



EUROPEAN COMMISSION  
HEALTH & CONSUMERS DIRECTORATE-GENERAL  
Directorate D – Animal Health and Welfare  
**D1 - Animal Health and Standing Committees**

Ref: SANCO/D1/2009/D

Version: 12/12/2009

## WORKING DOCUMENT

### QUESTIONNAIRE for business operators to collect data on:

"Administrative burden, administrative costs and compliance costs related to the legal obligations set out in the current legislation governing Animal Health and the possible new elements of the Animal Health Law"

**(point 4 of the Programming document<sup>1</sup>  
for the Animal Health Strategy 2007-2013)**

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

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

---

<sup>1</sup> [http://ec.europa.eu/food/animal/diseases/strategy/pillars/action\\_en.htm](http://ec.europa.eu/food/animal/diseases/strategy/pillars/action_en.htm).

### **Aims of this questionnaire:**

The purpose of this questionnaire is to collect readily available data on administrative costs (cost linked to information obligations) and compliance costs incurred by operators when implementing EU animal health legislation.

### **Structure of the questionnaire**

The first part of the questionnaire relates to administrative cost and compliance costs imposed by current EU legislation. In order to avoid duplication of work, administrative obligations imposed by the current animal health legislation that have been assessed in a different framework (identification and registration obligations) are not included in this questionnaire.

The second part of the questionnaire relates to the possible additional administrative burden and compliance costs that the new elements of the animal health law could have for the operators. It was considered that the element that it's likely to create more administrative burden is the implementation of biosecurity plans on animal holdings. The data provided by the operators together with other elements will help the Commission to carry out an estimation of the impacts that the application on the animal holdings of such plans and the possible related impacts.

### **Who should reply**

This questionnaire is addressed to stakeholders involved in keeping live animals and in the production of, trade in, import or export of live animals and animal products/reproductive material (semen, ova, embryos, hatching eggs, etc) or in legal and economic affairs related to these areas including non-professional animal keepers, national organizations, associations, etc.

### **How the answers will be used**

The answers will be used by the European Commission to assess the impact of the Animal Health Law. The results will be presented in aggregated form only or as representative of certain business operators without identifying the data source or disclosing confidential information.

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

### **What we are interested in receiving**

Data provided by the operators on current administrative costs are essential in order to assess the possible impacts (positive/negative) that the animal health law will have on administrative burden and compliance costs. Average numbers and estimations are welcomed as we understand the difficulties on providing exact figures.

In order to simplify the costs estimation, the majority of the questionnaire relates to the number of hours needed to perform an action. This has been done where the main costs relate to personnel costs.

However, also data on costs of material, visits, etc; have been included. To facilitate the calculations we kindly ask you to provide the data on costs in Euros.

We would like to apologise for submitting the questionnaire only in English, as due to time constraints we have decided to proceed only with one language version.

We would like to thank you in advance for your contribution, as it is highly valuable to us and is crucial in the process of assessing the feasibility of different options.

**Practical instructions for filling in the questionnaire**

1. You can download the Word file of the questionnaire and fill it in using Word. You can download the Word version of the questionnaire from here:

[http://ec.europa.eu/food/animal/diseases/strategy/pillars/consultation\\_process\\_en.htm](http://ec.europa.eu/food/animal/diseases/strategy/pillars/consultation_process_en.htm)

2. After preparing all the answers in Word, you should sent it to the functional mailbox [SANCO-animalhealthlaw@ec.europa.eu](mailto:SANCO-animalhealthlaw@ec.europa.eu)

3. If you have any further questions, please do not hesitate to contact us: [SANCO-animalhealthlaw@ec.europa.eu](mailto:SANCO-animalhealthlaw@ec.europa.eu)

**Deadline for filling in the questionnaire**

The questionnaire can be completed online until **15 March 2010** and will be deactivated after that.

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

## TABLE OF CONTENTS

<b>Basic Data on the operator filling the questionnaire .....</b>	<b>5</b>
<b>Part I. Data on current administrative costs .....</b>	<b>7</b>
<b>1.1. Data on approval and registration of assembly centres – (Directives 90/425/EC, 64/432/EEC, 91/68/EC, 90/426/EEC), sites for cleansing and disinfection (Directive 64/432/EEC), dealers premises (Directives 90/425, 64/432, 91/68, 90/426, 92/65), national markets, semen collection and storage centres and embryo production and collection teams (Directives 88/407, 90/429 and 89/556), poultry establishments, hatcheries (Directive 90/539/EEC), authorisation of aquaculture production business and processing establishments (Directive 2006/88/EC) and quarantine facilities or centres for imports of certain birds into the Community (Commission Regulation (EC) No 318/2007). .....</b>	<b>7</b>
<b>Part II. Data on administrative and compliance costs of the new possible elements of the Animal Health Law .....</b>	<b>10</b>
<b>2. Possible new elements of the Animal Health Law .....</b>	<b>10</b>
<b>2.1. Biosecurity plans .....</b>	<b>10</b>
<b>Annex. Relevant legislation. ....</b>	<b>14</b>



Annual turnover (in millions EUR)	<input type="checkbox"/> 0 - 10 <input type="checkbox"/> 25 - 50 <input type="checkbox"/> 100 – 250	<input type="checkbox"/> 10 - 25 <input type="checkbox"/> 50 – 100 <input type="checkbox"/> 250 –
<b>Your organisation's geographical area of activities</b>	<input type="checkbox"/> local <input type="checkbox"/> national <input type="checkbox"/> International	<input type="checkbox"/> regional <input type="checkbox"/> European

**Part I. Data on current administrative costs**

**1.1. Data on approval and registration of assembly centres – (Directives 90/425/EC, 64/432/EEC, 91/68/EC, 90/426/EEC), sites for cleansing and disinfection (Directive 64/432/EEC), dealers premises (Directives 90/425, 64/432, 91/68, 90/426, 92/65), national markets, semen collection and storage centres and embryo production and collection teams (Directives 88/407, 90/429 and 89/556), poultry establishments, hatcheries (Directive 90/539/EEC), authorisation of aquaculture production business and processing establishments (Directive 2006/88/EC) and quarantine facilities or centres for imports of certain birds into the Community (Commission Regulation (EC) No 318/2007).**

*1.1.1. Could you provide an estimate of the average used time for the preparation of the dossier to be submitted for approval of an EU premise by the competent authorities?*

Type of premises	Assembly centres	Sites for cleansing and disinfection	Dealers premises	Semen collection and storage centres, embryo production and collection teams.	Poultry establishments, hatcheries	Aquaculture production business, processing establishments
Preparation of documentation-records	hours	hours	hours	hours	hours	hours

*1.1.2. Is the same time (reference only to the activities specified in the table above) needed for the approval/registration of national markets (if relevant)?*

- Yes
- No

*If the answer is no, what are the differences (specify)?*

- *Preparation of documentation :*
  - more time needed
  - less time needed
- *Upgrading of facilities:*
  - more time needed
  - less time needed

- *Others (specify)*

- more time needed  
 less time needed

**1.1.3. Could you provide an estimate of the average time used per month for keeping registers and required documentation for EU approved premises?**

<b>Type of premises</b>	Assembly centres	Sites for cleansing and disinfection	Dealers premises	Semen collection and storage centres, embryo production and collection teams.	Poultry establishments, hatcheries	Aquaculture production business, processing establishments
<b>Keeping the records</b>	<i>hours</i>	<i>hours</i>	<i>hours</i>	<i>hours</i>	<i>hours</i>	<i>hours</i>

**1.1.4. Could you provide an estimate of the average time per month used for keeping register for non- EU approved premises?**

<b>Type of premises</b>	Assembly centres	Sites for cleansing and disinfection	Dealers premises	Semen collection and storage centres, embryo production and collection teams.	Poultry establishments, hatcheries	Aquaculture production business, processing establishments
<b>Keeping the records</b>	<i>hours</i>	<i>hours</i>	<i>hours</i>	<i>hours</i>	<i>hours</i>	<i>hours</i>

**1.1.5. Checks at origin/ Trade operation/ certification (Directives 90/425, 64/432, 91/68, 90/426, 90/539, 92/65, 2006/88,)**

**1.1.5.1. Could you provide an estimate of the average time used for preparing the accompanying documents for a consignment, the inspection visit linked to it and the certification?**

<b>Type of premises</b>	Assembly centres	Sites for cleansing and disinfection	Dealers premises	Semen collection and storage centres, embryo production and collection teams.	Poultry establishments, hatcheries	Aquaculture production business, processing establishments
<b>Preparing the required documents</b>	<i>hours</i>	<i>hours</i>	<i>hours</i>	<i>hours</i>	<i>hours</i>	<i>hours</i>

**1.1.5.2. Could you provide an estimate of the average costs of the administrative procedures (preparation of documents, visits of the official veterinarian, providing documentation for certification, etc) for dispatching a consignment?**

**1.1.5.3. Could you provide an estimate of the average number of consignments shipped annually by you?**

	<b>In one calendar year</b>
<b>Number of consignments</b>	

## **Part II. Data on administrative and compliance costs of the new possible elements of the Animal Health Law**

### **2. Possible new elements of the Animal Health Law**

#### **2.1. Biosecurity plans**

Biosecurity plan means a plan that identifies potential pathways for the introduction and spread of disease in a holding (farm) and describes the measures which are being or will be applied to mitigate the disease risks.

A biosecurity plan must describe at least the following elements:

- procedures for entering / exiting the holding with the vehicles (veterinarians, artificial insemination, milk collection, feed delivery, carcasses collection, etc)
- measures that address isolation of new animals brought to the farm,
- standstill period before introducing new animals in the farm
- isolation of sick animals,
- regulation of the movement of people, animals, ,
- surveillance system introduced on farm.
- rules and procedures for using the equipment
- division of the holding into the clean and unclean part and procedures to enter clean part (if applicable for the type of holding)
- protective biosecurity procedures at the entrance and exit of the farm or part of the holding (washing, cleaning, disinfection – shoes, hands, equipment),
- change of clothes, footwear (if necessary)
- procedures for closing, fencing, covering animals
- correct use of feed,
- procedures for cleaning and disinfecting facilities

It should also display from the side of the operator awareness of and compliance with existing legal obligations, e.g. on notification of diseases and describe the roles of the responsible persons being animal owner, keeper (if not the same as owner) and responsible veterinary practitioner.

##### ***2.1.1. Type and number of animals in your holding***

Pigs:

- Piglets under 20 kg
- Breeding sows over 50kg
- Pigs over 20 kg

Poultry:

- Broiler

- Laying hens
- Others

Bovine:

- Dairy cows
- Meat production
- Other bovines

Sheep:

- Breeding ewes
- others

Goats:

- Breeding goats
- Others

Equidae

Rabbits

Beehives

Others

**2.1.2. If biosecurity plans are to be introduced by the EU legislation, would you have the human resources needed for the drafting of a biosecurity plan (as described above) for your holding?**

- Yes
- No

***If the answer is no, which external resources you would need for the creation of your plan?***

- private veterinary practitioners
- approved veterinarians
- other third parties

**2.1.3. Could you provide an estimation of the cost (€) of drafting a biosecurity plan for your holding?**

	<b>Drafting biosecurity plan</b>
<b>Costs (€)</b>	

**2.1.4. Could you provide an estimation of the annual cost (€) of implementing a biosecurity plan for your holding?**

	<b>Implementing biosecurity plan</b>
<b>Costs (€)</b>	

**2.1.5. In your view, would the implementation of a biosecurity plan represent lower cost/advantages for you due to better prevention of animal diseases?**

- Yes  
 No

**2.1.6. Would additional training be necessary for you/ your staff in order to be able to draft and implement biosecurity plans?**

- Yes  
 No

**2.1.6.a. If the answer is yes, for which staff would additional training be needed in order to prepare biosecurity plans?**

<i>Type of personnel</i>	<i>Official veterinarian,</i>	<i>Approved veterinarians,</i>	<i>Private practitioners</i>	<i>Technicians</i>	<i>Others</i>
<i>Training needed (Yes/No)</i>					

**2.1.6.b. In your view, at which level/s this additional training should be organized?**

<i>Level</i>	<i>EU</i>	<i>National</i>	<i>Regional</i>	<i>Others</i>
<i>Training needed (Yes/No)</i>				

## **Annex. Relevant legislation.**

- Council Directive 90/425/EEC concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0425:20021119:EN:PDF>

- Council Directive (64/432/EEC) of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1964L0432:20081231:EN:PDF>

- Council Directive 91/68/EEC on animal health conditions governing intra-Community trade in ovine and caprine animals

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1991L0068:20080903:EN:PDF>

- Council Directive 90/426/EEC on animal health conditions governing the movement and import from third countries of equidae

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31990L0426:EN:HTML>

- Council Directive 90/539/EEC on animal health conditions governing intra-Community trade in, and imports from third countries of, poultry and hatching eggs

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1990L0539:20080903:EN:PDF>

- Council Directive 92/65/EEC laying down animal health requirements governing trade in and imports into the Community of animals, semen, ova and embryos not subject to animal health requirements laid down in specific Community rules referred to in Annex A (I) to Directive 90/425/EEC

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1992L0065:20080903:EN:PDF>

- Council Directive 88/407/EEC laying down the animal health requirements applicable to intra-Community trade in and imports of deep-frozen semen of domestic animals of the bovine species

[http://eur-lex.europa.eu/Result.do?T1=V3&T2=1988&T3=407&RechType=RECH\\_naturel&Submit=Search](http://eur-lex.europa.eu/Result.do?T1=V3&T2=1988&T3=407&RechType=RECH_naturel&Submit=Search)

- Council Directive of 26 June 1990 laying down the animal health requirements applicable to intra-Community trade in and imports of semen of domestic animals of the porcine species (90/429/EEC)

[http://eur-lex.europa.eu/Result.do?T1=V3&T2=1990&T3=429&RechType=RECH\\_consolidated&Submit=Search](http://eur-lex.europa.eu/Result.do?T1=V3&T2=1990&T3=429&RechType=RECH_consolidated&Submit=Search)

- Council Directive 89/556/EEC of 25 September 1989 on animal health conditions governing intra-Community trade in and importation from third countries of embryos of domestic animals of the bovine species

[http://eur-lex.europa.eu/Result.do?T1=V3&T2=1989&T3=556&RechType=RECH\\_naturel&Submit=Search](http://eur-lex.europa.eu/Result.do?T1=V3&T2=1989&T3=556&RechType=RECH_naturel&Submit=Search)

- Commission Regulation (EC) No 318/2007 of 23 March 2007 laying down animal health conditions for imports of certain birds into the Community and the quarantine conditions thereof (Text with EEA relevance)

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2007R0318:20090716:EN:PDF>