



Brussels, 16th October 2009

O/REF: note **N-100-2009-EN**

RE: Animal Health Law

1. **Background and introduction of the initiative**
2. **Minutes of the Steering Groups on Animal Health Law**
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Background and introduction of the initiative



Here below you can find an overview of the Commission's initiative and a short summary of the process and the Steering Group meetings in order to better understand the document referred to below and the future questionnaire.

The New Animal Health Strategy for the EU (2007–2013) adopted in 2007 and its Action Plan of 2008 provide for the adoption of a single and clearer Animal Health regulatory framework: an EU Animal Health Law (AHL).

The new legal framework will pursue the new objectives of the Animal Health Strategy, and particularly the prevention-driven and incentive-oriented approach, covering a wide scope of existing Animal Health legislation and re-defining interfaces with other areas of legislation.

The legislative proposal on AHL will be accompanied by an Impact Assessment report prepared by the Commission Services. The report will be based upon the studies to be carried out during 2009 in order to gather all the necessary and relevant data for a proper and comprehensive assessment.

Objectives and Strategy of the Animal Health Law (AHL):

The aim of the AHL is to set up the legal framework for the effective enforcement of the principles and objectives of the strategy and, at the same time, to bring Animal Health legislation in line with the principles of "*Better Regulation*".

The new legal framework needs also to address some fundamental issues having a major cross-cutting relevance, to which emphasis has been given in the new strategy, such as:

- Responsibility of the different players in the light of the principles of proportionality and subsidiarity and the need to reinforce the system of incentives to ensure effective implementation and compliance;



- Need to identify the issues which require legislative changes due to the new scientific developments, the new policy objectives of the new Animal Health Strategy, the need to improve the effectiveness, flexibility and user-friendliness of the legislation;
- Disease prioritization;
- Disease prevention and biosecurity;
- Links of the Animal Health policy and its coherence with other relevant Community policies, and in particular the animal nutrition, animal welfare, zootechnics, food safety and public health policies;
- Convergence with international standards (OIE, Codex).

An Impact Assessment will be prepared on the basis of the following studies:

- Detailed analysis of the baseline i.e. the precise scope and content of all the current pieces of legislation (compared to international standards),
- Evaluation of the active implementation of the basic acts across the Member states and identification of possible challenges for correct transposition and costs associated with failure for a timely and proper implementation,
- Current administrative costs and compliance costs linked to various aspects of legal texts and opportunities for reduction.

The Commission envisages a transparent approach in creating the Animal Health Law and the accompanying Impact Assessment report, and aims at a wide stakeholders' (SH) consultation. A programming document -prepared in the framework of the Action Plan for the implementation of the new Animal Health Strategy- provides for the involvement of the CVOs in the whole process and for the establishment of the Steering Group in the creation of the AHL, followed by a wide consultation process with SH. Input from experts is needed especially with the evaluation of the active implementation and the identification of possible challenges for correct transposition, and with the assessment of the current administrative and compliance costs and opportunities for reduction.

The role of the Steering Group in the creation of the Animal Health Law:

The Steering Group assisted the Commission in technical and legal matters relating to the content of the new Animal Health Law. In particular:

- Exchange of views and discussion on the subject, matter, scope of the legal framework, legal form.
- Technical input in defining the best options for interfaces with related policy areas in order to achieve effective, transparent and enforceable legislation.
- Technical assistance to identify the issues that need to be amended to ensure flexibility and adaptability with regard to new scientific developments, the policy objectives set out in the new Animal Health Strategy, problems with actual implementation.
- Scientific and technical advice on the levels of convergence to the international standards.
- Technical and legal advice on drafting flexible and user-friendly solutions.

- Discussion on draft text proposals and drafting inputs.
- Specific technical inputs for:
 - Evaluation of the active implementation and the identification of possible challenges for correct transposition.
 - Assessment of the current administrative and compliance costs and opportunities for cost-reduction.

More details can be found [here](#)

The choice of the legislative format

Four options are envisaged by the Commission Services i.e.:

1. Keeping the existing bulk of legislation intact,
2. Simplification and adaptation through amendments to the existing acts and possible use of non-regulatory instruments,
3. Animal Health Law as an instrument of basic principles and rules and additional set of measures as a second level of regulation,
4. Comprehensive Animal Health code that covers a significant part of the existing legal framework applicable to imports, notifications, disease eradication and control as well as horizontal rules of the legislation on veterinary checks/controls, animal identification and registration.

However, **the first two options do not appear adequate to meet the objectives of the new Animal Health Strategy**, while the last two options have to be considered and assessed carefully in order to use the optimal approach for the best results.

In summary, future work could be developed in accordance with two models: the first one would be in the form of a **"framework Animal Health law"**, while the second one would correspond to the **"Animal Health code"**. The final choice would depend largely on the detailed analysis of the legislation, the comparisons among various sets of acts, the assessment of different options and the discussions within the services and with other parties.



Relation to Linked Policy Areas

The discussions held so far within DG Sanco were to establish possible interfaces between the future Animal Health Law, on the one hand, and the legislation adopted in the areas of feed, animal welfare, zoonoses and veterinary checks, on the other hand. After these discussions, it can be concluded that the new legislation on AHL would draw close interfaces with the legislation on veterinary checks, feed and animal welfare. Among other things, closer integration is foreseeable with regard to the legislation on veterinary checks, while the areas of animal welfare and feed would retain their autonomous character. A common approach has to be found on the question of zoonoses. Finally interfaces with zootechnics should be drawn as far as necessary.

More details can be found [here](#).

DG Sanco presented a first draft of the **possible structure and chapters of the legal act (Code)**. Please find the draft document [here](#).

Impact assessment report:



The impact of the changes introduced with the new legal framework will be systematically assessed by the Impact Assessment, which will accompany draft proposals and will be completed within the same time framework. Three studies will serve as a basis for the proper and balanced assessment mentioned above.

The Commission Services presented a draft set of issues to be subjected to the future study on cost compliance and administrative burden. An external contractor will conduct the study. The Commission welcomes inputs and suggestions from the members of the Steering Group regarding any additional issues that might need to be considered in this study. The Commission informed the participants that Member States and stakeholders will be involved. The contractor would probably contact them. In addition, a questionnaire will be prepared and sent out in order to gather important data needed to complement the study.

The Commission identifies some issues that might be reflected within the Animal Health Law and need to be assessed within the study and included in the future Impact Assessment:

- Introduction of biosecurity measures on the farm - additional compliance costs for animal keepers.
- Trade facilitation mechanisms and possibilities for reducing controls for the holdings introducing higher biosecurity standards.
- Compartmentalisation.
- Trade/placing on the market.

More details regarding the problem definition, objectives, options and evaluation, can be found in the [working document](#) on "Considered issues to be assessed in the preparatory studies for the Impact Assessment (Animal Health Law)" of the above issues.

Some basic horizontal concepts as they are used during the Impact Assessment process of the new Animal Health Law



1. Basic concepts on the area of simplification of legislation

Simplification is a priority action for the EU. This is the response to the European Parliament's and the Council's requests to simplify EU legislation and enhance its quality.

Its overall objective is to contribute to a European regulatory framework that fulfils the highest standards of law making, respecting the principles of subsidiarity and proportionality.

Following these principles, the EU should only regulate if a proposed action can be better achieved at EU level. Such action should not go beyond what is necessary to achieve the policy objectives pursued. It needs to be cost-efficient and take the lightest form of regulation called for. In this respect simplification intends to make legislation at both Community and national level less

burdensome, easier to apply and thereby more effective in achieving their goals.

Simplification methods:

Simplification covers a broad range of instruments including repeal, codification, recast or modification of the regulatory approach.

2. Basic concepts on the area of regulatory costs

The European Commission is committed to reducing these unnecessary burdens to the maximum extent possible and has proposed a strategy to measure administrative costs and reduce administrative burdens in the EU. Therefore during the legislative work regulatory costs must be analysed in a broad context, encompassing the economic, social and environmental costs & benefits of the regulation.

A large part of EU legislation has been introduced to ensure a level playing field at Community level. That assurance can often only be secured through obligations to provide information and report on the application of legislative norms. However unnecessary and disproportionate administrative costs severely hamper economic activity. They are also an important irritant to business activity and are often identified as a priority in consultations on simplification.

Administrative costs are important since businesses across the EU are required to spend considerable amounts of time filling in forms and reporting on a wide range of issues. By reducing unnecessary reporting requirements, a company's employee can spend more time on core business activities which, in turn, should improve productivity and overall competitiveness.



More details on the above issues can be found [here](#)

Steering Groups on Animal Health Law

Four meetings with SH were held in order to discuss the creation of AHL:

- **First meeting: 18th February 2009** – discussing policy options (Scoping paper), interfaces with related areas, chapters to be included in the Animal Health Law, discussion on the most urgent legislative changes, introduction and preparation of studies.
Please find here the outcomes from the Steering group meeting of [18th February 2009](#).
- **Second meeting: 25th March 2009** – detailed discussions on the draft text itself, evaluation of the convergence to international standards, technical input for the studies.
Please find here the outcomes from the Steering group meeting of [25th March 2009](#).
- **Third meeting: 19th May 2009** – continuation of the discussion on the draft, detailed questions, further work and first conclusions of studies.
Please find here the outcomes from the Steering group meeting of [19th May 2009](#).
- **Fourth meeting: 3rd July 2009** – continuation of the discussion on the draft, detailed questions, further work and discussion on conclusions of studies.

The main discussion was the problem identification during the creation of the AHL. The Commission presented a Working Document ([link to the Working document](#)) on this issue, getting all the problems together. The meeting continued with a short discussion on the working document. The participants agreed on the problems identified by the Commission but not on all the solutions proposed by the Commission. The participants agreed that the problem “identification” was too detailed and there was a need of more simplification and to have general lines and not specific details.

The second part of the meeting was concentrated on the draft questionnaire for the wide stakeholders’ consultation. The Commission representative said that the questionnaire was still in development process and that there would be two questionnaires: one for stakeholders and one for Member States. Both questionnaires will address the evaluation of administrative burden and the procedure.

To conclude the Commission representative indicated that the stakeholders’ consultation would be an internet consultation.

It was decided to meet once again before the end of the consultation period.

Wide Stakeholders’ Consultation



On 29th September 2009, a special Animal Health Advisory Committee met in Brussels in order to open a wide Stakeholders’ (SH) consultation that will continue until 31st December 2009. The wide SH consultation follows 4 Steering group discussions with SH and CVOs, and 2 Animal Health Advisory committees where the Commission Services, CVOs and SH exchanged views on the creation of the Animal Health Law (AHL).

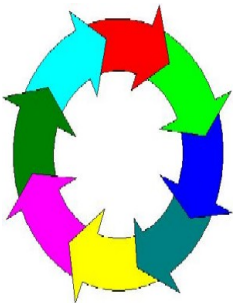
Please find below general information related to the questionnaire that was developed for this purpose.

The Commission representative (DG Sanco) in the chair opened the meeting by saying that the **formal questionnaire** would be finalized and available by the end of October 2009. This questionnaire can be completed online until **31st December 2009** (UECBV will provide you with the questionnaire and practical instructions to fill in the questionnaire).

Aims of this questionnaire:

This questionnaire serves to collect input on the main problems identified in relation to the current EU Animal Health policy and to verify, complete and -if necessary- redirect the possible approaches for their solution. The document reflects the preparatory work carried out by DG Sanco in view of the drafting of a new AHL and its impact assessment (this initiative is ongoing within the framework of the Animal Health Action Plan implementing the EU Animal Health Strategy 2007-2013).

The questionnaire is addressed to:



- Any stakeholder in the field of Animal Health and welfare, especially those related to the keeping of live animals and production, trade, import or export of live animals and products of animal origin, legal and economic affairs related to these areas.
- Essentially all those with an interest in Animal Health who wish to play a role in optimising the framework, the performance and the results of the veterinary public administration in the EU.
- In particular those who are in a position to confirm and -as much as possible- to complement with factual, quantifiable information, the proposed approach or any other approach.

There will be different questionnaires for CVOs, MS, candidate MS and SH.

How will the answers be used?

The answers will be used by the European Commission for the AHL Impact Assessment. An Impact Assessment aims at providing a transparent and rational basis for political decision-making. It consists of several steps: problem identification, data gathering, developing options, screening possible impact of each option, gathering further information, refining the impact analysis and possibly refining the options. It is then up to political decision-makers to choose the best options in the light of their likely predicted impacts. In this project, preliminary findings about certain options need to be verified and further data need to be 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 2010, leading to the adoption of a Commission proposal in the last quarter of 2010 or in early 2011.

Afterwards, one year and a half of debate and then -hopefully- an adoption of the legislation in 2013.

Structure of the questionnaire:

The questionnaire contains 2 main chapters:

- **Focus on prevention and involvement of different actors** and
- **Simplification of the legislation.**

Within these chapters, there are several sub-chapters of the identified problematic areas where existing EU Animal Health legislation could be reviewed or new elements could be laid down. In total: 14 main topics (not completed yet). The chapters contain an explanation of relevant problems, an outline of possible options to address these problems and the associated preliminary approach which is felt to be more in line with the preliminary discussion held so far.

DG Sanco's interest:

The purpose of the questionnaire is to verify whether and how the preliminary approaches are seen by the relevant actors as appropriate to handle the identified problems. In addition DG Sanco is very interested in receiving further information from and analysis by the actors on the likely impact that would occur if a particular option was to be implemented. Whether you support the preliminary findings or not, DG Sanco asks you to provide further factual / quantitative information in an open text box at the end of each section as much as possible.

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. **DG Sanco is looking for solutions and not only problems!**



Proposed approaches for a new EU Animal Health Law



Here below you will find a preliminary draft proposal on different approaches for a new EU Animal Health Law (in green = the approach preferred by DG Sanco).

I: Focus on prevention and involvement of different actors

I.1: Roles and responsibilities of different actors

1.1: Responsibilities and obligations of animal keepers/owners

Problem dimension:

- Current legislation already sets obligations for the animal keepers but not in a clear and consistent way.
- Need to clarify obligations and to determine which ones should be established at EU level and which ones are to be left to Member States.
- Regulation vs. Directive.

Potential solutions:

- AHL Regulation that clearly sets obligations for animal keepers/owners.
- AHL Directive that sets general principles to be transposed by Member States.
- Obligations for animal keepers/owners to be regulated by Member States.

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

Problem dimension:

- Not enough rules on the basic knowledge that people dealing with animals should have. This could lead to animal health and welfare problems.

Potential solutions:

- Training on animal health and welfare would be made obligatory for people dealing with animals.
- Introduce the possibility to give training for people dealing with animals, together with incentives and tools.
- Training for people dealing with animals would not be regulated by the Animal Health law.

1.3. Role of the veterinary services. Tasks and duties of official veterinarians and private veterinary practitioners

Problem dimension:

- Different definitions for "competent authority", "official veterinarian", "approved veterinarian" in current EU legislation.
- Different interpretations by the Member States; official controls-veterinary practitioners. Potential conflicts of interest.
- "Veterinary services" as defined in the OIE Code.

Commission's suggestions:

- Basic tasks and responsibilities of the official and /or approved veterinarians - Regulation (EC) No 882/2004 -, specific provisions in the Animal Health law.
- Specific tasks and duties in the field of Animal Health: a private veterinarian can undertake as an official/designated/approved veterinarian and under conditions. The system should be comparable and should not vary between the Member States.
- The EU legislation should take into account the OIE standards which provide the EU Member States with a normal functioning in the international trade.

1.4. Professional qualifications and training for official and approved private veterinarians

Problem dimension:

- Knowledge and skills in order to carry out their official tasks and controls adequately.
- Regulation (EC) No 882/2004, additional training for the staff performing official control tasks. Regulation (EC) No 854/2004, specific provisions for the professional qualifications and training of official veterinarians but limited to the fresh meat controls in establishments.

Commission's suggestion:

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

I.2: Increased focus on prevention

2.1. Biosecurity measures as a preventive tool on farms

Problem dimension:

- Few mechanisms at EU level which actively involve animal keepers in on-farm preventive measures.
- Few regulatory mechanisms to rate holdings according to the level of biosecurity within the EU and these mechanisms do not recognize or assist those who wish to achieve higher than minimum (additional) standards.

Potential solutions:

- Promote existing best practices for biosecurity at EU level, and encourage stakeholders to further develop these.
- Lay down the obligation to adopt biosecurity measures for all EU farms (minimum criteria providing flexibility, guidelines).
- Establish legal framework for voluntary introduction of biosecurity measures at farms (minimum criteria providing flexibility, guidelines, and basic criteria for rating of holdings). Provision of incentives such as trade facilitation mechanisms, reduced number of controls and, possibly, financial incentives.

2.2. Improvement of animal disease surveillance

Problem dimension:

- Systems working well but still room for improvement.

Potential solutions:

- EU wide compulsory surveillance for certain diseases or compulsory surveillance limited only to officially free territories for certain diseases.
- Development of the concept "surveillance networks" already established in Community legislation (Article 14 of Directive 64/432/EEC).
- Soft regulatory approach based on "guidelines" similar to those produced by OIE but adapted to different species/diseases.

Commission's suggestion:

- Extend the scope and purpose of surveillance networks as set in Directive 64/432/EEC for bovine animals and pigs, to other species. Animal keepers (including hobby keepers) registered and implementation of preventive measures, including surveillance, adapted to their activities. 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.

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

2.3.1. Intra-Community trade vs. placing on the market

Problem dimension:

- Movement of live animals is subjected to certification process, while products of animal origin are "placed on the market".

Potential solutions (i):

- Intra-Community trade replaced by "placed on the market".
 - Basis requirements for holding of origin (good hygiene practices, surveillance, biosecurity), regardless of destination.
 - Set standards for accepting animals at the holding, region, zone at destination taking into consideration the animal health status, the elements of biosecurity and surveillance

Flexibility to avoid unnecessary burden for local movements.

Potential solutions (ii):

- Intra-Community trade maintained but trade facilitation mechanisms in certain circumstances (biosecurity, surveillance).

2.3.2. Differentiation/unification of trade conditions and disease control measures on commercial and non-commercial farming

Problem dimension:

- Diseases do not distinguish between commercial and non-commercial farming, but some of the disease control and trade rules for hobby holdings are considered disproportionate.

Commission's suggestion:

- Same measures would be applied to commercial and non-commercial holdings as well as basic principles on when and how exemptions can be applied. Details rules would be laid down subsequently and made sufficiently flexible and controllable.

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

Problem dimension:

- The absence of specific Animal Health rules for trade and imports of 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 rules.

Commission's suggestion:

- 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 from special animal health rules, while leaving more specific provision for implementing the rules.

2.3.4. Certain emerging, re-emerging and exotic diseases are not properly addressed and the control rules for certain diseases are disproportionate

Problem dimension:

- Limited list of exotic and /or emerging diseases.
- Need to update rules for certain animal diseases:
 - Newcastle disease to be aligned with avian influenza,
 - Directive 2000/75/EC (bluetongue) outdated and not flexible enough. Not adjusted to the new disease situation,
 - Rules for swine vesicular disease are disproportionate to the risk.

Commission's suggestions:

- Exotic and /or emerging diseases reflected in the AHL, linked to the on-going exercise on categorisation of animal diseases and prioritisation of EU intervention.
- Provisions of certain diseases to be revised and aligned with general principles which will be set in the Animal Health Law. In addition some technical adaptations to existing rules under the chapter of simplification will be needed.

II. Simplification

1. Review and simplification of the current rules on identification and registration of animals

Problem dimension:

- Burden for animal keepers. More emphasis on technical details than on principles and objectives, difficult for some stakeholders to accept them. This problem could be overcome by a more consistent although simplified legislation.
- Need to extend rules to other species.

Potential solutions:

- The AHL would not include the Identification and Registration (I&R) provisions. I&R questions and policy will be discussed solely in the framework of specific Steering Groups and left out from the Animal Health Law discussions.
- The whole I&R legislative package could be consolidated into one text, while the Animal Health Law provides for basic principles and objectives only.
- I&R legislation remains unchanged, Animal Health Law provides for basic principles and objectives only.

Commission's proposal:

- The current provisions should be essentially confirmed, without lowering the current traceability standards. However, basic principles and objectives for identification and registration of animals should be clearly laid down in the AHL, while specific provisions for different species or categories of animals would be established by comitology. In the meantime, the current legislation would remain in place.

2. Specific Animal Health conditions related to imports

Problem dimension:

- 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.

Commission's proposal:

- Regulation (EC) No 882/2004 provides the legal framework for general import conditions and controls. The Animal Health Law should make explicit the specific principles that should guide the establishment of import conditions on the basis of Animal Health concerns and the principle that import conditions must be risk-based and therefore flexible to adjust to the level of risk.

3. Convergence with OIE standards

Problem dimension:

- OIE standards generally respected but some differences (important/minor):
 - Disease-free countries [paper evaluation (OIE) vs. inspections (EU)],
 - Level of protection (imports),
 - Flexibility EU (regionalization, etc).

Commission's proposal:

- In order to achieve its desired level of protection in relation to imports and the fulfilment of its international obligations, the EU should enhance cooperation with OIE on the adoption of international standards, while at the same time ensuring alignment of EU legislation with those standards as far as possible.

4. Epidemiological unit and holding not clearly defined in the legislation

Problem dimension:

- The definitions for “holding”, “herd” and “epidemiological unit” laid down in EU legislation are incoherent and do not address significant epidemiological factors. A clear definition is necessary for the establishment of biosecurity measures, the registration of animals and their movements, surveillance, and for the definition of the Animal Health status of the relevant population and, as a consequence, for granting incentives to prevention.

Potential solutions:

- Do nothing – keep current concepts of “holding” and “herd” as applicable.
- To establish a definition of an epidemiological unit based on the OIE Code.
- To establish an EU definition of an epidemiological unit.
- To refine existing concepts of “herd” and “holding” and establish cross-links between them.

The Animal Health Law should ensure a coherent and consistent definition of these units.

The DG Sanco representative concluded the presentation by inviting the participants to raise other issues that would be presented in the questionnaire. He also mentioned that the work on the AHL “skeleton” was still in progress.

