EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
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Opinion

Title **DG SANCO - Impact Assessment on the proposal for a Regulation on the production, placing on the market and use of medicated feed**

(draft version of 12 December 2012)*

(A) Context

Directive 90/167/EEC sets out the conditions under which medicated animal feeds (MF) may be manufactured, placed on the market and used within the EU. It introduced a number of important concepts into Community legislation, such as the provision that medicated feed has to be issued on the prescription of a veterinarian, while using authorised medicated pre-mixes and feed complying with feed law (a.o. Regulation (EC) No 767/2009). The Directive was based on Art 43 of the Treaty establishing the European Economic Community, implementing the Common Agricultural Policy. However, it does not seem to deliver on the ambition of safeguarding a high level of animal and public health protection and functioning internal market. This impact assessment therefore examines these issues. Simultaneously, the veterinary medicinal products legislation is also being revised (Directive 2001/82/EC and Directive 2004/28/EC).

(B) Overall opinion: NEGATIVE

The report needs a significant amount of further work in a number of important respects. Firstly, it should explain the concrete problems related to the production and use of medicated feed in the value chain, indicate their magnitude and support them with evidence. Factors determining the supply of and demand for medicated feed on national markets as well as issues related to the enforcement of the current legislation should be analysed. Secondly, the report should demonstrate the need for and value added of (further) EU action, including on pets, taking into account, for example, the regional specificities and localised character of the medicated feed market. Thirdly, it should present the policy options in concrete terms and demonstrate their relevance and proportionality against the identified problems and the level of ambition that EU action can realistically achieve. Fourthly, the report should strengthen the assessment of costs and cost savings, social, environmental and distributional impacts, based on credible assumptions and robust evidence. It should then assess and compare the effectiveness and efficiency of policy options in a more credible way, while taking into account the potentially significant costs of prescriptive regulation for the EU budget. Finally, the views of stakeholders need to be reported in a differentiated manner and on all key aspects of the analysis.

Given the nature of these concerns, the IAB requests DG SANCO to submit a revised version of the IA report on which it will issue a new opinion.

* Note that this opinion concerns a draft impact assessment report which may differ from the one adopted

(C) Main recommendations for improvements

(1) Better explain the problems, analyse their drivers and support them with concrete evidence. The report should evaluate the functioning of the Directive on medicated feed and should explain to what extent its original objectives have not been met, but are still relevant, particularly vis-à-vis the current extensive regulatory framework on veterinary medicinal products and food and feed safety. It should clarify what the main problems related to the production and use of medicated feed are and, on the basis of robust evidence, demonstrate their scope, scale and cross-border dimension. In particular, the report should substantiate: (i) the potential inferiority of alternative ways of administering medicines (such as top dressing or via drinking water) to medicated feed and the related animal, public and occupational health risks; (ii) the detriment to the functioning of the internal market; and (iii) the missed opportunity with respect to medicated pet feed. It should then provide an in-depth analysis by Member State (or groups thereof) and additional evidence for reasons behind these problems, clearly distinguishing between regulatory/market failures and implementation/enforcement difficulties. For example, the report should discuss in more detail the factors influencing farmers' decisions to use medicated feed (such as the availability of substitutes, perceived rather than real advantages, national tax rules or traditions) and the role of and incentives for veterinarians in this respect. It should explain which national systems and on what basis are classified as too permissive or too stringent, while illustrating their negative impact on animal and human health in Member States.

(2) Strengthen the baseline scenario and justify the need for EU action. The report should present up-front a fully developed baseline scenario better demonstrating how the use and safety of medicated feed is likely to develop. In doing so, it should duly take into account the continuous enforcement effort under the related feed hygiene legislation (Regulation 135/2005 and Directive 2002/32), the envisaged use of the existing European Feed Manufacturers' Guide and the expected market and technological developments. On the basis of an improved problem definition, the report should clarify if, and if so, why Member States are not able to adequately address the problems themselves. It should then provide a credible argumentation as to why and on what legal basis the EU could address the problems better, given, for example, the large variety of livestock farming practices, regional specificities and the apparently limited potential for intra and extra-EU trade. This should also include a better justification for the need to legislate medicated feed for pets at the EU-level.

(3) Better design policy options and demonstrate their proportionality. The report should explain in greater detail the content of policy options and provide a clearer overview of alternative solutions. It should demonstrate that the options retained for detailed analysis are relevant and broadly proportionate vis-à-vis the identified problems and the level of ambition that an EU action can realistically achieve. For example, the report should clarify why there is a need for precise EU manufacturing (process) requirements and how it can be ensured that they are universally applicable across the EU and keep up with technological progress. Similarly, it should explain why there is a need for setting the EU maximum residues levels of veterinary medicinal products in feed and how exactly such universal limits could be designed to be applicable to all the various animal species, active substances, dosing and types of diseases to be treated. The report should also clarify why and how the labelling and record keeping requirements would be changed and why the significant control burden related to mobile and on farm mixing or distribution of medicated feed for pets should be imposed on all Member States.

(4) Provide a credible analysis and comparison of impacts. The report should assess the economic, social and environmental impacts on the basis of credible assumptions and robust evidence. Given the significant distributional impacts of the initiative, these need to be also assessed from the perspective of individual/groups of Member States and sectors where relevant. The report should better analyse the costs and cost savings for business operators, assess to what extent these are likely to be passed on to final users (farmers, pet owners) and estimate the overall impact on demand and competition on the relevant medicated feed markets. For example, it should explain: (i) why, despite cost increases for half of the currently produced medicated feed, no significant shift to substitutes is expected; and (ii) how exactly the additional production of medicated feed is expected to materialise, including the impact on sectors producing substitutes. The report should better assess and compare the effectiveness and efficiency of the policy options, while accounting for the trade-offs and distribution of impacts. Finally, it should assess potentially significant costs for the EU budget related to the design, implementation and enforcement of a highly prescriptive regulatory framework.

Some more technical comments have been transmitted directly to the author DG and are expected to be incorporated in the final version of the impact assessment report

(D) Procedure and presentation

The report should systematically present the views of the main groups of stakeholders (such as national authorities, pharmaceutical and medicated feed industry, farmers and pet breeders/owners, veterinarians, EMEA, occupational health and safety-competent institutions or bodies), differentiating between their country of residence where relevant. This should be done for all the key elements of the analysis, such as the problems, subsidiarity, options and impacts. Public consultation results should be complemented by the results of targeted consultations of stakeholders. The report should also further develop the monitoring and evaluation arrangements. A glossary should be added to aid understanding of technical terms or abbreviations.

(E) IAB scrutiny process	
Reference number	2010/SANCO/055
External expertise used	No
Date of IAB meeting	16 January 2013