

Mr J. Moynagh  
Head of Unit  
DG SANCO  
EU Commission  
Rue de la Loi, 200  
1040 - BRUSSELS

16.05.2011  
(11) INST 19

**Online questionnaire on medicated feed – additional comments**

Dear Mr Moynagh,

FEFAC representing the EU compound feed and premixtures industry, including manufacturers of medicated feed, is delighted to provide its contribution to the impact assessment of the different options for the future review of the EU medicated feed legislation. Last year we shared with DG SANCO our preliminary thoughts as regards the future orientations to be given to the medicated feed legislation (see attached (10) PR 15 rev1).

We have therefore answered the online questionnaire and advised our Member Associations to do so as well in order to provide a national perspective. We would like first to congratulate your services for the well designed questionnaire, which in our opinion touches a number of important and relevant questions. However, we also feel strongly about the need to provide additional comments and justifications as some questions cannot simply be answered simply with “yes” or “no”. Therefore, we would like hereby to provide further explanations to most of our answers to the online questionnaire (see enclosed).

We thank you for taking into account these additional elements when considering the FEFAC answer to the consultation.

Yours sincerely,



Alexander Döring  
Secretary General

cc. Wolfgang Trunk (DG SANCO)

Annex: (10) PR 15rev1

## Online questionnaire on medicated feed – FEFAC additional comments

**Question 4.1.1.:** Do you agree that the standards for MF manufacturing have an impact on feed, food and occupational safety?

- Yes  
 No  
 Do not know

According to the General Food Law, MF are feed and therefore shall be manufactured in accordance with feed and food safety standards as laid down in EU legislation (Regulation (EC) No 1831/2003) and Good Hygiene Practices. In addition, manufacturing MF involves handling veterinary medicinal substances (VMPs) in the form of medicated premixtures. It is essential for feed and food safety that the right dose of the VMPs is delivered to the right animal during the right period and therefore requires that the VMP is properly mixed with feed ingredients to ensure an adequate homogeneity and stability of the feed at the time of distribution to the animal. Furthermore, medicated feed enables the farmer to better control the amount of veterinary medicines ingested by each animal and therefore the amount of residues in animal products, providing (s)he properly applies the withdrawal periods. When present in a feed not destined to a target species due to cross contamination, a VMP shall be regarded as an undesirable substance in feed and therefore measures should be in place to control this risk of cross contamination. Finally, direct exposure of workers to VMPs should be minimised to avoid adverse occupational health consequences. Therefore Good Manufacturing Practices based on appropriate technical standards are essentials to positively impact on feed, food and occupational health.

In addition, with industrially produced medicated feed, farmers no longer need to handle concentrated products and shall therefore be regarded as a safer route for the administration of VMPs to animals from an occupational health point of view.

**Question 4.1.2.:** If you represent /are based in a MS, do you think that the way MF is manufactured there, reflects the appropriate safety level in terms of animal and public health?

- Yes  
 No, too low  
 No, too high  
 Do not know

FEFAC is not based in a MS and therefore is not a direct target for such a question. However, we would like to share our views on this question based on an overview of the national situations. It can indeed be concluded that the legal requirements for MF manufacturing across the EU are extremely different, ranging from general provisions copying the general requirements laid down in the present EU Medicated Feed Directive to requirements equivalent to those imposed to the pharmaceutical industry itself. In the first case, the national legislation may be completed by voluntary good practices by MF manufacturers. It must also be stressed that in certain countries, the levels of requirements are different for industrial MF manufacturers and farmers producing their MF on the farm. In practice, notifications to the RASFF of non-compliant feed (i.e. non compliant MF or conventional feed contaminated with VMPs) are rare, which can be seen as an indication that MF manufacturing standards across the EU are working in practice.

**Question 4.1.4.:** The cost of manufacturing MF in a feed mill is higher than for non-medicated compound feed because specific measures have to be taken. If you represent /are based in a Member State, do you think that, apart from the cost of VMP, the additional costs for manufacturing MF are reasonable?

- Yes
- No, too low
- No, too high
- Do not know

FEFAC is not based in a MS and therefore is not a direct target for such a question. However, we would like to share our views on this question, in particular on how to read the answers. As pointed under question 4.1.2, the standards are extremely different across the EU and there is a direct correlation between the level of requirements and the added costs. Added costs should not be mixed up with extra-price: in certain countries, added costs are totally passed on to the farmers, whereas in other countries, this is not the case. This ability to pass on extra costs to the farmer can significantly impact on the perception of the reasonability of the added costs by either the supplier of medicated feed or the farmer.

**Question 4.1.5.:** If you represent /are based in a MS, do you think that MF is a practically feasible method for all livestock farmers to administer VMPs to their animals?

- Yes, for all
- No, only viable and feasible for very few farming systems
- Not for all, but for the vast majority of farming systems MF is viable and feasible
- Do not know

There are situations when water medication or other methods of administration might be a more effective means of administering VMPs to sick farm animals. Individual treatment may also be more appropriate when it is necessary to administer to a small number of animals and thus it would be inappropriate to produce a full batch of medicated feed. MF is also not appropriate for animals kept in remote areas and / or which may not normally receive concentrated feed on the top of the roughages.

**Question 4.1.6.:** The main aim of this initiative is to modernise and harmonise MF production at the appropriate standard. Do you agree that these objectives can only be achieved by taking action at EU level instead of national level (respect of subsidiarity and proportionality principles)?

- Yes
- No
- Do not know

FEFAC answered “yes” to this question. As a matter of principle, FEFAC indeed favours harmonisation of standards across the EU. Obviously, this depends on what is regarded as an appropriate standard. Should the legislator decide to harmonise to the highest existing national standard, this would mean in practice almost the end of industrial medicated feed production as already experienced in certain Member States.

**Question 4.2.1.:** The inclusion rates of the pre-mixes into MF differ currently from MS to MS. Do you agree that inclusion rates should be the same throughout the EU and depend only on the manufacturing standard (i.e. the quality of the manufacturing practice) of the MF producer?

- Yes
- No
- Do not know

Harmonisation of inclusion rates is not technically feasible as what matters is the amount of the active substance in the final feed, which often depends on the dose prescribed by the veterinarian. This is why for a given medicated premixtures, a range of inclusion rates is suitable to allow the medicated feed manufacturer to incorporate the right dose. However, we believe that a minimum inclusion rate should be established at EU level.

**Question 4.2.2:** The current rules allow MF to be manufactured before the specific prescription is available in the feed mill (anticipated production of MF). Do you agree that anticipated production of MF may raise concerns in terms of efficient and safe use of the VMPs?

- Yes
- No
- Do not know

FEFAC answered “no” to this question. There may be concerns but they are effectively addressed through the principle of “no delivery before the prescription is received”. On the other hand, pre-manufacturing may reduce the risk of cross-contamination in facilitating the scheduling for the manufacturing of compound feed batches.

**Question 4.2.3.:** Do you agree that the use of more than one pre-mix to manufacture a MF may raise concerns in term of safe and efficient use of VMPs?

- Yes
- No
- Do not know

FEFAC answered “no” to this question. There may be concerns but the supervision by a veterinarian is expected to properly address them.

**Question 4.2.4.:** MF can be manufactured in feed mills and in specifically equipped mobile mixers. Do you agree that the manufacture of MF in mobile mixers can meet the requirements for MF with respect to homogeneity and compatibility of the compounds?

- Yes
- No
- Do not know

Although there is no EU standard for homogeneity, FEFAC answered “yes” to this question, based on the existing practical standards used by the feed manufacturers. However, it must be clear that there cannot be different requirements for compound feed mills vs. mobile mixers and controls should be exerted the same.

**Question 4.2.5.:** Do you agree that on-farm manufacture of MF can meet the requirements for MF with respect to homogeneity and compatibility of the compounds?

- Yes  
 No  
 Do not know

Although there is no EU standard for homogeneity, FEFAC answered “yes” to this question, based on the existing practical standards used by the feed manufacturers. However, it must be clear that there cannot be different requirements for compound feed mills vs. on-farm manufacturers and controls should be exerted the same.

**Question 4.3.2.:** Sometimes, during a treatment, a change in medication is necessary. Do you agree that, compared to other methods of oral administration of VMPs (e.g. top dressing or on-farm mixing of VMPs), the use of MF reduces the flexibility and thus willingness to change a treatment?

- Yes  
 No  
 Do not know

FEFAC answered “yes” to this question. However, there are ways to overcome the flexibility problems, e.g. with fractionated deliveries. It must also be stressed that flexibility is not always suitable: stopping a treatment before the end of the period of prescription favours antibioresistance and this can be easily done in case of distribution in water or top-dressing but cannot with medicated feed as it is more economical to use all the quantity of medicated feed delivered than to destroy it.

**Question 4.3.3.:** Do you agree that left overs of MF on the farm might cause problems?

- Yes  
 No  
 Do not know

The quantity of medicated feed is always calculated to the amount strictly necessary to ensure the treatment until the end of the prescription period, taking into account possible lower feed intake caused by the disease. Leftovers are therefore exceptional and may be generated in case of massive mortality during the treatment or killing ordered by authorities.

As any drug, medicated feed shall be used only in accordance with the prescription. Leftovers of MF should be removed from the storage bin used to feed animals on the farm and farmers may not always have the adequate container for a safe storage of the left overs. These left overs shall be disposed of in a safe way, considering that in general MF manufacturers are not allowed (by law or good practices) to recover and rework left overs returned from the farms. Considering the costs incurred by the disposal by waste disposal facilities, farmers could be tempted to use them (e.g. as fertilisers or even feed).

**Question 4.3.4.:** Do you agree that the MF method has advantages in terms of animal welfare over medication that is not administered orally?

Yes

No

Do not know

Medicated feed assures freedom from stress compared to injection. This is valid not only for the treated animal but also for all animals from the same pen. In addition, medicated feed makes it more difficult for a farmer to stop the treatment before the end of the prescription period, which is essential for animal health and therefore animal welfare.

**Question 4.3.5.:** Do you agree that, prescription rules for VMP and MF should be identical?

Yes

No

Do not know

FEFAC answered “yes” to that question, assuming that the question was meant to tackle harmonisation of the rules for the prescription of e.g. a vaccine or a medicated feed to an animal. If the question was meant to call for the prescription rules for MF to also apply to the delivery of medicated premixtures to compound feed manufacturers, then we would disagree.

**Question 4.4.4.:** Do you agree that residual traces of VMPs in feed, e.g. from carry-over, can increase the occurrence of micro-organisms resistant to antibiotics?

Yes

No

Do not know

The “do not know” answer does not mean that FEFAC does not pay attention to this issue, on the contrary. However, there is presently a debate on this question with different views expressed at national level. We believe that EFSA should be asked for a review of the state of the art in this area and provide an opinion.