

General Q&A
New EU Regulation on transmissible animal diseases ("Animal Health Law")
March 2016

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Scope of the Regulation on transmissible animal diseases (Animal Health Law)

Q: What exactly is the Regulation on transmissible animal diseases about?

A:

This Regulation is about animal diseases that are transmissible to animals or humans. It provides for principles and rules for the prevention and control of such animal diseases in kept animals (i.e. animals under human control) and wild animals and animal products. It covers terrestrial and aquatic animals. More precisely, these rules consist of requirements for disease prevention and preparedness; disease awareness; biosecurity; traceability of animals and where necessary products thereof; intra-EU movements and entry into the EU of animals and animal products; surveillance; disease control and eradication; and emergency measures. Such rules contribute since decades to sustainability, competitiveness, growth and jobs in the EU livestock sector and related processing industries (e.g. meat processing, food production etc.).

This Regulation does not provide rules on animal welfare, although it recognises that animal health and welfare are linked and it requires, for the first time universally, that animal welfare is taken into account when considering the impacts of diseases and measures to combat diseases.

Q: Are these rules completely new?

A:

Animal health rules are essential for both to fight certain animal diseases and also to ensure safe and smooth functioning of the internal market for live animals and their products. As such, most of these rules have already existed in one way or another in current legislation. Some have been around for decades. Where possible, those rules have been adapted, aligned and made more comprehensive (e.g. on compartments), coherent (e.g. on vaccination policy) or made less burdensome (e.g. no more formal approval of contingency plans). Another change is that emerging diseases can be more easily listed for EU intervention, allowing the use of our “toolbox” for listed diseases also to tackle new ones.

Veterinary services and livestock keepers would largely have to follow rules similar to current ones in case of outbreaks of foot-and-mouth disease and avian influenza. The change is in the more enabling legal environment for them to be prepared and also to consider alternatives as they go along.

However, some of the elements are new in EU legislation, for example basic responsibilities of certain key actors (animal keepers, veterinarians, administrations), animal health visits, measures for the prevention and control of emerging diseases and health measures in wild animals.

Q: How big is the livestock sector in the EU, how many animals are there for which the Regulation is potentially relevant?

A:

In a nutshell, there are around 12 million livestock holdings in the EU¹. In 2013 there were around 104 million bovine, 150 million porcine animals, 83.5 million sheep and 10.5 million goats in the EU28². There are about 1.6 billion heads of poultry. The value of livestock

¹ http://ec.europa.eu/eurostat/statistics-explained/index.php/Agri-environmental_indicator_-_livestock_patterns#Livestock_population

² http://ec.europa.eu/eurostat/statistics-explained/index.php/Agricultural_production_-_animals

farming output in the EU is €149 billion of which pigs and poultry represent 38% (i.e. €57.6 billion). Animal output value represents 41% of the overall agricultural output.

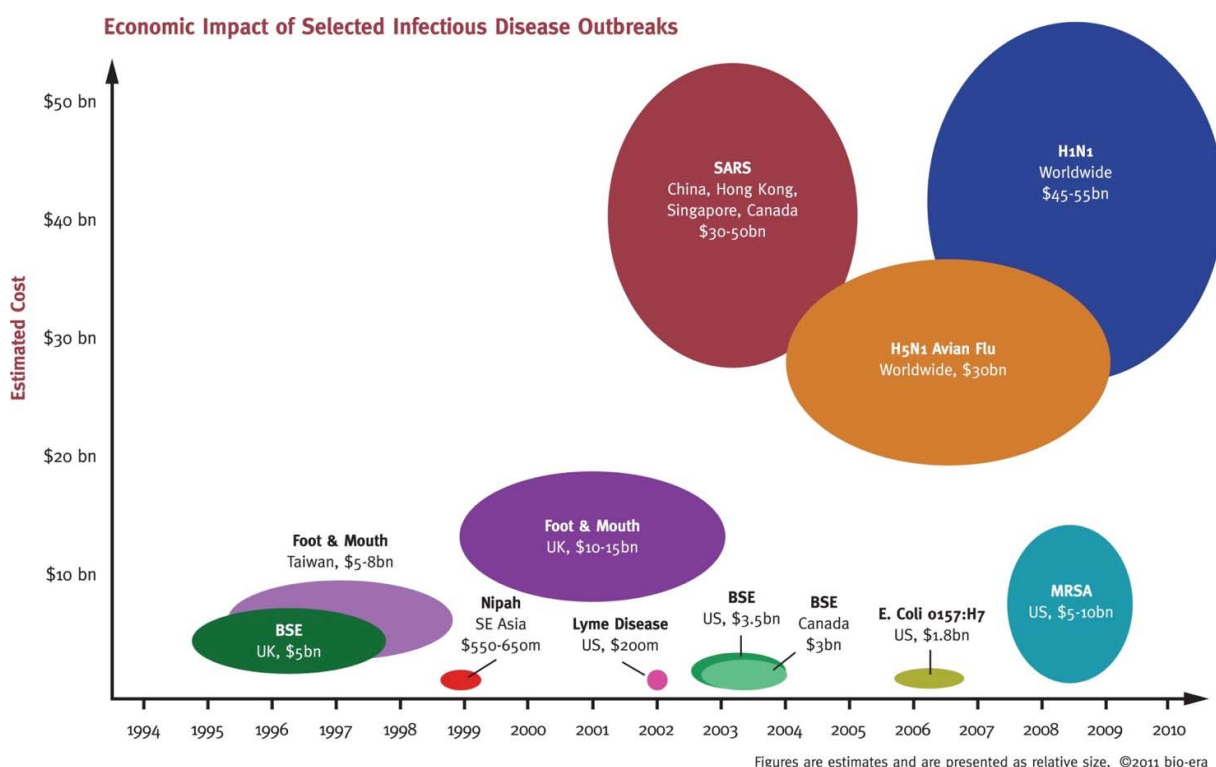
Pet animals represent the second largest category of animals. There are around 120 million dogs and cats, and approximately 35 million pet birds. Animals that are used for experimentation (pharmaceutical and cosmetic industries and public research bodies): count around 12 million animals in the EU, of which most are rodents. There are between 2,000 and 3,000 zoos in the EU and there are an estimated 800,000 captive wild animals. The fur farming sector also farms a significant number of animals, covering about 7,200 farmers and producing around 32 million pelts per year³.

Q: What are the potential effects of animal disease epidemics?

A:

The impacts of animal disease outbreaks can vary widely due to a variety of factors including the epidemiological characteristics of the disease, the structure of the sectors affected and the nature of the control measures imposed. These impacts can include negative effects for the health of animals and humans, the costs to farmers and related industries, the costs of dealing with disease and of business disruption, also public sector costs of disease eradication and monitoring, and changes in consumption patterns. Often, disease outbreaks also have significant impacts on international trade of animals and animal products. Finally, many animal diseases also affect wild animals, and may have detrimental effects on wild animal populations. Thus they can have a negative environmental impact, for example, on biodiversity. Some of the consequence of past animal health crises to illustrate the potential scale of the impacts of animal disease outbreaks:

- FMD (2001-2002): for UK only, GBP£10-12 billion (1.2% of GDP) mainly in agriculture / food chain (30%) and tourism (50%).
- Avian influenza in the Netherlands (2003): 30 million birds and direct economic costs of more than €150 million. A veterinarian died due to this disease.



Source: Bio-Era, 2008

³ http://ec.europa.eu/food/animal/docs/ah-law-impact-assesment_en.pdf

Entry into force, application date and transitional period between current and new rules

Q: When will the new Regulation enter into force and apply?

A:

The new Regulation will enter into force on 20th day after its publication in the Official Journal of the EU.

Some of the old, obsolete rules will be immediately repealed as soon as the Regulation enters into force i.e. in April 2016. Other rules are repealed from the date of application of the Regulation, i.e. 5 years after its entry into force. In the meantime delegated and implementing acts must be laid down by the Commission within 3 years of entry into force.

Q: Is there a longer transitional period envisaged between current and new legislation and how will it work?

A:

For some rules, such as the rules on identification and registration of animals and disease control, a longer transitional period can be set up by the Commission. However, this additional transitional period cannot be later than 3 years after the date of application of the Regulation.

For non-commercial movements of pet animals, the Regulation envisages a longer, 10-year transitional period.

Administration/administrative burden

Q: Will the new EU Regulation on transmissible animal diseases add extra administrative burdens for animal keepers and competent authorities?

A:

The new EU Regulation on transmissible animal diseases is the outcome of a major legislative simplification exercise (around 40 legal acts streamlined into one basic act). It should provide the basis for a solid and comprehensive set of Union animal health rules that is essential from both a health perspective and an economic one.

Care has been taken to reduce administrative burdens as much as possible by, for example, making use of new technological tools and releasing unnecessary administrative obligations where involved health risks permit so (movement of animals and their products, registration and approval of establishments, identification and registration of animals).

Additional guarantees

Q: Will "additional guarantees" for movements of animals and their products between Member States still apply in the EU and if so, for which diseases?

A:

The new EU Regulation will allow for a similar approach to the existing so-called "additional guarantees". It will list animal diseases for EU intervention and it will assign different sets of

disease prevention and control measures to them, based on their importance, characteristics and impacts.

Under one of the sets of measures (i.e. for animal diseases listed for EU intervention and for which a Member State applies disease eradication programmes on an optional basis) getting a higher health status envisages that such Member State will have the possibility to require additional guarantees for certain movements from other Member States.

Animal health visits

Q: What are animal health visits on farms all about?

A:

The animal health visits of the veterinarians on farms constitute a part of the overall on-farm surveillance system. The Regulation provides such visits as a complementary measure to other systems of surveillance and control, which are, or will be put in place by operators. In the future, operators will also have the possibility to benefit from such animal health visits taking place on their farms, by simplifying subsequent procedures for animal movements. Moreover, these visits will also provide operators with relevant advice on biosecurity and other matters related to animal health.

Antibiotics and antimicrobial resistance

Q: Will the new EU Regulation help to reduce the use of antibiotics?

A:

It will contribute to a better health status by introducing measures for the prevention of transmissible animal diseases. Together with clear responsibilities for the health of their animals and responsible use of veterinary medicines, this should lead to reducing the use of veterinary medicines including antimicrobial agents.

It will also set out a better legal basis for monitoring animal pathogens which are resistant to antimicrobial agents.

The Regulation on transmissible animal diseases will, in that respect, supplement two other proposals which are currently undergoing the ordinary legislative procedure in the European Parliament and in the Council, on veterinary medicines and on medicated feed, as well as a number of other non-legislative means.

Biosecurity

Q: The new Regulation introduces more biosecurity on farms. Does it envisage financial incentives to support farmers?

A:

This Regulation will not provide for any financial rules including financial incentives to support biosecurity on farms.

However, the Regulation will also provide for a number of other incentives. For example, for establishments with biosecurity above a minimum level, it provides for possibility for movements of animals or their products from compartments applying other disease preventive and control measures even from restricted zones.

Better biosecurity in itself represents an incentive for farmers, as it helps to prevent the introduction and spread of diseases into the premises and it minimises direct and indirect losses due to disease outbreaks.

Q. What are compartments and what does the Regulation say about them?

A:

Compartment means an animal subpopulation in one or more establishments, under a common biosecurity management system with a distinct health status with respect to a specific disease or specific diseases, subject to appropriate surveillance, disease control and biosecurity measures. This meant that they are free of diseases not on the traditionally used geographical basis (such as regions) but based on enhanced biosecurity and management.

So far in EU law that concept is only recognised for avian influenza and aquatic animal diseases. The Animal Health Law establishes the possibility of using the compartment system also for other animal species and diseases. This introduces more flexibility into disease control measures, e.g. the possibility of continuing movements and trade when a geographical region is affected by restrictions during outbreaks of animal diseases.

Disease listing, prioritisation and categorisation

Q: How is listing of diseases for EU or public intervention handled?

A:

The Regulation sets out a “master” list of diseases that may be amended where necessary to protect public and animal health in the Union. A disease can be added to the list quickly.

On the other hand, if a disease does not present any significant risk for the Union and if the measures related to it are causing only unnecessary burden for operators, taxpayers and competent authorities, it should be removed from that list. Therefore the list of diseases will not be static, but will be managed in a flexible way in the light of the epidemiological situation in the Member States and in third countries.

Q: What will happen if diseases are not listed as relevant for EU intervention?

A:

If a disease is not listed for EU intervention, either the national public administration or the private agricultural or aquaculture sector or any other stakeholders (e.g. those who are concerned about wild animals) in the Member States can take proportionate measures and improve the health situation concerning that disease in their territory. However, the measures applied should respect the rules of the single market.

Entry into the Union

Q: Does the new Regulation change rules for entry into the Union of animals and their products?

A:

Essentially not, the current system remains largely as it is. The new Regulation provides for more transparent international trade requirements for animals and their products. It will also foster convergence of EU rules towards international standards.

Environment

Q: How does the Regulation address environmental concerns or support initiatives for the protection of the environment?

A:

The new Regulation builds on the successful elements of current legislation. It will help to sharpen economic competitiveness for livestock farmers and improve EU tools to fight transmissible animal diseases, thereby assisting both their economic and environmental sustainability in general.

Environmental considerations have been part of the EU animal health policy for a long time, e.g. for the proper disposal of carcasses of animals killed during epidemics or robust rules for the collection and safe treatment of animal by-products, thereby decreasing the possibility of negative effects for the environment.

The new Regulation also considers that diseases occurring in wild animals may have a detrimental effect on the agriculture and aquaculture sectors, on public health, the environment and biodiversity. Hence its scope covers wild animals and the disease agents which may affect them or which may be spread by them and may support measures to prevent or control the occurrence of those invasive alien pathogens, which will be listed.

Financing of animal health measures

Q: Does the Regulation provide rules on EU financial contribution?

A:

No, this Regulation only establishes key principles, objectives and priorities for better animal health, along with clear responsibilities for all players and a framework within which to work. An adequate financial framework to achieve the objectives of this policy is provided for in Regulation (EU) No 652/2014 laying down provisions for the management of expenditure relating to the food chain, animal health and animal welfare, and relating to plant health and plant reproductive material.

Animal identification, registration and traceability of animals

Q: Have the rules for animal identification and registration changed?

A:

The Regulation covers all animals and contains the essential elements for the possibility to identify and register them. It will repeal much relevant existing EU legislation on the identification and registration of animals, including basic rules. The second step is to complement the essential rules with non-essential elements in delegated and implementing acts.

An adequate, proportionate and reliable EU system of identification and registration is currently in place for bovine, ovine and caprine animals to ensure traceability for food safety and to assist in the fight against epidemics. There is no necessity for the existing policy and system to be changed in substance. However, the Commission will review current identification rules for horses and improve and fine-tune its various elements, due to the revision of legal frameworks on animal health and zootechnics, which represent a basis for those rules.

Q: Does the Regulation regulate identification and registration of any other animals?

A:

The new Regulation is a framework, to contain the basic rules. As such it covers all animals and contains the essential elements for the possibility to identify and register them but it provides more specific rules only for those animal species where the identification and registration rules exist at present. However, the Regulation also provides a possibility to lay down further detailed requirements for identification and registration of other animal species, for which specific requirements do not exist until now.

Such measures can be adopted, where they are necessary, to ensure traceability and protect the health of that particular animal species in the Union. Naturally, the principles of subsidiarity and proportionality as well as possible effects on the EU's growth and jobs too, would have to be analysed.

Movements of animals and animal products within the Union

Q: Does the Regulation make movements of animals for direct slaughter any easier?

A:

The Regulation provides a legal basis, and envisages the relaxation of administrative procedures for movements of animals and their products between Member States. This could happen in cases, where such movements only represent an insignificant risk for animal or public health in the Union, provided that traceability can be ensured. Movements of animals for direct slaughter into another Member State, or movement of hatching eggs can certainly be considered as such examples. Detailed requirements and procedures for such movements will be laid down in the delegated acts adopted pursuant to the new Regulation.

Q: What could such changes mean to a livestock farmer in practice?

A:

For example, in a few years, a pig farmer – providing that such change is agreed in the future and the farmer complies with all other rules – could send his pig consignment to a slaughterhouse in another Member State at the exact time he prefers and would not have to wait for the official veterinarian to inspect the consignment and complete the certificate, as is currently the case. This could be an important time- and effort-saver to him and allow him to organise these consignments in a way that fits best his schedule and that of the slaughterhouse, not to mention reduced costs from fewer administrative procedures.

Given that there are around 80,000 such consignments in a year, there is the potential for important savings from administrative costs alone, which is estimated up to 20 million EUR. Such changes could also mean better welfare for the animals due to reduced waiting periods both at the farm and at the slaughterhouse, or the ability to transport them during lower temperatures such as at nighttime in summer.

Q: Does the Regulation remove existing requirements for assembly centres and dealers?

A:

Past experience with the spread of highly contagious animal diseases have shown that assembly operations carried out at assembly centres and dealers represent a major risk for spreading animal diseases. Therefore, for the future, the new Regulation also envisages strict animal health requirements for such risky operations.

Q: Will this Regulation provide for rules for non-commercial movements of pet animals?

A:

Yes, this Regulation introduces a special chapter on non-commercial movements of pet animals. These new rules take over the rules from the existing Regulation (EU) No 576/2013 on the non-commercial movements of pet animals. However, there will be a 10-year transitional period.

Vaccination

Q: Does the Regulation provide for more possibility to use vaccination?

A:

The new Regulation provides for a coherent policy for the use of vaccination in the EU, but it will also be largely up to Member States to what extent they use it.

Vaccination is already possible for the majority of relevant diseases. Prophylactic vaccination is only restricted for a handful of them, such as classical swine fever, foot-and-mouth disease and avian influenza. Even in such cases, emergency vaccination is possible as a supplement to other disease control measures after approval by the Commission of a vaccination plan.

Vaccine banks established by the EU and Member States

Q: What are vaccine banks and what does the Regulation provide on them?

A:

Vaccine banks store vaccines or their precursors in big quantities. They allow rapid access to these in case of epidemics and this can help the authorities to use one more instrument to control diseases.

Currently there are EU vaccine banks for foot-and-mouth disease and classical swine fever. In addition there are several national banks both for these diseases and also for other diseases as well. If there are EU vaccine banks, then Member States do not necessarily need to maintain national banks (they are still free to do so). This makes a lot of sense due to economics of scale, reduces associated administrative burden, ensures quality of the stored products and so on.

The Regulation provides a legal framework wider than these two diseases and clearer on the function and requirements of EU antigen, vaccine and diagnostics banks and also on how the Member States can have access to them.

Delegated and Implementing Acts

Q: What are delegated and implementing acts and what will they contain?

A:

These are both kinds of Commission acts. Delegated acts supply further non-essential elements to the already agreed basic Regulation. These are important to clarify and fine-tune important details.

Implementing acts will lay down elements which are necessary for uniform implementation and application of the rules, such as various forms, diagnostic methods, model certificates, lists of countries and suchlike.

The Commission will consult both Member States' experts and stakeholders during the laying down of these delegated and implementing acts.