

(C) Main recommendations for improvements

(1) Strengthen the evidence regarding the seriousness of problems. Additional evidence should be incorporated into the report to demonstrate that serious problems exist with the existing laws and failing to tackle them could have negative consequences. This could be largely achieved by summarising the evaluation conclusions and their supporting evidence in an Annex and referring to this from the main text. Where problems were initially pointed out by one or more stakeholders, their specific concerns should be summarised and the report should discuss further supporting evidence that indicates a problem. Additional examples of actual difficulties should be given, perhaps adding only one or two more "feature boxes" but adding several short sentences to concretely explain how the problems affect the everyday operations of one or two key groups of stakeholders. Problems linked to the implementation of the current *acquis* should be distinguished from problems in areas where there is currently no EU law. The groups most affected by regulatory over-complexity should be mentioned, to make readers aware if farmers or experts like veterinary professionals and staff from competent authorities are most likely to gain from simplification.

(2) Clarify what each option involves and add a "simplification only" option. As the report accompanies a framework proposal where significant details may only be fixed through later related measures, it should outline the follow-up proposals foreseen under the preferred option 3 and the legislative process that will be used to repeal existing laws. It should also clearly explain plans for follow-up Impact Assessments on specific issues. Annex 7 on legislation in this area should be used to more precisely outline the changes planned for now and for later under option 3, identifying items to be fully or partly repealed or retained. The report should clarify where its overarching options involve fixing on a detailed sub-option now and where they involve mentioning a broad principle in a framework law and settling the most impactful details later. Indicative sub-options that are only tentatively selected to enable a deeper analysis should be clearly identified as uncertain. The option descriptions should be reviewed to avoid giving a false impression that option 3 would be flexible in most regards (p35). It is currently difficult to disentangle simplifying changes from changes that extend EU competence, so the report should present a new "simplification only" option, which will allow the extra benefits of the preferred option to be better demonstrated.

(3) Present adequate information regarding vaccination issues. Because vaccination issues are analytically complex and views may differ about whether it should even be supported in principle, the report should more fully assess the topic. Its summary assessment should be clearly expressed, and uncertainties and assessment difficulties should be explained. This could be done by using a dedicated Annex for full assessment and summarising its findings in the main text. The assessment should complement the present Annex V by clarifying the problems in terms of both animal health and subsequent use of animal-derived products, clearly defining indicative sub-options for final legislation, presenting their pros and cons in a balanced fashion, and giving the views of stakeholders other than veterinary professionals. The extent to which animal-keepers or Member States would retain freedom of choice, and impacts on consumers and trade should be discussed.

(4) Properly assess administrative burden arising from familiarisation activities. The report should show that the administrative cost and burden arising from familiarisation with legislation has been systematically assessed. It should be quantified using the Standard Cost Model unless data can be supplied to show that the affected population is very small or spends very little time on this activity.

(D) Procedure and presentation

The report should better explain the overall priorities of key groups of stakeholders, mentioning their views on moving to a framework approach in the introduction. Stakeholder views should also be integrated into the discussion of options and impacts, both for sub-options where the preferred option would substantively fix on an approach and for indicative sub-options. The report should include a commitment to evaluate the initiative after a reasonable period of operation. A table of contents should be added.

(E) IAB scrutiny process

Reference number	2010/SANCO/015
External expertise used	No
Date of IAB meeting	13 July 2011