

ROADMAP

Title of the initiative: **Proposal for a New Single Regulatory Framework for Animal Health (so-called Animal Health Law)**

Type of initiative (CWP/Catalogue/Comitology): CWP

Lead DG/contact person/details: DG SANCO

Expected date of adoption of the initiative (month/year): 3/2011

Date of modification:

Version No: 1

Initial IA screening & planning of further work

A. Context and problem definition

(i) What is the political context of the initiative?

The New Animal Health Strategy for the EU (2007 – 2013) provides for the adoption of a "single regulatory framework for animal health" with a greater focus on incentives than penalties, consistent with other EU policies and converging to international standards"¹.

In their reaction to the Commission Communication on the new Strategy, the European Parliament² the Council³ and the European Economic and Social Committee⁴ welcomed this initiative.

(ii) How does this initiative relate to past and possible future initiatives, and to other EU policies?

This proposal is driven by the political commitments laid down in the Communications referred above. It will provide a single regulatory framework for animal health, which currently involves almost 60 basic directives and regulations some of them being adopted as early as 1964. Its aim is to provide a general legal framework for animal health; setting basic principles of animal health, providing health rules for animal movements and movements of animal products, disease control measures, ensure conditions for early detection, disease notification and surveillance including the provisions for the services in the Member States. As such, some of the current basic texts will be repealed by the new Law while others will be amended and/or gradually replaced over the coming years, by separate legal acts that could supplement the new law in annexes or be adopted as independent quasi legislative acts.

This proposal will be followed by a subsequent proposal to revise the current legal provisions on veterinary expenditure (Council Decision 2009/470/EC) and other proposal(s) on veterinary checks of live animals and products at import.

This present proposal will re-define interfaces of animal health legislation with the current legal framework on animal welfare, animal nutrition, food safety, public health, environmental protection, pharmaceutical products, Common Agricultural Policy legislation and rules established by relevant international organisations (OIE, Codex Alimentarius). A link with the general food law (Regulation (EC) NO. 178/2002) was studied in order to prevent duplications and to ensure a consistent approach. Furthermore, links to the official controls regulations were studied and showed that some part of the Regulation (EC) 882/2004 on official controls would need to be amended in order to properly address animal health controls (checks). A final decision has not yet been taken on whether the animal welfare basic principles should be included in the AHL as a separate chapter or the Animal Welfare Law should be a separate proposal with clear reference to the AHL (see also EP debate – the Paulsen report). The initiative however is not directly related to other SANCO initiatives on more detailed proposals on certain animal welfare areas (e.g. animal transport, animal welfare strategy.)

¹ Pillar 2, page 14 and 15 of the Communication COM 539(2007) final and page 3 of Communication COM 545(2008) final

² EP Resolution 2007/2260(INI)

³ Doc. 15481/07 ADD 1

⁴ NAT/376 – EU Animal Health Strategy

What are the main problems identified?

Current legislation does not fully support prevention. It is more reactive than proactive and doesn't provide real incentives for stakeholders (animal keepers, traders, business operators) to use mechanisms to prevent on one hand the introduction of the diseases to their holdings and on the other hand their spread to other holdings, regions and countries. The aim is to achieve an appropriate animal and public health protection in the EU by most efficient and competitive means and especially less disease outbreaks with substantial economical, trade, health, environmental and social effects.

-The role and responsibilities of all actors, for example animal keepers, operators and competent authorities is not fully and coherently laid down in existing legislation.

- Better integration is needed with the legal instruments adopted in the field of feed, zoonoses and animal welfare as well as with the general food law. For example all elements of animal health controls (veterinary checks in Intra-EU trade) and veterinary certification are not included in current rules for official controls. The intention is to streamline the legislation.

- Rules for some diseases have not followed the scientific developments (for example swine vesicular disease, Newcastle disease) and/or they don't reflect the actual situations (bluetongue); some diagnostic test are scientifically outdated long ago; certain intra-EU certificates are set in a basic legislation and cause problems in present reality. All these very technical provisions are regulated in the basic legislation and can not be changed with the necessary flexibility (only after legislative procedure in Council and EP).

-Provisions of EU legislation should as far as possible converge with the international standards. This was one of the main conclusions of the evaluation of Community Animal Health Policy 1995-2004. This has been further confirmed in more recent consultations with stakeholders. However, there is a strong commitment for keeping the appropriate health standards in the EU. Higher standards than those provided at the international level, should in fact be scientifically justified.

- Simplification of the basic legal framework seems indispensable for the achievement of the necessary clarity, consistency, transparency and user-friendliness. Too many details are set in basic legislation, which makes the provisions extremely inflexible (certain laboratory tests, etc.)

- Mechanisms should be put in place to address emerging and exotic diseases, that don't occur in the EU at present but might affect us in the future.

Who is affected?

Animal keepers, owners, related business operators (e.g. traders of animals and products of animal origin), national veterinary services, consumers and general public.

This proposal will mainly change EU internal approaches for disease control and will not significantly affect international trade. Some elements – like more transparent legislation even in terms of import conditions and greater convergence with international standards can bring benefits for third countries.

(i) Is EU action justified on grounds of subsidiarity?

Yes, this action is justified. Diseases don't respect borders, therefore general rules for their control across the EU should be harmonised. Furthermore, clear and harmonised rules for movements of animals within the single market need to be set in the EU legislation and apply equally to all member states. This applies also to import conditions that animals, animal products and products of animal origin, need to fulfil for the introduction into the single market.

(ii) Why can the objectives of the proposed action not be achieved sufficiently by Member States (necessity test)?

They are related to the fight against animal diseases with major cross-border implications and impact on the internal market of animals and animal products, including food of animal origin

(iii) As a result of this, can objectives be better achieved by action by the Community (test of EU Value Added)?

Yes

B. Objectives of EU initiative

What are the main policy objectives?

The main policy objectives are to contribute to:

(1) the achievement of a high level of protection of public health, animal health and food safety, (2) the support of farming and rural economy, (3) the improvement of growth cohesion and competitiveness through eliminating obstacles to free movement of goods and the promotion of appropriate farming practices and animal welfare to the extent possible and (4) the achievement of a high level of the protection of the environment and sustainable development.

Specific objectives:

- Introduction of the preventive approaches for disease control.*
- Incentive for farmers and operators should be provided (trade, financial, level of controls, educational,..) for the introduction more preventive mechanisms (physical biosecurity measures on farms, management, use of good practices, etc)*
- safe trade of animals and products should be ensured in the internal market, while at the same time we need to ensure that high level health status can be achieved in the EU, with no negative effects for human and animal health*
- Responsibilities of animal keepers, operators, farming sector for the health of their animals and health status of their products should be defined, and following this approach, the responsibility of the competent authorities. Stakeholders are willing to take the responsibility, but they wish to play a more important role in managing disease measures.*
- Veterinary practice and veterinary services should follow new challenges and new developments based on scientific facts. Roles of official veterinary services and veterinary practitioners need to be adjusted to the new developments (introducing biosecurity and surveillance concepts, more emphasis to their role of providing expertise to the farmers rather than only cure animals when the problem occurs). Appropriate use of all veterinary resources plays an important role.*
- Animal Health Law needs to be consistent with the legislation in the field of animal health, animal welfare and food safety (see Point A above) as well as broader EU policies on climate change and sustainability*
- The proposal will aim at reaching the appropriate level of convergence with the internationally established standards (OIE, Codex, SPS Agreement under the WTO) while ensuring high standards of animal health (see Point A above)*

Do the objectives imply developing EU policy in new areas or in areas of strategic importance?

No

C. Options

(i) What are the policy options?

Option 1: "No change scenario" which preserves the existing base-line

Option 2: Simplification and amendments to the legislation without changing the form of the acts.

Possible use of soft law instruments

Option 3: Introduction of new elements in a genuinely new legal framework. Two sub-options are possible:

3.1 "Animal Health Law" and implementing measures - a new legal framework of principles and objectives and a second level of implementing measures

3.2 An Animal Health Code - a single comprehensive legal instrument that covers both horizontal (for example, veterinary checks and control, animal identification and registration) and vertical provisions, (such as trade, eradication of diseases).

(ii) What legislative or 'soft law' instruments could be considered?

Legislative: Regulation or Directive of the European Parliament and of the Council

'Soft law': e.g. guidance for animal keepers. Each of the different policy options will incorporate 'soft law' alternatives to legislation to address certain issues outlined in the problem definition. These will be looked in detail in the impact assessment.

(iii) Would any legislative initiatives go beyond routine up-date of existing legislation?

Yes

Does the action proposed in the options cut across several policy areas or impact on action taken/planned by other Commission departments?

Yes, this action will cut across with several policy areas such as: animal welfare, animal nutrition, food safety, public health, environmental protection, pharmaceutical products, Common Agricultural Policy legislation and rules established by relevant international organisations (OIE, Codex Alimentarius)

Explain how the options respect the proportionality principle.

The proposal will contain principles and criteria to categorise diseases, which will allow for the prioritisation and future re-prioritisation of the EU intervention. Member States will be able to apply EU measures with a certain level of flexibility, so that those measures will be more adapted to their specific situations and needs. The outcome of the categorisation will also allow Member States the adoption of measures for those diseases that do not represent a significant health threat for the whole EU. The proposal will also provide legal basis to use non-regulatory tools as far as possible.

D. Initial assessment of impacts

What are the significant impacts likely to result from each policy option (cf. list of impacts in the Impact Assessment Guidelines pages 32-37), even if these impacts would materialise only after subsequent Commission initiatives?

Regardless of the option:

Economic impacts:

Positive impacts on functioning of the internal market and competition, competitiveness – impacts to agro-farming industry, agricultural sector and animal health (veterinary medicinal products) industry.

Operating costs and conduct of business (SMEs) and administrative burdens are under evaluation (see below)

Impacts on public authorities – mainly veterinary services

Indirect impacts on Innovation and Research

This proposal will not deal with financial issues, which will be dealt with in a subsequent proposal; it will also not affect the EU budget. However, the proposal will set a higher level of responsibilities for operators, which could have later impacts to the subsequent proposal on the veterinary expenditure.

Social impacts:

Impact on public health, food safety and food security, as animal diseases have major implications on the emergence of new pathogens and on the production of food of animal origin

There are possible indirect impacts on employment and labour market in agriculture.

Impact on the millions of citizens that own animals for farming purposes, as pets or as sport animals.

Environmental impacts:

Impacts on animal welfare.

Indirect beneficial impacts to biodiversity of fauna and landscapes.

Could the options have impacts on the EU-Budget (above 5 Mio €) and/or should the IA also serve as the ex-ante evaluation, required by the Financial Regulation?

No, this proposal will not deal with veterinary expenditure and financial issues, which will be dealt with in a subsequent proposal

Could the options have significant impacts on

(i) simplification,

Yes, simplification is one of main objectives. It should bring more clarity, transparency, user friendliness, remove duplications and avoid "grey zones" in legislation.

(ii) administrative burden changes

Yes, expected:

- Positive impacts due to simplification

- Impacts of possible new elements introduced by the new AHL are being assessed (see below)

(iii) relations with third countries?

No direct effect. More convergence with the OIE standards will however bring benefits to international relations and trade

E. Planning of further impact assessment work

When will the impact assessment work start?

Impact Assessment work has started in 2009. Formal kick-off meeting 26 January 2009.

(i) What information and data are already available?

- EUROSTAT data on agricultural production

- Internal SANCO data: TRACES, ADNS, results of disease eradication programmes, etc.

- Consultation results from wide stakeholders' consultation (September – December 2009)

- Consultation results "problem identification" as a part of the Stakeholders' steering group activity (first part 2009)

- DG ENTR study results on administrative burden reductions

- Available in the first part 2010: OIE study - disease categorisation (disease categorisation)

- Available in first part of 2010: results of "administrative burden, administrative costs and compliance costs questionnaires

(ii) Will this impact assessment build on already existing impact assessment work or evaluations carried out?

Yes

- Impact Assessment of the Community Animal Health Strategy 2007-2013

- Impact assessments of the Avian Influenza and Aquaculture Directives 2005/94 2006/88

- Evaluation of the Community Animal Health Policy (CAHP) 1995-2004 and activities for the future

(iii) What further information needs to be gathered?

Possibly: compliance costs derived from new provisions of the future Animal Health Law.

Consultation on administrative burden, administrative costs and compliance costs questionnaires is ongoing; EU standard cost model to measure administrative burdens will be used as appropriate.

(iv) How will this be done (e.g. internally or by an external contractor) and by when?

- We are collecting compliance costs data through the AHL consultation questionnaires for competent authorities and business operators on administrative burden, administrative costs and compliance costs. Deadline for submission of responses: 15 March 2010

- If necessary, another (limited) study evaluating compliance costs, will be needed (to be launched first part of 2010).

(v) What type and level of analysis will be carried out (cf. principle of proportionate analysis)?

Animal Health Policy is in place for already more than 45 years and its recent evaluation identified some areas where changes are needed. In this respect our intention is to measure a baseline scenario in terms of risks, costs and administrative burdens and assessing possible implications of the newly introduced elements of the AHL.

Which stakeholders & experts have been/will be consulted, how and at what stage?

- *EU MSs Chief Veterinary Officers (first discussions started in 2007) and other veterinary experts*
- *Special Stakeholders' steering group with the representatives of agricultural industry and producers and associations, competent authorities, non-governmental organisations (animal welfare), international organisations, professional associations, pharmaceutical industry (January- July 2009)*
- *Wide consultation involving all stakeholders' from the Animal Health Advisory Committee and representatives of competent authorities (2009)*
- *Special experts: epidemiologists from Task Force for Disease surveillance and Notification (late 2009, 2010)*
- *OIE*
- *EFSA, in relation to some specific diseases that may needed updated control measures*