EUROPEAN COMMISSION
IMPACT ASSESSMENT BOARD

Brussels,
D(2011)

Opinion

Title **DG SANCO - Impact Assessment on Proposal for an EU "Animal Health Law"**

(Resubmitted draft version of 2 September 2011)

(A) Context

The current EU legislative framework on animal health involves over 50 basic directives and regulations and 400 implementing and special acts. An independent evaluation which the Commission launched in 2004 found the system was functioning well in general terms but could be improved through the introduction of an overall strategy, a reduction of policy complexity and a greater focus on disease prevention particularly through biosecurity measures. A specific policy issue was also identified around the intra-EU trade in live animals. The EU Animal Health Strategy 2007-2013 was subsequently adopted and suggested moving to a "single regulatory framework for animal health [which will] define and integrate common principles and requirements of existing legislation". The Commission's Communication on the Strategy was welcomed by the European Parliament and Council and the European Economic and Social Committee.

(B) Overall assessment

The report has been improved on the basis of the Board's previous recommendations, although the wide-ranging nature of the initiative does make it hard to ensure that all planned changes are adequately assessed. Some further improvements are now recommended. Firstly, the report should clarify what the preferred option involves in terms of obligations for non-commercial animal keepers (e.g. pet owners, zoos), biosecurity provisions and future Impact Assessments. Secondly, the report should present further evidence preferably from the evaluation to demonstrate the need for further harmonisation to address particular problems. Thirdly, the report should consistently describe vaccination options so it is clear what is being proposed in the preferred option. Fourthly, the report should better explain the administrative burden analysis by clarifying whether new information obligations are foreseen. Plans for evaluation should also be stated.

Commission européenne, B-1049 Bruxelles - Belgium. Office: BERL 6/29. E-mail: impact-assessment-board@ec.europa.eu

(C) Main recommendations for improvements

(1) Clarify what the preferred option involves in terms of non-commercial actors, biosecurity and future Impact Assessments. The current draft now better explains the complex legal changes associated with the preferred option. However, the report should further clarify what preferred option 3 involves in terms of changed obligations for non-commercial animal keepers (e.g. pet owners, zoos), this being an issue of considerable stakeholder interest. In discussing impacts, it should be specifically shown that the option achieves an appropriate balance between disease-transmission risk, costs and subsidiarity considerations. On biosecurity, the report should ensure that the relevant analytical Annex (XI) uses option labels and descriptions which match those in the main text. Sub-option variants within the preferred option 3 should be mentioned only if the difference in impacts between them will be discussed with the aim of justifying favouring one over the other (p37). Furthermore, Annex IX which explains plans for adjusting legislation could usefully explain the foreseen timing for establishing a streamlined set of delegated and implementing acts below an Animal Health Law. It should indicate which of the future related proposals are likely to have significant impacts such that further Impact Assessment is envisaged, in order to clarify when detailed rules of interest to stakeholders would be adjusted.

(2) Present further evidence regarding the seriousness of particular problems. The current draft now gives a clearer indication of the nature of the problems with existing rules, and useful evaluation material is provided in an Annex. However, the report could still benefit from presenting some additional evidence from the evaluation or other source that better demonstrates the seriousness of problems which are felt to require greater harmonisation, e.g. around training for veterinarians, surveillance. For such problems, it would be useful to record the extent of inconsistencies within Member State practices and the consequences in terms of disease prevention and response. The report should be still clearer on the groups most affected by regulatory over-complexity.

(3) Consistently describe vaccination options. The current draft now provides a considerably improved discussion of issues relating to vaccination in a new annex. However, it should be ensured that the main text of the report accurately describes the vaccination options that have been considered and the one which is part of the preferred option 3 (e.g. in option description table, p37). The relevant annex could usefully refer to stakeholder views and subsidiarity considerations when discussing why it is important to leave Member States with the responsibility for taking decisions about when to vaccinate.

(4) Better explain administrative burden analysis. The current draft now gives a somewhat clearer explanation about why administrative burden arising from stakeholders' need to familiarise themselves with legal changes has been considered to be insignificant. The report should however further clarify whether new information obligations are foreseen, say for competent authorities or vets, and improve its analysis of any such impacts. If most information obligations will appear in subsequent legal instruments, this should be highlighted.

(D) Procedure and presentation

The report should explain when an evaluation is planned and how it will be ensured that the results are available for future decision-making needs.

(E) IAB scrutiny process	
Reference number	2010/SANCO/015
External expertise used	No
Date of Board Meeting	Written procedure The present opinion concerns a resubmitted draft IA report. The first opinion was issued on 15 July 2011.