1. ABOUT THE CONSULTATION

1.1. What is the scope and purpose of this consultation?

Veterinary medicinal products ('VMPs') can be orally administered using several methods, one being medicated feed ('MF'). Directive 90/167/EEC ('the MF Directive') sets out the conditions under which some authorised VMPs can be used to produce MF in the EU. All uses of VMP in MF are for therapeutic reasons and can, like most VMPs, only be administered to animals after a diagnosis and a prescription made by a veterinarian. This initiative does not cover the authorisation of VMPs and their use. VMP legislation is being revised under a parallel initiative.

The MF Directive stipulates, amongst others, that:
- Only authorised pre-mixes for MF ('pre-mixes') as defined by the VMP-Directive (2001/82/EC) may be used to manufacture MF;
- Manufacturers must have adequate premises and staff with proper knowledge of and qualifications in mixing technology;
- Manufacturers must have premises which have been approved by the competent national authorities;
- The manufacturing process must comply with the manufacturing hygiene rules and principles of the MS in question and with the rules of good manufacturing practice;
- Producers are responsible for the quality of the products (homogeneity and stability) placed on the market;
- MF may be supplied to livestock holders only on presentation of a prescription from a veterinarian containing instructions for use, subject to certain conditions;
- Food-producing animals fed with MF must not be slaughtered before the end of the legally stipulated withdrawal period for each VMP contained in the MF;
- There must be a dispute settlement procedure for the recognition of similar pre-mixes in other MS.

The aim of the review of MF rules is to cut unnecessary administrative burden regarding feed, to harmonise at an appropriate safety level the marketing of MF in the EU and to reflect technical progress in this field.

This public consultation is the vehicle for the Directorate-General for Health and Consumers (DG SANCO) to consult all stakeholders on specific issues that could be improved by smart legislation. Your comments will help DG SANCO draft the impact assessment on the revision of the MF Directive. Therefore please support your contribution, where possible, with detailed evidence such as quantitative data, studies and evaluations which will allow us to better analyse the impact of potential changes.

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1 This document does not represent an official position of the European Commission.
3 For the purpose of this document, animals and livestock have the same meaning and include terrestrial and aquatic animals.
An external study has already been conducted on the situation of MF in the EU. It can be found on:

The consultation paper is structured as follows:

- Chapter 2 sets out the main problems and weaknesses of the present situation.
- Chapter 3 sets out the objectives and options for reviewing the legal framework.
- Chapter 4 is the main part of the consultation with questions on the key issues.
- Chapter 5 requests information about respondents.

### 1.2. Who is consulted?

Contributions are welcomed from all stakeholders and interested parties involved in:

- research, production and marketing of VMPs, MF and compound feed,
- livestock farming in the EU,
- animal health and welfare (including the prescription of VMPs) and
- public health and consumer protection, in particular in the context of pharmaceuticals.

### 1.3. How can I get involved?

Respondents should indicate (see chapter 5) whether they are a citizen (name, telephone number, email address, Member State (MS) or country), non-business organisation, business organisation, enterprise or a public authority. For business organisations or enterprises, please indicate the type of stakeholder (farmer, veterinarian, manufacturer, wholesaler, pharmaceutical industry, importer, researcher, other) and which countries your enterprise or organisation covers. Business organisations or enterprises should indicate the yearly turnover and number of employees. Please also indicate whether you are aware of other members of an association to which you belong are also responding to the consultation. Associations should indicate the number and type of members they represent and whether they are a European, national or other organisation.

An acknowledgement of receipt will be issued for each contribution received, within five working days. A summary of the outcome of the consultation will be made publicly available on the ‘animal nutrition’ website of DG SANCO (http://ec.europa.eu/food/food/animalnutrition/index_en.htm) once the consultation period is over. This summary may contain details of the contributions received. If you do not wish your contribution to be made (partly) public, please indicate this clearly in your response. If so, we will only disclose an indication of the respondent.

Professional organisations are invited to register in the Commission’s Register of Interest Representatives (http://ec.europa.eu/transparency/regrin/) set up under the European Transparency Initiative to provide the Commission and the general public with information on the objectives, funding and structures of interest representatives.

### 1.4. What will happen next?

All contributions will be carefully analysed. A summary of the outcome of the consultation will be published on the ‘animal nutrition’ website of DG SANCO. The results of the consultation will be used for the impact assessment report on the revision of the legal framework for MF.

### 2 PROBLEMS AND WEAKNESSES of the STATUS QUO

MF is an important method of VMP administration, which can be (depending on the species of animal and production method) an effective method for farmers. However, this option is not available to all operators across the EU or only under dissuasive administrative burden and/or economic costs. Cross-
border trade is rather limited because rapid delivery of the MF is crucial once the veterinarian prescribes VMP for the animals.

Transposition of the MF Directive in the MS has led to significant differences throughout the EU, both for the manufacturers of MF and farmers, meaning that not all actors are able to use MF within a comparable level playing field:

1. Some MS have detailed national provisions for establishments manufacturing MF based on demanding, mandatory manufacturing standards whereas others have less legal requirements. This can increase prices of MF by up to 20% for livestock farmers and even more significantly lead to a reduction in MF placed on the market by industry.
2. Some MS allow ‘anticipated’ manufacturing of MF, whereas others authorise manufacturing only once the veterinary prescription is presented to the feed mill. This creates differences in timely availability, costs and usefulness of MF. The scope for cross-border trade is also rather limited because of differences among MS in authorised pre-mixes available for use in MF, and because rapid delivery of the MF is crucial for effective treatment once the veterinarian prescribes for it.
3. Some MS allow MF to be produced on farms, which is mandated in the Directive. This also has implications for the costs, availability and usefulness of MF.
4. Some MS allow MF to be sold to livestock farmers by authorised distributors and not directly by manufacturers of MF. This again has implications for the costs, availability and usefulness of MF.
5. Antimicrobials (AMs) are the most important VMPs currently used for the production of MF. In many MS, around three quarters of all authorised pre-mixes are AMs. There is concern about the use of therapeutic AMs in animals with respect to the development of antimicrobial resistance (AMR) with negative impacts on public and animal health.
6. Depending on the specific production methods of successive batches of MF, residual amounts of VMPs, including AMs, can be carried over into another batch of feed at low concentration ranges. There is evidence that this might contribute to the development of AMR among many other more important elements associated with mass therapy i.e. suboptimal dosage in some individuals or still active metabolites in excreta. Some MS have a zero tolerance for carry-over contamination of VMPs in MF, other MS have a less strict approach.

Consequently, the use of MF is a common method of administering specific VMPs in some types of animal farming in some MS; in others MS, it is only marginal. Particularly where a large number of animals requires medical treatment (or vaccination), individual administration is not a practical option. The method of administration of VMPs has evident implications on the competitiveness of livestock holdings and also on animal health and welfare (absence of alternative, over/under-dosage). Use of MF also raises specific public health issues such as occupational health or AMR considering the risk of carry-over of AMs in the manufacturing of successive batches of feed.

3 OBJECTIVES

The overall objective of revising the MF rules is to ensure that the use of MF to administer VMPs to animals affords the highest degree of animal health and welfare and public health whilst boosting the internal market and the competitiveness of the livestock sector.

To achieve this goal, the specific objectives are:

- To clarify the scope of MF legislation concerning other aspects of feed law and legislation on VMPs — avoid unnecessary administrative burden at the interface between feed legislation (MF) and VMP legislation.
- To give to all animal keepers access to MF based on a veterinarian’s prescription as a method of VMP administration where it is effective and appropriate in terms of animal welfare, animal and public health — Harmonisation at an appropriate efficacy and safety level.
- To assess the VMP administration via MF in terms of competitiveness of the livestock sector — economic feasibility.
- To set a clear legal framework that reflects developments in the feed industry and in livestock farming — reflect technical progress.
4 ISSUES TO BE DISCUSSED

4.1. General aspects and MF manufacturing standards

4.1.1. Do you agree that the standards for MF manufacturing have an impact on feed, food and occupational safety? (optional)

☐ Yes
☐ No
☐ Do not know

If ‘Yes’ please indicate such impacts (optional)

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? (optional)

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

If ‘No’ please indicate why (optional)
4.1.3. Do you agree that manufacturing standards have an **impact on the costs** of MF production? (optional)

- Yes
- No
- Do not know

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? (optional)

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

If ‘No’ please indicate why not (optional)

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? (optional)

- 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

If ‘No’ please indicate the systems/animal species and reasons that limit MF use (optional)
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)? (optional)

- Yes
- No
- Do not know

4.2 Specific provisions on MF manufacturing

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? (optional)

- Yes
- No
- Do not know

If ‘No’ please indicate arguments against harmonisation. (optional)
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? (optional)

- Yes
- No
- Do not know

If ‘Yes’ please indicate the concerns (optional)

4.2.3. Do you agree that the use of more than one pre-mix to manufacture a MF may raise concerns in terms of safe and efficient use of VMPs? (optional)

- Yes
- No
- Do not know

If ‘Yes’ please indicate the concerns. (optional)
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? (optional)

- Yes
- No
- Do not know

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? (optional)

- Yes
- No
- Do not know

4.3 Use of MF in practice

4.3.1. A homogenous incorporation of VMP into MF is crucial for the safe and efficient use of MF. Do you agree that transport of MF from the manufacturing feed mill to the farm significantly reduces the homogeneity of feed? (optional)

- Yes
- No
- Do not know

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? (optional)

- Yes
- No
- Do not know

4.3.3. Do you agree that left overs of MF on the farm might cause problems? (optional)

- Yes
- No
- Do not know

If ‘Yes’ please indicate the potential problems (optional)
4.3.4. Do you agree that the MF method has advantages in terms of **animal welfare** over medication that is not administered orally? (optional)

- Yes
- No
- Do not know

If ‘Yes’ please indicate the advantages (optional)

4.3.5. Do you agree that, **prescription rules for VMP and MF should be identical**? (optional)

- Yes
- No
- Do not know

4.3.6. Would you agree that **MF could be prescribed by qualified personnel other than veterinarians**, which is already a possibility for the prescription of VMPs? (optional)

- Yes
- No
- Do not know
4.4 Public and occupational health

4.4.1. Do you agree that, compared to other methods of oral administration of VMPs to animals, the MF method has a lower risk in terms of direct exposure of staff handling VMPs i.e. with respect to occupational health (e.g. sensitising, allergic or resistance-enhancing properties of VMPs)? (optional)

- Yes
- No
- Do not know

4.4.2. Residues of VMPs can be carried over into feed for animals for which the VMPs are not intended. Do you agree that finding of residues of non-prescribed VMPs can be minimised e.g. by flushing or production planning but not totally excluded in practice? (optional)

- Yes
- No
- Do not know

4.4.3. If you represent / are based in a MS, are you aware of tolerance levels for carry-over of non-target species VMPs under the current legal framework? (optional)

- Yes
- No
- Do not know

If ‘YES’ please indicate the tolerance values. (optional)

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? (optional)

- Yes
- No
Do not know

If ‘YES’, can you indicate a percentage (range) of the pharmacologically efficient level of the active substance below which increased resistance might be evident? (optional)

5. Information on respondents

5.1. Please give your name, telephone number, e-mail address and MS/country. (optional)

5.2. Please indicate to what category you belong: (compulsory)

- Citizen
- Non-business organisation
- Business organisation / enterprise / farmers
- A public authority

5.3. If you represent a public authority or an organisation, please indicate in which MS(s)/country you are located or whether you act at EU-level: (compulsory)
5.4. In case of a business organisation or enterprise, please indicate the type of stakeholder you belong to or represent: (compulsory)

- Farmer
- Veterinarian
- Manufacturer of MF
- Wholesaler/trader/importer of MF
- Pharmaceutical industry, manufacturer of VMPs
- Trader of VMPs
- Researcher
- Other

5.5. In case of companies and farmers, please indicate the yearly turnover in 1000 € (optional)

5.6. In case of companies and farmers, please indicate the number of employees (full time units) (optional)

Thank you for your contribution!