EUROPEAN COMMISSION
HEALTH & CONSUMERS DIRECTORATE-GENERAL

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

Brussels, 19/10/2009

ANNOTATED AGENDA

FOR STAKEHOLDERS' CONSULTATION

Questionnaire for stakeholders on possible approaches

to a new EU Animal Health Law

(point 4 of the Programming document[1]
for the Animal Health Strategy 2007-2013)

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

Questionnaire for stakeholders on possible approaches to a new EU Animal Health Law

Aims of this questionnaire

This questionnaire serves to collect input on the main problems identified so far in relation to current EU animal health policy and to check, add to and, if necessary, redirect possible approaches to solving them. The document reflects the preparations made by Unit D1 in the Animal Health and Welfare Directorate[2] of the Directorate-General for Health and Consumers with a view to drafting a new Animal Health Law and impact assessment. This initiative was included in the Action Plan[3] for the EU Animal Health Strategy 2007–2013[4].

Please note that this document has been drafted 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 the views of Commission staff. The European Commission does not guarantee the accuracy of the information provided, nor does it accept responsibility for any use made thereof.

Who should reply

This questionnaire is addressed to anyone with a stake in animal health and welfare, especially stakeholders involved in keeping live animals and in the production of, trade in, import or export of live animals and products of animal origin, or in legal and economic affairs related to these areas including non-professional animal keepers, national organizations, associations, etc**.** Essentially, we are calling on all those with an interest in animal health who wish to play a role in optimising the framework, performance and results of veterinary public administration in the EU, in particular those who are in a position to provide as much factual, quantifiable information as possible to confirm either the proposed approach or any other approach.

The participation of national veterinary authorities, and EU or other international bodies (such as the EFSA, EMEA, ECDC, OIE, FAO, WHO, and CODEX) is also welcome.

How the answers will be used

The answers will be used by the European Commission to assess the impact of the Animal Health Law. An impact assessment aims at providing a transparent and rational basis for political decision-making. It consists of a number of steps: identifying the problem, gathering data, developing options, screening possible impacts of each of these options, gathering further information, refining the impact analysis and possibly refining the options. It is then for political decision makers to choose the best options in the light of their likely predicted impacts.

In this project, we are at the stage where preliminary findings about certain options need to be verified and further data collected. The impact assessment is planned to be finalised in the first half of 2010.

The political decisions leading to a legislative proposal by the European Commission can be expected towards the end of that year, leading to the adoption of a Commission proposal in the last quarter of 2010 or in early 2011.

Please note that it is Commission policy that submissions from organisations will be considered to be individual contributions unless the organisations are listed in the Register for Interest Representatives (see http://ec.europa.eu/transparency/regrin/). As part of the European Transparency Initiative, organisations are invited to use the Register to provide the European Commission and the public at large with information about their objectives, funding and structures.

[2] http://ec.europa.eu/food/animal/index_en.htm.
[3] COM (2008)545 final, 10.09.2008.
[4] COM (2007)539 final, 19.09.2007.

Structure of the questionnaire
The questionnaire contains two main chapters and several sub-chapters on areas identified as problematic, in which existing EU animal health legislation could be reviewed or new rules could be introduced. The chapters contain an explanation of relevant problems, an outline of possible options for addressing them and the preliminary approaches felt to be most in line with the discussion held so far. Since the questionnaire covers a wide range of issues, please feel free to fill in only those parts that are applicable/relevant to you and/or your organisation.

What we are interested in receiving
The purpose of this questionnaire is to check whether the preliminary approaches are seen by the relevant stakeholders as appropriate ways of dealing with the problems identified, and if so how. In addition, we are very interested in receiving further information from and analysis by stakeholders regarding the likely impact if a particular option is implemented. Whether you support the preliminary findings or not, we ask you to provide further factual / quantitative information in an open text box at the end of each section as far as you can. In either case you are welcome to add more/other policy options or amend the ones presented and, if you wish, suggest alternatives which, again, should be accompanied by an appropriate factual justification.

What we are <u>not</u> interested in receiving
It is not useful to submit the same answers many times because what counts are the arguments, facts and figures that are submitted, not the number of times they are submitted.

Confidentiality
If you want to keep your name and organisation or any data confidential, **you** are responsible for ensuring that you do not mention the confidential information in any of the open text fields. The Commission may publish the responses to the open text fields on the Internet without any editing.

Practical instructions for filling in the questionnaire
1. Since the questionnaire aims to collect factual and quantifiable data, the replies need to be drafted in advance before you tackle the interactive questionnaire on the Internet, as you are only allowed 90 minutes to complete it.
2. We therefore recommend you download the Word file of the questionnaire and fill it in using Word. That will allow you to draft your answers to the open text questions carefully and check whether you have kept to the maximum number of characters (1 000 characters, which is about 75 lines for each open text field or roughly 2.5 pages of A4).
   You can download the Word version of the questionnaire from here:
   http://ec.europa.eu/food/animal/diseases/strategy/pillars/docs/questionnaire_en.doc
   or the PDF version from here:
   http://ec.europa.eu/food/animal/diseases/strategy/pillars/docs/questionnaire_en.pdf .
3. For technical reasons, the European Commission can only consider your contribution in good time if it is submitted via the online questionnaire. The online questionnaire is available here:
   http://ec.europa.eu/yourvoice/ipm/forms/dispatch?form=animalhealthlaw
4. After preparing all the answers in Word, please open the online questionnaire and fill it in. It is useful to begin with the closed questions and then copy and paste the answers you have drafted in Word into the open text fields of the electronic questionnaire. You will have 90 minutes to fill in the complete electronic questionnaire and to submit it (after 90 minutes, the system will automatically close and you may lose any answers that have not yet been submitted).
5. Please note that you should not use the 'Back' button in the upper left-hand corner of the screen to navigate the online questionnaire, because this will lead to a loss of all the data that you have already inserted. For navigation, you should use the buttons 'Next' and 'Previous' at the bottom of the questionnaire page instead.
6. If any of the compulsory fields have not been filled in, the system will not allow you to submit the questionnaire but will redirect you to the incomplete answer and give you an opportunity to

correct it. An error message will appear in a purple/red colour under the question in which a problem occurred.

7. When you successfully submit the questionnaire, a confirmation message will appear on your screen and you can print your answers.
8. If you have any further questions, please do not hesitate to contact us: SANCO-animalhealthlaw@ec.europa.eu

Deadline for filling in the questionnaire

The questionnaire can be completed online until **31 December 2009** and will be deactivated after that.

Thank you for your participation and for your valuable contribution to this process!

Questionnaire for internet consultation

1. Introduction and scope

The core of the new Animal Health Strategy for the EU (2007–2013) adopted in 2007, and the accompanying Action Plan, is to provide for the adoption of a single, clearer regulatory framework for animal health.

The new legal framework, referred to as the Animal Health Law, needs to address some key cross-cutting issues highlighted in the strategy:

- assigning responsibility to the different players and providing incentives for prevention,
- identifying priorities for EU intervention and categorising diseases,
- preventing disease, 'biosecurity',
- linking animal health policy to other relevant Community policies, in particular on animal nutrition, animal welfare, zootechnics, food safety and public health,
- converging with international standards (OIE).

Several problems with the current legislation have been identified and may be addressed in the Animal Health Law. The main ones are the need for a more prevention-driven approach to the Community Animal Health Policy (CAHP) and the complexity of the legislation. A tentative set of potential responses to these problems is included in this questionnaire.

Please note that this questionnaire deals only with certain issues. Therefore, it should not be considered a complete list of the items and topics to be addressed in the impact assessment or in the subsequent regulatory proposal. However, stakeholders are invited to send comments on any other issue relating to the new Animal Health Law that they feel appropriate.

Rules for aquaculture animals have recently been modernised via in a new Directive (Council Directive 2006/88/EC) that takes into account many of the principles set out in the Animal Health Strategy. These provisions do not appear to need substantial change. On the other hand, there are some generally applicable animal health principles to be introduced into the new legal framework that will be relevant to aquatic animal health, too, and these should supplement the new Directive.

Zoonoses monitoring (Directive 2003/99/EC) and zoonoses control (Regulation (EC) No 2160/2003), and the hygiene package (Regulations (EC) No 852/2004, 853/2004 and 854/2004) are discussed in other fora and are not covered by this questionnaire. The new Animal Health Law should, however, seek to be consistent with these provisions in order to keep the rules as simple as possible and uphold the 'Humans and Animals: One Health' principle.

2. Focus on prevention involving different stakeholders

The CAHP has worked reasonably well, but there is a need to focus more on disease prevention and to actively involve all stakeholders.

While animal health crises will always recur, the CAHP evaluation highlighted the need to focus policy more on disease prevention and effective risk management. Recent international developments[5] clearly show that the emphasis is shifting away from crisis response to building systems and capacity to prevent and respond to future outbreaks of infectious diseases more effectively.

[5] 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.

The key issue is how to build a more robust animal health system, based on good governance and compliant with international (e.g. OIE) standards, with a shift from short-term to long-term intervention, while facilitating a multi-sectoral approach and partnerships with all relevant stakeholders.

Another challenge is to reduce the impact of animal diseases as far as possible by enhancing disease awareness, preparedness, surveillance and emergency response systems at national and EU level. In particular, to what extent should these activities be governed by EU legislation and be complemented by Member States' legislation or by non-legislative tools?

In this context a number of issues have been identified. Some relate to the general policy approach, others to specific legal acts/diseases. Some are meant to be addressed by stakeholders as part of their responsibility to prevent animal diseases, others relate to the EU and competent authorities' responsibilities.

To ensure that all the relevant stakeholders act appropriately to prevent disease, responsibilities have to be clarified, training should be encouraged and incentives should be provided.

2.1 Roles and responsibilities of different actors

2.1.1 Responsibilities and obligations of animal keepers and owners

- Problem dimension

Most EU animal health legislation takes the form of Directives and Decisions to be transposed by the Member States. In this process, Member States carry out obligations laid down in EU law using national institutions and legal instruments, but this is not always done in a transparent or uniform way. In order to avoid complexity and disparities and ensure harmonised implementation of EU provisions, in recent years EU acts have increasingly taken the form of Regulations.

Current legislation already sets obligations for animal keepers and owners, such as:

- to notify the keeping or possession of animals
- to notify without delay the presence or suspected presence of disease
- to provide regular care and supervision for the animals
- to handle animals with a certain standard of care
- to report the dispatch and/or arrival of consignments
- to keep records and registers and provide for the traceability of animals
- to have a baseline knowledge of animal diseases and how to prevent them.

However, the obligations for animal keepers, owners and operators are not laid down in a consistent and clear way. Certain obligations, for example the obligation on animal keepers to report diseases like foot-and-mouth disease, are laid down in EU legislation, while others are left to the Member States.

There is a need to clarify the obligations of animal keepers, owners and operators and to determine which obligations need to be imposed at EU level and which should be left to Member States to impose.

- Potential solutions

Option 1: The Community Animal Health Law would take the form of a Regulation that clearly sets out the obligations of animal keepers/owners/operators, and would be applied equally in all Member States.

Option 2: The Community Animal Health Law would take the form of a Directive setting out general principles to be transposed into national law by the Member States.

Option 3: The obligations of animal keepers/owners and operators would be left to Member States to regulate.

- 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.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

2.1.2 Training on animal health and welfare for people dealing with animals

- Problem dimension

In order to achieve higher awareness of animal health and welfare problems, animal keepers, and operators need to be properly trained. Some parts of current EU legislation focus on training people dealing with / handling animals in dealers' premises and assembly centres and in transport. However, there is currently no provision in EU legislation for training people to achieve a higher level of awareness of animal disease and the potential health, social and economical impacts. A lack of awareness could lead to animal health and welfare problems.

- Potential solutions /options

Option 1: Training on animal health and welfare for animal keepers, operators and staff dealing with animals would be made obligatory under the animal health law in order to increase awareness of potential threats related to animal diseases.

Option 2: The animal health law would introduce the possibility to train animal keepers, operators and staff dealing with animals, and give incentives and tools (guidelines) to the Member States for such training, with the aim of increasing awareness of potential disease-related threats among staff dealing with animals.

Option 3: The animal health law would not regulate training of animal keepers/owners/operators and staff 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.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

2.1.3 The role of the veterinary services: clarifying the tasks and duties of official veterinarians and private veterinary practitioners

- Problem dimension

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', and 'approved veterinarian'. This lack of legal clarity has paved the way for different interpretations by the Member States.

For example, the majority of Member States veterinary practitioners are authorised to perform a range of official veterinary activities, including sampling (e.g. brucellosis, tuberculosis, Aujeszky's disease, tuberculosis skin test), vaccination (like Bluetongue) and also some clear-cut official controls, such as regular hygiene checks on dairy farms, or health checks of animals prior to intra-Community trade dispatch. It appears that in the future the official services may also need to use the veterinary practitioners for some official tasks arising from preventive driven approaches which are likely to be introduced with the new legislation. The question whether a private veterinary practitioner faces a 'conflict of interest' when certifying animals in his or her care has also been raised during the steering group consultation.

In accordance with the OIE Code, the concept of the 'Veterinary Services' involves many programming and management activities, including international certification, and especially the organisation of a veterinary network for the prevention, control and notification of disease outbreaks, etc. In addition, international trade in animals, animal products and products of animal origin is based on international standards, where the first step in the recognition of import conditions is an evaluation of the level of the veterinary services in a given potential exporting country. Without that, certification is not reliable and export is not possible.

- 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.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

2.1.4 Professional qualifications and training for official and approved veterinarians

- Problem dimension

Official and approved veterinarians need in-depth knowledge and skills to perform official tasks and official controls adequately. This knowledge may be gained through undergraduate veterinary education or postgraduate studies and/or vocational training. This qualification has to be comparable in all the Member States to ensure the same level of health protection and impartiality throughout the EU.

Current legislation, in particular 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 training of official veterinarians but this is limited to those responsible for fresh meat controls in establishments covered by Regulation (EC) No 854/2004.

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 has to be taken into account if as necessary in defining the required qualifications.

The basic arrangements governing the veterinary profession and, in particular, veterinary education do not fall under the scope of the animal health legislation. They are part of other legal frameworks.

- 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

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

2.2 Increased focus on prevention

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

- Problem dimension

Farmers (animal keepers in general) are often the best placed to prevent and detect animal diseases. In addition they should also bear their share of responsibility for preventing and controlling animal diseases. Currently, very few mechanisms exist at EU level which actively involve animal keepers in on-farm preventive measures. Similarly very few regulatory mechanisms exist to rate holdings in regard to their level of biosecurity within EU and these mechanisms 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).
The aquatic animal health directive already contains some general provisions related to biosecurity, good hygiene practice, general animal health surveillance and the requirement that all farms (aquaculture production businesses) shall be authorised.

- Potential solutions /options

Option 1. Promote existing best practices for biosecurity at EU level, and encourage stakeholders to further develop these.

Option 2. Lay the down the obligation to adopt biosecurity measures for all EU farms. The animal health law would establish the minimum criteria for biosecurity measures providing flexibility for adapting them to local circumstances. Guidelines at EU/national level will be drafted to facilitate compliance with this obligation.

Option 3. 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. The animal health law would set minimum criteria for biosecurity measures, allowing them to be adapted to local circumstances. Guidelines at EU/national level will be drafted to facilitate compliance with this obligation.

- 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.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

2.2.2 Animal disease surveillance needs to be improved

- Problem dimension

While some of the surveillance systems in place work reasonably well there is still room for improvement. The current legal framework for animal diseases and zoonoses surveillance, monitoring and eradication in the EU is complex and includes different surveillance/monitoring schemes such as:

- Compulsory / voluntary;
- Surveillance in disease-free areas / monitoring in areas where disease is present;
- EU surveillance co-financed / not co-financed;

- Active in-vivo surveillance / surveillance at slaughterhouses;
- Active surveillance in domestic animals / in wildlife;
- Passive surveillance for domestic/wild animals;
- EU surveillance harmonised / not harmonised.

For aquaculture animals, the Directive obliges all aquaculture production businesses to implement a risk-based animal health surveillance scheme with the aim of detecting increased mortality and incidence of listed diseases. In addition, Member States may decide to conduct active targeted surveillance to achieve or maintain freedom from disease as regards listed, non-exotic diseases.

Directive 64/432/EC on animal health problems affecting intra-Community trade in bovine animals and swine as amended and updated by Directive 97/12/EEC provides for the possibility that a Member State introduces a system of surveillance networks. This surveillance network enables the Member State in question to use some trade facilitation mechanisms. The surveillance network system comprises at least elements such as: the herds, the owner or any other natural or legal person responsible for the holding, the approved veterinarian or the official veterinarian responsible for the holding, the official veterinary service of the Member State, the official veterinary diagnostic laboratories or any other laboratory approved by the competent authority and a computer database. Official veterinarians for the slaughtering establishments and approved assembly centres are to be associated with the network system.

The main objectives of the surveillance network system are to make the official classification of holdings, to maintain such classification by regular inspection, to collect epidemiological data and to carry out disease monitoring so as to ensure compliance Community legislation on animal health.

➢ Potential solutions / options

Option 1: Introduce a new regulatory approach with EU-wide compulsory surveillance for certain diseases

Option 2: Compulsory surveillance limited only to territories officially free of certain diseases

Option 3: Develop the concept of ‘surveillance networks’ already established in Community legislation (Article 14 of Directive 64/432/EEC)

Option 4: Develop a soft-regulatory approach based on ‘guidelines’ similar to those produced by OIE but adapted to different species/diseases.

➢ 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.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

2.2.3 Disease control rules and their relation to intra-Community trade

2.2.3.1 Intra-Community 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-Community 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-Community 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-Community 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 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/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

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.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

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

- Problem dimension

Effective prevention and control of animal diseases requires surveillance and disease control measures to be applied to both commercial holdings and hobby holdings. There are some who say that the application of measures to hobby holdings is not always proportionate to the risks involved and especially that these measures are too restrictive for hobby animal keepers.

Current practices raise also some questions about intra-Community trade, specifically whether different conditions can be applied to commercial (trade) and non-commercial movements. Some species of animals do not represent a high risk for spreading animal diseases or are kept or bred in some particular conditions (labs, zoos, circuses etc.). However, their movements need to be traceable and controllable in case of disease outbreaks.

- 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.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

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

- Problem dimension

Animal health legislation covers all animal species and their germinal products. In principle, Directive 92/65/EEC governs all animal species that are not covered by other Directives. So, for example, it lays down animal health requirements for trade and imports of most animal species that are usually not intended for agricultural purposes such as pets, zoo animals, laboratory animals, wild animals, etc. However, specific rules are laid down only for those species that present a relevant animal health risk. The absence of specific animal health rules for certain species is interpreted in different ways, as certain Member States apply national health rules while others consider that those species do not have to comply with any specific rule.

- 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.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

2.2.3.4 Emerging, re-emerging and exotic diseases

- Problem dimension

General Community 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. In addition, control and eradication rules for certain animal diseases no longer correspond with the latest scientific knowledge, developments and agreed international standards. Also, in certain cases there is a need to align the measures with more recent EU legal acts for the sake of consistency. For example:

- Provisions for Newcastle disease need to be aligned with the new legal framework for Avian Influenza.
- Directive 2000/75/EC laying down the provisions to control and eradicate Bluetongue has proved to be outdated and not flexible enough. Some of its provisions are not suited to the new disease situation, with the introduction of new serotypes and large-scale epidemics.
- Rules for swine vesicular disease are disproportionate to the risk.

The Aquatic Animal Health Directive provides a general framework and a legal basis to deal with an emerging disease situation. ‘Emerging disease’ is defined in Annex I to the Directive as ‘a newly identified serious disease, the cause of which may or may not yet be established, has the potential to be spread within and between populations, such as by way of trade in aquaculture animals and/or

aquaculture animal products. It also means a listed disease identified in a new host species not yet included in Part II of Annex IV as a susceptible species.'

- 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.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

3. Simplification

3.1 Review and simplification of current rules on identification and registration of animals

- Problem dimension

The identification and registration of animals was seen as one of the most burdensome areas for animal keepers in recent consultations carried out within the Stakeholders' steering group of the Animal Health Law. Within this framework it was also stated that identification and registration of animals should be extended to other animal species or categories (for example companion animals).
The main objective of the identification and registration obligations is to prevent risks to human and animal health. These measures they may bring other significant benefits for animal owners, such as traceability for management purposes. However, current rules have sometimes put more emphasis on technical details than on principles and objectives. This has made it difficult for some stakeholders to accept them. This problem could be overcome by more consistent but simpler legislation.

- Potential solutions / options

Option 1: The Animal Health Law would not include Identification and Registration (I&R) provisions at all. I&R questions and policy would be discussed solely in the framework of specific steering groups and left out of Animal Health Law discussions.

Option 2: The whole I&R legislative package would be consolidated into one text, with the Animal Health Law laying down basic principles and objectives only.

Option 3: I&R legislation would remain unchanged; Animal Health Law provides for basic principles and objectives only.
.

- 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.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

3.2 Specific animal health conditions relating to imports

- Problem dimension

Animal health import requirements, for live animals, animal products and products of animal origin, are based on the need to prevent the introduction into the EU of animal diseases. These specific requirements are sometimes difficult to apprehend and implement both for competent authorities (in Member States and in countries outside the EU) and for business operators, due to the complexity of existing legislation.

Recent directives such as Directives 2002/99/EC and 2004/68/EC, governing animal health requirements for the introduction of animals, animal products and products of animal origin into the EU, have provided much more flexible import rules compared to previous legal acts.

To a certain extent the inclusion of sanitary and phytosanitary provisions in most EU bilateral agreements (Free Trade Agreements, Association Agreements or dedicated Veterinary Agreements) with non-EU countries has also facilitated imports and exports. Regulation (EC) No 882/2004 provides for common mechanisms and a comprehensive framework for creating the conditions under which goods are allowed to be imported into the EU. However, import conditions based on animal health concerns are at the moment often scattered in different legal acts and within the texts of import certificates. This makes the rules difficult to understand, apply and control.

- Proposed approach for comments

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.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

3.3 Convergence of EU legislation with international standards

- Problem dimension

EU trade and import legislation generally upholds OIE standards, but there are some important differences and some more minor ones. EU legislation is generally more stringent but in some cases it is more flexible. For example, the OIE uses only an evaluation on paper as its 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. In addition, the EU has its own level of protection for certain imports, based on scientific risk assessment, which is often higher than what can be achieved solely by applying OIE standards or guidelines. An example of this 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. On the other hand, the EU can act faster than the OIE and indeed can be more flexible in certain instances, such as recognising different regions of a country or reinstating disease-free status following a satisfactory outcome of an inspection by the Food and Veterinary Office.

There are some other differences, such as the definition of certain disease incubation periods or other time intervals or the approaches to evaluating competent authorities for animal health.
All this might lead to trade disputes.

- Proposed approach for comments

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.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

3.4 The definition of 'epidemiological unit' and 'holding' in EU legislation

- Problem dimension

The definitions of ‘holding’, ‘herd’ and ‘epidemiological unit’ laid down in EU legislation are inconsistent and do not address significant epidemiological factors. A clear definition of an epidemiological unit in terms of a common or shared exposure to disease risks, from inside and outside the herd, is needed in order to take bio-security measures, register animals and their movements, conduct surveillance, define the animal health status of the relevant population and, as a consequence, grant incentives for prevention.

Annex I to Directive 2006/88/EC on aquatic animal health contains a definition of epidemiological unit which corresponds to the definition given in the OIE Aquatic Animal Health Code.

- Possible solutions / options

Option 1: Adopt a definition of ‘epidemiological unit’ based on the OIE Code.

Option 2: Adopt an EU definition of ‘epidemiological unit’.

Option 3: Refine existing concepts of herd and holding and establish cross-links between them.

- Proposed approach for comments

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’.
.

Do you support this preliminary approach?
Agree/Strongly agree/Neutral/Disagree/Strongly disagree/ Not relevant / No opinion

Further remarks on the approach and (if appropriate) alternative proposal:
Your estimation of likely impacts (economical, social, etc.):

4. Are there any other issues that you would like to raise?

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?

If the answer is yes,

- *Could you briefly describe the problem?*

- *In your view, which are the possible solutions to this problem?*

- *In your view, which approach would be the most appropriate to solve the problem that you raised?*