



A draft new animal health law for the EU

Some basics

SUMMARY *Highly contagious animal diseases may have significant impacts on the health of animal populations. Certain animal diseases are also of particular concern to public health in cases where they may be transmissible to humans.*

Current EU legislation on animal health is made up of over 50 basic legal instruments, complemented by more than 400 specific and implementing acts.

Announced as part of the animal health strategy 2007-13, the Commission tabled a proposal for a new "animal health law" in May 2013. This single framework regulation would replace and encompass most of the present directives and regulations on animal health, striving for simplification and greater consistency under common principles and general rules. The fight against animal diseases would fall under clearly established responsibilities of the different actors, with more focus given to prevention. Control measures would build on risk-based categorisation of diseases. The proposal also aims at more flexibility and a reduced administrative burden, notably regarding some movements of animals in the EU, and at providing tools to adapt to new threats from emerging diseases.

The European Parliament has started its examination of the proposal, under the ordinary legislative procedure.

In this briefing:

- Background
- EU animal health policy: the basics
- The main challenges
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*In this briefing, "**animal diseases**" refers only to diseases related to infectious agents (such as viruses or bacteria) and which are transmissible (within the same species or to another susceptible species).*

Background

On 6 May 2013, the Commission finalised its [proposal for a Regulation on Animal Health](#) providing for a full revamp of EU legislation on animal diseases. This proposal was [presented](#) as part of a [broader package](#) on health rules in the agri-food sector.

Animals in the EU¹

Farming is the largest, but not the only, sector managing live animals in the EU, handling billions every year. In 2009, Europe's 13.7 million animal holdings hosted over 334 million farmed mammals (cattle, sheep, goats, pigs, etc.) and 2 billion poultry (chickens, laying hens, turkeys, ducks, etc.) and Europe's fish farms produced about 1.3 million tonnes of fish and shellfish.

EU citizens are among the world's top owners of pet animals, including about 120 million domestic dogs and cats, and about 35 million pet birds. Animals are also used for leisure and sport (notably [horses](#), estimated at over 5 million in the EU), for research and experimentation (around 12 million, mainly rodents) or for display and



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conservation (with an estimated 800 000 captive wild animals in zoos).

These animal-related industries are of significant economic importance. The output of the EU livestock farming industry is worth some €150 billion a year (about 41% of total EU agriculture output). Aquaculture production is valued at over €3 billion. Sales of dogs and cats alone are estimated at €1.3 billion.

Why care about animal diseases?

Beyond individual impacts on health and welfare, an animal disease is of general concern if it is also transmissible to humans. Such diseases, called [zoonoses](#), can have major impacts on public health and require proper consideration by public authorities. As an [example](#), measures on [salmonellosis](#) contributed to nearly halving cases in humans between 2004 and 2009.

Epizootic diseases (i.e. epidemics in animals) such as classical swine fever ([CSF](#)) or foot-and-mouth disease (FMD) can also have major negative effects in the agri-food industries, where they may affect the farming sector as well as the processing and trading of animals and derived products.

The [issues at stake](#) are complex. Apart from the impact of zoonoses on human health, the economic [costs of animal diseases](#), though difficult to estimate accurately, can be considerable. A [CSF outbreak in 1997 in the Netherlands](#) cost about €2.1 billion, and led to the destruction of over 12

million pigs. The economic costs of [FMD in the UK](#) in 2001 were estimated at at least £8 billion, while the environmental costs of the associated destruction of over 6 million animals were [valued](#) at £40 million.

EU animal health policy: the basics

Many reasons for coordinated action

Given the seriousness and highly communicable character of some animal diseases, and the cross-border threats they represent, coordinated approaches at EU level and beyond are deemed necessary.

Animal health policy is essential to EU policies on agriculture, aquaculture (within the common fisheries policy), public health

and consumer protection, internal market, trade and the environment. Interacting with other animal-related policies, notably welfare, nutrition, veterinary medicines, animal by-products or controls, it also receives [EU financial support](#).

Numerous laws

Animal health in the EU is currently governed by over 50 basic directives and regulations, which set general rules on animal identification, disease surveillance and control, intra-EU and international trade, veterinary controls, among others. They are complemented by about 200 implementing acts (e.g. on registration, veterinary certification, and "authorised" countries). Around a further 200 acts provide for application of special protection rules or transitional measures, in

The international context

The [World Organisation for Animal Health](#), known as the OIE (formerly "Office International des Epizooties") is the global intergovernmental body responsible for improving animal health. It approves international standards and recommendations for over a hundred [listed](#) diseases identified as of global importance for both [terrestrial](#) and [aquatic](#) animals. Gathering international scientific expertise, the OIE is also able to provide support to its member countries.

Highly transmissible diseases do not recognise frontiers, and there is global recognition of the need to address [transboundary animal diseases](#) through joint efforts. Freedom from animal disease is considered as a global public good, promoted under the "[one world - one health](#)" concept. The OIE acts in association with other institutions, [collaborating](#) notably with the [UN Food and Agriculture Organisation](#) and with the [World Health Organisation](#). The OIE is also the reference organisation for the [World Trade Organisation](#) for standards relating to animal health and zoonoses and international [trade](#).

All EU Member States are OIE members and the [EU](#) has formal observer status. Common [EU positions](#) are taken on issues discussed in the OIE.

particular with regard to specific disease outbreaks.

Science-based disease controls

The design of measures to fight against a given transmissible disease needs to be based on epidemiological data, notably the nature of the disease agent, its transmission routes, the geographical distribution of the disease, its health impacts and evolution in a population. In the EU, scientific advice can be provided by the [European Food Safety Authority](#), while measures are developed in consultation with [advisory groups and committees](#), in particular the Standing Committee on the Food Chain and Animal Health (which is also regularly [informed](#), notably on the disease situations in MS).

The EU animal health strategy 2007-13

An [evaluation](#) made in 2004 concluded that the EU's animal health policy had been successful in reducing risks and occurrence of animal diseases. However, it also highlighted some major weaknesses, notably the complexity of the system and the absence of a general guiding strategy. This contributed to the development of an [EU animal health strategy 2007-13](#). One of the four pillars of this strategy was to aim for a single and clearer regulatory framework.

The main challenges

A large and complex set of legislation

The current EU animal health rules are very complex². Legal instruments are disparate, with different subjects and mixtures of general, species-oriented or disease-specific measures³. Some problems relate to:

- lack of consistency across the legal acts in terms of policy approach, roles and responsibilities of the different actors,
- different definitions and unclear duties of the competent authorities (veterinary services), "official" or "approved" veterinarians and practitioners (including on qualifications and training needs),
- unclear responsibilities, for example on prevention measures to be taken by

animal keepers) and different interpretations between MS,

- high administrative burdens, not always proportionate to the risk (notably when keeping animals with no business aim),
- specific animal health rules (notably on imports) are difficult to master and burdensome to apply.

Difficulties in intra-EU live-animal trade

Infectious agents are transmitted either directly, mainly through close contact between live individuals, or indirectly (via contaminated equipment or transporters for example). Movements of live animals in the EU are therefore not free, but subject to health requirements with possible heavy, or even duplicate, procedures. For example, prior veterinary checks, health certificates, notifications of movements (to both the national animal registration databases and to the EU [TRACES](#) system) are required, not necessarily in proportion to the actual risk level. In this regard, risks are comparable within zones (areas) or "compartments" (e.g. one or more farms) where the animal population has the same health status and is subject to the same disease-management measures. However, the concept of "compartments" is not yet applied to movements and exchanges of animals (expect for [aquatic animal diseases](#) and [avian influenza](#)). Rules are also developed at national level, based on Member States' (MS) internal health status. Though it has proved successful in eradicating some animal diseases in some areas, this system is seen as too prescriptive and not in line with a single market.

A lack of overall guiding strategy

The EU's animal health policy developed over time, often triggered by disease crises (e.g. first [blue-tongue](#) cases in several northern MS in [2006](#) or the [Schmallenberg virus](#) detection in [2011](#)). Resources may also have been allocated on the basis of short-term crisis-driven needs, without a clearly established framework for priorities, based on risk and threat categorisation of the

different diseases. As a result, the successive sets of legislation lack over-arching principles, and consistent objectives and tools. This piecemeal approach (including for surveillance systems, which may or may not be harmonised, may or may not be EU funded and may be voluntary or mandatory) does not always include suitable mechanisms to react to re-emergence or appearance of a new disease.

In addition, while EU measures on trade and import of animals (aimed at ensuring a high level of animal health) generally reflect the main OIE principles, they differ in some standards, however⁴.

This may lead to lack of competitiveness for EU farmers, and possible trade disputes.

A lack of focus on disease prevention

The [EU animal health strategy 2007-13](#) enshrines the principle that "prevention is better than cure". However, disease surveillance mechanisms are suboptimal. Only a few mechanisms in EU law promote disease-prevention measures by animal keepers. People dealing with animals also often lack access to appropriate information and training on animal health. EU legislation is still not adapted to allow more use of vaccination⁵ (see box).

Overview of the proposal

A single "animal health law" (AHL)

The Commission [proposes](#) to streamline and simplify about 40 directives and regulations under a single framework regulation. The main instrument to implement the animal health strategy (2007-13), it is [presented](#) as aiming to last for decades. It would set

general principles and rules for a risk-based and more preventive animal disease policy (more biosecurity and surveillance, reporting, clearer policy for vaccine use), allowing

for safer and easier trade (in line with OIE), while being more flexible in reacting to threats (emerging risks, climate change) and adjusting to local circumstances, the aims of animal keepers and system sizes.

The AHL proposal does not cover related [expenditure](#) and [official controls](#), (subject to separate proposals within the wider package on the agri-food sector). It does not concern animal welfare, feed and medicated feed or veterinary medicine.

Disease prevention through vaccination

Vaccination helps to reduce the seriousness and occurrence of a disease and limit the spread of a highly contagious agent.

However, for major animal transmissible diseases (e.g. FMD, CSF) vaccination in the EU is prohibited mainly on economic grounds (including indirect costs due to possible trade restrictions). To eradicate such a major disease after an outbreak, the EU requires the culling (killing and destruction) of all susceptible animals in the contaminated area.

In recent decades, major episodes of animal destruction have led to significant debates on this no-vaccination plus stamping-out policy. Limited societal acceptance of animal culling and progress made on marker vaccines and diagnostic tools, to allow differentiation of infected from vaccinated animals, have led to a general recognition by EU stakeholders and policy-makers that "vaccination is better than unnecessary culling".

The [draft regulation](#) would affect existing legislation by:

- taking over the essentials of about 25 current legal acts (among over 40 it would repeal)
- preparing, via delegated or implementing acts, for (re)setting more specific measures which have been developed under most of the acts above (a few of these are completely obsolete).

Though they could also fall under the scope of this new law, the current specific rules on [animal by-products](#), on [transmissible spongiform encephalopathies](#), and on [zoonoses](#) (notably [Salmonella](#)) would not be touched.

A broad scope

This new framework on animal diseases should address all possible situations. All types of animals would fall under its scope, not only those kept by people for any

purpose (farming, companions, sport, zoos) but also animals in the wild where control of a disease so justifies. Rules would cover terrestrial animals (vertebrates and invertebrates, notably [bees](#)) as well as aquatic ones. For this latter category, the Commission foresees no substantial change, as the present [aquatic animal health rules](#) already build on the policy elements proposed in the new AHL⁶. [Changes](#) there would mainly be about alignment with the Lisbon Treaty, some harmonised, all-animal provisions and certain clarifications.

Clear responsibilities for operators

The AHL would set general responsibilities for all operators: owners, animal health professionals, laboratories, competent authorities, etc. (see notably part I, chapter 3 of the proposal), as well as their general duties, notably in terms of surveillance, notification and reporting (see part II).

Risk-based and preventive approaches

The proposal envisages the EU listing certain diseases and species, to which specific measures would apply (see notably part I, chapter 2). Specific measures would also relate to emerging diseases.

The proposal (Art. 6) provides for general criteria for risk-based assessment and categorisation of diseases. The listing of diseases would be decided by the Commission through implementing acts⁷.

Art. 8 identifies the main types of prevention and control measures for different categories of identified diseases; these measures are further detailed in developed sections of the proposal (notably part III).

Disease control measures

Most serious listed diseases would be subject to EU-mandated control and preparedness measures (e.g. contingency plans in case of outbreak, possibility to use vaccines and vaccine banks). Eradication programmes would be compulsory or voluntary depending on the seriousness and category of the disease. Additional measures may be taken by MS for EU-listed

and for non-listed diseases, under certain conditions (notably relating to the internal market). The Commission is to be kept informed, and coordinate.

The draft AHL also covers the possibility for emergency measures (e.g. under Art 81 or part VI), at national and EU levels, notably in case of an outbreak of a listed disease or an emerging disease (i.e. a "new" disease agent or a disease "new" to a territory).

Movement of animals

The AHL would provide for essentials regarding needs for animal traceability (registration or approval of establishments and transporters, record-keeping and registers, identification of animals, requirements for movements and certification systems). Specific measures would apply to live animals and their products (e.g. sperm and other germinal products). These basics are set separately for terrestrial (part IV, title I) and aquatic animals (part IV, title II).

Provisions regarding terrestrial animals are split by groups (e.g. pet, poultry, bovine) or depending on their destination (notably slaughter). However, for terrestrial animals, rules on movements would remain primarily based on national frontiers (cross-border transfers), while for aquatic animals, they build on disease zones or compartments.

Entry into the European Union

Requirements for entry of animals (and some products thereof) to EU territory (part V of the draft) would be maintained along the main existing principles whereby they should originate from authorised (i.e. listed) countries and establishments, be accompanied by animal health certificates and comply with specific rules on disease.

European Parliament

EP positions

In a 2008 [resolution](#) on the animal health strategy for the EU 2007-13, the EP took the view that the fundamental rules governing action on animal health should, where

possible, be set out in a single legislative act. Recognising the importance of risk categorisation and the central roles played by farmers, breeders, owners and veterinarians in prevention and detection of diseases, the EP expressed its support for some main principles, notably that 'prevention is better than cure'. It also called for action towards more protective vaccination without unjustified trade discrimination.

In June 2013, the EP amended a [Directive](#) and a [Regulation](#) on health rules for pets. These acts would in the future fall under the scope of the new AHL and be repealed by it.

Next steps

The proposed animal health regulation has been [referred](#) to the Committee on Agriculture and Rural Development (which has appointed Marit Paulsen (ALDE, Sweden) as rapporteur), while the Committees on Environment, Public Health and Food Safety and on Fisheries are to provide opinions.

Some first reactions

The [Federation of Veterinarians of Europe](#) generally welcomed the proposal, applauding the promotion of prevention (notably through animal health visits) and

the recognition of the need for well-functioning veterinary services, although it regrets the lack of a clear definition of a veterinarian. In its preliminary views, [COPA-COGECA](#), the EU farmers' representatives, welcomed the aim of simplifying the rules based on prevention of actual risks, but remained cautious on the overall impact at farm level. The NGO [Eurogroup for animals](#) questioned the possible impact of the draft AHL in terms of animal welfare.

Main references

Proposal for a Regulation of the European Parliament and of the Council on Animal Health ([COM\(2013\)260 final](#)), European Commission.

Impact assessment accompanying the proposal, staff working document ([SWD\(2013\)161 final](#)), European Commission.

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Endnotes

- ¹ Most of the data used in this chapter are taken from the [Commission impact assessment report](#).
- ² The main challenges are set out in the impact assessment report presented by the Commission, as well as in the different [consultation](#) and working documents on [problem identification](#) and other specific topics that were discussed with stakeholders — who also met in a so-called [AHL steering group](#) — during the preparation of this initiative.
- ³ To illustrate just a few: Directive on intra Community trade of bovine and swine (1964), Directive on the eradication of brucellosis, tuberculosis and leucosis in cattle (1977), Directive on classical swine fever (1980), Directive on notification of animal diseases (1982), Directive on mutual assistance to ensure correct application of veterinary legislation (1989), Council Decision on veterinary expenditure (1990), Directive on movements and imports of equidae (1990), Decision on Community reserves of foot-and mouth disease vaccines (1991), Regulation on the identification and registration of bovine animals (2000), Regulation on the non-commercial movement of pet animals (2003).
- ⁴ Some examples are provided in the [Commission impact assessment report](#), page 24.
- ⁵ See notably section 2.2.3.3 and annex VII of the impact assessment report.
- ⁶ The Commission thereby justifies that its impact assessment report mainly focuses on terrestrial animal diseases issues.
- ⁷ In this regard, the Commission also performed a study [on categorisation and prioritisation of animal disease](#) in partnership with the OIE. Some indications were also given during consultation with stakeholders and competent authorities (e.g. disproportionate rules on Swine Vesicular Disease or outdated measures against New Castle Disease). In a 2009 [Communication](#), the Commission had also announced that it would assess and possibly review the list of important diseases for aquatic animals.