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Comments on the Proposal (draft status: 25 June 2012) for a Regulation of the European Parliament and of the Council on animal health law (SANCO/7221/2010/REV5)

We expressly welcome the aims of the EU Animal Health Strategy including, for example, placing greater emphasis on preventative measures. Unfortunately, however, this is not sufficiently reflected in the Draft of the Animal Health Law.

It is not so easy to evaluate this comprehensive work, since its content and structure have been changed so many times. Much of the content of the Draft Proposal is extremely general, as a result of which it hardly has any substance. Some rules appear redundant and unnecessary. As more detailed provisions are to be left to follow-up legal acts, which will above all be framed as delegated legal instruments on which the Member States have hardly any influence, it is hardly possible to reach an assessment of the overall work and its practicability.

On the positive side, veterinarians are given the status of key actors in the investigation of diseases and represent a key link to operators and the competent authorities.

The Draft at hand does not appear to contain a European **vaccination strategy** within the framework of disease control. In our opinion, the latest scientific findings in regard to diagnostics and vaccination should be incorporated into Union legislation in order to prevent the culling of healthy animals. This piece of legislation could finally be used to lay the foundation for a paradigm shift in animal health policy. If the Animal Health Law does not at the very least evidence rudimentary efforts to prevent the mass culling of healthy animals, a unique opportunity to make progress in this matter – which all involved professional groups are concerned about – will be missed.

The fact that two thirds of the rules are to be included in **delegated acts** and not in this basic act raises problems. We believe that rules, for example on biosecurity measures and the role of farmers and veterinarians, as well as the aims of and conditions for animal health visits must be set out in this Regulation. There is no reason to avoid including concrete rules in a legal instrument that is of such particular significance to animal health. Quite the contrary, uniform rules in particular need to be found, in consultation with the Member States, in regard to important preventive measures. It was possible to achieve that goal in regard to the "hygiene package" for the food sector.

Re individual provisions

Recital 59

This Recital sets forth that **vaccination** should be considered as an integral element of a comprehensive disease control strategy. Nevertheless, Articles 46, 49, 64 and 69 contain only weak references to the possibility of emergency vaccinations in the event of the occurrence of diseases. It should be set out much more clearly that the mass culling of healthy animals in the event of an outbreak must always be avoided by means of emergency vaccination if marked vaccines are available or the situation permits the use of a conventional vaccine and the free testing of animals in the surveillance zone. In particular, this applies to swine fever, foot and mouth

disease, and avian influenza. Trade policy considerations should not play a role. The value of an animal should also be appreciated in the event of an outbreak. A fund should be established to finance the logistics involved in a temporary increase in national trade. In addition, we propose setting up a Vaccine Commission under the auspices of EFSA to make recommendations on preventative vaccinations.

Re Art. 5

The definition of "official veterinarian" in **No. 24** should not refer to the "competent authority" but to the "competent **veterinary** authority" in order to make it clear that the authority is headed by a veterinarian and is responsible for veterinary matters. This also corresponds to the nomenclature of the OIE.

Since the rules and competences vary quite considerably across Europe, the delegated act should not only include a definition of "official veterinarian", but also of "**veterinarian**", who may possibly carry out official tasks. The OIE definition reads:

Veterinarian

means a person registered or licensed by the relevant veterinary statutory body of a country to practice veterinary medicine/science in that country

Re Art. 10

As mentioned in the above, this article must describe **biosecurity measures** in more detail. In view of the diversity of threats from known and formerly exotic diseases, for example African swine fever, the Regulation should contain provisions on hygiene and the conditions under which animals are kept in order to prevent the introduction and spread of disease. Germany has an Ordinance on Hygiene in Pig Husbandry (*Schweinehaltungshygieneverordnung*) and Guidelines on Hygiene Requirements in Regard to Ruminant Husbandry (*Leitlinien für hygienische Anforderungen an das Halten von Wiederkäuern*). They both take account of various husbandry systems and contain rules that have stood the test of time in pig husbandry and that could be transferred to EU law without any problems.

Re Art. 13

Given the historical reasons for the tasks they undertake in different countries, there is no guarantee that the **aquatic animal health professionals** referred to here and in Recital 30 will be sufficiently qualified. It would be preferable if the diagnosis and control of animal diseases were the responsibility of veterinarians, since only their training guarantees they are sufficiently qualified.

Individual Member States should be permitted only in exceptional cases to entrust other professions with these tasks. In such cases their knowledge must be defined and, insofar as they do not undergo academic training, their tasks limited to assisting others, for instance carrying out sampling.

The article must make it clear that the veterinarian must be **charged** with being involved in animal health visits. Veterinarians cannot be made responsible for mistakes made in the animal keeper's sphere of competence. This could, at best, be guaranteed by prescribing the frequency of visits for various animal species and requirements in regard to obligatory visits and the visiting veterinarians.

Re Art. 26 and 27

These articles must specify more precisely which aims and conditions the obligatory **animal health visits** must meet and fulfil. That is the only way to guarantee that animal health will improve and the introduction of disease can be effectively prevented. The aforementioned Ordinance on Hygiene in Pig Husbandry has successfully established animal health visits by law and includes rules on minimum frequency of visits, objectives and training. These could be transferred into EU law without any problems. Guidelines applicable in Germany set out rules on visits to individual kept animals. These could also be drawn on.

Re Art. 56

Despite making reference to Art. 19, this article should explicitly refer to the fact that the animal keeper "must" not "shall" call in a veterinarian in the event of disease suspicion.

Re Art. X+6 (2d)

The **responsibilities**, **competence and training of personnel and veterinarians** must be regulated in connection with the approval of establishments in this Regulation and should not be left to the delegated acts. These issues are essential when it come to guaranteeing that the farms visited do not introduce and spread diseases and that they provide the right environment for their animals. The Member States should be able to reach agreement on these issues in the course of negotiations on this Regulation. That would then also guarantee that the conditions are compatible with national systems.

Re Art. Z+28

Reference is made to "**self-certification**" for the movement of animals in exceptional cases in various articles, namely in Articles Y+4, Y+6, Z+28, A+38. It is not clear for which cases such exceptions are required. We have the gravest concerns that, particularly in Intra-Community trade, animal health certificates, movement documents and passports are no longer duly presented. A clear definition of and reasons for exceptions must be provided here or else the exceptions should be deleted.

Berlin, 28 Sept. 2012