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on the
"Annotated agenda
for stakeholders' consultation"

Summary of the consultation questionnaire on the new EU Animal Health Law

Brussels, March 2010

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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)
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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*

- Reduction 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 if 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'.

➤ 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 biosecurity 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 to 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 all 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. Convergence 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. The 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%)

➤ 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 lower 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).
- Amphibians 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, 2000/75/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