a significant percentage of the replies argue that this will imply an increased risk of animal disease outbreaks and spreading. Discrepancies were also observed on the risk attached to non-commercial farming activities.

3.9. Animal health requirements for trade and import for certain animal species under Directive 92/65/EC

Results of the consultation show a general support of stakeholders on the proposed approach by the Commission, however discrepancies were observed on the risks attached to these "special species" imports and on the level at which the exemptions should be granted.

3.10. Emerging, re-emerging and exotic diseases

Framework AHL should provide general rules for different groups of diseases (like vector borne diseases, highly contagious diseases with direct transmission, etc.). Basic EU animal health legislation is too rigid (difficult to change) to accommodate all emerging and re-emerging diseases. It should take into consideration wildlife as a permanent reservoir of disease agents, different exotic animal species and pet animals that might introduce new diseases especially zoonotic agents. Vaccination policy should be less restrictive and the importance of vaccination strengthened. More emphasis should be given to vaccine development and innovation.

3.11. Review and simplification of current rules on identification and registration of animals

The Commission's approach was generally supported. However, only basic principles, objectives and outcomes should be set in the AHL; excluding detailed provisions or rules for identification. Traceability is perceived as an imperative but it can be achievable with different means; individual identification is not always necessary. Specificity of species should be considered and a good balance of efficiency, feasibility and costs should be established. Identification and registration of pet animals, zoo animals and some others, was largely perceived as a necessary step further for animal health and/or welfare reasons.

3.12. Convergence of the EU legislation with international standards

OIE convergence is by the majority welcomed and should apply for animal health and welfare. However, the current EU health standards should not be lowered where the EU has reached higher standard. Only few expressed the need to review current higher EU standards to see if they can be adjusted to a level provided for in international standards. When creating new measures, higher standards than the OIE can be introduced only if scientifically justified. In these cases the EU should take a proactive role and all efforts should be engaged to reach the consensus to modify the relevant international standards. EU membership in the OIE is perceived as a beneficial step forward. Concept of aligning with international standards should not limit the onset of private standards at a higher level.

3.13. Specific animal health conditions relating to imports

General support to the Commissions' proposed approach was observed in the replies. Concerns were expressed on the fact that EU operators have to face stricter rules than international standards. Discrepancies on the level of detail of the legislation needed at EU level were also observed.

3.14. The definition of 'epidemiological unit' and 'holding' in EU legislation

Although there was a general agreement to the proposed approach by the Commission, the majority of replies highlighted the difficulties in establishing a definition of epidemiological unit that could be adapted to all animal species and relevant diseases and the implications that this definition could have for movement registration and disease control measures.

End

ANNEX VI Summary of the questionnaire on artificial insemination and related issues

EUROPEAN COMMISSION
HEALTH AND CONSUMERS DIRECTORATE-GENERAL

Directorate D - Animal health and welfare
Unit D1 - Animal health and Standing Committees

EU Animal Health Law – consultation process

Commission staff working document

Summary of the replies to Questionnaire on the potential impacts (economic and social) that the introduction of the "placing on the market" concept could have for semen collection and storage centres, embryo collection and production team

Brussels, 10 September 2010

Summary of the replies to Questionnaire on the potential impacts (economic and social) that the introduction of the "placing on the market" concept could have for semen collection and storage centres, embryo collection and production teams

The Commission, in the context of preparatory activities for the new EU Animal Health Law, launched a wide stakeholders' consultation, the so called "Annotated agenda for stakeholders' consultation". The intra-EU trade vs. the "placing on the market" concept was presented in this consultation with the aim to obtain the views of interested parties.

A specific questionnaire addressed to producers of semen, ova and embryos was distributed to the Rep Vet group of COPA-COGECA. In this questionnaire operators were asked to express their views about the "placing on the market" vs. intra-EU trade question and to provide quantitative data that would enable us to assess impacts of possible changes of the concepts to your respective sector.

Replies were received from operators of several Member States Belgium, Czech Republic, France, Germany, Poland, Spain, Sweden, the Netherlands, Hungary and United Kingdom. Also operators from Norway and Switzerland replied to the questionnaire.

Intra-EU trade / placing on the market concept

- Problem dimension

Current animal health provisions for commercial movements of live terrestrial animals and control of their diseases are largely based on the Intra-EU trade concept. This concept is based on fulfilment of the animal health requirements established in the EU legislation and subsequent certification prior to the movement of live animals between Member States. The EU legislation allows Member States to maintain, to a certain extent, animal health rules on national movements in live animals, provided that these national rules comply with the relevant provisions on the control of diseases that are regulated at EU level.

The concept of intra-EU trade is different from the one of 'placing on the market', which is currently used in food safety legislation for products of animal origin (hygiene package and for live aquaculture animals). In this case the general rule is that the products or animals in question have to comply with the same harmonised standards when placed on the market, regardless whether this is a national market or a market of another Member State(s). For example, Directive 2006/88/EC introduces certain prerequisites for placing on the market animals and products obtained from aquaculture production, such as an obligation to hold an authorisation, recording and traceability obligations and obligations to implement good hygiene practice, in addition to the animal health surveillance scheme.

- Potential solutions / options

Option 1:

Similarly to the approach already introduced for aquaculture animals in Directive 2006/88/EC, the concept of intra-EU trade in live terrestrial animals would be replaced by the concept 'placing on the market'.

There are two important sets of requirements to be met to support this option:

- basic standards for holding of origin, and prerequisites for authorisation such as good hygiene practices (biosecurity) and surveillance obligation on farms regardless of the destination of the animals being dispatched (within the same Member State or in another Member State), and
- standards for accepting animals into the holding, region, or zone at destination, taking into consideration the animal's health status, and biosecurity and surveillance information. This approach would shift more responsibilities onto operators (animal keepers) and standards could be better met if a 'HACCP approach' were put in place in primary production, too.

However, flexibility could be introduced to ensure that these additional standards do not lead to an additional burden on those operators who move animals only locally.

Do you support this preliminary approach?

- **Agree:** **3 representatives (plus NO and CH)**
- **Neutral:** **3 representatives**
- **Strongly disagree:** **2 representatives**
- **Not relevant :** **1 representative**

Option 2:

Maintain the concept of intra-EU trade as the basis for regulating commercial movements of terrestrial animals between Member States. However, the implementation of enhanced biosecurity measures and surveillance schemes and subsequent trade facilitation mechanisms should, in principle, narrow the gaps between the rules governing intra-EU trade and those on national movements in live terrestrial animals, and eventually make it possible in the long term to move towards a 'placing on the market' system for live terrestrial animals, too.

Do you support this preliminary approach?

- **Agree:** **2 representatives**
- **Neutral:** **4 representatives**
- **Disagree:** **1 representative**

Comments:

Representatives in favour of the first option are from Member States where same rules apply for intra-EU trade and national trade. No changes are expected for national trade while for intra-EU trade they perceive simplification of procedures as an advantage.

Opinions against the first option are based on the difficulties for small farms to make the necessary investments for complying with all the requirements to be authorised for intra-EU trade. Concerns on the measures to be taken in case of an epidemic disease spread were also expressed.

For some, current situation creates unfair competition (different requirements for trade within the Member States depending on the Member State).

Can you specify the main differences between the national and EU approved centres (if relevant)?

Member States applying the same standards are: Czech Republic, France, Germany (almost, certain differences for horses), Poland, Spain, and the Netherlands (but for the Netherlands representative it would be unacceptable to apply the same rules to storage tanks for use in the same farm where collected).

Member States with different rules for intra EU trade and trade within the Member State are:

- Hungary: different requirements for black and white areas. For them, applying intra-EU trade rules to national movements would imply significant investments for the farms that cannot be afforded, due to the low profitability of the activity. They estimate decrease on AI for pigs.

- UK: semen for national use is subjected to lower standards than semen for intra-EU trade. The use of semen collected and stored in the same holding is common practice and is not regulated.

Could you estimate the possible economic and social impacts of introducing the concept of placing on the market? (Meaning that in order to trade nationally the centres would have to comply with the same requirements as those for intra-EU trade?)

Special rules would have to be provided for semen produced before the legislative changes.

For artificial insemination within the herd or farms it seems disproportionate to apply the standards required for intra-EU trade but on the other hand full traceability has to be ensured.

Questions on how additional guarantees will be applied in a credible way.

Semen for exports to third countries will still be subjected to certification.

Porcine: concerns were expressed on the use of antibiotics and PRRS positive boar stations.

Conclusion:

Placing on the market seems more feasible for bovine and porcine semen. However, this view is not shared by all contributors, as in certain Member States placing on the market could also have a considerable impact for bovine an porcine semen use. For the rest of the species negative impacts on society, the economy and biodiversity are expected due to the need for investments needed to change protocols and equipment and the fact that valuable genetic material will be lost because of non-compliance with EU standards.

DATA

Estimate of the number of semen collection centres approved for intra-EU trade and the number of semen collection centres approved/authorised only for national trade within your Member State

BELGIUM

Species	Intra-EU	National
Porcine	3	30
Bovine	3	
Sheep		1
Goats		
Rabbits		
Bees		
Equine	16	102
Total	22	133

CZECH REPUBLIC

Species	Intra-EU	National
Porcine	20	20
Bovine	8	8
Sheep		
Goats		
Rabbits		
Bees		
Equine	5	5
Total	33	33

FRANCE

Species	Intra-EU	National
Porcine	23	23
Bovine	32	32
Sheep	11	11
Goats	2	2
Rabbits		
Bees		
Others		
Total	68	68

GERMANY

Species	Intra-EU	National
Porcine	38	11
Bovine	37	4
Sheep	2	
Goats		
Rabbits		
Bees		
Equine	139	92
Total	216	107

POLAND

Species	Intra-EU	National
Porcine	12	
Bovine	10	
Sheep		
Goats		
Rabbits		1
Bees		
Others		
Total	22	1

SPAIN

Species	Intra-EU	National
Porcine	37	0
Bovine	9	0
Sheep	8	0
Goats	7	0
Rabbits		0
Bees		0
Equine	21	0
Total	82	0

SWEDEN

Species	Intra-EU	National
Porcine	3	
Bovine	2	1
Sheep		
Goats		
Rabbits		
Bees		
Others		
Total	5	1

THE NETHERLANDS

Species	Intra-EU	National
Porcine	5	0
Bovine	5	0
Sheep	0	
Goats	0	
Rabbits	0	
Bees	0	
Equine	22	80
Total	32	80

HUNGARY

Species	Intra-EU	National
Porcine	6	4
Bovine	3	
Sheep	1	
Goats		
Rabbits	1	
Bees	1	
Others		
Total	12	4

UNITED KINGDOM

Species	Intra-EU	National
Porcine	14	1
Bovine	9	1
Sheep	3	
Goats		
Rabbits		
Bees		
Equine	22	
Total	48	2

Estimate of the number of semen storage centres approved for intra-EU trade in your Member States and the number of semen storage centres approved/authorised only for national trade in your Member State

BELGIUM

Species	Intra-EU	National
Porcine	5	41
Bovine	4	5
Sheep		1
Goats		
Rabbits		
Bees		
Equine	16	80
Total	25	127

CZECH REPUBLIC

Species	Intra-EU	National
Porcine		
Bovine	11	11
Sheep		
Goats		
Rabbits		
Bees		
Others		
Total	11	11

FRANCE

Species	Intra-EU	National
Porcine	23	more than 23
Bovine	67	67
Sheep	11	11
Goats	2	2
Rabbits		
Bees		
Others		
Total	103	80

GERMANY

Species	Intra-EU	National
Porcine		no data
Bovine	20	no data
Sheep		no data
Goats		no data
Rabbits		no data
Bees		no data
Others		no data
Total	20	no data

POLAND

Species	Intra-EU	National
Porcine	12	
Bovine	10	
Sheep		
Goats		
Rabbits		1
Bees		
Others		
Total	22	1

SPAIN

Species	Intra-EU	National
Porcine		
Bovine	21	0
Sheep		
Goats		
Rabbits		
Bees		
Equine	1	0
Total	22	0

SWEDEN

Species	Intra-EU	National
Porcine	4	
Bovine	7	all DYI + ai co-ops
Sheep		
Goats		
Rabbits		
Bees		
Others		
Total	11	

THE NETHERLANDS

Species	Intra-EU	National
Porcine	1	
Bovine	7	all inseminators and private farmers for DYS AI
Sheep	0	
Goats	0	
Rabbits	0	
Bees	0	
Others		
Total	8	

HUNGARY

Species	Intra-EU	National
Porcine		
Bovine	6	
Sheep		
Goats		
Rabbits		
Bees		
Others		
Total	6	0

UNITED KINGDOM

Species	Intra-EU	National
Porcine	4	no data
Bovine	10	4 (and on-farm)
Sheep	3	no data
Goats		
Rabbits		
Bees		
Others		
Total	17	0

Estimate of the number of embryo collection and production teams approved for intra-EU trade in your Member States and the number of embryo collection and production teams approved/authorised only for national trade within your Member State

BELGIUM

Species	Intra-EU	National
Porcine		
Bovine	4	
Sheep		
Goats		
Rabbits		
Bees		
Equine	12	
Total	16	0

CZECH REPUBLIC

Species	Intra-EU	National
Porcine		
Bovine	3	3
Sheep		
Goats		
Rabbits		
Bees		
Others		
Total	3	3

FRANCE

Species	Intra-EU	National
Porcine	1	1
Bovine	37	37
Sheep	2	2
Goats	2	2
Rabbits		
Bees		
Others		
Total	42	42

GERMANY

Species	Intra-EU	National
Porcine	2	no data
Bovine	40	no data
Sheep	6	no data
Goats		no data
Rabbits		no data
Bees		no data
Equine	10	no data
Total	58	no data

POLAND

Species	Intra-EU	National
Porcine		
Bovine	4	
Sheep		
Goats		
Rabbits		
Bees		
Others		
Total	4	0

SPAIN

Species	Intra-EU	National
Porcine		
Bovine	13	0
Sheep		
Goats		
Rabbits		
Bees		
Equine	2	0
Total	15	0

SWEDEN

Species	Intra-EU	National
Porcine		research
Bovine	3	a couple
Sheep		
Goats		
Rabbits		
Bees		
Others		
Total	3	0

THE NETHERLANDS

Species	Intra-EU	National
Porcine	0	0
Bovine	8	20
Sheep		
Goats		
Rabbits		
Bees		
Equine	3	30
Total	11	50

HUNGARY

Species	Intra-EU	National
Porcine		
Bovine	2	1
Sheep		
Goats		
Rabbits		
Bees		
Equine		
Total	2	1

UNITED KINGDOM

Species	Intra-EU	National
Porcine		
Bovine	23	16
Sheep		
Goats		
Rabbits		
Bees		
Others		
Total	23	16

ANNEX VII Vaccination policy

Part 1
EU vaccination policies – background and additional assessment

I. BACKGROUND OF THE ANIMAL VACCINATION POLICY WITHIN THE EU

I.1 Introduction

The EU animal health policy has been developed progressively and supported by harmonised legislation since the early 1960s. This policy is fundamental to ensuring the health and welfare of animals, profitability for farmers, food safety, the functioning of the EU single market and the possibility of exporting animals and animal products.

EU strategies for the control of major animal diseases of food producing animals often rely on strict surveillance and rapid containment of disease outbreaks. This is achieved by means of a 'stamping out' policy consisting in the culling of the animals in the infected and other at-high risk farms. In this way the confirmed and possible sources of infection are eliminated and the disease agent is eradicated. This strategy is suitable for diseases which occur rather sporadically, but which are easily spread from farm to farm and across state borders, such as classical swine fever (CSF), foot-and-mouth disease (FMD) and Avian Influenza (AI). By using the stamping out policy, the affected MS can quickly regain their "disease free status". For these diseases, the EU policy foresees only a rather limited use of vaccines, mainly in cases of emergency. In fact, the Commission has put in place vaccine banks for FMD and CSF, so that vaccines could be made rapidly available to MS in case of need.

Conversely, regular vaccination against other diseases is widely applied in the MS in accordance with EU disease control legislation. For example, vaccination against Brucellosis has proven to be an effective tool not only to control and facilitate its eradication in livestock but also to protect human health, as the disease can be transmitted to humans. Another example is the substantial investment of resources in the vaccination of wildlife against rabies. This significantly improved the rabies situation in Europe, reducing risk to human health and making travelling with pets easier.

Vaccination is used in accordance with the EU legislation to control and eradicate diseases with large production losses, such as Aujeszky's Disease, Infectious Bovine Rhinotracheitis (IBR), etc.

For many diseases, vaccination of farmed, sports or pet animals is not regulated by EU legislation and it is usually applied because of industry standards or veterinary recommendation e.g. equine influenza, equine herpes virus, parvovirosis for dogs, etc..

I.2. The reasons behind the EU "non-vaccination" policy against major animal diseases

Before the strategies against major animal diseases were established at EU level in the last few decades, MS routinely using vaccination against diseases such as CSF and FMD had faced considerable problems in trade with other MSs and third countries which were not applying vaccination and were considered as "free from the disease". Trade in vaccinated animals and their products was considered unsafe, because vaccinated animals – although not showing signs of disease - can still become infected with the virus in the field, leading to a "masked infection".

In the late '80s EU legislation was therefore adopted that included the prohibition of prophylactic vaccination against FMD and CSF. The Single Market in cattle, pigs, sheep and goats and their products was established in the early '90s thanks to this "non-vaccination" policy and to the improvement in the disease situation, leading to the achievement of the "disease free status" across the EU (except the areas where limited outbreaks of disease occurred, which were however "regionalized"). In this way EU farmers could trade more easily and transparently not only within the EU but also with third countries, leading to considerable economic benefits.

Resources were therefore focused on the prompt eradication of new introductions of diseases when they occurred, rather than investing in very extensive and expensive vaccination campaigns and surveillance of vaccinated populations.

I.3. The impact of major animal health crises on the "non-vaccination" policy

At the end of the '90s and beginning of the 2000s serious animal disease outbreaks in the EU (CSF in 1997-98 and 2001-02, FMD in 2001, AI in 1999 and 2003) resulted in the destruction of many millions of animals, many on the grounds of prevention of disease spread rather than because they were infected, in accordance with the 'stamping out' policy. This raised serious economic and ethical concerns. Those crises highlighted the need to review disease control policies, including the approach to vaccination.

The serious problems encountered in controlling those outbreaks were caused by a combination of factors, including:

- the dramatic raise of the global trade (legal and illegal) in animals and their products, resulting in an increased risk of introduction of diseases to the EU and their spread within the EU;

- the difficulty in controlling diseases in areas at higher risk due to a high density of animals and/or insufficient biosecurity measures at farm level;

- the presence of diseases in the wild fauna (e.g. CSF in wild boar, AI in wild birds) in the EU and/or in many neighbouring countries, combined with increased contact between wildlife and domestic animals;

- insufficient disease preparedness in the MS.

Several corrective actions have been taken in the last years to address these problems both at EU and MS level, including a more flexible approach to vaccination, with results that can be considered by and large positive. For example, as from the early 2000s the EU has supported the development of a vaccination strategy of wild boar against CSF, by means of legislation and funding. This strategy has led to a major improvement of the disease situation in Europe, both in wild and domestic pigs.

Nevertheless, legislation adopted after 2000 (on BT in 2000, on CSF in 2001, FMD in 2003 and AI in 2005) confirmed that vaccination is not to be routinely used against these diseases, as the benefits would not justify the costs. However, there is now a wider possibility than in the past to use vaccines, both as an emergency response to outbreaks which might get out of control and, for some diseases, namely AI and Bluetongue, also as a prevention tool.

This revised approach was also made possible by technical developments such as better quality and purity of vaccines, new marker vaccines (which allow diagnostic tests to detect infection in

vaccinated animals) and diagnostic tests allowing more effective surveillance in vaccinated populations. At the same time, legislation on trade in vaccinated animals and their products has become more flexible and less punishing when vaccination is used. Indeed, in certain cases, like BT (and also rabies), vaccination is envisaged by the legislation as a tool for facilitating movement and trade of animals, if certain conditions are met.

It must be mentioned, however, that despite the additional flexibility introduced in the legislation on the possible use of vaccines, there is still limited experience of their emergency use for some diseases (CSF, FMD, AI). This makes difficult or even prevents its use by MS. Fears also exist that other MSs will not accept the flexibility of legislation allowing the application of only minimal trade restrictions on products originating from vaccinated animals. In this regard, some MSs have traditionally shown a quite negative attitude *vis-à-vis* vaccination. Even if this is overcome, traders may still be cautious of possible trade restrictions from third countries, while retailers may refuse to buy products from vaccinated animals, as they are also concerned about negative reactions of consumers (although these reactions would not be justified by the scientific evidence). All this would finally affect the decision (that is largely up to the affected Member State(s)) to use or not vaccines in case of an emergency. This is true of CSF and FMD in particular.

I.4. International standards and impact on international trade

The Terrestrial Code of the World Organisation for Animal Health (OIE) is revised every year. With respect to vaccination, when an approved vaccine exists its use is permitted, and the code only requires that the health certificates accompanying animals contain the relevant information about any vaccinations. In some cases laboratory testing of animals is required and/or that the surveillance of the territory is adapted according to the vaccination policy adopted.

EU legislation largely reflects OIE standards on vaccination and its effects on trade in animals and animal products. However, third countries may be very reluctant to fully accept OIE standards, even when the OIE (in parallel with the EU) has been very open and rapid in adapting them to new technical developments.

The positions of trading partner countries regarding vaccination policies and their impact on trade are widely diverse, depending on the country and on the disease. It can be said that vaccination still increases the risk of trade barriers being applied (even if unjustified). The barriers that are technically justified and supported by EU legislation and OIE standards are usually not insurmountable. However, in some circumstances they may be sufficiently severe to discourage vaccine use, particularly in MSs which have strong interests in export.

II. ADVANTAGES AND DISADVANTAGES OF VACCINATION

In summary, on the bases of the lessons learned in the last two decades, the advantages and disadvantages of vaccination as a control tool against major epidemic diseases can be summarised as follows:

Advantages:

a) Reduction of clinical disease and mortality and associated losses;

b) Reduction of risk of infection;

c) Reduction of virus excretion from vaccinated animals and spread to other animals/farms;

d) Possible reduced risk of disease outbreaks of major size, of massive killing of animals and of direct and indirect economic losses (although the limited experience in the emergency use of vaccines does not allow definite conclusions to be drawn).

Disadvantages:

a) Vaccination may be technically challenging to administer and require several injections to build up immunity (e.g. cumbersome individual vaccination of large numbers of poultry or vaccination of dangerous animals);

b) The immune response induced by vaccination is not always fully satisfactory so it is possible for some vaccinated animals to still get infected;

c) It may mask the occurrence of infection and thus delay its detection;

d) It may require vaccination of a high number of animals to establish sufficient protection of the population ('herd immunity');

e) It may induce a false sense of security and thus encourage relaxation of biosecurity and surveillance measures;

f) The vaccine strain may not always match the virus in circulation – e.g. there are several different FMD virus strains which will make vaccination expensive, when several vaccine strains are needed.

g) Where vaccination does not prevent the possibility of infection, a suitable surveillance programme must be installed to prove absence of infection.

III. PRACTICAL EXAMPLES OF THE EU POLICY DEVELOPMENTS ON VACCINATION

The examples of AI, ND, CSF, FMD and BT are used below to demonstrate how the EU legislation foresees different vaccination possibilities according to the nature of the disease agent, available vaccines, acceptable vaccination policies and consequences for economy and trade; and how this legislation has evolved in the last decade.

III. 1. Avian Influenza and Newcastle Disease

The approach to vaccination against AI and ND, the two most important highly contagious poultry diseases in the world, is entirely different.

Vaccination against AI is used only very seldom. This is due to a number of factors

i) until 2000, AI was a very rare disease in the EU and therefore a preventive vaccination had never been justified;

ii) AI vaccination prevents the disease but does not fully protect against infection. This could lead to undetected virus spread; therefore costly surveillance is required to detect infected animals in a vaccinated population;

iii) vaccines that would allow an easy and cheap application are not yet available (currently injection of each individual bird is needed); and

iv) the use of a vaccine may lead trading partners to impose trade restrictions

Preventive routine vaccination against ND is used widely and fully supported by the industry. This is due to a number of factors:

i) several ND outbreaks occurred in various MS, causing serious losses;

ii) the risk of continuous spill-over from wild birds into domestic poultry farms;

iii) cheap, effective vaccines are available; and

iv) the OIE Code does not establish significant trade restrictions in relation to vaccination.

The different approach towards these two poultry diseases is reflected in the requirements for intra-EU trade and imports into the EU.

III.2. Classical Swine Fever

Following the CSF crises of 1997-98, the experience gained through oral vaccination of wild boars against CSF (mainly in Germany) and the development of marker vaccines for domestic pigs allowed more flexibility towards vaccination in EU legislation (Council Directive 2001/89/EC).

If wild boar are vaccinated against CSF, EU legislation does not impose trade restrictions on unvaccinated domestic pigs and their products in addition to the restrictions normally applied in an area where the disease occurs in the wild boar. Trade in pig meat is not restricted.

As regards vaccination of domestic pigs, Directive 2001/89/EC introduced the use of marker vaccines and a discriminatory test which were developed in the late 1990s/early 2000s.

If a marker vaccine is used, which allows identification of infected animals in a vaccinated population; trade in pig meat from vaccinated animals may regularly take place, provided that the herd of origin is shown to be disease-free via discriminatory testing.

III.3. Foot and mouth disease (FMD)

In the early '90s, after FMD was eradicated from Europe, the EU adopted a policy prohibiting prophylactic vaccination against FMD. For this disease, in addition to the policy considerations explained in chapter 1 above, the adoption of a policy of prophylactic vaccination posed (and still poses) serious technical problems, notably because of the several distinct strains of virus existing outside Europe. This causes significant uncertainties as regards which vaccine strains ought to be used for such vaccination.

For these reasons, following the FMD crisis in 2001, the prohibition of prophylactic vaccination was confirmed, even though new FMD control legislation was adopted (Directive 2003/85/EC) which moved emergency vaccination further to the forefront of the disease control measures. MSs had to review their contingency plans to be better prepared for emergency vaccination. MS have retained a substantial degree of sovereignty over the decision whether to employ vaccination or not; however they now have the legal obligation to put in place all necessary arrangements for a possible emergency vaccination at the very early stage of an outbreak and not wait until it becomes evident that the outbreak is out of control.

However, so far FMD emergency vaccination has not been used, e.g. during the UK 2007 FMD outbreak or the BG 2011 outbreak, as in both cases it was possible to successfully contain the

disease in small areas and then eradicate it by means of a limited stamping out of the infected animals and those at high risk.

III.4. Bluetongue

BT is an insect transmitted disease of wild and domestic ruminants; its expansion in the EU follows the climate changes observed over the last years. In the last decade this disease has shown a tendency to become endemic in southern Europe; however, it is also able to cause major epidemics in central and even northern Europe, as observed in 2007-2008.

Given that it is transmitted by insects this disease cannot be effectively controlled by stamping-out. Vaccination is the most efficient veterinary measure that can be implemented in an infected territory, together with surveillance. The wide use of the vaccine is explicitly foreseen by EU legislation. Whether to use vaccines or not is in principle up to the MS. However, harmonised vaccination programmes are preferred and if EU co-financing is requested, a harmonised approach is required.

Vaccination can be used for the purpose of controlling the disease, to facilitate safe trade under certain conditions or even with the objective of eradicating the disease from limited regions. Vaccination is currently possible after virus introduction in an area, while it is forbidden in disease-free areas because of the safety problems posed by the "live-attenuated" vaccines. These consist in live although attenuated viruses which may spread from vaccinated to unvaccinated animals and cause undesired side effects. Newly developed "inactivated virus" vaccines are undoubtedly safer than the "live-attenuated" ones and are the best choice when available. However, the availability of inactivated vaccines is for the moment limited to only a few serotypes of the BT virus.

In 2010 the Commission proposed a change in legislation to facilitate the use of inactivated vaccines and also make their use possible in disease-free areas. The proposal is still under discussion in the European Parliament and Council.

IV. FUTURE APPROACHES FOR THE AHL

The CAHP evaluation has already addressed the issues of vaccination and the relevance of vaccine banks. It also noticed that although significant funds were spent on this issue, MS very seldom used vaccination during crises. The AHS has clearly emphasised the need for better preparedness for animal disease related emergencies, which must be dealt with swiftly and effectively by means of an agreed approach. Taking fast-track decisions by the Commission and MS for emergency action is of high value in limiting and controlling animal-related threats at EU level.

In response to ethical concerns and the growing demand for improved animal welfare, the EU has already moved to a more flexible approach towards vaccination, as well as improving its policy to control major animal diseases. One of the objectives of the AHS is to reduce the risk of massive culling and destruction of animals. However, different elements (e.g. vaccine availability and effectiveness, demands for validated tests able to differentiate infected from vaccinated animals, OIE international guidelines and possible trade implications, cost-effectiveness analysis, possible risks related to the use of vaccines) have to be considered before a decision is taken as regards the use of vaccines. This decision can therefore be taken only on a case-by-case basis, in line with the principles agreed at EU level.

In line with the AHS's Action Plan, EU vaccine banks for emergency situations shall be strengthened in addition to those already existing for FMD and CSF. An expert group has produced a "policy paper on the necessity of EU vaccine banks". It recommended EU vaccine banks for five major diseases, namely FMD, AI, CSF, African Horse Sickness and BT. An extensive consultation on this subject with the CVOs took place and the results of both activities are presented in Part 2 of this Annex.

The "added value" of vaccine banks established at EU level is widely recognised and it is therefore likely that follow-up to the recommendations of the policy paper will be welcomed by MS and other stakeholders.

Objectives

Following the commitments of the AHS, EU legislation must establish a comprehensive and flexible legal framework for vaccination policy and vaccine banks in the EU that could be used for different diseases and circumstances, taking into account the following aspects for each different disease:

- Nature of disease agents and related availability and reliability of vaccines, including availability of valid tests to differentiate vaccinated from infected animals
- Susceptible animal species and their natural environment (domesticated, wild animals)
- Purpose of vaccination: preventive (prophylactic) or emergency vaccination
- Possible risks related to vaccine use
- Different approaches and control measures for endemic and exotic diseases, considering economic implications
- Relevance of the disease for EU intervention in terms of the importance of the disease (disease categorisation) or animal categories (livestock, farmed animals versus pet animals and animals kept for hobby and sport / recreation)
- Emergency preparedness: need for vaccine bank at EU level
- Ethical considerations concerning stamping out eradication measures
- Consumers acceptance of products originating from vaccinated animals
- Cost-effectiveness analysis (including vaccination costs).

Policy options on vaccination:

A.i. AHL provides a single vaccination policy for all diseases and provides a legal basis for vaccine banks.

A.ii. AHL provides a single vaccination policy for all diseases and doesn't provide a legal basis for vaccine banks.

Both options A.i. and A.ii. fit most comfortably into of option 5 in the main impact assessment – a prescriptive legal framework.

B.i. AHL sets up a flexible legal framework for vaccination, providing possibilities for different approaches to be used for different diseases under different circumstances and provides a legal basis for vaccine banks.

B.ii. AHL sets up a flexible legal framework for vaccination, providing possibilities for different approaches to be used for different diseases under different circumstances and does not provide a legal basis for vaccine banks.

Both options B.i. and B.ii. are possible sub-sets of option 4 in the main impact assessment, providing a flexible legal framework.

C. AHL shall not set the vaccination policy at all.

Assessment of impacts:

Options A.i. and A.ii. AHL provides a single vaccination policy for all diseases, with or without a legal basis for vaccine banks.

Following the information, analysis and examples provided in sections 1 to 3 above it is very clear that a single vaccination policy valid for all diseases cannot exist. This is for many reasons, for example; the differences amongst diseases and their appearance or absence in the EU, vaccination possibilities, vaccine development and availability, the relevance of diseases for EU intervention, different uses of animals, economic consequences, ethical considerations, and so on. To provide one single policy would be nonsense.

B.i. AHL sets up a flexible legal framework for vaccination, providing possibilities for different approaches to be used for different diseases under different circumstances and provides a legal basis for vaccine banks

EU legislation on vaccination should be rapidly adapted to new developments, including new scientific evidence and experience gained with disease control. Furthermore, the EU legislation would take into account the divergence of situations and approaches for vaccination possibilities. Vaccination against major animal diseases shall remain flexible, giving the MS the clear possibility of vaccinating and the responsibility to decide to do so when it is feasible and desirable.

EU rules must also foresee the possibility for a rapid adaption to take account of technical developments of new vaccines and diagnostic tests. An inability to quickly include new available tools due to an inflexible and outdated legal framework would put the credibility of the EU in cases of emergencies at significant risk.

As regards the lack of consumer acceptance of products from vaccinated animals, the EU legal framework cannot solve this issue, but can contribute to better understanding of the safety and benefits of a well-implemented vaccination policy. EU intervention should be limited to major diseases, taking into account disease categorisation.

Emergency preparedness can only be achieved if a clear legal basis for vaccine banks is provided for the diseases on a case-by case basis, where this is considered necessary.

B.ii. AHL sets up a flexible legal framework for vaccination, providing possibilities for different approaches to be used for different diseases under different circumstances and does not provide a legal basis for vaccine banks.

As for option B.i, the possibility of vaccination would be available, decisions on its use left to the MS, and a flexible approach is applied but no legal basis for vaccine banks is provided. This omission would compromise the EU emergency preparedness and ability to react quickly.

C. AHL shall not set the framework for vaccination policy at all.

To withdraw any kind of EU framework for vaccination policy would be extremely unpopular amongst the MS and other stakeholders. This option does not uphold the objectives of the AHS which confirmed the value of a coherent approach at EU level.

Table VII.1: Pros and Cons of Options Considered

	Options A.i. and A.ii	Option B.i	Option B.2	Option C
Pros	▪ EU approach ensured ▪ Health status harmonised	▪ EU approach ensured ▪ Flexible legal framework for vaccination possibilities ▪ Measures can be adjusted to changed circumstances, different diseases and vaccine developments ▪ Flexibility for the MS ensured; quite broad freedom of choice ensured for animal keepers ▪ Better emergency preparedness ▪ Better availability of vaccines ▪ Costs for the MS can be lower (no need for national vaccine banks)	▪ EU approach partially ensured ▪ Flexible legal framework for vaccination possibilities ▪ Measures can be adjusted to changed circumstances, different diseases and vaccine developments ▪ Flexibility for the MS ensured; quite broad freedom of choice ensured for animal keepers ▪ In short term lower cost for the reasons of absence of vaccine / antigen banks	▪ No interference from legislation ▪ Full flexibility for the MS and full freedom of choice for animal keepers

Cons	▪ Burdensome for animal keepers and veterinary services; it would affect all vaccinations of all animals and all diseases with substantial practical problems
	▪ No freedom of choice for animal keepers and MS (no subsidiarity)
	▪ High costs
	▪ Non-flexible, rigid
	▪ Loss of prioritisation possibly leading to waste of resources
	▪ Unrealistic due to:
	  ▪ different animal species, different uses and relevance for the EU intervention
	  ▪ variety of diseases, disease agents, development / availability of vaccines, vaccination options, trade impacts
		▪ Costs of vaccine banks at EU level (purchase, maintenance)
		▪ Freedom of choice for animal keepers is limited to some diseases (harmonised EU intervention)
			▪ Difficult availability of vaccines
			▪ Weaker emergency preparedness due to lack of vaccine banks
			▪ Inability to react quickly, higher costs and negative welfare impacts if disease occurs and vaccine is not available
				▪ AHS objectives not met
				▪ Possible negative impact on health situation in the EU
				▪ Consequential trade implications (confidence of trade partners)

V. CONCLUSIONS

1. The EU policy on vaccination against animal diseases only concerns a limited number of diseases of major importance because of their tendency to spread irrespective of national borders and of their trade impact. There is no proposal to address vaccination for diseases other than this limited set.

2. In order to avoid large-scale killing of animals as a disease control measure as much as possible, in the last decade EU legislation has already included several elements of flexibility to facilitate the use of vaccines both as a preventative and an emergency tool, as shown during the recent epidemics of highly pathogenic avian influenza H5N1 and BT.

3. The EU policy and legislation, however, must duly consider the technical specifications and limits of the available vaccines and accompanying diagnostic tests, as well as the practical feasibility of vaccination and its costs.

4. In reality, there are obstacles and limitations to the use of vaccines against some major diseases (CSF, FMD, AI) that are not dependent on legislation.

5. Inappropriate use of vaccines may pose additional risks and jeopardise disease control, have a negative impact on safe trade from areas in which the vaccine has been used and ultimately make large-scale killing of animals inevitable.

6. Subsidiarity is important to maintain because of particular local contexts and the need for MS to develop their own particular rules on vaccination accordingly.

7. However, EU legislation must also allow for the possibility of rapidly assessing and permitting the use of vaccination for newly developed vaccines and accompanying diagnostic tests.

8. In addition, quick availability of reliable vaccines in case of emergencies is essential. Therefore, future policy has to continue to make use of these concepts and promote them in order to avoid massive killing of animals as much as possible.

9. The legal basis for the MS and the farmers has to mirror this strategy. Only option B.i (the preferred option) fulfils all elements and addresses the concerns raised in the CAHP evaluation, AHS and stakeholders' consultation (see "Vaccination" under Point 2.15 of Annex V).

10. This option B.i is also the one most in line with the risk-based preferred option (option 4) for the AHL as a whole: a coherent and flexible EU approach providing proportionality and subsidiarity, but with support at EU level (through the vaccine bank) providing added value over and above what MS can achieve by themselves

11. However, the future EU law cannot resolve issues such as a lack of consumer acceptance of products from vaccinated animals (this is a task for a good communication strategy), but can contribute to better understanding of the safety and benefits of a well-implemented vaccination strategy.

Part 2

Questionnaire to EU CVOs on emergency vaccination policy and an analysis of the replies

EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

Directorate D — Animal Health and Welfare
D1-Animal Health and Standing Committees

Brussels, 30 June 2010

SANCO/7117/2010

Results of the

QUESTIONNAIRE

for Chief Veterinary Officers of the EU Member States and Norway
to collect information and opinions on:

VACCINE AND/OR DIAGNOSTIC BANKS FOR MAJOR ANIMAL DISEASE

(point 24 of the Programming document[41]
for the Animal Health Strategy 2007-2013)

[41] http://ec.europa.eu/food/animal/diseases/strategy/pillars/action_en.htm.

I. Introduction

The European Commission launched an external evaluation to review its animal health policy in 2005. Based on the results of this evaluation, strategic aims and objectives for animal health were set out in the Commission Communication on the new EU Animal Health Strategy where 'Prevention is better than cure'.

Identifying problems before they emerge while being ready to manage major animal disease outbreaks and crises is one of the expected outcomes of the Animal Health Strategy. It is widely agreed that in many cases, the best means of combating animal diseases once they occur is in accordance with the principle that 'vaccination is better than unnecessary culling'.

The recently published "Expert Opinion on Vaccine and/or diagnostic Banks for major Animal diseases has been presented to the Member States during the SCFCAH meeting in May 2010.
It can be found on the SANCO web page:
http://ec.europa.eu/food/animal/diseases/strategy/pillars/antigen-vaccine-banks-task-force_en.htm

Based on the above-mentioned document questions arose. Therefore DG SANCO Unit D1 wished to consult the Chief Veterinary Officers of the EU Member States (and Norway, as an agreement is in place between the EU and Norway in relation to the EU animal diseases vaccine banks) in charge of implementing animal health legislation on those questions.

23 Member States and Norway responded to this questionnaire, resulting in a response rate of 86%. In the following document the opinions and have been gathered and are presented in both graphical and descriptive form.

The information and opinions given serve as valuable base for the discussion between Commission and Member States. Moreover, they will be used by the Commission Services as inputs to finalise a policy paper on possible options for the reinforcement of the EU antigen and vaccine banks and on the establishment of EU reserves for essential diagnostics for certain diseases.

Following this introduction the second part presents the key messages of the paper produced by a group of experts (see *page 3*). In the third part the answers to all questions will be analysed separately (see *pages 4–17*). The fourth part attempts to summarize the opinion of all participating countries in form of 12 conclusions (*see page 18*).

Thank you for your participation and for your valuable contribution to this process!

II. Key Messages Of The Expert Opinion

The key messages of the "Expert Opinion on Vaccine and/or diagnostic Banks for major Animal Diseases" are as agreed among the experts:

1. Vaccination is a fundamental tool in a strategy to control and eradicate major emerging diseases.

2. Emergency vaccination has to be considered as one tool in a whole range of measures as a part of a complex strategy to control and eradicate major animal diseases.

3. Emergency vaccination for most relevant infectious diseases should in general be seen in a new light, directly linked to the availability of effective diagnostic tools substantiating that vaccinated animals, or meat and other products obtained from vaccinated animals, are free from pathogens and can be traded safely.

4. Emergency vaccination has to be understood as *vaccinate-to-live*, meaning that vaccinated animals are kept to the end of a normal production cycle, and that their meat and other products can be marketed.

5. Diagnostic banks for particular infectious diseases are necessary to supplement vaccine banks to enable a holistic strategy of disease control and eradication.

6. The establishment and maintenance of vaccine and diagnostic banks must be part of a strategic plan prepared during ‘peace time’, ready for an emergency.

7. The issue of vaccine and diagnostic banks can only be treated in the context of a control and eradication strategy specific to each major animal disease (e.g. FMD, CSF, AI) and various outbreak scenarios.

8. For most of the relevant infectious diseases, existing legislation regarding emerging vaccination should be amended so that vaccination becomes a realistic option in the event of a crisis.

9. Trade issues regarding vaccinated animals or fresh meat and meat products obtained from vaccinated animals should be resolved.

10. Relevant legislation regarding veterinary medicinal products is not well suited to approve the use of vaccines in emergency situations.

11. The current review of legislation dealing with veterinary medicinal products is an ideal opportunity to introduce a mechanism to approve vaccines for emergency use at European level.

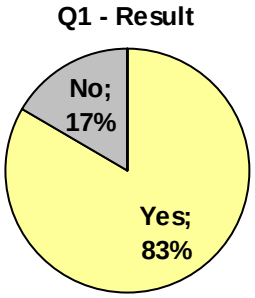
12. Proposals to be considered could include alternatives to vaccine banks, such as vaccine master seed stocks and ‘mock up’ authorisations for particular vaccines.

13. Vaccination and testing should replace unnecessary culling.

III. RESULTS OF THE QUESTIONNAIRE

1. SUPPORT OF NATIONAL LEGISLATION

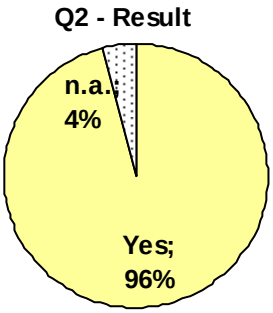
Do your national legislation and contingency plans support the use of an EU vaccine bank in your strategy to control and eradicate major emerging diseases?



- In 20 (83%) of the responses of participating countries it was stated that the use of an EU vaccine bank is supported by their national legislation and contingency plans, even though the term "EU vaccine bank" is not specifically mentioned yet. However, stamping out policy was still mentioned as the first option by two Member States.
- In general, the option of emergency vaccination is already included in the contingency plans of the respective countries for a variable number of diseases; so do some countries currently consider vaccination only for FMD, others list up to four out of the following diseases: FMD, AI, CSF, ASF and BT.
- One out of four countries where present national legislation does not include provisions for the use of an EU vaccine bank stated that amendments of national legislation and of contingency plans are possible, whenever required.

2. VACCINATION IN A NEW LIGHT, LINKED TO DIAGNOSTICS

Do you think that emergency vaccination for most of the relevant infectious diseases should in general be seen in a new light, directly linked to the availability of effective diagnostic tools?

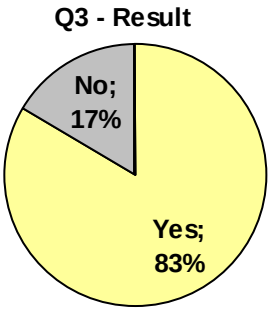


n.a.: not answered

- 23 (96%) responses share the opinion that vaccination has to be seen in a new light, (Q2 was not answered by one country, 4%). The availability to effective and safe diagnostic tools that help to distinguish between vaccinated and infected animals or detect possible carriers in vaccinated animals are seen as absolute prerequisite.
- This change of view is not only linked to the availability of effective diagnostic tools, but also technical, economical, commercial, societal issues and the global strategy of disease control have to be kept in mind. Tradability has to be granted.
- DIVA vaccines are specifically mentioned as pre-requirement for a change in control strategies. One opposing response clearly expressed reservation against the use of DIVA vaccines, but promoted the strategy of prior testing in combination with a well established surveillance system.
- The importance to share practical experience gained from successful vaccination campaigns to support decision making was mentioned. Furthermore, more research should be done in this area.

3. DISEASES TO BE CONSIDERED

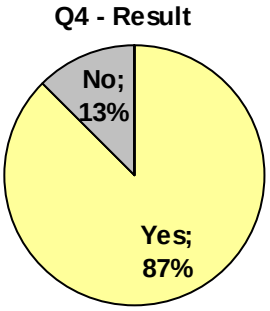
Do you consider that the list of infectious diseases identified in the expert paper for which vaccine and diagnostic banks should be available in the EU in the near future is appropriate (or correctly identified)?
Note: the expert paper lists the following diseases: FMD, AI, CSF, AHS, BT and ASF.



- 20 (83%) responses agreed with the list of infectious diseases identified in the expert paper. One response stressed the need to concentrate efforts and resources on the major diseases listed and not to include others (at the moment).
- 4 (17%) responses proposed to add one or more of the following diseases: Rabies, Peste des Petits Ruminants, Rift Valley Fever, Sheep Pox, Aujeszky's Disease, Crimean-Congo haemorrhagic fever and zoonoses in general.
- The stored vaccines / diagnostics should be timely available both to prevent spread of an "old" re-introduced disease (as Rabies) and of "new" diseases that might be introduced in future.
- In addition it was pointed out that certain vector-borne diseases might have a higher probability to occur in future due to climate change and that for such emerging diseases sufficient diagnostic knowledge should be made available. Furthermore, terrorist threats should be considered.

4. VACCINATION TO COMPLEMENT / REPLACE CULLING

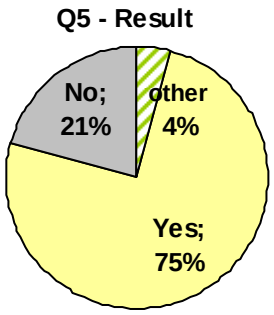
Do you agree with the principle that emergency vaccination in combination with testing, at least in cases where vaccination does not prevent infection, should complement or wherever possible replace culling (except the infected herd)?



- 21 (87%) responses support the principle that emergency vaccination can be part of a control strategy if the disease status of vaccinated animals can be assessed unambiguously.
- The opposing 3 (13%) responses stress that vaccination can complement but not necessarily replace culling. The latter issue was also mentioned by countries which agree with the principle; emergency vaccination must be always part of measures which prevent spreading of the disease and/or pathogen, ensure safe animal products and protect public health.
- Decision has to be taken case by case (country specific decision according to epidemiological situation, density of susceptible population, disease specific factors, etc.)
- Costs and benefits of vaccination and culling should be compared.

5. EMERGENCY VACCINATION FOR VACCINATE-TO-LIVE

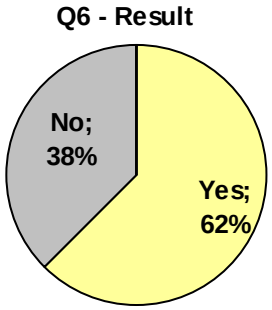
Do you agree that emergency vaccination, except where specifically carried out as suppressive vaccination to damp down virus shedding from infected animals, should be understood as *vaccinate-to-live*, meaning that vaccinated animals are kept to the end of a normal production cycle, and that products derived from vaccinated animals can be marketed without additional requirements?



- In 18 (75%) responses consented that emergency vaccination should be understood as *vaccinate-to-live* in the above mentioned sense. A *Vaccinate-to-live* strategy also complies with a sustainable food production cycle.
- Sound diagnostic regime constitutes the pre-requisite so that a specified degree of freedom from infectious agent can be granted.
- International trading partners have to be included into the debate.
- However, for certain diseases countries additional requirements and / or restrictions are preferred; specifically for FMD or zoonotic agents as AI. One possible restriction mentioned was that trade of vaccinated animals should only take place between countries with the same disease status.
- It has to be assured that no public health issues arise (residues of vaccine or vaccine components)

6. LEGISLATION AS OBSTACLE

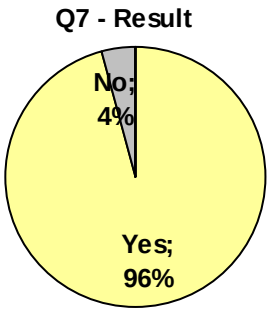
Do you consider that for most of the relevant infectious diseases, some of the existing legislation regarding emergency vaccination is an obstacle for *vaccination-to-live* and therefore should be amended?



- 15 (63%) responses report obstacles of the existing legislation, specifically restrictions on the trade in vaccinated animals and products thereof in combination with the duration of the restrictions.
- The remaining 9 (38%) responses think believe that legislation gives enough flexibility to apply vaccination-to-live approach. However, limited acceptance of the market is still a major problem.
- It has been proposed to amend legislation as a first step to make *vaccination-to-live* a reasonable option for the Member States. In a second step trade issues regarding vaccinated animals or fresh meat and meat products obtained from vaccinated animals should be resolved.
- FMD, CSF and AI legislation are in particular concerned.
- The BT history was mentioned as a positive example for the changed way of thinking regarding vaccination.

7. USE OF EU BANKS IN EMERGENCY SITUATION

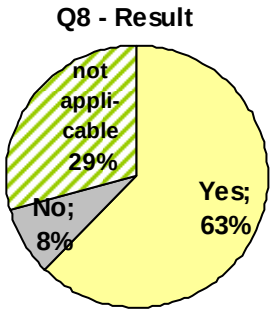
In case of an emergency situation would you consider the use of vaccines and/or diagnostics from EU banks if there is no immediate alternative and/or by bridging the period until you can obtain vaccines and diagnostic tests through your own budget?



- All except one response (23; 96%) consider the use of vaccines and / or diagnostics under certain circumstances and if a range of pre-requisites are met.
- Following pre-requisites were pointed out:
  - A quick decision about the availability in case of an emergency has to be taken ("chain of command" at EC level);
  - National marketing authorisation of vaccine is obtained; diagnostics would have to be OIE recognised or equivalent;
  - Quality and quantity: vaccines must be effective and available in large enough amounts to be successfully applied in high-risk areas;
  - National laboratories must be familiar with the handling of used diagnostics;
  - Sufficient financial resources can be dedicated by the Member State for this purpose.
- Reported situations where the use of vaccines and / or diagnostics from EU banks would be considered are:
  - The outbreak already has spread beyond the primary outbreak; occurrence in different parts of the country;
  - If national vaccine / diagnostics reserves do not protect against outbreak strain or if an exotic disease has to be dealt with;
  - The use of vaccine depends on disease: a clear yes for FMD, but as well for CSF and AI;
  - If the products are not immediately commercially available at an affordable price.

8. NATIONAL BANK VS. EU BANK

Would you consider giving up a national vaccine or diagnostic bank in favour of a centralised EU bank if legislation on contingency planning so allows?

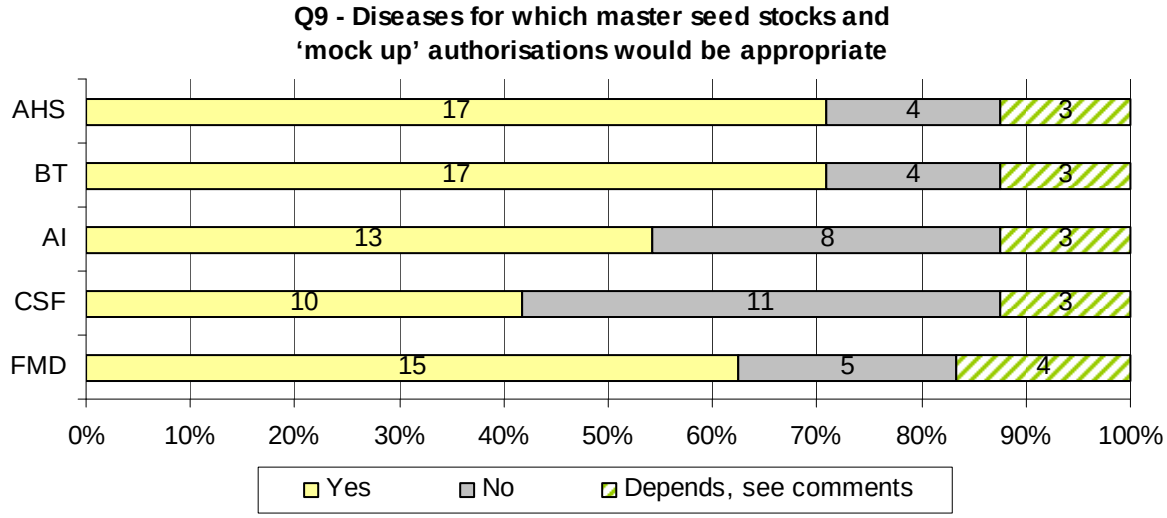


- This question is not applicable to 7 (29%) countries as they responded not to have a national vaccine and / or diagnostic bank.
- 15 (63%) of the remaining 17 responses take the closure of their national banks in consideration, for 2 (8%) countries this is no option.
- Centralised banks appear to be reasonable from an economical point of view (e.g. reduction of spoilage due to the short shelf-life); nevertheless an economical evaluation should be undertaken to describe costs of establishment and maintenance of a centralised bank for the single participating country and the EU.
- Moreover, aspects such as management and technical support are probably favourable compared to national banks.

- Agreement exists on the need of clear criteria how vaccines and diagnostics can be assessed, particularly in the case when more than one Member State is affected by or at risk of introduction of a disease.
- As regards of diagnostics, several countries consent that these should remain within the responsibility of national reference laboratories. An adequate amount of diagnostics should be available both for routine and for emergency situations.
- Several of those countries witch currently hold vaccine banks point out that the quantity of stored vaccines will be a crucial factor – national vaccine banks could only be closed if a centralised bank can provide enough vaccine in a short amount of time. Another influential factor will be the effectiveness of the EU bank. So far no experience is available on this point.

9. MASTER SEED STOCKS AND 'MOCK UP' AUTHORISATION

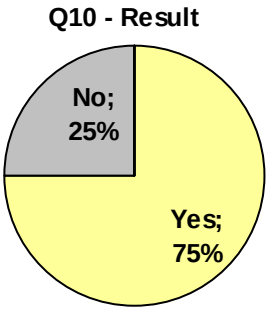
For which diseases do you consider that master seed stocks and 'mock up' authorisations would be appropriate (instead of ready to use vaccines):



- Favour for master seed stocks depends on:
  - How long production and distribution of vaccines would take in case of emergency;
  - Serotypes (AI and BT).
- Possibilities for master seed stocks to be tested in line with the European Pharmacopoeia should be examined with scrutiny. Moreover, discussion has to be started on who will be in charge of the availability and quality control of the seeds.
- Several countries agree that for FMD ready to use vaccine should be available in the vaccine bank as emergency vaccination might be required in a very short period of time; serotypes A & O are specifically indicated. For the more rarely occurring serotypes seed stock is seen as a good option.
-
- Other diseases for which master seed stocks and mock-up authorisations are mentioned as desirable: oral vaccines for CSF and Rabies.

10. Rapid Decision On Distribution Of Vaccine

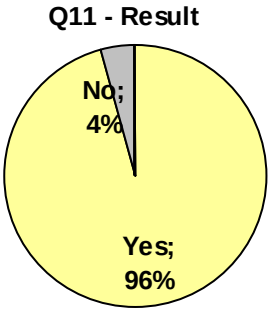
Do you agree that the Commission should be fully empowered to make rapid decisions on the distribution of the vaccines available in stock after consultation with the Member States concerned or at direct risk because of an outbreak?



- 18 (75%) responses agree to fully empower the Commission to take decisions as long as concerned Member States are consulted.
- 6 (25%) responses request that not only the directly concerned but all Member States should be consulted before decisions are taken. This could be done via SCoFCAH and / or a CVO meeting. To assure that rapid decisions can be taken teleconferences or written procedures were mentioned as an alternative to a live meeting. Besides SCoFCAH consideration of the epidemiological situation was mentioned as second axis to come to a decision.
- Several responses claimed that irrespective of any outbreak scenario procedures on how to distribute vaccines or tests between Member States must be agreed on in advance.

11. EURL To Supplement Vaccine Banks

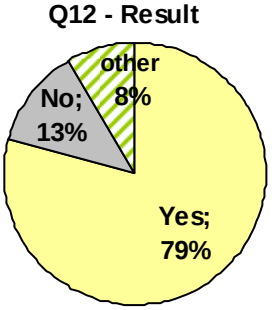
Do you think diagnostic banks for particular infectious diseases should be within the remit of the EURL to supplement vaccine banks, if diagnostic kits are not commercially available?



- 23 (96%) responses agree that the EURL is the appropriate institution to ensure that diagnostic kits for particular infectious diseases are made accessible if not commercially available.
- Additionally, it was pointed out that it is mandatory that all Member States have an effective diagnostic capability for the diseases that are considered of importance for the EU. Therefore, other national laboratories could be entitled to cooperate with EURL, on the basis of documented expertise and capacity.
- The reason given for the opposition of one country (4%) is that the primary function of the EURL should remain to provide expertise.

12. Guarantees For Safe Trade

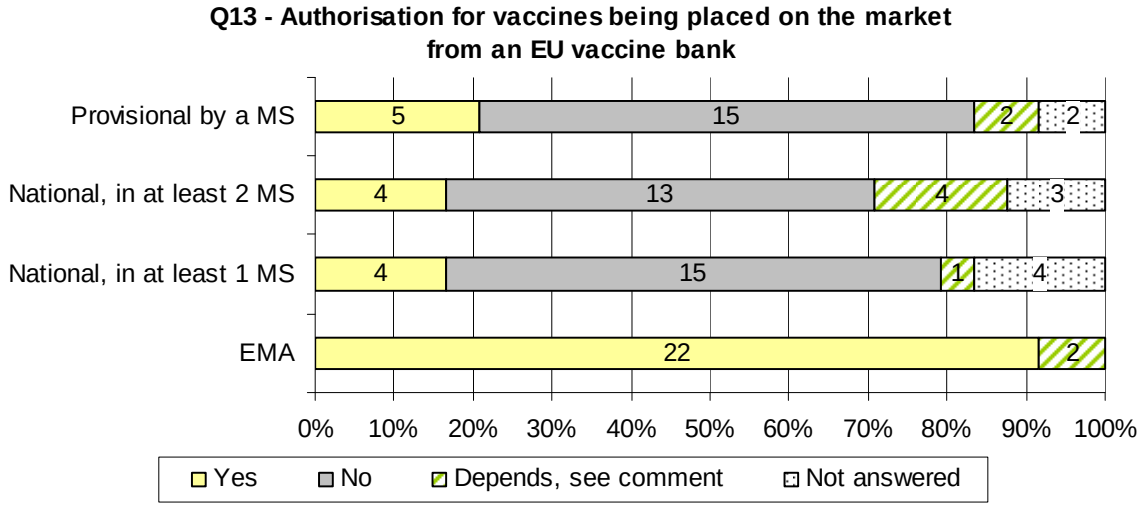
Do you think that vaccinated animals and their products could be traded safely if appropriate diagnostic tool and surveillance schemes were available and used properly, so that this surveillance gives the appropriate guarantees that those animals and products are not infected?



- The opinion was shared in 19 (79%) responses that a combination of appropriate diagnostic tools with surveillance schemes offers the possibility that vaccinated animals and their products could be traded safely.
- Conditions:
  - Clearly defined rules for movement of animals and animal products in the framework of eradication measures;
  - Dependent from disease, vaccine (DIVA, live), international acceptance, availability of approved tests;
  - Traceability is indispensable for every vaccinated animal.
- 3 (13%) responses did not agree, 2 (8%) responses could only envisage trade of products, but not of live animals.
- BT and AHS were examples given for current legislation that already allows vaccinated animals and their products to be traded safely.

13. AUTHORISATION OF VACCINES

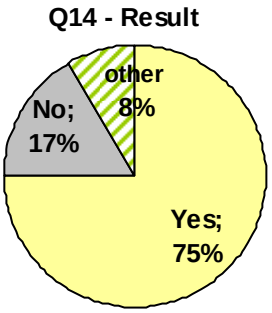
In your view *vaccination-to-live* with vaccines from an EU vaccine bank and subsequent intra-EU trade in vaccinated animals and their products could only take place provided that vaccines used have received the following authorisation for being placed on the market:



- A large majority of responses (22; 92%) shares the opinion that EMA authorisations could ensure the required standards. In addition, international acceptance was deemed to be more forthcoming following an EMA authorisation rather than any of the other three options.
- Besides this positive reputation of EMA opinions vary considerably: whereas several Member State only opt for EMA authorisation other Member States have the opinion that in an emergency situation any authorisation is welcome if a minimum of guarantees regarding quality and safety of the vaccines can be assured. The national authorisation in the case of BT has shown that the system worked excellently; an EMA authorisation is deemed as not absolutely necessary.

14. MOVEMENT WITHIN NATIONAL MARKET

Would you in general accept moving vaccinated animals or products obtained from vaccinated animals within your national market?



- 18 (75%) responses report general acceptance of movement of vaccinated animals or their products.
- Conditions quoted are:
  - If tested with approved tests and with an appropriate surveillance scheme in place, giving a guarantee of freedom (of infectious agent) and safety of products;
  - After discussion with stakeholders;
  - No negative implications for international trade.
- Comments in those 6 responses (25%) which would not accept such movement include the need for additional guarantees for absence of virus circulation in the country. This should be decided on the disease in question. In case of BT vaccinated animals could be placed on the market.
- One response emphasized that moving of products would be acceptable but not of live animals as important trading partners request for non-vaccinated animals. Furthermore, special conditions for products and live animals were claimed with regard to FMD

15. UNSOLVED TRADE ISSUES

Please explain briefly which are in your opinion the main still unsolved trade issues related to vaccination by disease and problem (maximum 3).

- In total 51 comments were made in relation to trade in all 24 responses. The comments quoted both
  - already existing and
  - possible future trade hindrances if vaccination would be applied.
- As several levels of trade-related issues were addressed they were summarized in three categorical levels in Table 1: 1.) technical level, 2.) legislative level and 3.) customer (or user-end) level. This structured form should highlight the different stages which have to be taken in consideration.
- Procedure of categorisation: One category was selected for every comment. In case a comment addressed more than one trade issues it was grouped into the category which mentions the cause, i.e. not the consequence.
  Example: "*a safe vaccine to enhance international trade*" would be categorised as "1a.) safe vaccine and diagnostics" as "*to enhance international trade*" is the consequence.
- This categorisation is only indicative.
- Comments given in relation to specific diseases are listed separately below Table 1.

Table 1: Summary of trade-related comments

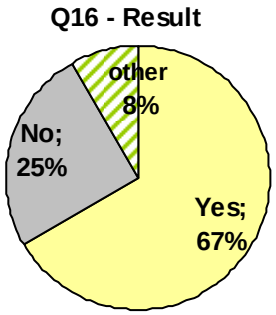
Level	Description	Number of quotations
1.) Technical level		**Sum: 21**
	a.) General comment made	1
	b.) Safe vaccine and diagnostics Vaccines have a high protective efficacy and matching diagnostics are highly sensitive and specific. Movement of vaccinated animals can be allowed given that vaccine and diagnostics properly applied and according surveillance scheme is in place.	9
	c.) Distinguishability Applied vaccines and / or diagnostics allow distinguishing between infected and non-infected animals despite vaccination.	8
	d.) Identification and traceability Identification and registration of vaccinated animals, products are traceable.	3
2.) Legislative level		**Sum: 7**
	a.) Acceptance and authorisation Vaccinated animals are accepted as safe in the legislation, vaccines have received authorisation accordingly.	4
	b.) Discrimination Vaccinated animals have comparable conditions in relation to trade as non-vaccinated animals originating from the regions which share the same disease status.	3
3.) Customer level		**Sum: 21**
	a.) General comment made	5
	b.) Consumer	3
	c.) Industry / retail	2
	d.) EU – wide market Trade of vaccinated animals and their products between Member States	1
	e.) Trade with third countries Trade of vaccinated animals and their products with third countries	8
	Specific case: **i.) Loss of "disease-free" status for EU/MS** EU/MS may lose its/their “disease-free” status if vaccinated animals/products were traded within the EU, thus resulting in disadvantages in the trade with third countries as third countries may consider the EU as one economic and epidemiological entity.	2

ADDITION: TRADE-RELATED ISSUES MENTIONED BY DISEASE

- FMD: Vaccination and DIVA testing on farm level;
  Carrier status.
- AI: Trade issues in relation to meat;
  Lack of acceptance of regionalisation by third countries.
- CSF: Absence of DIVA vaccine; traceability and transparency still open questions;
  Trade of meat products from free compartments from countries not free;
  Time period till permission of trade of live pigs is regained when vaccination is applied.
- ASF: Trade of meat products from free compartments from countries not free;
- BT: No individual records about vaccinated animals if traded between Member States;
  Vertical transmission;
  Trade of live animals in absence of effective surveillance.
- AHS: Vertical transmission;
  No DIVA capability.

16. MOVEMENT BETWEEN MEMBER STATES

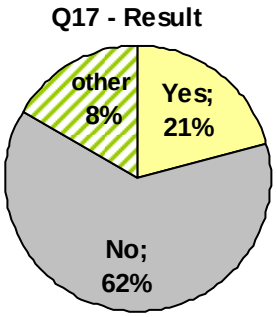
Would you in general accept vaccinated animals or products obtained from vaccinated animals originating from other Member States into your national market where this is not expressively forbidden by OIE rules?



- Out of the 18 responses (see Q14) that in general would accept the nation-wide trade of animals plus products which were vaccinated in their own country 16 (67%) also consider the possibility to accept animals or products thereof that were vaccinated in another Member State. It has to be highlighted that only 2 responses express their preference to act differently depending on the outbreak location.
- It was pointed out that it has to be distinguished between preventive vaccination and emergency vaccination – for emergency vaccination a clearly stipulated system of movement and processing has to be defined case by case, disease by disease.
- Furthermore Member States with a similar disease status should fulfil similar conditions to be able to move animals and their products between Member States.
- In addition to the conditions listed under Q14 it would be welcomed if a certain time period would be determined after which trade can be allowed to obtain guarantees that there is no virus circulation at the place of origin. Also the vaccination of live animals should be made traceable (as by recording in TRACES and in a central register), see present BT legislation as an example.
- The position that trade of live animals should be limited to regions following the same vaccination policy is among those responses which do not favour trade of vaccinated animals between Member States.

17. Necessity Of Mitigating Measures

Do you believe that mitigating measures applied to the product (e.g. deboning and maturation and/or removal of the head from the food chain) are needed to market meat from vaccinated animals?



- 15 (63%) responses state not to believe that additional mitigation measures are needed to be able to market meat from vaccinated animals.
- Again this will depend largely on the disease in question and the animal health status of the affected country. So it was proposed that a differentiation could be made between vaccinated animals from countries which are free of the disease after containing the disease with a good vaccination plan and a surveillance scheme in place and countries where the disease is still present.
- Exception: several countries think that for FMD deboning and maturation is certainly necessary.
- Scientific evidence on the animal health safety of products derived from vaccinated animals still has to be provided in many cases.

18. Further Comments

Do you have any further comments on the issue of vaccine and/or diagnostic banks for major animal diseases?

- The following sections present a summary of concerns (18.1) and open questions (18.2) which were not specifically addressed by an earlier question and/or mentioned as a further comment under this open question.
- Furthermore a collection of factors which are deemed important to take the decision for vaccination is listed up (18.3); this list tries to grasp the essential points mentioned in the participating countries' comments.
- Numerous actions to be undertaken by the Commission, Member States and scientific and industry partners were highlighted in the questionnaires. In 18.4. an attempt was made to assign these tasks to the specific group. It has to be kept in mind that these lists are not indicative and make no claim to be complete.
- All comments made under this point and all numerous comments made under the remaining question shall be summarized in the following four categories:
  - 18.1 Concerns
  - 18.2 Open questions
  - 18.3 Factors important to take decision for vaccination
  - 18.4 Action needed

18.1 CONCERNS

- Vaccinate-to-live could be connected with an excessive additional administrative burden.
- Insufficient data available convincing scientific evidences with vaccinate-to-live strategy.
- Safe trade if appropriate diagnostic tool and surveillance schemes were available: surveillance systems do have limitations. Therefore the risk is always present, but it may be considered as reduced enough to accept this trade.
- A centralised EU decision process may risk paying less attention to local national conditions.
- The financial consequences for a bank of this size (30-40 million doses) are likely to be high and the likelihood of it being used low.

CONCERNS RELATED TO SPECIFIC DISEASE

- FMD: With the numerous strains of this disease even a well stocked bank may not hold the right antigen to vaccinate against the field strain seen in an outbreak.
- AI: vaccinated birds would still be capable of spreading disease. Mutation of influenza viruses could render a vaccine less useful. Furthermore practical issues around delivering vaccine by injection to individual birds have to be considered; another matter of concern was the length of time until immunity would be developed after vaccination.

18.2 OPEN QUESTIONS

- Which subtypes for vaccine and for diagnostic purpose should be stored? Is it necessary to keep all serotypes (e.g. for BT)?
- How quickly can Member States gain access to vaccine? Where would the banks be located? How much time is needed to make up vaccine? How can the issue be solved when more than one Member State demand vaccines or diagnostics? How quickly can the vaccines provide immunity?
- How will the master seed stock be accessible? Which producers are empowered to process antigens to vaccine?
- How will the EU banks work in relation to banks that are held by individual member states?
- How to organize re-stocking of vaccines and diagnostic kits?
- Can master seed be tested in should in accordance with the European Pharmacopoeia already when laid down? Who will be in charge of the availability and quality control of the master seed?
- What costs arise for the Member States as a user of the EU banks? How can a practical financing system look like? Where does the funding come from if EURL supplements vaccine bank with diagnostics that are not available commercially?

18.3 FACTORS IMPORTANT TO TAKE DECISION FOR VACCINATION

- Epidemiological situation
  - One single infected premise (culling) vs. more extensive outbreak (vaccination)
  - High animal density vs. low animal density
  - Phase of the outbreak: acute stage where vaccination could lower risk of spread vs. later stage when outbreak is under control and the focus lies on regaining disease free status to support trade.
  - Endemicity of disease or new outbreak
- Type of vaccine
  - DIVA / marker vaccine
  - Live vs. attenuated vaccine
  - Quality of vaccine / it's ability to prevent both infection and disease
- Matching validated diagnostic tests
  - Sensitivity and specificity to differentiate between infected and non-infected animals
  - User-friendliness: a high number of samples can be analysed in a reasonable time period
  - Availability in big enough quantities at reasonable price
- Effective surveillance scheme in place
- Disease
  - For BT generally accepted.
- Risk – benefit calculation
- Assuring conditions
  - If tradability is granted
  - If disease / pathogen spread can be prevented
  - If safe animal products can be ensured to protect public health

18.4 ACTION NEEDED

18.4.1 ACTION OF MEMBER STATES AND EUROPEAN COMMISSION NEEDED

- If vaccination is applied rules have to be set up for animal products, animal by products, foodstuffs and feeding stuffs.
- The proposal for the vaccine and diagnostic bank has to be clearly defined:
  - which subtypes of virus should be part of the stock;
  - the source of the virus and amendment of the storage subtypes;
  - which diagnostics the national laboratories need to be familiar with;
  - an optimal balance between vaccine, “mock up” authorisations and vaccine alternatives has to be developed and evaluated;
  - how to assure that the bank is arranged in an effective, dynamic (e. g. dimension and updating) and cost saving way, as regards the priority of diseases.
- A cost/benefit analyses for setting up the banks is needed.
- The mechanisms of accessing the vaccines/diagnostics have to be clarified.
- It has to be agreed on how quick decision about the availability of vaccines and diagnostics in case of an emergency can be taken (“chain of command” at EC level)

- Prior to trade clear requirements have to be set up for a specified degree of “freedom from infectious agent”, i.e. introduction of a “disease free” status with vaccination.
- Additional rules for Identification & Registration and movement control of vaccinated animals have to be adopted.
- Risk mitigating measures should be defined for animals and products if a vaccinate-to-live strategy is applied.
- If such rules are defined for vaccinate-to-live, standards for the vaccinate-to-kill policy should also be set up.

18.4.2 ACTION OF MEMBER STATES NEEDED

- The Member States should prepare contingency plans with their vaccination strategy during peacetime and share them with the other Member States and the Commission to make their principles of vaccination and testing during an emergency situation transparent to all Member States.
- The effective operation of the vaccine bank and the allocation of vaccines should be tested in simulation exercises.

18.4.3 INVOLVEMENT OF SCIENCE (AND INDUSTRY)

- Science / industry should be motivated as safe vaccines are required.
- Scientific institutions must be able to provide support service (risk assessments, epidemiological information, tracing, etc.) so that decisions can be taken on a sound basis.
- Specifically, the risk of virus transmission through vaccinated animals and the role of products in the spread of the disease should be assessed.
- Wider social and economic consequences of vaccination should be considered.

IV. DRAFT CONCLUSIONS FROM THE QUESTIONNAIRE

The following 12 conclusions were drawn from the information and opinions gathered from all participating countries:

- Vaccine and diagnostic banks should be set up in a manner that best storing standards of stored equipment can be guaranteed / should be strived for.
- Vaccination should be understood to complement and not replace current disease control strategies.
- Vaccines need to be safe; spread of disease by vaccinated animals will jeopardize reliability of the whole strategy.
- Vaccines and / or matching diagnostics must allow distinguishing between infected and non-infected animals in a reliable manner.
- National and international acceptance should be improved in a way that vaccinated animals and products obtained from vaccinated animals can be traded at comparable / similar conditions as non-vaccinated animals and their products.
- Authorisation of vaccine should be done by EMA procedure; this has to go hand in hand with quick availability in emergency situations.
- Decision to vaccinate should be taken case by case.
- Third countries and stakeholders have to be involved in the discussion at an early stage.
- If emergency vaccination is conceived as *vaccinate-for-live*, a realistic exit strategy should be outlined, taking in consideration international trade and additional resources needed.
- The mechanisms of accessing the vaccines/diagnostics have to be clarified. A procedure should be established to assure guaranteed supply.
- Requirements for vaccination in context with FMD have to be discussed separately from other infectious diseases due to the special role of this disease.
- An evaluation of EU banks has to be undertaken in relation to its cost - effectiveness; a financing plan has to be set up.

ANNEX VIII Additional assessment on Intra-EU trade

Background

The concept of free movement applies in theory to almost all aspects of life in the EU. However, for reasons of protecting both animal and human health, movement within the EU is not considered possible for live animals and their products without fulfilling certain health requirements. Current animal health regulations require specific health obligations to be respected when animals and their products are moved between the MS (which vary dependent on the context, but might include, for example, certification by an official veterinarian at place of origin, notification of the movement or provision of relevant data to the relevant authority and/or non-discriminatory checks at the destination). This is due to disease control provisions which aim to reduce the risk of those movements spreading diseases and the according consequences for the health of other animals and/or humans in other countries or territories. Some of the most common routes of transmission for infectious agents are direct animal-to-animal contact and indirect contact through equipment, persons, transporters, etc. This is most often caused by the movement of infected animals towards with non-infected animals, and being in close physical or indirect contact. Economic forces can lead to animals being moved over large distances, and this increases the possibility of the geographical spread of disease. Besides the health and welfare considerations themselves, disease outbreaks or poor animal (or human) health can have significant negative impacts on international trade and national economies.

This current concept of 'Intra-Community Trade' is therefore used for movement of animals and products and it retains certain international trade rules for movements within the EU (although border checks have long since been abolished). The legislation allows MS to develop their own animal health and movement rules and requirements in their own territories to a large extent, and does not interfere with them unless there is a financial contribution from the EU for surveillance and eradication programmes, there is an EU level eradication programme, or if the animals may be traded across borders within the EU at a later stage. The current system has been widely criticised as being too prescriptive and somewhat outdated, most notably in the CAHP evaluation in 2006. Nevertheless, the current system has proven itself to be very useful, successful and relatively safe, for example, enabling the near-eradication of brucellosis, bovine leucosis, and bovine tuberculosis in some areas of the EU.

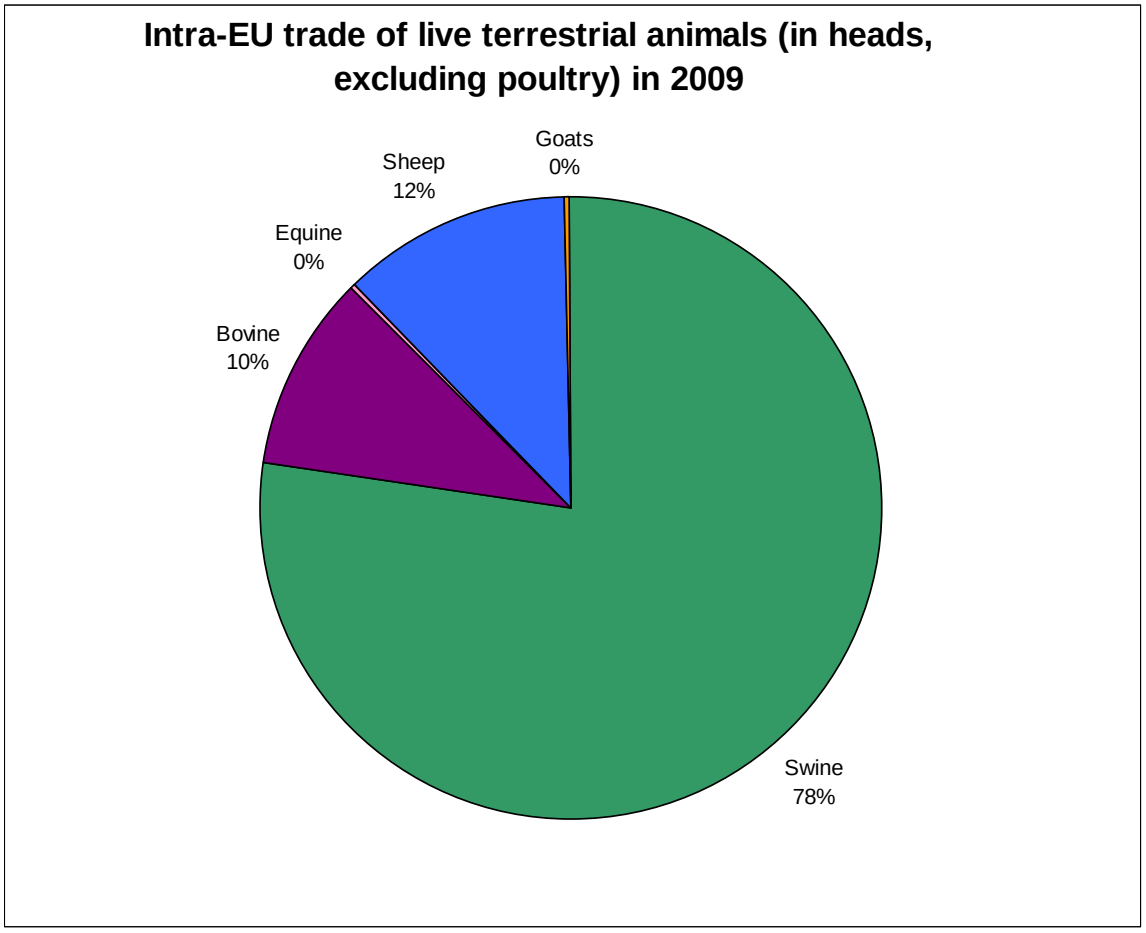
The current system for the movement of terrestrial animals is very different from the 'placing on the market' concept. This concept was introduced in general feed and food law for products of animal origin, and later also for aquatic animals and animal by-products for reasons of animal health. The current system for terrestrial animals of 'Intra-Community Trade' uses MS as the basic geographical unit for deciding on certification requirements. 'Placing on the market' for aquatic animals instead specifies 'zones' with similar health statuses, which may or may not be based around MSs' borders. Animals moving within a zone, independent of whether it is within the same MS, do not need certification (although the movement does need to be notified to TRACES if crossing a national border). There are certain guarantees required when moving from one type of zone to another. This means that the administrative burden required with a particular movement could be more in proportion with the health risk it potentially poses. However, certification is required for movements within a MS if an animal is moving to a different health zone.

Current Intra-EU trade in live terrestrial animals: evidence

Trade in live terrestrial animals has increased in the EU since the creation of the single market (1993). The enlargement of the EU has provided further opportunities for such trade. According to TRACES, trade in live terrestrial animals within the EU increased on average by 9% per year between 2005 and 2009. However, part of this expansion can be explained by the progressive development of the TRACES system since its start in 2004.

In 2009, 36 million farm animals (28 million swine, 4 million cattle, 0.08 million equine, 4 million sheep and 0.1 million goats) and 731 million poultry were transported between EU MSs (see Figure VI.1)

Figure VIII.1



Source: TRACES

According to TRACES, 46% of farm animals and 51% of poultry transported within the EU in 2009 were intended for slaughter. Of consignments of bovine animals destined for slaughter in 2009, 56% went directly to slaughter whilst the remaining 44% passed through at least one Assembly Centre operation. In 2005 75% of bovine consignments destined for slaughter went directly there, but the proportion has decreased since then.

Table VIII.1
Intra-EU trade in animals destined for slaughter (heads of animals) in 2009

Equine	Bovine	Swine	Sheep	Goats	Poultry	Total	Total excl poultry
57,058	652,193	12,669,820	2,941,629	81,403	377,511,981	393,914,084	16,402,103
As a percentage of total intra-EU trade:							
72%	18%	46%	69%	78%	52%	51%	46%

Source: TRACES

For this analysis, we will largely focus on the number of consignments sent and received for intra-EU trade in live terrestrial animals. This is because European policy on intra-EU trade in live terrestrial animals is based on consignments rather than animals.

Trade in live terrestrial animals takes place in order to exploit the price differentials which exist between livestock markets. Both buyers in recipient MS and sellers in producing MS can benefit financially from this trade. The table below shows selected MS that were the main senders and recipients of intra-EU consignments (for all species) during 2009. Interestingly, some of these MS have a large trade deficit (Italy) or surplus (France and Denmark). Yet other MS both sent and received a similarly large number of consignments, leading their net figure to be relatively small (Spain).

Table VIII.2
Total number of consignments of animals sent and received by certain MSs in 2009

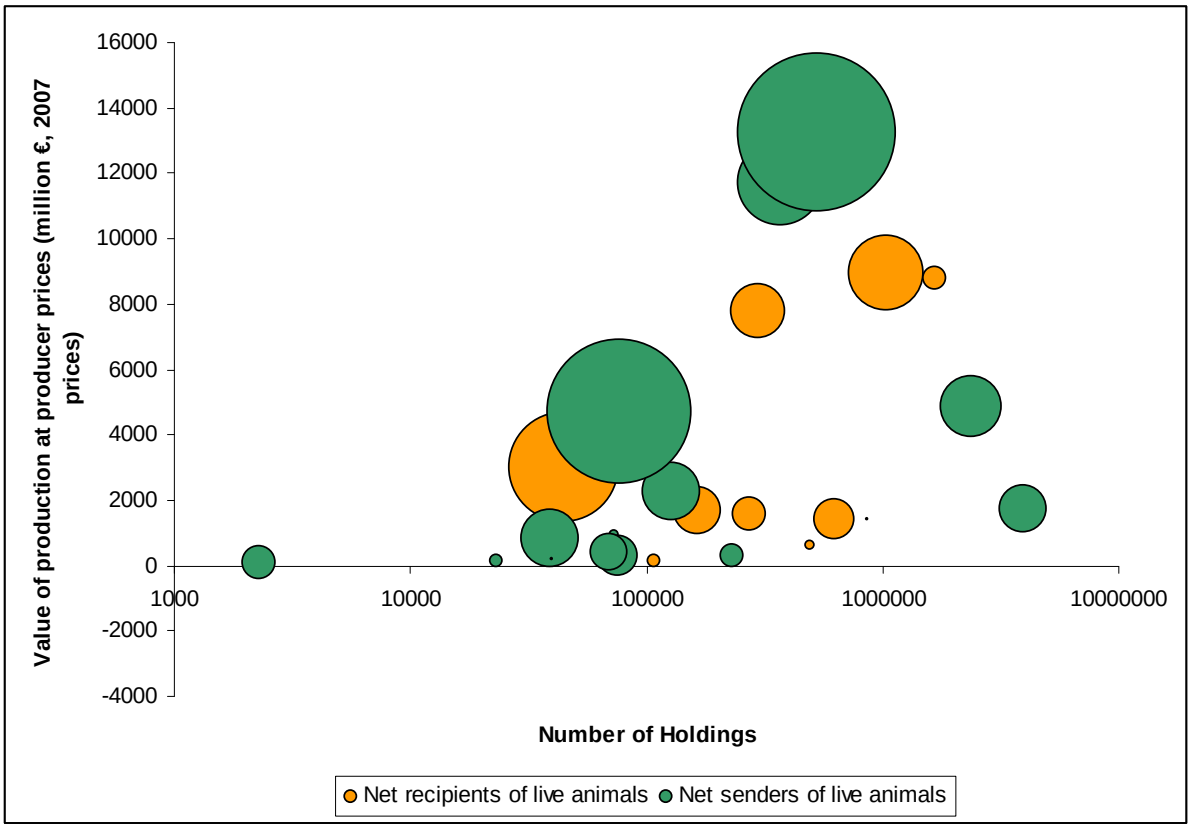
	BE	DE	DK	ES	FR	IT	NL
Consignments sent	16,040	50,074	31,684	18,500	74,047	2,536	74,193
Consignments received	40,515	83,057	240	21,208	9,589	65,693	44,483
Net consignments sent	-24,475	-32,983	31,444	-2,708	64,458	-63,157	29,710

Source: TRACES

Together these 7 MS were involved in approximately ¾ of all consignments sent and ¾ of all consignments received in 2009. The high degree of concentration of movements in these MSs was true for all the different movement purposes of all species.

MS which send a high proportion of consignments do not necessarily represent the nations with the largest livestock sectors. This is shown in the chart below, where the size of the circles represents the number of consignments sent by each MS.

Figure VIII.2: Total number of consignments originating from each MS, displayed depending on the number of holdings and value of production in the MS (2007)



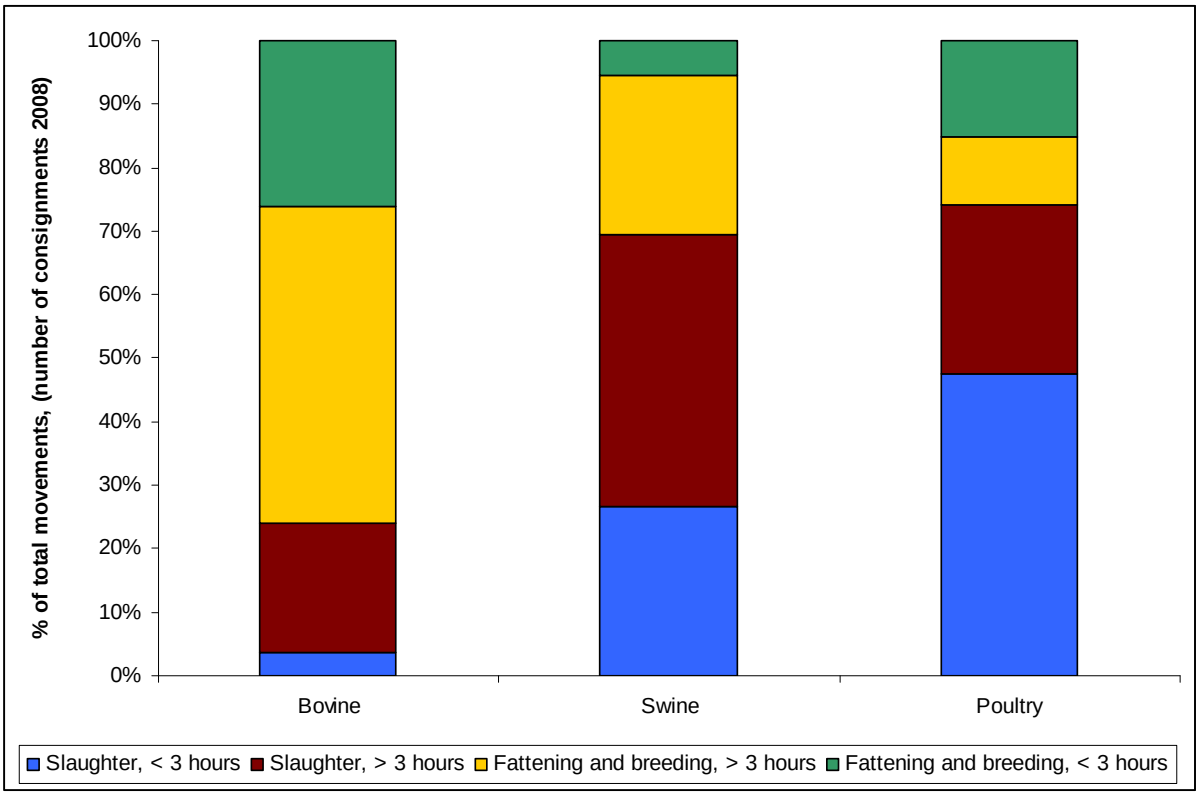
Source: Eurostat and TRACES

As comprehensive national internal movement data is very time consuming to consolidate, the size of livestock sectors has been used as a rough proxy for the total amount of movements, both national and intra-EU. It is reasonable to expect that MS with larger livestock sectors would, on average, have a larger volume of movements of live terrestrial animals than MS with smaller livestock sectors. From the chart above, we can see that there are some MS which have a relatively large livestock sector but a relatively small level of intra-EU movements. We could infer therefore that these MS have a relatively large level of national movements, compared to their intra-EU movements.

Movements over short distances are particularly highlighted when discussing intra-EU trade in live terrestrial animals. In 2008, 116,000 bovine, swine and poultry consignments made journeys of less than 3 hours. This accounts for 38% of all consignments of these species. Of these short movements, 59% of them (68,000) were destined for slaughter.

However, these proportions vary when you look at different species, as illustrated in the chart below. A higher proportion of poultry movements last for less than 3 hours than the proportion for other species – 63% of poultry consignments compared to 30% of bovine and 32% of swine consignments in 2008.

Figure VIII.3: Proportion of bovine, swine and poultry consignments in 2008 separated by type of movement and journey time



Source: TRACES

Examples of notable movements between adjacent MS are those of pigs and poultry between Germany and the Netherlands, cattle between France and Italy, and sheep between Ireland and the United Kingdom (particularly Northern Ireland). As shown in the table below, these movements account for a large proportion of an individual MS's trade in live terrestrial animals, for a particular species.

Table VIII.3 Particular examples of high density cross-border movements

From:	To:	Species	Total no. sent (2009)	% of all EU movements of this species	% of total movements of this species from this MS	% of total movements of this species to this MS
Netherlands	Germany	Pigs				
		No. Consignments	33,660	27%	69%	55%
		No. Animals	7,122,498	26%	62%	50%
Germany	Netherlands	Poultry				
		No. Consignments	21,635	27%	89%	90%
		No. Animals	164,389,846	22%	85%	89%
France	Italy	Bovine				
		No. Consignments	34,591	27%	73%	68%
		No. Animals	970,058	26%	75%	67%
United Kingdom	Ireland	Sheep				
		No. Consignments	1,282	10%	83%	100%
		No. Animals	347,845	8%	84%	100%

Source: TRACES

Questions about intra-EU trade and the 'placing on the market' concepts in relation to germinal products were asked in the questionnaire for operators in various MSs and its results are presented in Annex V above.

Problem definition:

Intra-Community trade approach for animals and animal products is criticised by stakeholders and MSs as being too burdensome and outdated

The current system of Intra-Community trade has often been criticised as being outdated and putting too many burdens on animal keepers and operators.

The different rules for animals and products within a particular MS and between MSs do not fit well with the concept of the EU single market. Though veterinary checks at borders between MS were abolished long ago, and certain certification rules for movements have been eased; to a certain extent the system still supports different market approaches in different MSs. Furthermore, it has been criticised as too burdensome for both the competent authorities and animal keepers to implement systematically and for individual animal movements. For example, there is an obligation for the animal to have a veterinary check and examination before it is moved to comply with animal health and welfare provisions; there is also an obligation to have a health certificate in each particular case of movement; and a requirement to notify the movement to both the national identification and registration databases and to the TRACES system. This procedure is perceived as complicated, expensive and administratively burdensome for both operators and competent authorities. In addition, the system doesn't differentiate in what burdens it imposes according to the level of health risk of a particular type of movement.

In many cases, those measures which can be perceived as burdensome may be justified, especially when animals or their products are moved between holdings or zones with different health statuses. In these cases it is appropriate that health status guarantees are provided to prevent the spread of disease and protect animal and human health. On the other hand, in many cases the level of bureaucracy associated with the movements cannot be said to be proportionate to the risk involved. For example, there are cases of movements of animals between two adjacent holdings in neighbouring MS with the same health status (or even owned by the same person) which pose extremely low risk of disease spread. Movements of animals between MSs of the same health status for direct slaughter is also very low risk because of the low likelihood of contact with live animals at destination. Table VI.1 shows that a high proportion of intra-EU animal movements (with the exception of bovine movements) are for direct slaughter. Many of the high density cross-border movements highlighted in Table VII.3 also fall into these low-risk categories.

Policy Options:

1. Keep Intra-EU Trade regime unchanged

2. Keep Intra-EU Trade regime but introduce some facilitation mechanisms (such as derogations from the requirement for health certification) for low risk movements such as for slaughter or between adjacent zones of two MS of the same health status, with the possible use of bilateral agreements.

3. Introduce Intra-EU movements regime, retaining certain elements of the current certification requirements for movements between MSs but introducing some facilitation mechanisms (such as derogations from the requirement for health certification) for low risk movements. These could include movements for slaughter, for certain low-risk products such as bovine semen, hatching eggs or day-old chicks, or between adjacent zones of two MS of the same health status (such as through the introduction of cross-border zones), without the possibility of bilateral agreements.

4. Introduce 'placing on the market' concept to live animal movements.

Assessment of impacts:

Option 1: Keep Intra-EU trade regime unchanged

The Intra-Community Trade concept has been in past years proven to be relatively effective in ensuring that, as far as possible, only animals with the appropriate level of health are moved. It has therefore provided industry and authorities with sufficient health guarantees for those animals which are moved, and so avoided many preventable diseases outbreaks in the EU.

On the other hand, as we have seen, certain burdens of administration and certification are imposed for some low-risk movements which are difficult to justify on the basis of upholding health standards. As an example, the same health certification requirements would be necessary for animals being moved from one side of the EU to the other, from one MS with a very different health status from the destination MS; as for animals being moved to an adjacent holding, perhaps even owned by the same person, but which happens to be across a national border.

Option 2: Keep Intra-EU Trade regime but introduce some facilitation mechanisms (such as derogations from the requirement for health certification) for low risk movements such as for slaughter or between adjacent zones of two MS of the same health status, with the possible use of bilateral agreements.

This option would retain Intra-EU Trade provisions (as described and assessed in Option 1) but would aim to enable MS to resolve cross-border issues with the use of bilateral arrangements (agreements or other measures).

In addition, exemptions, derogations or simpler procedures could be permitted for movement of animals for direct slaughter. However, even if the health certification requirements were removed, there would still be obligations for veterinary checks at origin because of animal welfare requirements.

This system would lead to bilateral solutions where there is felt by MSs to be a particular need (where there is a lot of low-risk cross-border trade, including much of that shown in Table VI.3). While this might facilitate those particular movements, it would likely entail different approaches from each pair of MSs concerned, with limited transparency of these agreements and the movements concerned to the EU. It could also lead to complicated solutions to specific problems, with possible impacts on the single market.

Option 3: Introduce Intra-EU movements regime, retaining certain elements of the current certification requirements but introducing some facilitation mechanisms (such as derogations from the requirement for health certification) for low risk movements such as for slaughter or between adjacent zones of two MS of the same health status (such as through the introduction of cross-border compartments), without the possibility of bi-lateral agreements.

This option would set some basic principles for all cross-border movements; keeping certification as a baseline requirement, but applying it in a much more risk-based manner. This baseline requirement would ensure that movement controls are retained where it is important to do so, thus retaining the low level of risk of animal disease outbreaks as at present.

More derogations would be introduced for low-risk movements. Examples of low-risk movements which could be released from the certification obligations could include animals moved directly to slaughter and the movement of bovine semen, hatching eggs, and day-old chicks, which all pose very minimal health risks. There might also be the possibility of removing certain cross-border administrative burdens where there is a high frequency of certain low-risk trade patterns by introducing cross-border compartments. Examples will include many of those high-density cross-border movements shown in Table VI.3.

Subsidiarity would largely be retained for national movements, allowing MSs to maintain their own specific requirements where particular issues are concerned. Exceptions would include identification and registration requirements, traceability and registration of holdings. Certification would also be retained for welfare certification, in line with current requirements.

In addition, certain elements of the 'placing on the market' concept could be introduced for operators entering quality assurance schemes. For example, a farm (or other operator such as an assembly centre) which is participating in a quality assurance scheme might be able to obtain a 'licence' which would enable it to guarantee (with a 'stamp') any products it exports, rather than getting individual certification guarantees for every consignment. Their health status and compliance with the relevant scheme would need to be guaranteed through regular inspection.

Option 4: Change to 'placing on the market'

The 'placing on the market' concept was introduced in general feed and food law for products of animal origin and in the animal health area for aquatic animals and animal by-products. This concept doesn't require animal health certification for each consignment, but (for aquaculture animals) their health status is defined by which 'zone' they originate in. For foodstuffs, health marking is used which is based on systematic surveillance and control of the Competent Authority, and not linked to individual cases or consignments. These zones may or may not align with national borders. In practice, to guarantee the status of a particular zone, this means compliance with higher standards for all animals and products in all cases unless there are possibilities for exemptions. So, movements are within or between health zones rather than cross-border; and no particular guarantees or certification are required other than verification of the origin.

This system was developed with the aim of protecting consumers and ensuring the same level of protection and the same quality of products across the EU. This is fairly straightforward to achieve with products, which undergo certain production or treatment processes and remain in a controlled environment. It is less straightforward but still possible with aquaculture animals which are often kept and particularly transported in an isolated environment, and this concept was indeed introduced for aquaculture animals in Directive 2006/88/EC. This Directive regulates specific areas of aquaculture businesses, which are on the whole more uniformly industrialised and business-focused than terrestrial farms. But even in this case, certain certification requirements and TRACES notifications have been preserved for movements between zones with different health statuses.

If this were to be introduced for terrestrial animals, it would enable a much more risk-based approach to be taken to movements. Health zones would be established which would set out which areas were high or low risk for particular diseases. Animals making a low risk movement would then have a lower burden of proof of status. Rather than rigid rules for crossing national borders, administrative requirements would be genuinely based on the risk that a particular movement posed of spreading disease. However, there would be additional certification requirements for certain national movements, when moving between different health zones.

However, this approach is felt by stakeholders (see consultation on artificial insemination and related issues in Annex V) to be inapplicable to terrestrial animals. This is partly because terrestrial animals are in constant contact and interaction with their natural environment, including both wild fauna and flora. So, it is much more challenging to isolate them from their environment and guarantee the health status of a particular geographical area. But it is also because the overall context is much more complex in terms of the large number of species and their interactions, more varied production types, complexity of different diseases and their epidemiology, the current system of disease free statuses, etc. The health zones for each disease for each animal would be different, leading to a complicated multi-layered map of different health zones. The picture would also be constantly changing. In addition, the burden of understanding the requirements when moving animals is on the operator, rather than on the certifying veterinarian, as at present. This has the potential to introduce an unnecessarily large administrative burden on animal keepers and dealers.

The possibility here is that by introducing a system based on genuinely risk-based measures, a much greater degree of complexity would inevitably (and necessarily) be introduced. This complexity would have the potential to totally undermine any benefit that is obtained from attempting to introduce a more proportionate system.

Table VIII.4 Pros and Cons of Each Option Considered

	Option 1	Option 2	Option 3	Option 4
Pros	▪ Safe, consistent and controllable system ▪ Animals and products checked before dispatch to verify health status ▪ Low risk of disease transmission ▪ Guarantees provided in certification serve for further assurance for third countries should the animals subsequently be moved out of the EU ▪ Allows MSs flexibility to determine their own internal requirements concerning movements (should there be specific local circumstances such as lots of backyard or hobby keepers or less developed areas, etc)	▪ Would retain safety and health standards ▪ Would resolve the administrative burden and expense problems of option 1 for low-risk short distance movements and movements for slaughter ▪ Would not put health status of MSs at risk ▪ Might discourage long distance movements which would have a positive impact on animal welfare	▪ Enables MS to maintain specific solutions for particular issues ▪ Facilitates movements by removing certain administrative burdens ▪ Allows new options for sector development ▪ Introduces a more modern approach towards the single market ▪ Retains movement controls where important to do so, ensuring good health management ▪ Provides a better and more proportionate risk-based system	▪ Higher standards applied in all holdings and by all operators ▪ Consistency: the same standards would apply across the EU ▪ Would resolve some of the problems of Intra-Community Trade by providing a more proportionate risk-based system ▪ Potentially less burdensome for movements between MS with the same health status ▪ Potentially encourages movements ▪ Good for big traders who often move animals across borders within the EU – potential reduction of administrative burden
Cons	▪ Often burdensome, sometimes unjustifiably so ▪ Often expensive for MSs and stakeholders ▪ Many notification duplications, such as for both the EU-wide TRACES system and national databases, increasing administrative burden and the likelihood of conflicting information being held ▪ Not really necessary for short and low risk cross border movements and movements to slaughterhouses	▪ Less consistent and controllable system (especially in the case of health problems such as a disease outbreak). ▪ Opaque system in terms of its comprehensibility across the EU ▪ Many potential bilateral agreements, causing inconsistency and confusion. ▪ Possible problems of certification/guarantees not being available to other MSs and countries outside the EU if animals are subsequently moved. ▪ Limitations of uses of the exemption for animal welfare reasons	▪ Could be difficult to obtain an overview if different movement rules for different types of movements Reduction of administrative burden is somewhat limited because of the continued welfare obligations ▪ Certification and therefore administrative burden still retained to a certain extent ▪ Could increase the risk of limited control systems being in place and therefore increase the risk of lowering health status	▪ Less understandable controllable system ▪ Could potentially lead to lower health statuses if certification is lifted for low-risk movements ▪ Veterinary checks for welfare purposes would still be required, so administrative burden is only partly lifted ▪ Less flexibility for MS to decide on their own national requirements ▪ Could be more burdensome for national movements if more certification required ▪ Disadvantageous for small and medium average farms, which don't often move animals outside national territory, because increased administrative burden

Summary

It is clear that the burden of certification is not appropriate in all current cases of movements. Our goal is to find a solution that eases this burden and simplifies the system where appropriate, without introducing an overly complex and confusing system, which would undermine the goal of simplification. While no option is entirely without its disadvantages, option 3 seems to offer us the most appropriate solution. Option 1 offers no change to the status quo. Option 2, although easing some administrative burden, risks introducing a level of complexity for derogations which might lead to confusion at EU level and lack of transparency in an animal health emergency. Option 4 moves to a completely risk-based system but introduces a vast degree of complexity in the assessment and understanding of risk which undermines the gains made from easing certification administrative burdens. However, option 3 would allow the removal or easing of administrative burden in low-risk cases, without introducing the opaqueness of option 2, or the vast complexity that option 4 would entail. Therefore, option 3 is the preferred option.

Consultation:

Consultation on this issue took place in the following forums:

- within the Animal Health Law Steering group (January – July 2009)
- in the framework of wide stakeholders' consultation (September – December 2009)
- administrative burden and administrative costs assessment including special assessment for the sector for production of germinal products (December 2009 – March 2010)
- consultation of the sector for artificial insemination on Intra-EU trade and placing on the market concepts (May-September 2010)
- Animal Health Advisory Committee (2008-2010)
- Chief Veterinary Officers (2008-2010)

ANNEX IX Key elements of the new Animal Health Law, including indicative list of existing legislation affected

1. New key elements of the new AHL

An overview of the new key elements of the new AHL, if options 4 and/or 5, as explained in chapter 4 of the Impact assessment is given below:

- Clarify and codify the obligations of animal keepers/owners/operators.
- Introduce an obligation to obtain knowledge on animal health for animal keepers, operators and staff dealing with animals in order to increase awareness of potential threats related to animal diseases.
- Clarify and enhance farm level biosecurity measures to reduce the risk of on-farm outbreaks.
- Introduce disease categorisation and prioritisation and new principles for the EU intervention, to ensure a coherent approach to disease management.
- Clarify and simplify general disease control rules.
- Establish an efficient legal framework to facilitate timely, adequate and efficient response towards emerging and exotic diseases, in light of the disease categorisation and prioritisation exercise.
- Introduce a new regulatory approach concerning EU-wide surveillance, to enhance surveillance while ensuring that resources are used as efficiently as possible, including the further development of "surveillance networks".
- Clarify and codify the basic principles and objectives for identification and registration of animals.
- Clarify and simply the rules on movements of live terrestrial animals within the EU to better reflect the actual risk of disease spread, taking into account the burden on operators and competent authorities related to the movement of animals. [Different options were considered and assessed in Annex VIII.]
- Clarify and codify the general animal health requirements for import of live animals and products thereof, based on assessment of animal health risks of trade with third countries, while leaving the legal framework for general import controls and procedures to be provided by Regulation (EC) No 882/2004.
- Extend the concept of compartments to other animal species and diseases, beyond existing legislation for poultry and avian influenza and aquaculture, to allow for increased flexibility in disease control and encourage the enhancement of animal health standards.
- Align the EU legislation with the international standards as far as appropriate (OIE) without lowering EU health standards which have already been achieved.

2. The new AHL and its relationship with the current European Animal health legislation

Currently, animal health issues are regulated in 49 different legal acts from the Council and European Parliament. Following a preliminary assessment, the issues covered by these legal acts would be dealt with in the following manner under the AHL:

- For 16 legal acts, the main provisions would be integrated in the AHL, while Annexes and certain specific articles would be integrated in delegated/implementing acts or subject to deregulation.
- For 11 legal acts, only the basic principles and a legal basis to lay down delegated/implementing acts would be included in the AHL, whereas the majority of the provisions would be included in delegated/implementing acts or subject to deregulation.
- For 7 legal acts, all provisions would be included in delegated/implementing acts or subject to deregulation. The AHL would only contain a legal basis to lay down those rules.
- For 3 legal acts, the majority of the provisions would be included in the general control framework regulation of Regulation (EC) No 882/2004 and the rest included in delegated or implementing acts.
- 7 legal acts are obsolete and would be repealed.
- 5 legal acts would remain unchanged due their particular nature, but the main principles of the AHL will apply and they might be integrated with the AHL at a later stage.

To summarise, following this exercise the AH acquis, which today consists of 49 basic legal acts, will be reduced to one single legal act (AHL) and 5 specific basic acts, which may also in the future be integrated into the AHL. In addition, an exercise will be initiated to establish a simplified and streamlined set of delegated and implementing acts replacing relevant parts of the above mentioned basic acts and the large body of current implementing acts.

A list of these 49 legal acts, indicating their relevance for the AHL or its subsequent legislation is reported below.

Table IX.1 Indicative list of existing legislation affected by the Animal Health Law

Much of the legislation mentioned below will simply be replaced by the AHL. However, some material changes to the legal framework are envisaged.

A full list of proposed delegated and implementing acts to be prepared under the AHL has yet to be fully drawn up. Nevertheless, where material changes are envisaged to the current legal framework and their impacts have not specifically been assessed in this impact assessment, further impact assessments would be prepared. For example, impact assessments would be needed if delegated powers are used to significantly change the approach to vaccination for particular diseases; if the requirements for electronic certification significantly changed; or if the certification and identification requirements around animal movements were to be considerably amended.

No	Celex number	Title of the existing legislation	Preliminary assessment: relevance for the AHL (basic act) or its subsequent legislation
1.	31964L0432	Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine	AHL: Articles setting health requirements for movements and trade principles Obsolete: Articles transitional provisions and amendments Delegated or implementing acts: Annexes; detailed health provisions set out in certain articles
2.	31977L0391	Council Directive 77/391/EEC of 17 May 1977 introducing Community measures for the eradication of brucellosis, tuberculosis and leucosis in cattle	Delegated and implementing acts
3.	31978D0642	Council Decision 78/642/EEC of 25 July 1978 on health protection measures in respect of the Republic of Botswana	Obsolete, repeal needed
4.	31978L0052	Council Directive 78/52/EEC of 13 December 1977 establishing the Community criteria for national plans for the accelerated eradication of brucellosis, tuberculosis and enzootic leukosis in cattle	Delegated and implementing acts
5.	31979L0110	Council Directive 79/110/EEC of 24 January 1979 authorizing the Italian Republic to postpone the notification and implementation of its national plans for the accelerated eradication of brucellosis and tuberculosis in cattle	Obsolete, repeal needed
6.	31980L1095	Council Directive 80/1095/EEC of 11 November 1980 laying down conditions designed to render and keep the territory of the Community free from classical swine fever	Delegated and implementing acts

No	Celex number	Title of the existing legislation	Preliminary assessment: relevance for the AHL (basic act) or its subsequent legislation
7.	31981L0006	Council Directive 81/6/EEC of 1 January 1981 authorizing the Hellenic Republic to communicate and to implement its national plans for the accelerated eradication of brucellosis and tuberculosis in cattle	Obsolete, repeal needed
8.	31982L0894	Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community	AHL: All articles Delegated or implementing acts: Annexes
9.	31989D0455	Council Decision 89/455/EEC of 24 July 1989 introducing Community measures to set up pilot projects for the control of rabies with a view to its eradication or prevention	Obsolete, repeal needed
10.	31989L0556	Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species	AHL: Articles setting health requirements for movements and trade principles Delegated or implementing acts: Annexes; detailed health provisions set out in certain articles
11.	31189L0608	Council Directive 89/608/EEC of 21 November 1989 on mutual assistance between the administrative authorities of the Member States and cooperation between that latter and the Commission to ensure the correct application of legislation on veterinary and zootechnical matters	AHL: No. Will be introduced in the new version of Regulation (EC) No. 882/2004 on official controls in feed and food area Zootechnical aspects to be considered in zootechnical legislation
12.	31989L0662	Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market	AHL: Article 9 - Safeguard provisions and parts of Article 3 – rules for movements All other text will be a part of official controls legislation (new Regulation 882/04 and/or delegated act); certain parts in the AHL
13.	31990D0424 32009D0470	Council Decision 90/424/EEC of 26 June 1990 on expenditure in the veterinary field Council Decision of 26 June 1990 on expenditure in the veterinary field	AHL: No A separate legislative proposal for financial rules (initiative following the AHL).
14.	31990D0678	Council Decision 90/678/EEC of 13 December 1990 recognizing certain parts of the territory of the Community as being either officially swine fever free or swine	Obsolete, formal repeal needed

No	Celex number	Title of the existing legislation	Preliminary assessment: relevance for the AHL (basic act) or its subsequent legislation
		fever free	
15.	31990L0423	Council Directive 90/423/EEC of 26 June 1990 amending Directive 85/511/EEC introducing Community measures for the control of foot-and-mouth disease, Directive 64/432/EEC on animal health problems affecting intra- Community trade in bovine animals and swine and Directive 72/462/EEC on health and veterinary inspection problems upon importation of bovine animals and swine and fresh meat or meat products from third countries	Obsolete, formal repeal needed
16.	31990L0425	Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market	AHL: Article 10 - Safeguard provisions and parts of Article 3 – rules for movements All other text will be a part of official controls legislation (new Regulation 882/04 and/or delegated act); certain parts in the AHL
17.	31990L0426	Council Directive 90/426/EEC of 26 June 1990 on animal health conditions governing the movement and import from third countries of equidae	AHL: Articles setting health requirements for movements and trade principles Obsolete: Articles transitional provisions and amendments Delegated or implementing acts: Annexes and detailed health provisions laid down in some articles
18.	31990L0429	Council Directive 90/429/EEC of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species	AHL: Articles setting health requirements for movements and trade principles Delegated or implementing acts: Annexes; detailed health provisions set out in certain articles
19.	32010L0158	Council Directive 2009/158/EC on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs	Delegated or implementing acts: Annexes and detailed health provisions laid down in some articles
20.	31991D0666	Council Decision 91/666/EEC of 11 December 1991 establishing Community reserves of foot-and-mouth disease vaccines	Delegated or implementing acts
21.	31991L0068	Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community	AHL: Articles setting health requirements for movements and

No	Celex number	Title of the existing legislation	Preliminary assessment: relevance for the AHL (basic act) or its subsequent legislation
		trade in ovine and caprine animals	trade principles Obsolete: Articles transitional provisions and amendments Delegated or implementing acts: Annexes and detailed health provisions laid down in some articles
22.	31992D0438	Council Decision 92/438/EEC of 13 July 1992 on computerization of veterinary import procedures (Shift project), amending Directives 90/675/EEC, 91/496/EEC, 91/628/EEC and Decision 90/424/EEC, and repealing Decision 88/192/EEC	AHL: No New legal basis in official controls regulation (new Regulation 882/2004)
23.	31992L0035	Council Directive 92/35/EEC of 29 April 1992 laying down control rules and measures to combat African horse sickness	AHL: only a legal basis and broad outlay of the measures Delegated act and implementing acts: all text of the directive including annexes
24.	31992L0065	Council Directive 92/65/EEC of 13 July 1992 laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC	AHL: Articles setting health requirements for movements and trade principles Obsolete: Articles transitional provisions and amendments Delegated or implementing acts: Annexes and detailed health provisions laid down in some articles
25.	31992L0066	Council Directive 92/66/EEC of 14 July 1992 introducing Community measures for the control of Newcastle disease	AHL: only a legal basis and broad outlay of the disease control measures Delegated act and implementing acts: all text of the directive including annexes
26.	31992L0102 32008L0071	Council Directive 92/102/EEC of 27 November 1992 on the identification and registration of animals Council Directive 2008/71/EEC of 15 July 2008 on the identification and registration of pigs	AHL: legal basis of animal identification, registration and traceability Delegated and implementing acts: Provisions of existing regulation Temporarily remains untouched
27.	31992L0118	Council Directive 92/118/EEC of 17 December 1992 laying down animal	Delegated and implementing acts

No	Celex number	Title of the existing legislation	Preliminary assessment: relevance for the AHL (basic act) or its subsequent legislation
		health and public health requirements governing trade in and imports into the Community of products not subject to the said requirements laid down in specific Community rules referred to in Annex A (I) to Directive 89/662/EEC and, as regards pathogens, to Directive 90/425/EEC	
28.	31992L0119	Council Directive 92/119/EEC of 17 December 1992 introducing general Community measures for the control of certain animal diseases and specific measures relating to swine vesicular disease	AHL: basic principles of disease control set up in Articles Delegated an implementing acts: Annexes and detailed rules laid down in articles
29.	31995D0410	95/410/EC: Council Decision of 22 June 1995 laying down the rules for the microbiological testing by sampling in the establishment of origin of poultry for slaughter intended for Finland and Sweden	Delegated and implementing acts
30.	31996L0093	Council Directive 96/93/EC of 17 December 1996 on the certification of animals and animal products	AHL: No Legal basis in new Regulation (EC) No 882/2004 on official
31.	31997L0012	Council Directive 97/12/EC of 17 March 1997 amending and updating Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine	Same as Directive 64/432/EEC
32.	31998L0099	Council Directive 98/99/EC of 14 December 1998 amending Directive 97/12/EC amending and updating Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine	Same as Directive 64/432/EEC
33.	32000D0258	Council Decision 2000/258/EC of 20 March 2000 designating a specific institute responsible for establishing the criteria necessary for standardising the serological tests to monitor the effectiveness of rabies vaccines	Delegated or Implementing acts
34.	32000L0075	Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue	AHL: only a legal basis and broad outlay of the disease control measures Delegated act and implementing acts: all text of the directive including annexes
35.	32000R1760	Regulation (EC) No 1760/2000 of the	AHL: legal basis of animal

No	Celex number	Title of the existing legislation	Preliminary assessment: relevance for the AHL (basic act) or its subsequent legislation
		European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97	identification, registration and traceability Delegated and implementing acts: Provisions of existing regulation Remains untouched
36.	32001L0089	Council Directive 2001/89/EC of 23 October 2001 on Community measures for the control of classical swine fever (Text with EEA relevance)	AHL: only a legal basis and broad outlay of the disease control measures Delegated act and implementing acts: all text of the directive including annexes
37.	32009R0999	Regulation 999/2001/EC - laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalophaties	Remains untouched
38.	32002L0060	Council Directive 2002/60/EC of 27 June 2002 laying down specific provisions for the control of African swine fever and amending Directive 92/119/EEC as regards Teschen disease and African swine fever (Text with EEA relevance)	AHL: only a legal basis and broad outlay of the disease control measures Delegated act and implementing acts: all text of the directive including annexes
39.	32002L0099	Council Directive 2002/99/EC of 16 December 2002 laying down the animal health rules governing the production, processing, distribution and introduction of products of animal origin for human consumption	AHL: Major part of the text of articles Delegated and implementing acts: Annexes
40.	32003L0085	Council Directive 2003/85/EC of 29 of September 2003 on Community measures for the control of foot-and-mouth disease repealing Directive 85/511/EEC and Decisions 89/531/EEC and 91/665/EEC and amending Directive 92/46/EEC (Text with EEA relevance.)	AHL: only a legal basis and broad outlay of the disease control measures Delegated act and implementing acts: all text of the directive including annexes
41.	32003R0998	Regulation (EC) No 998/2003 of the European Parliament and of the Council of 26 May 2003 on the animal health requirements applicable to the non-commercial movement of pet animals and amending Council Directive 92/65/EEC	AHL: Legal basis for movements, import and disease control rules Delegated and implementing acts: Detailed rules and annexes
42.	32004L0068	Council Directive 2004/68/EC of 26 April 2004 laying down animal health rules for	AHL: Major part of the text of articles

No	Celex number	Title of the existing legislation	Preliminary assessment: relevance for the AHL (basic act) or its subsequent legislation
		the importation into and transit through the Community of certain live ungulate animals, amending Directives 90/426/EEC and 92/65/EEC and repealing Directive 72/462/EEC (Text with EEA relevance.)	Delegated and implementing acts: Annexes
43.	32004R0021	Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC	AHL: legal basis of animal identification, registration and traceability Delegated and implementing acts: Provisions of existing regulation Remains untouched
44.	32005L0094	Council Directive 2005/94/EC of 20 December 2005 on Community measures for the control of avian influenza and repealing Directive 92/40/EEC	AHL: only a legal basis and broad outlay of the disease control measures Delegated act and implementing acts: all text of the directive including annexes
45.	32006L0088	Council Directive 2006/88/EC of 24 October 2006 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals	AHL: articles governing aquaculture production, health rules for movements, import, diseases control rules. Delegated / implementing acts: annexes and some detailed provisions form articles
46.	32008L0073	Council Directive 2008/73/EC of 15 July 2008 simplifying procedures of listing and publishing information in the veterinary and zootechnical fields and amending Directives 64/432/EEC, 77/504/EEC, 88/407/EEC, 88/661/EEC, 89/361/EEC, 89/556/EEC, 90/426/EEC, 90/427/EEC, 90/428/EEC, 90/429/EEC, 90/539/EEC, 91/68/EEC, 91/496/EEC, 92/35/EEC, 92/65/EEC, 92/66/EEC, 92/119/EEC, 94/28/EC, 2000/75/EC, Decision 2000/258/EC and Directives 2001/89/EC, 2002/60/EC and 2005/94/EC	With the adoption of AHL: obsolete for the articles amending animal health directives. Remains in place for the Articles amending zootechnical legislation
47.	32009R1069	Regulation (EC) No of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No. 1774/2002 (Animal by-products regulation)	Remains untouched – a link in the AHL

No	Celex number	Title of the existing legislation	Preliminary assessment: relevance for the AHL (basic act) or its subsequent legislation
48.	32003L0099	Directive of the European Parliament and of the Council 2003/99 on the monitoring of zoonoses and zoonotic agents amending Council Decision 90/424 and repealing Council Directive 92/117	Remains untouched
49.	32003R2160	Regulation of the European Parliament and of the Council (EC) No. 2160/2003 on the control of salmonella and other specified food-borne zoonotic agents	Remains untouched

ANNEX X Preliminary structure of the legislative proposal – options 4 and 5

Part I General rules

- Subject matter scope etc.
- General principles
- General responsibilities
- Categorisation and prioritisation

Part II Surveillance and disease freedom

- Surveillance general obligations (operators + MS)
- Notification (national + Union)
- Surveillance and eradication programmes
- Disease free Member States and zones

Part III Disease prevention, control and eradication

- Disease preparedness (contingency plans, simulation, union vet experts)
- Vaccination
- Emergency measures
- Control measures A diseases
- Control measures B and C diseases

Part IV Requirements concerning establishments, identification and registration of animals and movements

Title 1 Terrestrial animals

- Registration, approval, traceability
- Movement within the Union

Title 2 Aquatic animals

- Registration and approval
- Movement within the Union

Title 3 Other animals

- Part 2 and 3 shall apply to extent relevant for species concerned for a disease of Union concern

Part V Introduction and Export

Part VI Transitional measures and final provisions

ANNEX XI Additional assessment on biosecurity

Background

Following the external evaluation of the Community Animal Health Policy, the vision of the AHS is to improve the prevention of animal health related problems before they happen: the principle of 'prevention is better than cure'. Biosecurity and systematic surveillance are the main elements in putting this principle into practice.

It is difficult to give a single definition of biosecurity, because of the wide use of the concept in many areas (human, animal, plant health) for different needs and objectives and using the differing available tools and resources. Biosecurity can be described as a wide set of preventive and control measures, but can also be the prevention of the risk of spreading one specific pathogen by using only one tool, such as disinfection, for example.

In general, biosecurity is a set of precautions taken to minimise the risk of the introduction and spread of diseases to humans, animals or plants. This can consist of management measures or physical and/or chemical measures and the measures used are often dependent on the nature of disease, its transmission methods and epidemiology, and climatic conditions.
These measures could include:

Management measures to reduce disease risks due to direct and indirect contact with potentially disease-carrier or infected animals, vectors, equipment, means of transport, persons, or other objects such as:

- procedures for entering / exiting the holding for persons, vehicles, animals;
- rules for movement within the different parts of the holding;
- rules and procedures for using equipment;
- quarantine, isolation or separation of new animals;
- conditions for accepting the animals on holdings/farms including standstill;
- isolation of sick animals;
- safe disposal of carcasses;
- in the case of aquatic animals, measures on water supply and discharge;

Physical protection and hygiene barriers such as:

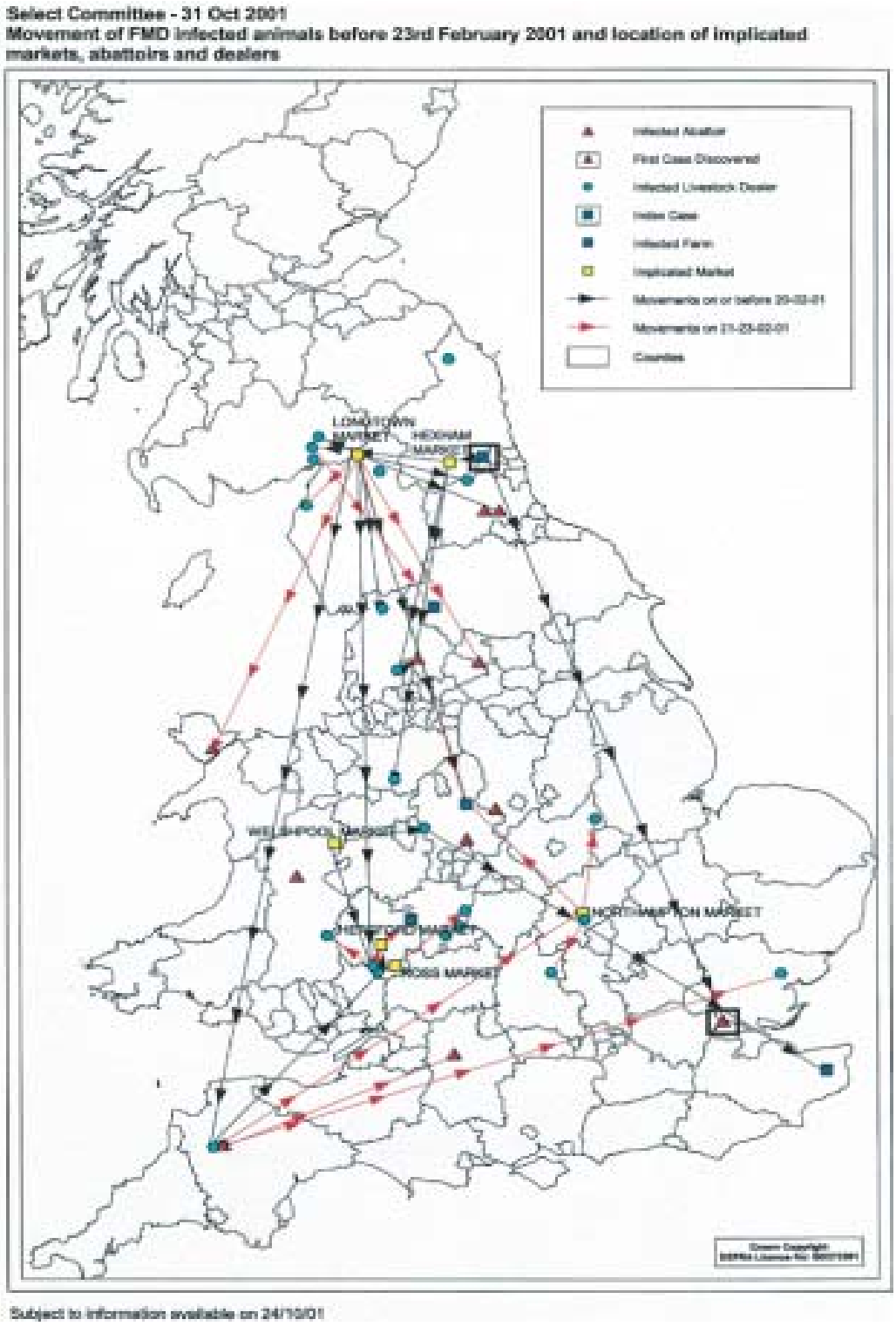
- Keeping indoors, fencing-in, providing cover for animals;
- cleaning and disinfection, de-infestation and pest control;
- in the case of aquatic animals, natural or artificial barriers from surrounding water courses that prevent aquatic animals from entering or leaving the farm, including measures against flooding or infiltration of water from surrounding water courses.

Benefits of biosecurity:

While health protection benefits from biosecurity measures have been known throughout history, it is not easy to measure their exact effect in terms of the reduction of risk of disease outbreaks occurring, or the reduction of the impact of a disease outbreak once it has occurred. Specific case studies in controlled circumstances would be extremely difficult, and very costly to perform. Even if they were feasible, the results obtained could provide evidence only for a particular disease and species under certain specific climatic conditions and so could not be extrapolated very widely.

But we can illustrate the effects of a lack of effective biosecurity behaviours. Widespread movements of animals with relatively poor biosecurity management measures in the very early stages of FMD in the UK in 2001 led to the extensive spread of the disease in a very short time. The relevant movements are presented in a chart below.

Chart XI.1 Spread of foot and mouth disease by livestock moved through markets before 23 February 2001 *Source: UK Department for Environment, Food and Rural Affairs* (DEFRA)



In addition, we can demonstrate that a lack of biosecurity leading to the rapid spread of disease such as that shown above can lead to serious economic losses for the agricultural industries, as well as potentially serious wider consequences. In section 5.1 of the report we show the economic effects of some serious outbreaks. Below is a further demonstration of the effects of the recent AI outbreak on poultry consumption.

Impacts of recent Avian Influenza outbreaks on consumption (source: Eurostat)
A special Eurobarometer survey conducted in March/April 2006 on consumers' responses in the EU- 27 following the world **HPAI (Highly Pathogenic Avian Influenza)** outbreaks revealed that nearly a fifth of citizens had reduced their consumption of poultry meat (18% on average, with large country differences). Although three quarters of this group did so only on a temporary basis, some 13% intended to cut down on consumption permanently. Sales of poultry and eggs were reported in early 2006 to have fallen by 70% in Italy and by 20% in France, following announcements of AI outbreaks in other parts of Europe/the world. The Italian farmers' association estimated that the industry was losing €6m a day, and that it had lost a total of about €650m so far.

Disadvantages of requiring more stringent biosecurity measures:

Additional costs and burdens for the operators are the main reason not to require more stringent biosecurity measures. These costs and burdens would vary across the agricultural sector, since many operators have already established well-developed biosecurity systems, but others have no systematic biosecurity schemes. The schemes in highly industrialised food production and intensive farming, such as intensive poultry or pig production, are very well-developed and require a high level of biosecurity from the operator. As an example see the 'Guide to Good Hygiene Practice for the Prevention and Control of Pathogenic Microorganisms with particular Reference to Salmonella in Gallus gallus (Broilers) reared for meat - on farms'[42], or the examples of biosecurity schemes in the Danish pig industry, as presented at the CVO seminar in Sweden by the Danish Agricultural Council[43]. These industrial sectors would not incur much additional cost or have large adjustments to make. But on the other hand, much extensive animal production and particularly 'backyard' or small family holdings, might find it expensive, time-consuming and problematic to introduce new schemes. The benefits (including both the health benefits and wider economic benefits from reduced disease impact) of introducing such a requirement would need to be balanced with the additional costs. Therefore this issue was specifically addressed in the questionnaire addressed to operators and Competent Authorities. The results are presented below.

Sometimes stringent biosecurity measures may have some negative consequences on animal welfare, for example, if animals are continually kept indoors.

Biosecurity – data on administrative burdens and costs

Biosecurity potential administrative burden – questionnaire results

At present, few biosecurity rules or incentives exist at EU level, and there are a variety of biosecurity guidelines set at other levels, both at national level and by industry. A

[42] http://www.avec-poultry.eu/Default.aspx?ID=4764
[43] http://www.agricultureandfood.dk/

questionnaire by the European Commission to collect information about on-farm biosecurity[44] found that many biosecurity guidelines already exist, but there is little consistency between guidelines in terms of their scope, coverage, degree of obligation, strength of the biosecurity measures and by whom they are organised. For example, the questionnaire found that current guidelines were mainly organised by national and local veterinary authorities and by industry, and that coverage varied for different species and production systems. Nearly half the guidelines were designed to cover specific animal diseases, but many also covered both infectious and non-infectious diseases and good husbandry more generally.

Questionnaire results

During the consultation period, questionnaires were issued to MS CA and Operators in MS to help provide estimates for any additional administrative burden following from the proposals in the AHL. The following section sets out the results of the questionnaire which are relevant to biosecurity. The biosecurity administrative burden calculation in the IA is based on these results.

Competent Authority administrative burden

Forty-two MS Competent Authorities responded to the questionnaire. Twenty-three of these were Central Authorities and the remaining respondents were at regional or local level.

Competent Authorities estimated the average time (in hours) and the personnel needed for developing protocols or guidelines for the drafting of on-farm biosecurity plans. For all respondents, time to develop guidelines ranged from 16 hours to 2,400 hours. The median time for central Competent Authorities was 200 hours.

The proposed biosecurity schemes would require Competent Authorities to assess the biosecurity plans drafted by operators, as a desk exercise, and also perform a field inspection of the implementation of the biosecurity plan. Responding Competent Authorities estimated that on average each plan would take 13 hours to assess. On average, this broke down as around 7 hours of official veterinarian time, and 6 hours of policy staff, approved veterinarians, technicians and others' time. For the field inspection, two thirds of all respondents thought that the Competent Authority should approve biosecurity plans. Estimates for the time to verify plans on the spot ranged from 30 minutes to 40 hours. The average time to verify the plans was 16 hours.

All respondents to the Competent Authority questionnaire thought that training would be necessary. They all thought that official veterinarians would need training, and the majority thought other types of personnel would also need training. All respondents wanted training to be organised at a national level, and nearly half also wanted training at regional or EU level. The questionnaire did not ask Competent Authorities to estimate the duration of training.

Operators' administrative burden

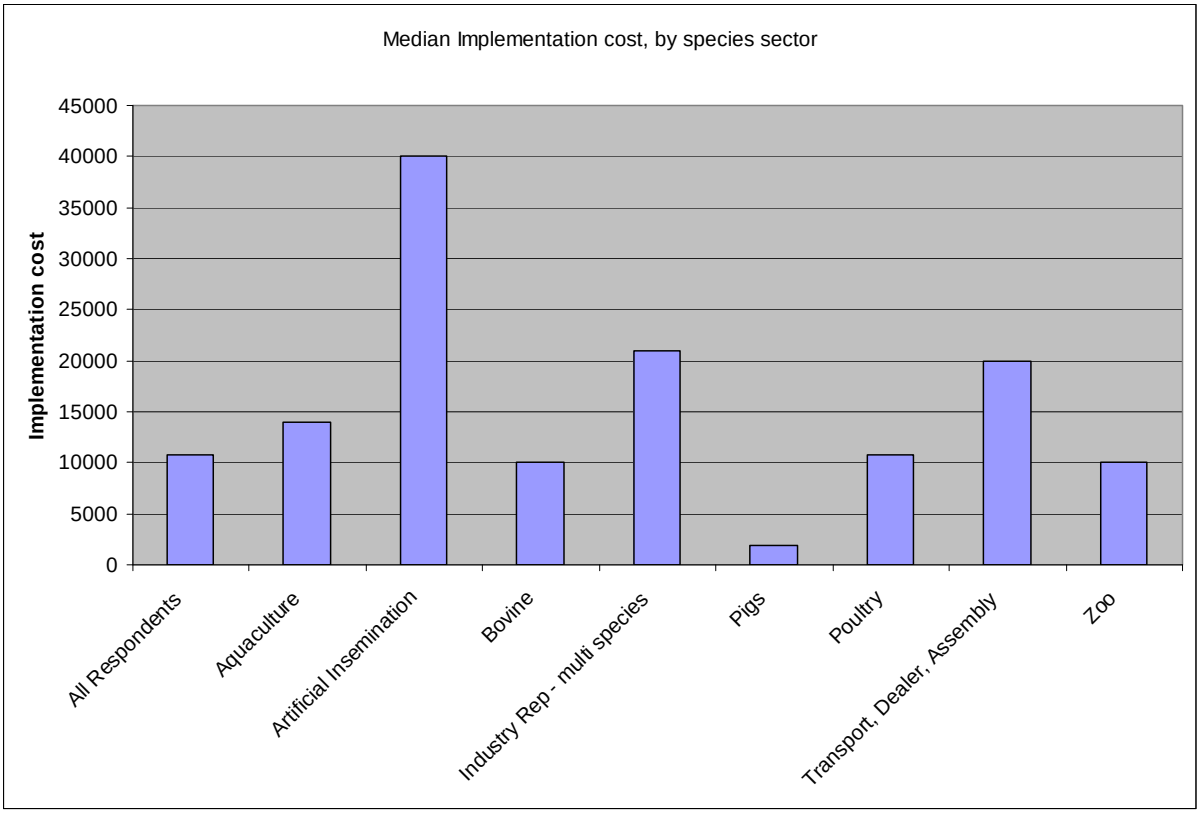
Forty-three unique, and substantially completed, questionnaires were used to estimate the administrative burden of the biosecurity requirements. Nearly one half of respondents were animal breeders or animal producers; the remaining respondents covered a range of stakeholder groups, including industry representatives, transporters, and zoos. Of course, this is a self-selecting group of respondents, so it cannot be claimed that this is representative of the EU as a whole. However, it gives an interesting indication of relevant views.

[44] Questionnaire to collect data on: "On-farm biosecurity guidelines for animal keepers" based on point 11.1 of the Programming document of the Animal Health Strategy. http://ec.europa.eu/food/animal/diseases/strategy/docs/draft_questionaire.pdf

The cost of drafting a plan was, on average €2,000, although a large range of costs were estimated and varied across sectors. There was a positive skew in the responses to this question – most results were clustered around low drafting costs but there were a few estimates for much higher drafting costs.

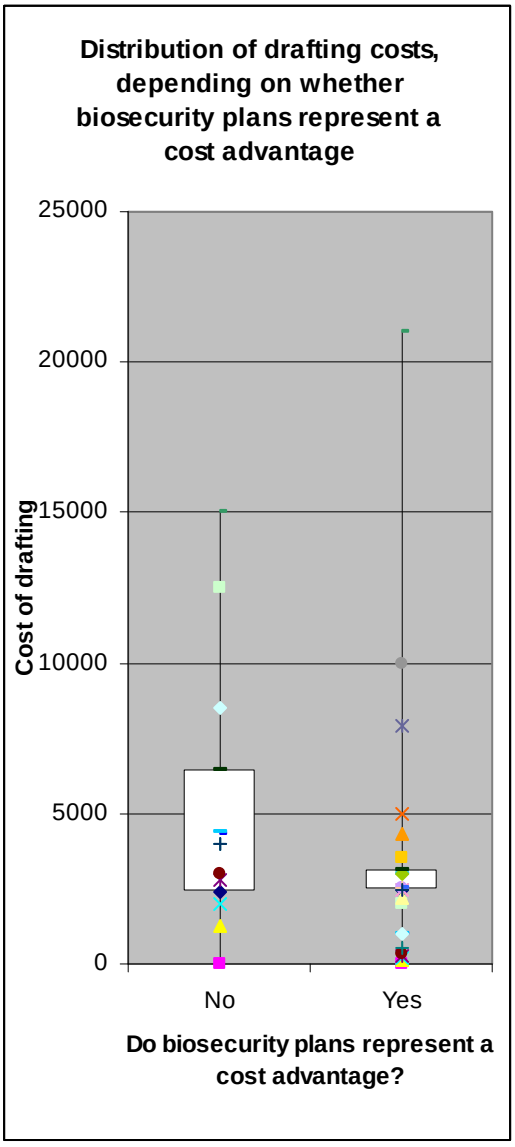
A similar pattern was observed with the estimated implementation costs, although the range of costs was much wider – from 'working time' only to a maximum of €365,000. The median implementation cost for all respondents was €10,750, although this varied between different sectors represented in the questionnaire. Several respondents also highlighted that there were likely to be ongoing costs of maintaining higher biosecurity standards.

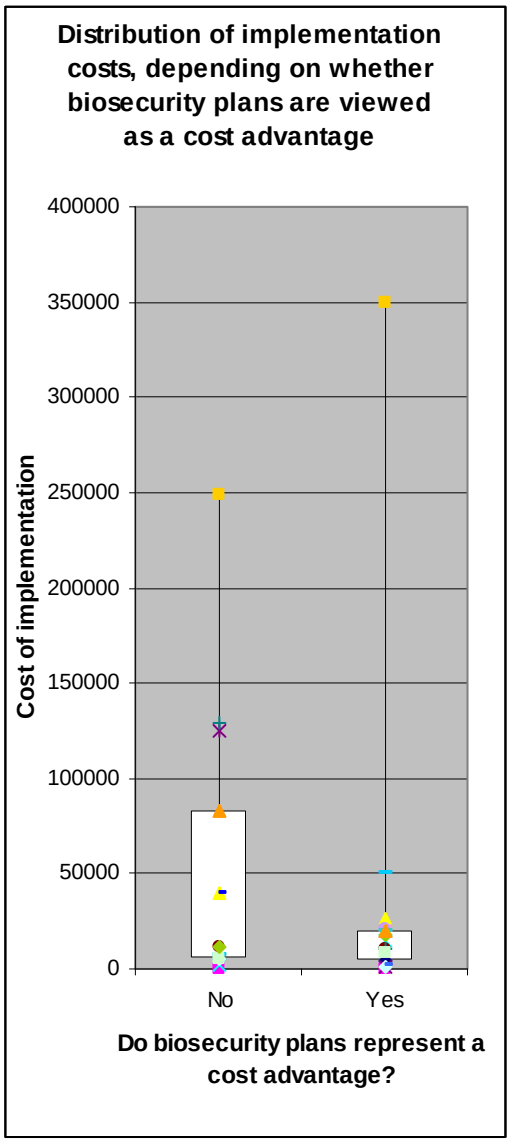
Chart XI.2: Median implementation cost of biosecurity plans by sector



Just over half of all respondents thought that biosecurity plans would represent cost savings. Those that thought biosecurity plans would represent cost savings gave, on average, lower and less varied costs of drafting and implementing plans. The two box plots below show how the drafting and implementation costs varied on whether operators believed biosecurity plans would represent a cost advantage:

Charts XI.3 Distribution of drafting costs and implementation costs





Operators were also asked whether they would require external human resources help or training to help fulfil the proposed biosecurity requirements. There was no overall consensus about whether these would be required in order to draft and implement biosecurity plans. There were different preferences for the type of human resources and training required, but many respondents stated that they would require assistance on several different levels.

Incentives:

Biosecurity benefits the farming industry as a whole, but individual farmers do not always have a personal incentive to optimise their biosecurity measures. We discuss this in some detail in the main text of the impact assessment.

Options Considered:

A. Promote existing best practices for biosecurity at EU level, and encourage stakeholders to further develop these, but with no introduction of additional legal measures.

B. Establish a legal framework for the voluntary introduction of biosecurity measures at farms. Encourage implementation by providing incentives such as trade-facilitation mechanisms and reducing the number of controls. Legislation would set minimum criteria for biosecurity measures, allowing them to be adapted to local circumstances. Guidelines at EU/national level would be drafted to facilitate compliance with this obligation.
C. Lay down the obligation to adopt biosecurity measures for all EU farms. Legislation to establish the minimum criteria for biosecurity measures, providing some flexibility to adapt them to local circumstances. Guidelines at EU/national level would be drafted to facilitate compliance with this obligation.

Assessment of options:

Option A: Promote existing best practices for biosecurity at EU level, and encourage stakeholders to further develop these, but with no introduction of additional legal measures.

This option would not impose any additional burdens or costs to the food production sector EU-wide other than those which they voluntarily incur, but would not meet the objectives of the AHS nor meet the expectations of the industry. Above all, it would not fit with the prevention principle, and would retain existing animal disease risks.

This option is a sub-set of option 3 in the main impact assessment text – using the existing legal framework but promoting best practice guidelines.

Option B: Establish a legal framework for the voluntary introduction of biosecurity measures at farms. Encourage implementation by providing incentives such as trade-facilitation mechanisms and reducing the number of controls. Legislation would set minimum criteria for biosecurity measures, allowing them to be adapted to local circumstances. Guidelines at EU/national level would be drafted to facilitate compliance with this obligation.

This option aims at introducing basic biosecurity rules in order to protect against the risk of spreading diseases and to ensure farmers within the EU take their responsibilities seriously. It could be a flexible option adjusted to local circumstances in MS, and also be adjusted to the differing needs of specific sectors (poultry, pigs, bovines, semen collection centres, etc).

It would also promote a higher level of biosecurity for those who wish to enter quality assurance schemes and benefit from incentives such as easier trade, possible additional financial and health benefits, lower production losses, and international trade advantages. This option would entail certain obligatory costs and burdens, but to a much lesser extent than for option C (see below), and only for those sectors which have few existing biosecurity guidelines or requirements for primary production in animal health and food safety.

The flexibility of this option avoids the universal implementation of potentially large costs that option C entails (see below). The decision about whether a higher level of biosecurity is economically worthwhile is therefore left to the individual farmer or manager, and will encourage the implementation of plans where benefits will be gained.

This option is a sub-variant of option 4 in the main text of the Impact Assessment – a flexible framework.

Option C: Lay the down the obligation to adopt biosecurity measures for all EU farms. Legislation to establish the minimum criteria for biosecurity measures, providing some flexibility to adapt them to local circumstances. Guidelines at EU/national level would be drafted to facilitate compliance with this obligation.

This option would likely reduce the risks of spreading animal diseases (assuming widespread compliance with the legislation) as it would require a relatively high level of biosecurity (every farm or holding drafting their own plan as envisaged in the questionnaire outlined above). Different production systems in different geographical contexts entail very different levels of biosecurity risk, and therefore an appropriate level of biosecurity for a particular farm or holding can vary very significantly. The measures taken need to be adjusted to local circumstances.

Nevertheless, it would impose very significant costs and administrative burdens in some sectors, particularly those who do not currently have widespread biosecurity measures or self-regulated guidelines or plans. It is difficult to extrapolate exactly the administrative burden associated with implementing this option EU wide. However, it is clear from the answers to the questionnaires above that many stakeholders consider that this would be an unnecessary and burdensome option. Leaving aside the need for Competent Authorities to develop guidance, the average time needed by them to assess and verify each plan would on average be 29 hours. If the number of agricultural holdings across the EU is 7,310,000[45], this amounts to 212,000,000 hours.

The cost to operators is more difficult to assess as some operators will already have quite significant measures in place, while others would need to introduce considerable changes. Taking the average cost of drafting and implementing a plan as €12,750, this would represent a total cost of €93.2bn across EU farming. In 2009, the gross value added (GVA) at producer prices of all EU farming amounted to €125 billion[45]. So, the estimated costs of introducing biosecurity plans would represent some 75% of the total annual GVA of agricultural output. It would be extremely hard to demonstrate that the benefits of introducing universal biosecurity plans would generate anything like the total costs involved, so under these assumptions, these measures can be said to be completely disproportionate.

Another thing to consider in setting a very high regulatory bar is the serious risk of non-compliance. The potentially large costs involved in implementing biosecurity plans across the board risks a high level of non-compliance, thus undermining the objective of the legislation and the credibility of the EU.

This option is a sub-set of the strict framework of option 5 in the main text of the impact assessment.

[45] Eurostat Pocketbooks Agricultural Statistics 2008/09
http://epp.eurostat.ec.europa.eu/cache/ITY_OFFPUB/KS-ED-10-001/EN/KS-ED-10-001-EN.PDF

Table XI.1: Options Compared

	Option A	Option B	Option C
Pros	▪ no additional costs or burdens for farmers ▪ does not entail the negative impacts of biosecurity measures on welfare (for example keeping animals continually indoors)	▪ introduction of a basic level of protection against the risks of spreading diseases ▪ farmers taking more responsibility ▪ incentives for those who wish to develop more advanced systems ▪ beneficial impacts on animal welfare, since fewer diseases ▪ system more tailored to specific circumstances; subsidiarity respected ▪ avoids imposing disproportionate burdens on local farming practices and local economies	▪ harmonised biosecurity systems, preventive approach taken EU-wide ▪ higher protection against the risks of spreading disease and therefore lower expected incidence of disease ▪ fewer diseases leading to fewer associated animal welfare problems ▪ farmers taking more responsibility
Cons	▪ current risks of health threats persist ▪ costs because of impacts of diseases, when they occur (direct and indirect costs for farmers) ▪ negative impacts on animal welfare, when more animals are sick; necessity to cull animals in restricted zones due to welfare reasons, etc.	▪ a certain level of additional costs and burdens introduced in many cases ▪ possible negative impacts of biosecurity measures on welfare (for example: keeping animals indoors)	▪ very high additional costs and/or burdens for many farmers EU-wide ▪ no incentives for those who wish to do more than the minimum required ▪ rigid biosecurity measures may negatively impact animal welfare

Summary

Option B is clearly the most viable option. Option C is too administratively burdensome for many sectors, requiring them to make very large and potentially expensive changes which are not necessarily proportionate to the risk they bear. And to do nothing, as in option A, would mean continuing with the present situation, which, while not causing massive problems, could be improved. Option B offers a good solution: requiring a basic level of biosecurity which could be tailored to specific MSs, sectors, production methods, and other circumstances; but is not too unnecessarily administratively burdensome. It would also encourage those who wish to introduce biosecurity measures at a higher level than the legal baseline.

Consultation

Consultation on this issue took place in the following forums:

- within the Animal Health Law Steering group (January – July 2009)
- in the framework of wide stakeholders' consultation (September – December 2009)
- administrative burden and administrative costs assessment including special assessment for the sector for production of germinal products (December 2009 – March 2010)
- Seminar on biosecurity; Chief Veterinary Officers (2009)
- Animal Health Advisory Committee (2008-2010)