EUROPEAN COMMISSION
Impact Assessment Board

Brussels,
D(2013)

Opinion

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

(Resubmitted draft version of 12 July 2013)*

(A) Context

Directive 90/167/EEC sets out the conditions under which medicated animal feeds 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 (namely 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 appear to have delivered on the ambition of safeguarding a high level of animal and public health protection and a functioning internal market. This impact assessment therefore examines these issues.

Simultaneously, the veterinary medicinal products legislation is also being revised (Directive 2001/82/EC).

(B) Overall opinion: POSITIVE

While the report has been enhanced to some extent along the lines of the recommendations in the Board's first opinion, it should be further improved in a number of respects. In particular, the report should provide stronger arguments in support of further EU harmonisation of medicated feed's mixing technologies and medicated feed for pets. In doing so, it should better explain the reasons behind the overly prescriptive standards or bans on anticipated production and the activity of distributors in some Member States. This analysis should be corroborated with stakeholder views. The report should further develop the comparison with the legislation on feed additives (namely coccidiostats and histomonostats) to demonstrate the need for aligning the medicated feed legislation. With regard to the options and their assessment, it should better explain how the envisaged EU standards in terms of homogeneity and mixing would be designed and how the medicated pet feed would be produced and distributed (and which effects on the relevant markets this would have). The report should justify why the costs for the EU and national authorities are expected to be limited. Finally, it should better explain how exactly this initiative would affect the treatment of pets and should indicate across which operators/Member States the anticipated extra profits in the pet sector are likely to be distributed.

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

(C) Main recommendations for improvements

(1) Further streamline and develop the problem definition. While the presentation of problems causing the unavailability of medicated feed has been improved, the analysis should be further streamlined. For example, overlaps can be eliminated by merging the presentation of: (i) the presence of residues of veterinary medicines in feed (i.e. carry-over and 'zero tolerance') and the corresponding national production standards; (ii) the (poor) homogeneity of medicated feed and the corresponding mixing technologies (including mobile mixers, on-farm mixing); and (iii) the baseline scenario in chapters 2.6., 5.1. and 5.3.4. In doing so, the report should clarify which Member States are considered as having low/appropriate/high standards (e.g. Hungary is currently presented under low as well as high standards) and better explain the reasons behind the alleged overly prescriptive national standards (e.g. in Austria the medicated feed seems to be, counter-intuitively, produced only by individual farmers). It should then explain how competent authorities in these Member States are trying to solve the problems that occurred following the shift to alternative routes of animal treatment. As regards mobile mixers and on-farm mixing, the report should further assess their efficacy and controllability and clarify if the concerns expressed by some authorities/stakeholders can be supported by evidence (particularly as the report seems to equally argue that the quality of medicated feed from specialised feed mills is superior). Moreover, the report should further elaborate on the need to harmonise medicated feed for pets, namely by: (i) describing the differences in the production and distribution system between "standard" medicated feed and medicated feed for pets; (ii) clarifying if the non-authorisation of anticipated production and distributors of medicated feed in some Member States causes problems for medicated feed in general or for pets only; (iii) illustrating the analysis with relevant stakeholder views, including pet breeders; and (iv) providing more insights into the concerns of some Member States, for example as regards distributors. Finally, the arguments for a "strong single market" or "huge potential for high quality medicated feed" should be revisited, namely in view of the apparent limited potential for intra and extra-EU trade (e.g. due to relatively high transport costs).

(2) Better explain the link to the regulatory framework on coccidiostats. Given that experience seems to be largely drawn from the implementation of related legislation on feed additives (namely the coccidiostats and histomonostats), the report should explain in more detail: (i) why medicated feed needs to be regulated separately from feed additives; (ii) how similar the problems related to feed with additives and medicated feed are; and (iii) why the two corresponding regulatory frameworks are considered inconsistent. For example, it would seem that in the case of coccidiostats and histomonostats, the Commission in its 2008 report considered that the accuracy and homogeneity of the mixture can be ensured only by approved feed compounders, where the farmers would obtain ready-to-use complete or complementary feeding-stuffs.

(3) Better explain the options and the envisaged implementing measures. The report should further describe the content of each option, namely by explaining how exactly it will be implemented in practice. First of all, it should clarify which measures are envisaged under the "clarifications concerning the scope of the Directive and streamlining it with the currently revised veterinary medicines legislation" and to which problems these relate. Secondly, the report should also clarify how exactly the precise EU standards in terms of homogeneity will be established (most likely by implementing measures). Thirdly, it should explain what is foreseen under "tightening the standards" for mobile and on-farm mixing, why these standards should differ as compared to feed mills and what kind of authorisation and control procedures would need to be put in place by Member States (namely where these schemes are currently forbidden). Finally,

the report should describe in detail what role the veterinarians would play as regards prescribing and/or distributing the medicated pet feed).

(4) Improve the assessment of the preferred policy option. The report should clarify what the "potential shortcomings of the EU-wide established regime" are and how they would be tackled in the envisaged Regulation. In particular, given the link between the stringency of the regulatory framework and its disruptive effect on the medicated feed market, it should better assess the proportionality of the envisaged measures by demonstrating that they do not go beyond the absolute minimum necessary. The report should indicate how robust the main assumptions and calculations are, particularly as regards the costs, profits and prices (such as the "implicit" price increase for medicated feed of 2% in Member States with currently low manufacturing standards or the envisaged price decrease and shift from alternative routes of animal treatment in Member States with high standards). It should justify why the costs for the EU and national authorities are expected to be limited, despite the potentially significant additional workload for the "EU-Authority for the risk assessment" and the authorisation/enforcement costs related to mobile mixers, on-farm mixing and distributors in particular. The illustrative table summarising the impacts should differentiate between the Member States with low and high standards, particularly as regards the compliance costs (currently assigned an overall 'positive' score). Finally, the report should better explain how exactly this initiative would affect the treatment of pets and indicate across which operators/Member States the anticipated extra profits in the pet sector are likely to be distributed.

(D) Procedure and presentation

While the report includes a general "plausibility check" with respect to the views expressed by stakeholders, it should report on their feedback more concretely, particularly where important concerns may exist. This is for example the case for the homogeneity of medicated feed manufactured on-farm, the activity of distributors or medicated pet feed. It should also report on the high number of identical comments received. As regards the suggested 'additional' monitoring indicators, the report should clarify what their purpose vis-à-vis the envisaged proposal is and to what extent the data collection would entail extra costs for business operators. A glossary should still be added to aid understanding of technical terms or abbreviations. The report should briefly describe the changes made on the basis of the recommendations of the Impact Assessment Board.

(E) IAB scrutiny process	
Reference number	2010/SANCO/055
External expertise used	No
Date of IAB meeting	Written procedure An earlier version of this report was submitted to the IAB in December 2012, for which the Board issued an opinion on 18 January 2013