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EXECUTIVE SUMMARY OF THE IMPACT ASSESSMENT

Accompanying the document

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on Animal Health

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1. Problems identified

Background

1. Across the EU, the farming sector is the largest user of animals with at least 2 billion birds (chickens, laying hens, turkeys, etc.) and 334 million mammals (pigs, sheep, goats, cattle, fur animals, etc.). There are 13.7 million animal holdings in the EU. The value of livestock farming output in the EU is €149 billion annually. Animals are also part of aquaculture, are companion animals, are farmed for fur, and are used in or form part of various other activities such as experimentation, zoos, circuses, entertainment and sporting pursuits.
2. EU intervention is currently focused primarily on the prevention and control of transmissible diseases that can have significant health and economic impacts. The impacts of an animal disease outbreak can vary widely, usually posing a direct risk to animal and often public health. However, there can also be other negative indirect impacts, such as economic or social effects, including costs to livestock farmers and related industries of dealing with disease and of business disruption, public sector costs of eradication and monitoring, and changes in consumption patterns. Often, disease outbreaks also have significant impacts on international trade of animals and animal products.
3. The current EU animal health legislative framework involves around 50 basic directives and regulations, some of them adopted as early as 1964. The veterinary *acquis communautaire* now covers more than 400 acts. This set of animal health legislation interacts with the current legal framework on animal welfare, food safety, public health, animal nutrition, veterinary medicinal products, environmental protection, official controls and the Common Agricultural Policy.

Consideration of current policy and problems identified

4. In 2004, the Commission launched an independent evaluation to assess the performance of the Community Animal Health Policy (CAHP) over the previous decade. The EU Animal Health Strategy 2007-2013 (AHS) was developed as a result of the outcome of this exercise. Stakeholders and competent authorities of the Member States were asked to identify problems with current legislation on animal health as part of the Animal Health Law Steering Group. The CAHP Evaluation and the stakeholders' consultation broadly agreed that the current system functioned well, however a number of issues were identified that need improvement.
5. The main problems identified during the CAHP evaluation by the stakeholders were: the high complexity of the current CAHP; the lack of an overall animal health strategy; and an insufficient focus on disease prevention (with a particular focus on the need for increased biosecurity). A specific policy issue was also identified related to intra-EU trade in live animals. Each of these is explained in greater detail below.
6. Both the need for simplification and the need for changes in policy proposed in this exercise were identified and emphasised by the stakeholders.

High complexity of current policy

7. The current CAHP is highly complex in a number of ways. First, the large number of pieces of animal health legislation means that it is difficult for those directly affected (such as farmers and other stakeholders) to understand their responsibilities without consulting legal experts. Second, the responsibilities and obligations of animal keepers are not always clear. Some existing responsibilities are not consistent across different pieces of legislation, and some are interpreted differently in different Member States. This could potentially lead to problems if the legislation does not adequately reflect the roles and needs of animal keepers. In addition, differences across Member States can lead to an uneven playing field for animal keepers when it comes to complying with their legal duties. Third, the rules for commercial farming do not always apply in a proportionate manner to non-commercial animal keeping. Non-commercial animal keeping (such as that in hobby or backyard holdings) usually entails a different kind and level of disease risk compared to industrial farming and the administrative burdens imposed on non-commercial animal keeping are not always proportionate to the level of disease risk. Fourth, the definition of the role of the veterinary services has aspects of legal uncertainty that need to be rectified to ensure that veterinarians are clear about their legal duties, to avoid conflicts of interest, and to encourage the development of better veterinary networks. Fifth, there is currently a lack of rules on the professional qualifications and training for official and approved veterinarians, which can lead to differences between levels of health protection across Member States and within the single market. Sixth, specific animal health conditions relating to imports are difficult to understand and apply. This creates complexity and administrative burden for competent authorities, importers and third countries who may find it difficult to understand their legal duties.

Lack of single overall animal health strategy

8. There is a lack of a single overall animal health strategy. The final report of the CAHP evaluation highlighted the lack of a single general approach behind the CAHP. Instead, the CAHP is perceived to be a patchwork of specific measures and actions, with inconsistent objectives and an unclear overall direction. Resources, personnel and management attention have tended to follow animal health crises with a subsequent tendency to reduce focus on the definition and achievement of longer-term strategic objectives. There are four main problems here. First, the lack of categorisation and prioritisation of animal disease policy measures. This has often led to a tactical rather than strategic, and therefore (in the long term) sub-optimal allocation of resources for disease control. Second, there is still poor co-ordination of animal disease surveillance with various surveillance systems and actors not working together in the most effective ways possible. A better co-ordination effort could reduce the risk and impact of disease outbreaks. Third, there is insufficient harmonisation of EU legislation with agreed international (OIE, the World Organisation for Animal Health) standards. Greater convergence would lead to improved competitiveness in international markets and would avoid trade disputes (whilst respecting the need to retain the high health standards expected in the EU). Fourth, a long-term view of emerging, re-

emerging and exotic diseases is not sufficiently taken in current EU legislation. There is a need to promote a more strategic outlook in order to respond to, control and monitor future disease threats.

Prevention rather than cure

9. Lastly, there is an insufficient focus in the current EU framework on disease prevention rather than cure. Freedom from animal diseases is widely considered to be a *global public good*, as it protects the health of animals and public health, as highlighted in the 'One World – One Health' concept developed by the WHO (World Health Organisation), OIE (World Organisation for Animal Health) and FAO (Food and Agriculture Organisation). Its importance is not limited to the rural economy but has an impact on the whole of society. While animal health crises will always occur, the CAHP evaluation highlighted the need to focus more on disease prevention and rapid and effective risk management in order to reduce the incidence and scale of animal disease outbreaks. This deficit manifests itself in poor co-ordination of animal disease surveillance and monitoring, as noted above; the lack of EU level promotion of biosecurity measures on-farm to prevent disease outbreaks; the absence of a vaccination strategy to better prevent and control animal diseases; and the inconsistent provisions on training in animal health for those dealing with animals.

Intra-EU trade in live animals

10. Whilst the previously described problems fit under the thematic headings, the CAHP evaluation steering group and the wide public consultation both highlighted problems with intra-EU trade that fell under several of these different categories. First, the current animal health rules for intra-EU trade are not always proportionate to the animal health risks posed by movements. In particular, some low-risk movements are required to comply with stricter requirements than necessary. Second, in many cases, there is replication of procedures which adds to the administrative burden associated with movements. Third, the concept of compartmentalisation has been used successfully in some areas, but not yet extended to other appropriate parts of EU animal health law, and could be in the future.

2. Analysis of Subsidiarity: is EU action justified on grounds of subsidiarity?

11. Articles 43, 114 and 168 of the Treaty on the Functioning of the European Union provide the legal basis for the EU legislative measures on animal health, as they are an essential part of EU agricultural, public health and consumer protection, trade and single market policy.
12. The need for action passes the 'necessity test' and the 'added value test'. The objectives of animal health policy cannot be achieved by Member States acting alone, and can be better achieved by the EU acting in harmony. In very general terms, good animal health gives not only private benefits for the particular animal keepers and owners concerned with individual animals, but is a public good with wider societal benefits. The transmissible and trans-boundary nature of many animal diseases means that a common approach,

rather than a series of individual actions, is likely to have the greatest overall benefits. Therefore, both in 'peace time' and in the case of an outbreak, the cost of not having action at an EU level is potentially much greater than working together.

13. The benefits of harmonised rules for the prevention, notification, control and eradication of animal diseases at EU level have been demonstrated during animal disease outbreaks in recent times. These crises showed the EU's capability to react quickly, limiting the spread of diseases and minimising their impacts. This was largely due to the harmonised approach to disease control. The current system also enables the development of sustainable surveillance and monitoring programmes by providing co-financing at the EU level. In the past, the EU harmonised approach to disease control has enabled the EU to defend the interests of its Member States on the international scene.
14. Trans-boundary spread of animal diseases is a permanent threat for livestock keepers and Member States as it can have major economic implications for both the private and public sectors. Many diseases can easily spread from one country to another and can reach pandemic proportions. Wild animals can play an important epidemiological role in the transmission of animal diseases and their movements are extremely difficult to control or restrict between Member States (for example, classical swine fever in wild boar posing a potential threat to farmed pigs). For this reason control measures and harmonised surveillance systems are needed at EU level.
15. Given the above, the future legislation should confirm the high degree of competence already attributed to the EU in this area during the last decades, which is well accepted by the Member States and stakeholders alike.

3. Objectives of EU initiative: What are the main policy objectives?

16. The EU as a whole is working towards the objectives of the Europe 2020¹ strategy. Animal health objectives should uphold these crucial overarching objectives by reducing the risk of the negative economic, social (including public health) and environmental impacts of poor animal health or animal disease outbreaks; and consequently by supporting the economic security and success of animal keepers, particularly farmers and thus contributing to smart, inclusive and sustainable growth.
17. It is worth reiterating here that animal health objectives do not stand in isolation. Good animal health is a critical factor in ensuring the viability and sustainability of the internal market; and particularly of the food sector, which is the largest single economic sector in the EU. There is inevitably overlap and interaction with other areas of policy, such as animal welfare, food safety, animal nutrition, veterinary medicines, and official controls, but also wider agricultural and environmental issues such as invasive alien species.

¹ http://ec.europa.eu/europe2020/index_en.htm

18. The general objectives of EU animal health policy are as outlined in the EU Animal Health Strategy 2007-2013, and are:
 - to ensure a high level of public health and food safety by minimising the incidence of biological and chemical risks to humans.
 - to promote animal health by preventing/reducing the incidence of animal diseases, and in this way to support farming and the rural economy.
 - to improve economic growth/cohesion/competitiveness assuring free circulation of goods and proportionate animal movements.
 - to promote farming practices and animal welfare which prevent animal health related threats and minimise environmental impacts in support of the EU Sustainable Development Strategy.
19. Animal welfare in particular has close links with animal health and any objectives for animal health need to pay full regard to the welfare requirements of animals, in accordance with Article 13 of the Treaty on the Functioning of the European Union (TFEU).
20. These general objectives demonstrate that the basis for EU action is wider than simply preventing public or animal health problems from arising or ensuring the economic security of farmers. The scope of any new measures will need to encompass not just kept animals (including production animals, animals used for work, sport, recreation or display, companion animals and animals used in research); but also, to an extent, wild animals, where their poor health has the potential to jeopardise any of these objectives.
21. The scope of this exercise is to build a simplified and more coherent legislative framework for animal health, based on good governance and compliant with international (e.g. OIE) standards.
22. The report outlines the specific and operational objectives of the Animal Health Law in more detail.

4. Policy Options

23. In order to solve the problems identified and achieve the above-mentioned operational objectives, we have considered the 5 policy options below.
24. Option 1: Do nothing (i.e.: continue with current policy). Current animal health rules would remain, with technical updates and adaptations made as necessary but without a horizontal framework establishing overall strategic objectives. Where possible, existing regulatory tools would be used to tackle problems identified.
25. Option 2: Simplification of existing legislation with no major content or policy changes. This option would enable the bringing together of all the existing Animal Health legislation into one large piece of legislation, but would not make any significant changes to the content of the legislation itself.

Changes would only be made as circumstances required, and in order to comply with the Lisbon Treaty.

26. Option 3: Existing legal framework with more self-regulation. This option would complement the current animal health policy and existing legislation with additional initiatives of a non-regulatory nature (self-regulation is defined by the Commission as "voluntary agreements between private bodies to solve problems by taking commitments between themselves").
27. Option 4: A new simplified flexible general legislative framework on animal health issues, based on achieving certain animal health outcomes. Under this option, a new simplified legal framework would set out the principles and objectives for animal health policy required to achieve desired outcomes. The outcomes, such as certain animal health and linked public health standards, would be agreed at EU level. However, the framework would be flexible to allow Member States to apply EU rules as appropriate in accordance with local circumstances to achieve the desired outcomes.
28. Option 5: A new prescriptive legislative framework on animal health issues, based on setting specific processes and standards for animal health policy. Under this option, a new comprehensive legal framework would set out the principles and objectives of animal health. This framework would set specific standards for animal health rules and procedures which would be required across Member States, with little flexibility for Member States to adapt the rules to their differing circumstances.

5. Assessment of impacts

Option 1 – No Change

29. To allow for a proper comparison of the options, Option 1, continuing with current animal health policy, is being used as the policy baseline and the impacts of the other options will be assessed in relation to it.
30. The no change option has already been rejected by both the impact assessment for the Animal Health Strategy and the CAHP assessment, and would therefore be extremely difficult to justify. No change will mean a continuation of the current EU level approach to tackling animal health issues and the problems identified in the report.

Option 2 – Simplification of existing legal framework with no significant policy change

31. This option assumes there would be a simplification of the existing legal framework, by bringing together the several pieces of existing legislation into one overall piece of legislation but without addressing policy objectives and developments set out in the AHS.
32. Animal health policy would not change materially; the benefits associated with this option are solely those from the simplification of the legislation. By bringing together all the existing legislation into one place, there would be some improved simplicity and duplications avoided.

33. However, the existing legislation has no set of principles of overarching coherence and so to put everything in one piece of legislation would lead to a long list of the existing *aquis*, really achieving very little in the way of genuine simplification, so the objectives set out in the AHS will not be met.

Option 3 – Existing legal framework with more self-regulation

34. This option is composed mainly of non-regulatory actions that will be carried out with the resources currently available and will not create additional administrative burdens. These actions would include the Commission and/or Member States either developing guidance and best practice to improve animal health measures or encouraging stakeholders to do so. These would complement the existing animal health legal framework and would aim to achieve better prevention of animal diseases. Legislation would be updated individually as necessary to comply with new requirements (such as the new decision-making processes following the introduction of the Lisbon Treaty), or with technological developments.
35. In general terms, offering guidance and promoting best practices for animal health measures will make animal keepers and other actors in the food chain better informed about animal health measures and the animal disease risks and responsibilities of their actions. If animal keepers are more aware of best practices for preventing diseases, they are more likely to implement measures, such as biosecurity and surveillance, which would be worthwhile for them in terms of reducing the frequency and impact of animal diseases.
36. However, these actions will not be mandated. They rely on the willingness of stakeholders to develop guidance in the first place; and the co-operation of animal keepers in voluntarily following this guidance, under circumstances where it may not always be in their direct interest to do so. Therefore the actual effects of this option being put into practice are very uncertain, ranging from no change at all at one end to a potentially fairly positive impact at the other.

Option 4 – flexible general legislative framework for animal health issues

37. The economic and public health impacts of option 4 are expected to be largely positive. First, there are the benefits expected from reduced disease instance. Overall, resources will be better targeted according to risk, saving time and money. A strategy to make the best possible use of vaccines will be developed and may have positive economic impacts in the reduction of the instance of animal disease and all the associated positive impacts.
38. Undoubtedly there would be some initial impact from the need for familiarisation with the new legislative framework for farmers and other animal keepers as well as competent authorities. Nevertheless this initiative aims to simplify existing legislation, so it is considered that any burden will actually be very limited, and derogations introduced where appropriate. Where new measures might be introduced, such as for biosecurity, they will be based on giving possibilities and incentives to improve rather than introducing compulsory measures. This means e.g. that the additional familiarisation and implementation will be the farmer's or operator's choice to create positive (economic and animal health) benefits. As due to the very nature of animal

diseases, regular updates of valid rules are already a standard procedure; one-off familiarisation costs are likely to be integrated into business-as-usual costs. In the long term, the simplified, more coherent strategic framework should benefit all, and in particular, make more sense to those learning about their obligations for the first time (for example, for new entrants to farming).

39. Overall and in the long term, it is fair to assume that a simplified, flexible and outcome-based framework will impose a lower administrative burden on farming and related industries and animal keepers than the prescriptive framework of option 5. This is because its inherent flexibility means obligations and requirements could be tailored to national or regional circumstances, introducing derogations for low-risk situations where appropriate, and enabling Member States to tailor any administrative obligations to that which is only strictly necessary according to a reasonable assessment of risk.
40. There are three examples that were felt particularly important to analyse in more detail: biosecurity, trade and vaccination, which are set out in the report text and in some detail in the accompanying annexes to this report. An example of the potential impact on administrative burden is summarised in Table 5.2 of the main report.
41. As noted above, there should be a slightly positive social effect with respect to the flexibility of the veterinary labour market and in particular, some benefits from achieving the same standard of safety of animals and animal products.
42. Assuming that there is a reduced instance of animal disease outbreaks, we can extrapolate several other positive environmental impacts. Animal diseases found in kept animals can have negative impacts on wildlife (for example, avian flu, as wild birds may not only actively spread this disease to domestic poultry but also be infected by domestic poultry). Thus reducing their incidence should have an overall positive impact on wildlife.

Option 5 – prescriptive general legislative framework for animal health issues

43. Option 5 is likely to lead to a significant reduction in the instance of animal disease in the EU, with all the associated economic, social and environmental benefits analysed in some detail in the report. However, option 5 is likely to have a significant administrative burden. In addition, more prescriptive rules are likely to become obsolete much more quickly with environmental and technological changes.
44. Option 5 should entail a reduction in animal disease, but it is difficult to assert with any confidence that requiring the same standards across the board, as in option 5, will have a better or worse effect than a well-executed risk-based approach, as that in option 4. It depends at what level resources are applied and standards are set. One could assert that (assuming the same level of resources applied to each option) a good risk-based application of resources will have a more beneficial effect than a uniform standard applied across the board.
45. The administrative burden for Member States is potentially very large with this option. The size of the burden would depend on exactly how it was

implemented, but if there were requirements for Member States to provide training for animal keepers; as well as developing, administering and enforcing new animal health measures in biosecurity and surveillance; the burdens would be very significant.

46. The prescriptive legislative framework will set the knowledge and skills which much be attained in the professional qualifications and training for official and approved veterinarians at EU level. Ensuring that veterinarians have the same knowledge and skills throughout the EU will make it is easier for official and approved veterinarians to work in other Member States without compromising health standards.
47. There should largely be positive environmental impacts from the implementation of option 5, very similar to those outlined in option 4. On the one hand, more mandated actions might be expected to produce more positive environmental impacts of the kind outlined in relation to option 4. However, the increased rigidity of option 5 may mean that measures are less adaptable to particular environmental circumstances, perhaps leading to some negative environmental, including welfare impacts. It is very difficult to assess even the relative direction of travel here, let alone to quantify the expected impacts.

6. Comparison of Options

48. Overall, option 4 seems to be the option most likely to deliver a good level of effectiveness, efficiency and coherence with EU objectives. It should achieve the main objectives of delivering the clarity and coherence of an overall strategy and framework, but leaving flexibility to allow for particular circumstances in particular Member States or areas, and to adapt to rapidly changing circumstances. Therefore, it is also the option which best respects the principles of subsidiarity and proportionality. Options 2 or 3, while offering more continuity with the present context, simply lack any guarantee of positive outcomes, and retain the existing confusing myriad of legislation. Option 5 would deliver the objective of simplicity with an overarching strategy and framework, but is likely to be too rigid to adapt successfully to differing circumstances across the Union, so potentially undermining its own objectives.
49. The main benefit of option 4 is in its flexibility. As noted previously, the nature of the overarching enabling framework means that it is possible for certain specific policy measures to use the tools outlined in general terms in options 3 or 5. The tools of option 3 (some self-regulatory schemes or elements) could be introduced or encouraged if it was felt to be unnecessary or inappropriate to cover a specific issue in legislation. The more prescriptive legislative framework described in option 5 could be introduced for particular issues, species or diseases under delegated or implementing legislation under the flexible legislative framework if more detailed measures were necessary or appropriate.

Table 6.1: Comparison of Options 3-5

Objectives	Option 3	Option 4	Option 5
Effectiveness	Option 3 has a range of outcomes from no change compared to the baseline, to a relatively significant self-regulatory system. Its effectiveness in relation to achieving the objectives is therefore more likely to be positive than negative. +	Option 4 is likely to be effective in achieving or working towards these objectives. +	Option 5 is likely to be effective in achieving or working towards these objectives, but may be less likely to maintain this effectiveness in the long term because of its lack of flexibility. +
Efficiency	Its efficiency depends on the amount of resources devoted to getting a self-regulatory system up and running. However, it will not require time consuming regulatory change. +/-	The flexible framework will require limited familiarisation costs; because this will mainly be undertaken within already existing training networks (e.g. BTSF, etc). It is likely to be more understandable and efficient in the longer term for stakeholders, both animal keepers and MS. ++	Option 5 is likely to require more administrative burden to familiarise and implement. While it will allow for more coherence in the legislation and may lead to an overall benefit, the lack of flexibility means that as circumstances change, more resource will be required to change the legislation. +
Coherence with EU objectives	It would not achieve the objectives set out in the EU AHS of bringing together all AH legislation under one framework. -	Would achieve the EU AH strategy goal of bringing together all AH legislation into a coherent and flexible framework. Is in line with flexible approach taken elsewhere and is most likely to achieve the operational objectives in section 3. ++	Would achieve the EU AH strategy goal of a single legislative framework but the lack of flexibility means it is less likely to achieve some of the operational objectives as it is less able to be adapted to changing circumstances in the future. +

7. Monitoring and Evaluation

50. Simple and reliable performance indicators will help to measure progress. They should cover both hard indicators of animal health and softer indicators tracking the confidence, expectations and perceptions of European citizens.
51. It is very difficult to prescribe a set of precise indicators here that will definitively show that such a wide-ranging initiative such as the Animal Health Law has succeeded in its objectives. Nevertheless, a series of measurements over a fairly generous timeframe should give an indication of the general direction of travel.
52. Examples of what the hard indicators of success are:
 - the proportion of EU veterinary expenditure for eradication and monitoring measures vs. emergency measures;
 - restrictions (number of areas x length of restrictions) due to outbreaks of regulated notifiable diseases;
 - the number of large scale disease outbreaks and of animals culled due to eradication measures;
 - overall costs and losses for the EU, MS and farmers and other stakeholders due to animal disease outbreaks;
 - animal consignments moved across borders under the simplified regime;
 - the number of training sessions taken up by animal keepers, especially farmers.
53. As noted above, this impact assessment is necessarily a wide-ranging overview. When specific secondary legislative measures are introduced, more specific impact assessments will likely need to be completed, and as part of this, much more specific indicators for each measure. It is envisaged that an evaluation should take place around five years after the implementation of the AHL, and the results will be made available for future decision-making.