Possible Delegated and Implementing Acts Structure

1. Previous discussion

1.1. The non-paper of November 2013 suggested five possible options for the structure of the future delegated and implementing acts to be made under the Animal Health Law. At that time, option 3 was indicated as preferred, although it was clear that further reflection was required. No significant feedback on the options was received from Member States or other stakeholders. The options were:

- **Option 1**: a single Commission delegated act could complement the Commission proposal, similarly to the approach used for the implementation of the animal by-products Regulation, i.e. Regulation (EC) No 1069/2009;
- **Option 2**: several empowerments could be grouped into a limited number of acts (possibly 3) based on the topic, for example one for disease prevention and control measures, one for movements, and a third for entry into the Union;
- **Option 3**: a few more specialised packages of rules (e.g. Commission delegated acts) for example for the movements and entry of ungulates, poultry, bees, aquatic animals, pet animals, etc., for semen, ova, embryos and a separate set of disease prevention and control rules;
- **Option 4**: a higher number of Commission delegated acts, keeping for each empowerment its own separate delegated act;
- **Option 5**: a combination of the different options described above.

2. Reflection since the non-paper

2.1. Further reflection on the structure of the possible future delegated and implementing acts has tried to identify packages of delegated and implementing rules that logically fit together. There are additional choices to be made about whether they could or should be combined or separated any further. **The final structure must ensure that the separate delegated and implementing acts are not too large and remain practical and usable; but are not split into too many different acts, creating uncertainty about where a particular rule or measure sits.**

2.2. As well as an approach which meant keeping similar rules together in ‘packages’, Option 3 also identified and analysed an alternative structure which was based on a species and categories approach. The idea would be to make one delegated act for each major species or group of species eg: poultry, ungulates (or sub-categories of bovines, porcines, etc), aquatic animals, germinal products, etc, covering all the possible rules for that species or category of animal (disease control for relevant diseases, movement requirements, identification, etc).
However, after further consideration of the content of the rules needed, it was felt that this approach would duplicate too many of the rules which are common across species (for example, disease control for different species of ungulates). In addition, for some ‘special’ categories of animals or products, such as germinal products or live animals moving to or from a confined establishment, there are likely to be rules common to those animals or products irrespective of their species, which could cause some confusion about where the correct rules are to be found. One possible exception is for aquatic animals, where it may be desirable to make one specific delegated act for readability and ease of use. However, more work will need to be done on the content of the delegated acts before it is clear whether the advantages of keeping a common approach as far as possible outweigh the advantages of keeping all the aquatic aspects together.

3. A possible way forward

3.1. This paper suggests a preferred approach of a version of option 2 with elements of option 3. The main bulk of the rules to be made could be grouped into three delegated acts, with supporting related implementing acts. However, it is clear that in addition to those three, there will have to be a small number of ‘standalone’ delegated and implementing acts, for various reasons (outlined above in section 2.2 in relation to aquatic animals and below in section 6).

3.2. Note that the structure as discussed in this document uses the original Commission proposal as a basis for analysis and explanation – given the advanced nature of the discussions in the Council and the Parliament this structure would seem fairly stable and may need only minor amendments to work for the final agreed regulation.

4. Implementing Act on list of diseases, species, categorisation

4.1. This paper does not consider the question of the listing of diseases and species, and their categorisation. The original Commission proposal envisages a single implementing act for the empowerments in Articles 5, 7 and 8, creating a list of diseases and species, and categorising those diseases. This issue is not yet settled. Nevertheless, whatever the final outcome of the ongoing discussion, it is logical that the list(s) should be dealt with separately from the others in the Regulation and it/they should be adopted as soon as possible after the entry into force of the basic Regulation.

5. Three main delegated acts

5.1. The main three packages of rules envisaged to be grouped in single delegated acts are explained below. Of course, it would be possible to split the packages suggested here into more pieces of legislation, and where that seems to offer the possibility of a workable and sensible alternative, it has been indicated as a possible option. It is clear that more work is needed on the practical contents of the delegated acts before making final decisions as to what
solutions are most useful and practical, as well as meeting the requirements of better regulation. The structure of the complementary implementing act(s) would be dependent on the choice made about the structure of the delegated act(s), and would ideally match that structure. **It seems clear that the Animal Health Law will need to be supplemented by at least these three delegated acts (plus one specifically for aquatic animals, if found appropriate, see point 2.2 above) for it to function successfully on its application.**

**A. Delegated Act on notification, surveillance, eradication programmes and disease-free status, disease awareness, preparedness and control**

5.2. **This delegated act would be based on the empowerments in Part II and Part III of the proposal.** Part II covers notification and reporting, surveillance and surveillance programmes, and disease-free status of Member States, territories, zones and compartments. Ideally, this would include detailed rules to be set down under Article 24 on animal health visits (where those rules are necessary). Part III of the proposal covers contingency plans, suspicion, confirmation and control measures for (a) diseases; and suspicion, confirmation and control measures for (b) and (c) diseases. As far as possible, a single set of rules for different diseases could be introduced.

5.3. **This delegated act would meet one of the main objectives of the Animal Health Strategy, which was to clarify and simplify animal health legislation.** Where differences in rules for different diseases are necessary, they could be spelt out in technical annexes (for example, defining disease-specific measures to be taken in the case of an outbreak, size of restricted zones, particular disinfection requirements etc). All rules for the prevention and control of listed diseases would therefore be in one place, so those concerned with dealing with those diseases would know where to find the relevant rules, enabling easy use of the legislation by those dealing with diseases.

5.4. However, an alternative would be to separate this delegated act based in the empowerments in Parts II and III into two or more delegated acts. A disadvantage of having a single delegated act on these subjects is that it would make a very large piece of legislation. It may be sensible to keep the empowerments in Parts II and III separate, keeping notification, surveillance etc. distinct from disease control. Alternatively, if too many of the rules to be made are different across different diseases, it may be reasonable to develop certain disease-specific delegated acts, which would ensure that all the rules for a particular disease are in one place and clear and easy to use. These disease-specific acts could cover all of the rules discussed here together (Parts II and III), or just Part III dealing with disease control. However, even if this disease-specific approach is taken, some common rules will undoubtedly be needed.

5.5. **The structure of the complementary implementing act(s) would be dependent on the choice made about the structure of the delegated act(s), and would ideally match that structure.**
B. Delegated Act on establishments, registers and record keeping, identification and registration and intra-EU movements

5.6. **It would seem that the rules in Part IV of the proposal logically fit together in a single delegated act.** This delegated act would cover the registration and approval of establishments, competent authority registers and record keeping, comprising the empowerments in Articles 85-100 (terrestrial animals) and 174-188 (aquatic animals), as well as certain rules based on the empowerments provided for in Article 9(2) on biosecurity in establishments, if needed. These requirements could be combined with all the relevant requirements for identification and registration of animals and germinal products, namely the empowerments in Article 114, 115 and 119, and the rest of Part IV of the proposal, on intra-EU movements and certification.

5.7. **The objective in combining all these rules would again be to meet the objectives of the Animal Health Strategy: clarifying and simplifying animal health legislation by keeping common rules as far as possible, with variations for different species or categories of animals and products in technical annexes, as necessary.** Combining all these rules may make for a large piece of legislation, but is likely to be much easier and more usable for those needing to identify and find the rules, rather than separating them. It is worth noting that for all of these empowerments, unlike the delegated act described in 1, the variations in the common rules would be by species or category of animal or product, rather than by disease.

C. Delegated Act on entry into the Union

5.8. **A single delegated act would describe the criteria, animal health requirements for the entry of animals and certain products into the Union, derogations from those rules, and animal health requirements and rules for certification for animal health for entry into the Union.** Consequent implementing acts (probably several of them) would contain the lists of third countries, model certificates and Combined Nomenclature codes, where necessary. **There are likely to be advantages in keeping those rules separate from the rules for intra-EU movement, so that our rules are clear for importers and third countries.**

6. **Other empowerments: delegated act and implementing act empowerments which are not needed immediately or do not fit into this general structure**

6.1. **A number of the empowerments in the proposal do not fit easily or immediately into the general structure of the three main delegated acts described here.** Some are legal technicalities which stand alone. Others do not need to be made immediately for the whole set of animal health legislation to function, for various reasons. They broadly fall into four groups as below:
• **Regular business**: those that are ‘demand-led’ of sorts – either emergency measures or regular standing committee business that will always need to be adopted in the future as part of the EU’s ongoing business. They will not be needed at the start of the application of the regulation, but are adopted only when they are asked for, or needed. These include implementing acts on temporary or emergency measures (for example, in Articles 71, 81, 138, 206, 227, and 248-251) or regular standing committee business such as approval or withdrawal of surveillance or eradication programmes and disease-free statuses (for example, in Articles 30, 36, 37 and 42).

• **Legal technicalities**: delegated acts on legal provisions such as the dates of repeals. They cover the empowerments in Articles 259-261 and although needed from the date of application of the regulation, they stand alone.

• **Future amendments to the basic act**: those only to be used in the event of the regulation needing to be amended in the future. These include those in Articles 6, 233 and 252.

• **New possibilities for the future**: Those empowerments which are highly unlikely to be used immediately, but are possibilities for the future. These include measures affecting animal species other than those that have conventionally been covered under EU animal health legislation (Article 229). Nevertheless, if they were to be used, the most sensible course of action would probably be to combine any delegated and implementing rules with the respective measures for other species. For example, if new requirements on identification and registration of different species were introduced by using Article 113 with empowerments provided for in Article 114, it seems to make sense to include those rules in the same delegated act as the identification and registration rules for other species.

7. **Empowerments to be considered further**

• **Biosecurity measures**: Biosecurity is not a new concept, but is more developed and used for different purposes across the proposal. It is used as an incentive for a number of facilitation measures. The empowerments are provided across the proposal in many places. Article 9 introduces an overall obligation for operators on biosecurity. Rather than a standalone delegated act, it makes sense to use that empowerment throughout the various delegated acts when biosecurity measures are appropriate and necessary, together/in combination with other more specific empowerments on biosecurity in those acts, where provided for. That needs some further thought and development.

• **Biosecurity in laboratories**: There is a delegated empowerment in Article 15(2) which covers safety measures in laboratories including biosecurity and movement of disease agents. This also applies to Union antigen, vaccines and diagnostic reagents referred to under Article 48, and there is also a link with the empowerment in Article 242 governing the (intentional and controlled) entry into the Union of disease agents. Further consideration would be needed as to whether to include these rules with the provisions on disease control in point 1, or the rules described in 2 and 3 about movement and entry into the Union. Alternatively, consideration could be given to
using those empowerments together with similar empowerments regarding laboratories in the official controls regulation (note particularly Articles 91 and 98 and the empowerments in Articles 97(2) and 98 (2) in the official controls proposal).

- **Continuous professional development of veterinarians:** Like biosecurity in Article 9, the empowerment in Article 11 on the continuous professional development (CPD) of veterinarians and aquatic animal health professionals could also be used across the various delegated and implementing acts where necessary and appropriate (although this empowerment is under discussion in the Council and it is possible it may be removed by the legislator).

- **Activities delegated to veterinarians:** Article 13’s empowerment, on which activities in the regulation can be delegated to veterinarians (other than official veterinarians) could be dealt with in two ways. First, one single delegated act could be prepared which would set out all the possibilities. Second, like the biosecurity and CPD empowerments, it could be used within the relevant provisions as necessary.

- **Animal Health Visits:** Articles 23 and 24 describe the animal health visits which are one of the cornerstones of promoting prevention rather than cure. Note that these empowerments have been challenged in both the Parliament and the Council and may be removed. However, if retained, the further detailed rules to be set down under Article 24 (where necessary) could constitute an integral part of the notification and surveillance in the group described in point 1 (current preference), or alternatively could be set down in a standalone delegated act.

8. **Delegated and Implementing Acts: Planning**

8.1. Further consideration also needs to be given to a timetable for planning this work. An indicative timetable has been indicated below, but this is based only on a provisional analysis and will need to be planned in more detail in due course.

**Table 1: Indicative planning and timeline assuming agreement on the basic Regulation by early 2015**

<table>
<thead>
<tr>
<th>Act</th>
<th>Act type</th>
<th>Timeline</th>
<th>Expert groups</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementing Act on list of diseases, species, categorisation</td>
<td>IA</td>
<td>First draft: as soon as possible after agreement. Final draft end 2015</td>
<td>YES. As soon as agreement is reached.</td>
</tr>
<tr>
<td>Delegated Act and Implementing Act on intra-EU movements, establishments, registers and record keeping and identification and registration</td>
<td>DA</td>
<td>COM Preparatory work starting 2015. On ID and registration, possible longer transitional periods for specific species/</td>
<td>YES: 2nd half 2015-2016 on intra-EU movements. WG on ID and registration possibly later.</td>
</tr>
<tr>
<td>IA</td>
<td>COM Preparatory work starting 2015.</td>
<td>YES. Working groups 2nd half 2015-2016</td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>Delegated act and Implementing Act(s) on entry into the Union</td>
<td>COM Preparatory work starting second half 2015.</td>
<td>YES: 2016</td>
<td></td>
</tr>
<tr>
<td>IA</td>
<td>COM Preparatory work starting second half 2015.</td>
<td>YES: 2016-2017</td>
<td></td>
</tr>
<tr>
<td>Delegated Act and Implementing Act on notification, surveillance, eradication programmes, disease-free status and disease awareness, preparedness and control</td>
<td>COM Preparatory work starting in second half 2016. 2017 for general disease control measures. If longer transitional periods for certain diseases (currently covered by directives), from 2018-2019.</td>
<td>YES. Working groups on notification, surveillance, erad progs 2017, followed by WGs on disease-specific measures after 2018.</td>
<td></td>
</tr>
<tr>
<td>IA</td>
<td>&quot;ADIS&quot; legislation. Formats and procedures for submission of programmes. 2017 tbc. Disease-specific after 2018</td>
<td>YES. &quot;ADIS&quot; legislation: 2017 tbc (or other according to the ADIS project plan). Programmes: 2018 Disease-specific after 2018</td>
<td></td>
</tr>
<tr>
<td>Other DA/IA</td>
<td>DA/IA</td>
<td>Depending on the need</td>
<td></td>
</tr>
</tbody>
</table>
Figure 1:

Provisional workload timeline planning (assuming agreement on the basic regulation early 2015)